## CANADIAN BILL OF RIGHTS

1. It is hereby recognized and declared that in Canada there have existed and shall continue to exist without discrimination by reason of race, national origin, colour, religion or sex, the following human rights and fundamental freedoms, namely (a) the right of the individual to life, liberty, security of the person and enjoyment of property, and the right not to be deprived thereof except by due process of law; (b) the right of the individual to equality before the law and the protection of the law; (c) freedom of religion; (d) freedom of speech; (e) freedom of assembly and association; and (f) freedom of the press.

Marginal note:Construction of law

2. Every law of Canada shall, unless it is expressly declared by an Act of the Parliament of Canada that it shall operate notwithstanding the *Canadian Bill of Rights*, be so construed and applied as not to abrogate, abridge or infringe or to authorize the abrogation, abridgment or infringement of any of the rights or freedoms herein recognized and declared…….

In other words, it is recognized & declared in Canada that there have existed & shall continue to exist without discrimination human rights & fundamental freedoms and all Laws must be written to honour and respect the Bill of Rights and everyone is entitled to Life, Liberty and Security of Person & Property without discrimination.

## CANADIAN CHARTER OF RIGHTS AND FREEDOMS

S.2 Everyone has the following fundamental freedoms(a)freedom of conscience and religion; (b)freedom of thought, belief, opinion and expression, including freedom of the press and other media of communication; (c) freedom of peaceful assembly; and (d) freedom of association

S.6 Every citizen of Canada has the right to enter, remain in and leave Canada.

S.7 Everyone has the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice.

S.8 Everyone has the right to be secure against unreasonable search or seizure.

S.9 Everyone has the right not to be arbitrarily detained or imprisoned.

S. 15 Every individual is equal before and under the law and has the right to equal protection and equal benefit of the law without discrimination and, in particular, without discrimination based on race, national or ethnic origin, colour, religion, sex, age or mental or physical disability.

S.52 The Constitution of Canada is the Supreme law of Canada and any law that is inconsistent with the provisions of the Constitution is, to the extent of the inconsistency, of no force or effect.

## ONTARIO HUMAN RIGHTS CODE

All people have inherent dignity & equal inalienable rights. We must provide equal rights & opportunities without discrimination that is contrary to the law. We seek to create a climate of understanding & mutual respect where each person feels a part & is able to contribute to the development & well being of society

1.1 We all have equal treatment to services goods & facilities without discrimination based on RACE, ANCESTRY, PLACE OF ORIGIN, COLOUR, ETHNIC ORIGIN, CITIZENSHIP, CREED, SEX, SEXUAL ORIENTATION, GENDER IDENTITY, GENDER EXPRESSION, AGE, MARITAL STATUS, FAMILY STATUS or DISABILITY

1.13 Can't publish or display notice of intention to infringe on a right or to incite infringement of a right in the Ontario Human Rights Code.

## FREEDOM OF INFORMATION & PROTECTION OF PRIVACY ACT 1990

2 .Personal information is anything personally identifiable including Education, Medical, Psychiatric, Psychological, Criminal, Employment, Identification Numbers, Opinions, and even one's Name

38. No person shall collect personal information on behalf of an institution unless authorized by statute, for law enforcement, or regarding a lawfully authorized activity

61. No person shall wilfully disclose personal information in contravention of this act

(2) every person who contravenes subsection 1 is guilty of an offence & fine not exceeding $5000

## QUARINTINE ACT 2005

14. A quarantine officer may determine if a traveller has a communicable disease with screening technology NOT involving entry into the body

14.2 If you refuse the screening you must immediately tell the screening officer

32. A quarantine officer shall not detain a traveller if there are reasonable grounds to believe the person doesn't pose a significant threat to public health

## NUREMBURG CODE

1.Voluntary consent is essential to any treatment

The individual must exercise the free power of choice without any element of force, fraud, deceit, duress, overreaching, constraint, or coercion

The person must have sufficient knowledge & comprehension of the elements of the subject matter involved… to make an enlightened decision. The person must be told the nature, duration, purpose, method, inconveniences, hazards, & effects upon health.

3.Treatments must be designed & based on the results of animal experimentation & natural history

5.No experiment should be conducted where there is prior reason to believe that death or injury will occur

6.The degree of risk must not exceed the humanitarian importance of the problem to be solved

7.They must provide adequate facilities to protect experimental subjects against even remote possibilities of injury disability or death

## CRIMINAL CODE 1985

264.1.(1) Every one commits an offence who, in any matter, knowingly utters or conveys or causes any person to receive a threat (a) to cause death or bodily harm to a person (2) (a) indictable offence for a term not to exceed 5 years (b) punishable on summary conviction

265. It is Assault (a) without the consent of another person to apply force intentionally to the other person directly or indirectly

269.Unlawfully causing bodily harm is an indictable offence of a term not exceeding 10 years

269.1.Torture means any act or omission by which severe pain or suffering, whether physical or mental, is intentionally inflicted on a person – inflicting torture on another person is guilty of an indictable offence for a term not to exceed 14 years

269.3. It is No Defence – That an action was ordered by a superior or public authority to perform the act or omission… including because of exceptional circumstances including internal political instability or any other public emergency

318.Advocating or promoting genocide is guilty of an offence and liable to imprisonment for a term not exceeding 5 years (genocide means Any of the following acts committed with intent to destroy, in whole or in part, a national, ethnical, racial or religious group, as such: killing members of the group; causing serious bodily or mental harm to members of the group; deliberately inflicting on the group conditions of life, calculated to bring about its physical

destruction in whole or in part; imposing measures intended to prevent births within the group; [and] forcibly transferring children of the group to another group.)

346.(1) Everyone commits extortion who, without reasonable justification oe excuse and with intent to obtain anything by threats, accusations, menaces or violence induces or attempts to induce any person to do anything or cause anything to be done.

423(1) It is intimidation to compel another person to abstain from an activity they have a lawful right to do, or to do anything they have a lawful right to abstain from. (The penalty is imprisonment up to 5 years)

## ONTARIO REGULATION 364/20 – REOPENING ONTARIO (A Flexible Response to COVID-19) ACT 2020

Schedule 1, 2 (4) (a) thru (l) – numerous mask exemptions listed

Schedule 1, 2 (6) it is not necessary for a person to present evidence to the person responsible for a business or place that they are entitled to any of the exemptions set out in subsection (4)

## TRESPASS TO PROPERTY ACT 1990

2.1 Every person who is not acting under a right or authority conferred by law & who (a) without expressed permission of the occupier (i) enters on premises when entry is prohibited under this Act (ii) engages in an activity on premises when the activity is prohibited under this Act; or (b) does not leave the premises immediately after he or she is directed to is guilty of an offence and liable of a fine of not more than $10,000.

In other words, if you are participating in the advertised activity/service lawfully, you are not trespassing. A public business that holds a business licence to conduct business with the public is not a private building or business, so Private Business/Establishment cannot be used as an excuse to kick you out.

## GENETIC NON-DISCRMINATORY ACT, SC 2017, C3

S.3 (1)It is prohibited for any person to require an individual to undergo a genetic test as a condition of

(a)providing goods or services to that individual;

(b)entering into or continuing a contract or agreement with that individual; or

(c)offering or continuing specific terms or conditions in a contract or agreement with that individual

S.3 (2)It is prohibited for any person to refuse to engage in an activity described in any of paragraphs (1) (a) to (c) in respect of an individual on the grounds that the individual has refused to undergo a genetic test.

S. 4 (1) It is prohibited for any person to require an individual to disclose the results of a genetic test as a condition of engaging in an activity described in any of paragraphs 3 (1)(a) to (c)

S.4 (2) It is prohibited for any person to refuse to engage in an activity described in any of paragraphs 3(1) (a) to (c) in respect of an individual on the grounds that the individual has refused to disclose the results of a genetic test

# An Example of Courageous Pushback for Those Facing Vaccine Mandates in the Workplace

This letter/legal notification was sent by Police Constable Adrienne Gilvesy (a member of the Toronto Police Service) to her Chief of Police in response to mandatory vaccination and mandatory COVID testing requirements.

I am posting it here with her permission and for your benefit. Never flinch. Be informed about the law. And call an employment lawyer.

Adrienne, thank you for allowing me to make your letter public! I hope your courage inspires many others to take a stand for their rights. Creating an unstoppable flood begins with a single drop.

**Update:** The good folks at *Police On Guard For Thee* have posted a generic template of Adrienne's letter that you can download and modify for your employer. As always, it is not a replacement for legal advice from your employment lawyer.

~ ~ ~

(This is not intended as legal advice. Provided for informational purposes only.)

~ ~ ~

Saturday, August 28th, 2021

To: Chief of Police James Ramer
Toronto Police Service
40 College Street

Toronto, ON
[redacted]@torontopolice.on.ca

**and**

To whom it may concern,

I am writing in relation to the recent eUpdate "Mandatory Vaccination Requirement for TPS Members" sent to all members via email on Tuesday August 24th, 2021.

I am not going to disclose my vaccination status to the Toronto Police Service as my medical health is protected by privacy laws. My medical health and choices are private and confidential and I am not required to disclose these to anyone. The Toronto Police Service does not have the right to ask me about my vaccination status. My privacy is protected under the Personal Information Protection and Electronic Documents Act, 2000 (PIPEDA) as well as the Personal Health Information Protection Act, 2004 (PHIPA) as well as the Ontario Occupational Health and Safety Act, R.S.O. 1990, c. O.1 and the Municipal Freedom of Information and Protection of Privacy Act, RSO 1990. The same privacy laws apply to all members.

I am not going to consent to any type of COVID-19 testing that the Toronto Police Service may mandate. I do not give my informed consent.

Informed consent means that the person who will administer the medical treatment or procedure, needs to **inform** you of all the benefits and risks associated with the medical treatment or procedures as well as alternative treatments before you decide if you will consent or not. This is medical freedom. These are our God-given inalienable rights.

Elements of consent: your expressed, informed and explicit consent (voluntary) must be obtained **prior** to treatment. Without consent it is considered assault under the Criminal Code of Canada. Consent given under fear or duress is **not** consent. Section 265(3) of the Criminal Code of Canada defines consent in relation to assault as:

**Consent**

**(3)** For the purposes of this section, no consent is obtained where the complainant submits or does not resist by reason of

- **(a)** the application of force to the complainant or to a person other than the complainant;
- **(b)** threats or fear of the application of force to the complainant or to a person other than the complainant;
- **(c) fraud;** or
- **(d) the exercise of authority.**

The Ontario Health Care Consent Act, 1996 defines "consent" as well :

Consent to Treatment

**No treatment without consent**

**10** (1) A health practitioner who proposes a treatment for a person shall not administer the treatment, and shall take reasonable steps to ensure that it is not administered, unless,

(a) he or she is of the opinion that the person is capable with respect to the treatment, and the person has given consent; or

(b) he or she is of the opinion that the person is incapable with respect to the treatment, and the person's substitute decision-

maker has given consent on the person's behalf in accordance with this Act. 1996, c. 2, Sched. A, s. 10 (1).

**Elements of consent**

**11** (1) The following are the elements required for consent to treatment:

1. The consent must relate to the treatment.
2. The consent must be informed.
3. The consent must be given voluntarily.
4. The consent must not be obtained through misrepresentation or fraud. 1996, c. 2, Sched. A, s. 11 (1).

Treatment is defined in the Ontario Health Care Consent Act, 1996 as follows:

"means anything that is done for a therapeutic, preventive, palliative, diagnostic, cosmetic or other health-related purpose, and includes a course of treatment, plan of treatment or community treatment plan". This definition would include any vaccination or any COVID-19 test, as they are both, allegedly, "preventive", "diagnostic" and for a "health-related purpose".

The Nuremberg Code, to which Canada is a signatory, states that it is essential before performing a medical procedure on human beings, that there is voluntary informed consent. It also confirms a person involved should have legal capacity to give consent, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him/her to make an informed decision.

Nuremberg Code: Article 6, Section 1:

Any preventative, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the

person concerned, based on adequate information. The consent should, where appropriate, be expressed and may be withdrawn by the person concerned at any time and for any reason **without disadvantage or prejudice**.

Nuremberg Code: Article 6: Section 3:

In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual's informed consent.

By forcing members to submit to a COVID-19 vaccination or test (including the rapid antigen test), you will also be in breach of the Nuremberg Code.

Furthermore, the Supreme Court of Canada has well established case law that deals with medical treatment without the informed consent of the patient. Case law, to some in the legal field, would be regarded as the most recent, gold-standard-type of law. As you know, being the Chief of Police for the biggest police service in Canada, case law cannot be overturned or overruled without new case law on that issue. We, as police officers, have a duty to be up to date and knowledgeable on recent case law. The Supreme Court of Canada has made it clear that it is **unconstitutional** to force medical treatment of any kind without the informed consent of the patient. Any action taken by police in contravention of case law, would be unlawful. Furthermore, ignorance of case law could be considered willful blindness or neglect of duty, to name a few.

**In terms of accessing my health records, the Ontario Occupational Health and Safety Act also speaks to this. Under the Ontario Occupational Health and Safety Act, R.S.O. 1990, c. O.1 under Section 63(2) it states:**

**Information confidential**

**Employer access to health records**

(2) No employer shall seek to gain access, except by an order of the court or other tribunal or in order to comply with another statute, to a health record concerning a worker without the worker's written consent. R.S.O. 1990, c. O.1, s. 63 (2).

Also under the Ontario Occupational Health and Safety Act, R.S.O. 1990, c O.1 it outlines penalties:

**PART IX**
**OFFENCES AND PENALTIES**

**Penalties**

**66** (1) Every person who contravenes or fails to comply with,

(a) a provision of this Act or the regulations;

(b) an order or requirement of an inspector or a Director; or

(c) an order of the Minister,

is guilty of an offence and on conviction is liable to a fine of not more than $100,000 or to imprisonment for a term of not more than twelve months, or to both. R.S.O. 1990, c. O.1, s. 66 (1); 2017, c. 34, Sched. 30, s. 4 (1).

While I recognize that Section 63(2) of the Ontario Occupational Health and Safety Act, 1990, states that accessing the health records of an employee is subject to any other statue (which presumably includes the Reopening Ontario {A Flexible Response to Covid-19} Act, 2020), it is nonetheless important to highlight this Act, for a several reasons. We have, after all, been relying partly on this Act to govern our internal Toronto Police routine orders and mandates surrounding COVID-19. Laws surrounding mask exemptions for employees, for example, found within the Reopening Ontario Act, is one example where the Toronto Police Service has relied on (legally or not) the Ontario Occupational Health and Safety Act over the Reopening

Ontario Act. Furthermore, "any other statue" is a very broad legal inclusion and would include many of the laws I have referenced in this letter.

Furthermore, the Canadian Charter of Rights and Freedoms Section 2 (a) (freedom of conscience and religion) and Section 7 (everyone has the right to life, liberty, and security of person and the right not to be deprived thereof except in accordance with the principles of fundamental justice), apply to these mandates. Human bodily autonomy is as basic as it gets in terms of rights. I have the right to liberty – and this includes my right to refuse medical treatment (including vaccines or any of the available or future tests for COVID-19).

The PCR test is a form of genetic test and also would fall under the definition of a medical procedure. The following legislation also applies: Bill S-201, Statues of Canada 2017: "An Act to prohibit and prevent genetic discrimination". In it, it clearly defines "genetic test": ***genetic test*** means a test that analyzes DNA, RNA or chromosomes for purposes such as the prediction of disease or vertical transmission risks, or monitoring, diagnosis or prognosis. (*test génétique*)

Furthermore, in this legislation it also outlines Prohibitions:

Prohibitions

**Genetic test**

**3 (1)** It is prohibited for any person to require an individual to undergo a genetic test as a condition of

**(a)** providing goods or services to that individual;

**(b)** entering into or continuing a contract or agreement with that individual; or

**(c)** offering or continuing specific terms or conditions in a contract or agreement with that individual.

This legislation also outlines "Offences and Punishment"

**Contravention of sections 3 to 5**

**7** Every person who contravenes any of sections 3 to 5 is guilty of an offence and is liable

**(a)** on conviction on indictment, to a fine not exceeding $1,000,000 or to imprisonment for a term not exceeding five years, or to both; or

**(b)** on summary conviction, to a fine not exceeding $300,000 or to imprisonment for a term not exceeding twelve months, or to both.

Lastly, as indicated by Ontario Public Health numerous times (and as evidenced in our ICU statistics), vaccinated persons can still get and transmit COVID-19 despite their inoculation. With this "scientific" evidence, if you target only the non-disclosed, unvaccinated or accommodated persons under the Human Rights Code to COVID-19 testing, this is grounds for discrimination.

The testing, hypothetically, is to ensure that you don't transmit COVID-19 to other co-workers or the citizens of Toronto that you interact with on a regular basis. If you do in fact outwardly target unvaccinated, accommodated or non-disclosed employees only, this is grounds for discrimination and harassment and is liable for legal action as well. In addition, by discriminating against non-disclosed,

unvaccinated or accommodated employees, the Toronto Police Service will be breaking its own Procedure. Contained within the Toronto Police Service's Procedure 08-12 titled "Workplace Harassment" it states in the first line: **"The Toronto Police Services Board (Board) and the Toronto Police Service (Service) are committed to providing a workplace that is free of discrimination and harassment to all its members".**

I would also like to bring the Service's attention to an eUpdate that was sent via email to all Toronto Police Service employees on February 10th, 2021. Contained within the contents of the eUpdate was the following paragraph: **"As all medical decisions, you will have the right to choose. Below are some links to get you started and help you make an informed decision".** I have retained a copy of this eUpdate, if required, for reference. In February of 2021, the Toronto Police Service recognized that informed consent was required for any medical procedure, yet in August of 2021 their message has changed. What laws have changed between the months of February 2021 and August of 2021 that would overrule this fact?

It is evident that the Toronto Police Service is in breach of various federal and provincial legislations, as well as case law and their own internal procedures with the recent COVID-19 vaccine disclose requirement, vaccination and possible testing mandates.

In conclusion, I hereby notify you that I will hold you personally liable for any financial injury and/or loss of my personal income and my ability to provide food and shelter for my family if you use coercion or discrimination against me based on my decision to not participate in Toronto Police Service's COVID-19 vaccination and testing mandates nor will I disclose my vaccination status to you.

Name: DC Adrienne GILVESY

Signature: [redacted]

Ontario

Ministry of the
Attorney General

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# Private Prosecutions

Return to the home page



Generally, allegations of criminal activity are reported to the police. After the police investigate, they may lay criminal charges. However, anyone who has reasonable grounds to believe that a person has committed an offence may lay an information in writing and under oath before a Justice of the Peace.

When the information is presented to the court by a private citizen, it is then referred to either a provincial court judge or a designated justice of the peace, who holds a special hearing. The purpose of the hearing is to determine whether a summons or warrant should be issued to compel the person to attend court and answer to the charge.

This hearing, held under s. 507.1 of the Criminal Code, takes place in private, without notice to the accused person. At the hearing, the judge or justice of the peace must hear and consider all of the allegations and available evidence.

The Crown must also receive a copy of the information, get notice of the hearing, and have an opportunity to attend. The Crown may attend at the hearing without being deemed to intervene in the proceedings.

If the judge or justice of the peace decides not to issue a summons or a warrant, then the information is deemed never to have been laid.

If the judge or justice of the peace issues a summons, the person will be served with a copy of the summons, which notifies them of the charge and compels them to attend court. If the judge or justice of the peace issues a warrant, the person will be arrested and brought before a justice.

To avoid any abuse of the private prosecution process, the Criminal Code and the Crown Attorneys Act authorize Crown Counsel to supervise privately laid charges to ensure that such prosecutions are in the best interest of the administration of justice. If a summons or warrant is issued and the case involves an indictable offence, the Crown is required to take over the prosecution. So, a private citizen's right to swear an information is always subject to the Crown's right to intervene and take over the prosecution.

If the Crown intervenes, the Crown will review the matter, as it does in every other criminal case, to determine whether there is a reasonable prospect of conviction and whether a prosecution is in the public interest. If so, the Crown will proceed with the prosecution. If not, the Crown is duty-bound to withdraw the charge.

www.StandUpCanada.Solutions

# Canadian Charter Rights - Businesses

Empower Yourself – Know the Rights of Your Business, Employees and Patrons!

Understanding how COVID-19 measures violate YOUR Charter Right under Section 7
(Note: Section 7 *Charter* rights does not apply to corporations)

AND

Understanding how COVID-19 measures YOU ENFORCE violate Your Employees' and Patrons' Charter Rights under Sections 2, 7, 8, and 15 including other provincial/territorial legislation

Risk of Fines, Human Rights Complaints and being Sued

*The following article is for general information only, and should not be construed as legal advice.*

**Important Information for Business Owners**

There are two (2) separate but equally important issues which business owners need to know and understand with respect to the COVID-19 measures. The first is how your right as a business owner has been and continues to be violated. The second is how you are now violating your employee and patron rights by enforcing COVID-19 measures. This is a long but worthwhile read and so we will apologize upfront.

**Issue #1 – Closure of all "non-essential" businesses – violation of YOUR Charter Right**

**Note: Section 7 *Charter* rights does not apply to corporations**

If your business was deemed to be in the category of "non-essential businesses" this part will be of great interest to you, particularly if your business is not incorporated. We are extremely curious as to where the legal definitions of "essential businesses" and "non-essential businesses" can be found on any government website. It seems that this loose definition not only varies from province to province, but within the same province itself like Ontario.

First of all, you may not be aware, but the closure of all "non-essential businesses" was a direct violation to your *Canadian Charter of Rights and Freedoms* – section 7. The limiting of the number of patrons you are allowed to have in your stores or venues is also another violation to section 7.
Listed below is section 7, its meaning, identification of responsible parties who violated this, and what actions you may wish to consider.

STAND UP CANADA DEBOUT CANADA

Excerpt from the *Canadian Charter of Rights and Freedoms*.
Section 7 is about "**Legal Rights**":

"**Life, liberty and security of person**"

Section 7. **Everyone has the right to life, liberty, and security of the person and the right not to be deprived there of except in accordance with the principles of fundamental justice.**

What does Section 7 mean?
This is a very important section as it covers many meanings with the words "life" "liberty" and "security" which applies to all Canadians. As a business owner, you have the right to WORK, to EARN A LIVING, to run a business, to PROVIDE "security" for yourself, your family and your employees. The decision to close all "non-essential businesses" was not only arbitrary, but it was unjustified.

NOTE: We have been unable to find the legal definition of "non-essential business" in any government website

Examples:
– *We're so fortunate to be able to own and operate a business in Canada, a free and democratic society!*
– *Small business is THE back bone of Canada's economy and we're proud to fill that vital role!*
– *We have the best staff who meet all of our customers needs!*

Who is violating this - In respect to Business Owners?
Canadian Federal government and Canada's Chief Medical Officer
Provincial governments
– Premiers' Declarations of Emergency who ordered the closure of all "non-essential businesses" (no legal definition found); limited the number of patrons you can have in your place of business; enticing your minimum wage employees to stay home and collect the Canadian Emergency Response Benefit (CERB) rather than return to work, making it very difficult to fill entry level positions which are essential to running your business
– Provincial Chief Medical Officers' recommendations

What can I do as a business owner about this Section 7 *Charter* violation?
Considering this is a "constitutional" matter, you may wish to seek legal advice from a Constitutional Lawyer. The Charter only applies to all non-incorporated businesses.

Legal Referrals
There are two constitutional centres that you may wish to contact. Please note we are not affiliated with these centres nor are they with us. We are only providing this information as a source of support to those who need it. Canadians helping Canadians.

Constitutional Rights Centre (CRC)
The CRC is established as a private corporation whose sole mission and aim(s) are the protection, defence, enforcement, and enhancement of constitutional rights, and the supremacy of the Constitution, and the Rule of Law, without government funding, interference, or influence whatsoever.

Justice Centre for Constitutional Freedoms (JCCF)
The JCCF is uniquely positioned to help Canadians who have faced shocking and stressful intrusions on their freedom. Their experienced in-house legal team provides legal advice and representation to clients without charge. JCCF is a registered charity and as such, can issue tax receipts.

We ask that you keep in mind the particular aspect of “pro bono time” as the wonderful people in both centres are not receiving any payment for their services. With this said, please be very aware of this fact before reaching out to them. Given the insanity of our current situation they may be overwhelmed with requests. Thank you for considering this.

**Small Claims Court**
In addition, you may wish to consider filing a claim for financial damages in a small claims court. The maximum amount you could receive is $35,000. We understand that this amount would pale in comparison to lost revenue, but it would send a strong message to the Government of your ability to stand up for your rights. You do not need a lawyer for this – you can represent yourself.

## Issue #2 – Government and Public Health Measures – How Business Owners are Violating their Employees and Patrons Charter Rights and How they are 100% Liable for all Injuries

If you are a business owner, you would have been dealt a severe financial blow during the initial arbitrary and unjustified lock-down measures. The forced closures of all “non-essential businesses” in all provinces and territories had a devastating and crippling effect on Canada’s economy.

More personally, the impact was felt by all businesses who were deemed “non-essential” and were forced to close their doors. This IS personal, it is NOT business.

Again, can anyone find the legal definition of “non-essential businesses”?

For a list of current covid-19 “related” deaths in Canada, you can find this information out from the government of Canada, by clicking HERE.

As of our reporting on December 31, 2021, there have been 15,605 COVID-19 “related” deaths in Canada. The above link shows the breakdown by province. Why is this important information for you to know? Because all of these government measures (forced “non-essential businesses closures, etc.) are based on the number of COVID-19 “related” deaths.

Based on our own data, none of these “measures” are reasonable nor justified in a free and democratic society.

With the four (4) new measures the Government and Public Health Officials are asking you to comply and enforce, now place you squarely at risk for *Charter* and other provincial and territorial legislative violations. Including the potential to be sued by employees and patrons.

1. Businesses have been instructed to comply and enforce the mandatory wearing of face coverings (face masks) for their employees and patrons. Most businesses are not even aware of any mask exemptions which is written in either the municipal bylaw or public health order for their jurisdiction – and by not complying with these exemptions, they are breaking the law and exposing themselves to risk of fines, human rights complaints and being sued!
2. Businesses have been instructed to place hand sanitizers at the entrance of their place of business for patrons and employees use.
3. Businesses have been instructed to take patrons medical temperatures as a prerequisite (a condition) to providing service.
4. Businesses have been instructed to obtain ID from patrons.

As a business owner, you need to be aware that you are now BREAKING THE LAW by enforcing these measures.

**Passing the LIABILITY Buck to Business Owners!**

This next piece of information is by far the MOST important information for you to fully understand as a business owner. If the Federal or Provincial Governments felt that these measures were that crucial to stopping the spread of covid-19, they would have written new federal or provincial and territorial laws for all Canadians to comply with. Period. Punishable in a court of law for breaking them.

But the government did not do this. Why not? Because these measures ARE Charter violations. Which means hypothetically:
– there would have been only ONE Federal constitutional lawsuit; or
– TEN Provincial and THREE Territorial constitutional lawsuits

In other words, these “measures” would have been dealt with quickly and efficiently in a legal challenge. Life would have returned back to pre-covid normal relatively fast.

What did they do instead?

– passed these unlawful measures down onto unsuspecting business owners
– HUNDREDS OF THOUSANDS, if not MILLIONS of potential lawsuits to businesses (all across Canada) for violations to the Charter and other Acts
– including LIABILITIES for any physical or psychological injuries arising from mask-wearing and using hand sanitizers by employees or patrons
– including risk of fines, human rights complaints and being sued

**Introducing Ontario Public Health**

BREAKING NEWS: June 17, 2020 – ONTARIO Public Health created their Synopsis on wearing masks, given to all 35 local Public Health Units in Ontario (who are in turn responsible for 444 municipalities).

This 14-page document which contains 43 cited references on wearing masks, but has only ONE feature that makes all the difference in the world. Their DISCLAIMER. It is found on the last page and is something everyone including business owners need to read.

DISCLAIMER: “The application and use of this document is the responsibility of the user. PHO assumes no liability resulting from any such application or use”

What is a “Disclaimer”?
It is a statement that denies responsibility to any “claims” made. Thus the term “dis” “claimer”.

Why is their Disclaimer so important?
This means that Ontario Public Health has ZERO responsibility for any and all injuries (physical and psychological) resulting from mask-wearing.

OK, so if Ontario Public Health is not responsible for mask-wearing injuries, who is then?
– Business owners and staff who enforce mask-wearing
– anyone who enforces mask-wearing
– anyone who voluntarily wears one

**THIS IS ALL YOU NEED TO KNOW.**

If the Canadian and Provincial Governments, including the Federal, Provincial and local Public Health Units do NOT take full responsibility for enforcing mask wearing on citizens, then why in the world would anyone wear one? Let alone force employees and patrons, including school children to wear one. Please note, we suspect all other provincial Public Health Synopsis have the same type of Disclaimer. Unfortunately, we have not yet had time to verify this, but will be doing so when time permits.

**Time to Engage Critical Thinking!**

Why do you think Ontario Public Health has this DISCLAIMER?

Let's breakdown their "DISCLAIMER" so you can fully understand it.

Who are the "users"?
– anyone who "uses" a face mask or face covering

Who are the ones "applying" their recommendations "any such application"?
– any businesses enforcing the "application" of mask-wearing
Who is protected by this Disclaimer? Is it the "user" or the people "applying" their mask-wearing recommendations? No! The only one protected by this Disclaimer is Ontario Public Health. Ontario Public Health assumes no liability!

**If mask-wearing poses no harmful physical or psychological risks – which is what they've been telling us for months now, then WHY THE DISCLAIMER?**

**Understanding How the Four (4) Measures Businesses Enforce Violate the Charter Rights of their Employees and Patrons including other Provincial/Territorial legislation**
**1) Mandatory Face Coverings**
**2) Hand Sanitizers**
**3) Temperature taking**
**4) Asking for ID**

**COVID-19 Measures 1), 2), and 3) Violate Sections 2 (a), 2 (b) and 7 of the Charter**

**Here is the latest information on mandatory face coverings, or face masks:**
– unconstitutional
– ineffective and pose physical and mental health dangers
– violates the physical and psychological integrity by seriously restricting a person's primordial right to breathe
– restricting the very right of liberty, to choose HOW to breathe
– mandating masks to stop the spread of a disease (the Government has deemed COVID-19 to be a disease) is a medical treatment requiring people's consent under section 10 of the Health Care Consent Act, Ontario
– section 11 are the elements required for people's consent (this is Ontario only – each province/territory is different – please check your provincial/territorial health care consent policies)
– mask exemptions are provided in either bylaw or public health recommendations/orders

Employer responsibilities / Employee rights – mask exemptions:
– if an employee declares they have a mask exemption, the employer would be responsible to accommodate them for the protected code of disability under the Human Rights Code Ontario, for example. Note, each

province/territory may have different protected codes under their provincial/territorial Human Rights Code - find your area and double check that “disability” is a “protected code”.
– employers would need to ensure they are not in violation of the Occupational Health and Safety Act, Ontario (OHSA), under Part III Section 25 "Duties of an employer", subsection (2) an employer shall (a) provide information, instruction and supervisor to a worker to protect the health or safety of the worker (this is Ontario only – each province/territory is different – please check your provincial/territorial Occupational Health and Safety policies)
– certain employees have the right to refuse to work under Part V Section 43 of the OHSA
– employees who would assert their rights under OHSA, are protected from reprisals by the employer or anyone acting as the employer under Part VI Section 50 of the OHSA
– Reprisals by Employer Prohibited – no discipline, dismissal, etc., by employer
– employers would need to ensure they are compliant with their duties under the Workers Safety Insurance Board (WSIB), Ontario
– employers would need to ensure their employees are fit for duty to be able to wear a mask while they are working; employees would require a medical evaluation BEFORE being instructed by their employer to wear a mask; employees could have underlying medical conditions which they may not be aware of

Employer has NO legal authority – medical exemptions:
– they would have no legal authority whatsoever to “approve” a medical exemption that a medical doctor “issues” for patrons or employees (for anyone!)
– they would have no legal authority whatsoever to disregard the medical assessment of an employee's or patron's medical doctor (medical doctors are the only legal profession allowed to issue medical exemptions)

Risks for businesses:
– are at risk for constitutional LAWSUITS from employees and patrons for the violations of their rights and freedoms under the *Charter*
– are at risk for FINES from bylaw officers for not complying with mask exemptions under municipal bylaws or public health orders (businesses not complying with mask exemptions are breaking the law)
– are at risk for HUMAN RIGHTS COMPLAINTS on the grounds of discrimination upon disability (businesses denying service to anyone declaring a medical exemption under the bylaw or public health recommendation); financial compensation is awarded to the person making the complaint, if approved
– are at risk for being SUED in small claims court for damages resulting from being denied service in your place of business
– are at risk for being SUED in civil courts for any and all physical and psychological damages arising out of mask use and hand sanitizer – by employee's and patron's, including service workers who deliver goods or provide services to your business
– are at risk for CLAIMS to Workers Safety Insurance Board of Ontario (all provinces and territories which apply)
– are at risk for health and safety COMPLAINTS to the Ministry of Ontario

**Latest information on hand sanitizers:**
– there are NO hand sanitizers approved by the Government of Canada
– Health Canada has 115 recalls of hand sanitizers due to their toxicity levels to humans

**Latest information on taking temperatures of patrons’:**
– should only be done by a medical professional
– should NEVER be done by a waitress or store clerk, anyone who is NOT a medical professional
– requires people’s consent under section 10 of the Health Care Consent Act
– section 11 are the elements required for people’s consent (this is Ontario only – each province/territory is different – please check your provincial/territorial health care consent policies)

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– a business has NO legal authority to administer medical treatments – taking someone's medical temperature is a medical treatment and requires their explicit consent

**COVID-19 Measures 4) Violate Section 8 of the Charter**

**Latest information on asking anyone for their ID:**
– your ID is your name, address and phone number including your date of birth
– the only person who has the right to ask anyone for their ID is a medical professional, and ONLY if that person agrees to give this information to them
– businesses and staff have NO RIGHT TO ASK ANYONE THIS
– bartenders know this!
– not even the police to some extent
– doing so also violates provincial and territorial privacy rights
Not only are business owners and their staff in violation of these Sections, but so are multiple parties as well.

**Understanding all the Violations under the Charter**

Section 2 is about "Fundamental freedoms". If your business enforces Mandatory face coverings – Hand sanitizers – Temperature taking, you are now violating these rights of your employees and patrons under this section. Including violations to the provincial/territorial health care consent policies.

Excerpt from the Canadian Charter of Rights and Freedoms:
Section 2. Everyone has the following fundamental freedoms**:**
**(a) freedom of conscience and religion**;

What does Section 2 (a) mean?
This is your guaranteed right to have the FREEDOM of CONSCIENCE. FREEDOM of RELIGION. This is your right to participate in any religious association you want.

Example:
*– I believe wearing a mask is potentially harmful to my child's psychological and physical health; I cannot in good conscience allow my child to be required to wear a mask while in school*
*– My religion does not permit me to cover my face or wear a face mask*
*– I am free to practice any religion of my choice, in any religious place of worship*

Who is violating this?
Canadian Federal government and Canada's Chief Medical Officer
Provincial governments
– Premiers' Declarations of Emergency
– Provincial Chief Medical Officers' recommendations
Municipal bylaws or Public Health recommendations
Bylaw officers who enforce any measure
Business owners and staff who enforce any measure
Schools and teachers who enforce any measure

Section 2. Everyone has the following fundamental freedoms:
**(b) freedom of thought, belief, opinion and expression, including freedom of the press and other media of communication**;

What does Section 2 (b) mean?
This is your guaranteed right to have the FREEDOM to THINK what you want. The right to have your own BELIEFS, OPINIONS and the right to EXPRESS them in any way.

Examples:
– *I don't want to wear a mask because I think its harmful*
– *I think people should have the right to choose if they want to wear a mask or not*
– *I don't think anyone should take my temperature except my family doctor, and ONLY if I let them do it!*

Who is violating this?
Canadian Federal government and Canada's Chief Medical Officer
Provincial governments
– Premiers' Declarations of Emergency
– Provincial Chief Medical Officers' recommendations Municipal bylaws or Public Health recommendations
Main-stream media, in particular, CBC (one sided reporting)
Bylaw officers who enforce any measure
Business owners and staff who enforce any measure
Schools and teachers who enforce any measure

**Section 7 is about "Legal rights"**
If your business enforces
– Mandatory face coverings
– Hand sanitizers
– Temperature taking
you are now violating these rights of your employees and your patrons under this section.

Excerpt from the *Canadian Charter of Rights and Freedoms*:
Section 7. **Everyone has the right to life, liberty, and security of the person and the right not to be deprived there of except in accordance with the principles of fundamental justice**.

What does Section 7 mean?
This is a very important section as it covers many meanings with the words "life" "liberty" and "security" which applies to all Canadians. This is your guaranteed RIGHT to LIFE, to have SECURITY, to WORK as an employee or own and operate a BUSINESS.

Examples:
– *We're so fortunate to be able to own and operate a business in Canada, a free and democratic society!*
– *Small business is THE back bone of Canada's economy and we're proud to fill that vital role!*
– *We have the best staff who meet all of our customers needs!*
– *I'm so lucky that I live Canada and have the freedom to choose HOW I want to breathe*
– *There is no way I'm rubbing anything on my hands that is toxic (hand sanitizers)! That poison gets absorbed through my skin, into my body and will make me sick!*

Who is violating this?
Canadian Federal government and Canada's Chief Medical Officer
Provincial governments

– Premiers' Declarations of Emergency
– Provincial Chief Medical Officers' recommendations
Business owners and staff who enforce any of these measures

**Section 8 is about "Protection from search and seizure"**
If your business enforces asking for ID, you and your staff are now violating the rights of your patron's under this section. Not only will you be violating this Section of the Charter, but you will also be violating provincial and territorial privacy rights. If patrons are asked for their ID in your place of business, they have no legal obligation to respond. In fact, they have every right to walk away from the person asking, and still have every right to receive service in your business.

Excerpt from the *Canadian Charter of Rights and Freedoms*:
Section 8. **Everyone has the right to be secure against unreasonable search or seizure**.

What does Section 8 mean?
This is your guaranteed RIGHT for a reasonable expectation of YOUR PRIVACY. Simply stated, police and other government agents cannot, without sufficient reason, invade the personal privacy of individuals. Your NAME, ADDRESS, PHONE NUMBER, and your DATE OF BIRTH is YOUR PRIVACY and no one else!

Example:
*– Waitress to patron: "Can I have your name, address and phone number please?" Patron to Waitress: "Are you kidding? You have no right to ask me this. Can I have yours?"*

Who is violating this?
Canadian Federal government and Canada's Chief Medical Officer
Provincial governments
– Premiers' Declarations of Emergency
– Provincial Chief Medical Officers' recommendations
Municipal bylaws or Public Health recommendations
Bylaw officers who enforce asking for your ID
Business owners and staff who enforce asking for your ID

To make things worse, if your employee's or patron's declare they have a medical exemption, you do NOT have any right to ask them for any information about it or to ask them to provide proof. If you do, you will also be in violation of Section 15 of the *Canadian Charter of Rights and Freedoms*. Including violations to the provincial/territorial human rights code. In addition, if your business denies service to anyone declaring their medical exemption, you could be subject to (a) fines under the Municipal bylaw for not complying with mask exemptions under the bylaw; (b) complaints to the Human Rights Tribunal for discrimination upon disability, with possible awarded damages; and (c) sued in small claims court for damages.

**Section 15 is about "Equality rights"**

Excerpt from the Canadian Charter of Rights and Freedoms:
Section 15. (1) **Every individual is equal before and under the law and has the right to the equal protection and equal benefit of the law without discrimination and, in particular, without discrimination based on race, national or ethnic origin, colour, religion, sex, age or mental or physical disability**.

What does Section 15 mean?
Anyone who has a mental or physical disability is protected from discrimination under the Human Rights Code, Ontario (this is Ontario only – each province/territory is different – please check your provincial/territorial human rights code).

If employee's or patron's declare they have a medical exemption, no one has the right to ASK them about it except a "Health Information Custodian" AND no one has the right to ask them to prove it under this Section. Doing so also violates personal health information protection which falls under the provincial/territorial privacy policies.

If you DENY SERVICE to anyone declaring a medical exemption, you will be breaking the law and could be subject to: (a) fines from a bylaw officer for not complying with the mask exemptions stated in the bylaw; (b) complaints to the Human Rights Tribunal (with maximum compensation for damages) for discrimination upon disability; and (c) sued in small claims court for damages (maximum is $35K).

If your EMPLOYEE DECLARES that they have a MEDICAL EXEMPTION, as the employer, it is your duty to accommodate your employee under the protected code of disability under the Human Rights Code Ontario (this is Ontario only – please check your provincial/territorial human rights codes)
– you must either (a) find work for your employee where they don't need to wear a mask; or (b) create an environment where the employee does not need to wear a mask to do their job
– employees have the right to file a complaint with the Human Rights Tribunal and ask for maximum compensation for damages, if either option is not provided by their employer
– in addition, if you terminate an employee because they are unable to wear a mask, your employee could sue you for wrongful dismissal

Who is violating this?
Anyone asking your employee's or patron's about their medical condition; asking for proof of it; asking for a medical exemption from their doctor.
– Business owners and staff who ask patrons or employees about their medical condition, or even proof of such
– Municipal bylaw officers who ask
– Schools and teachers who ask

These violations could cost you plenty. Not only in fines, but in your time and legal funds needed to defend yourself in court. Businesses have already lost so much revenue from the arbitrary closure of all "non-essential businesses". Please, do not add to your financial losses from something that can be avoided by this knowledge.

**Hand Sanitizers – CAUTION!**
Did you know that there are NO hand sanitizers approved in Canada? We just recently discovered this information and as a business owner, it's vital that you know this! "To date, there are no hand sanitizers in Canada approved with COVID-19 related claims" ~ Government of Canada

Here's why the Government of Canada cannot approve any.

Were you aware that Health Canada has 115 recalls of hand sanitizers as they are toxic to humans.

Did your business receive any of these notifications?

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Possible adverse reactions – skin irritation and cracking; eye irritation; upper respiratory system irritation; and headaches. If we were in your shoes, we would remove ALL hand sanitizers immediately. This is our opinion and we hope you will sincerely take it.

**Notice of Liability**

Canadians citizens are waking up to this important measure of how they can protect themselves in a court of law for any violated rights under the *Charter*. Basically, individuals will file a "Notice of Liability" with your company. This notice indicates that should you enforce any measure which is a violation to the *Canadian Charter of Rights and Freedoms*, your company will be held liable in a court of law. This notice will also include liabilities for any and all injuries related to forced mask-wearing. This is catching on like wild-fire across Canada.

Ready for some Good News? Suggestions to Mitigate Liability! Mandatory mask-wearing has either been done as a Municipal by-law or a Public Health Unit "recommendation". Who can enforce what?

Municipal by-law for mandatory masking:
– By-law officers are the ONLY ones legally authorized to enforce by-laws
– if they enforce this one, they will be in violation of the *Charter*

Public Health Unit "recommendation" for mandatory masking:
– NO ONE is legally authorized to enforce this because it is ONLY a "recommendation", it is not a law or by-law

There is a BIG difference between "complying" with Municipal by-laws or Public Health recommendations and "enforcing" them. Your only legal responsibility as a business owner is to COMPLY, not enforce. There is so much confusion about this subject. Business owners have no legal authority to ENFORCE these measures. Since when was there a swearing in of oath and office for business owners on these measures? Remember that only a by-law officer has the legal authority to enforce mandatory mask by-laws. Enforcing these two measures puts you and your business in jeopardy of the many risks and violations explained here.

**So how do you meet your legal obligation to COMPLY?**

Simply post the Municipal by-law or Public Health Unit recommendation at the front entrance of your place of business. If someone walks in without a mask, you have NO legal obligation to even point out the notice. That's it. You have met your legal obligation to comply. You absolutely need to leave it at that. You have NO legal obligation to do anymore. In fact, any attempts to enforce mask-wearing, denying mask exemptions, asking for ID or taking anyone's temperature will put you and your business, including your employees at risk for *Charter* violations and possible lawsuits.

This is vital to understand where your legal obligations start and end. In addition, you have every right as a business owner to make your own store policy. You know this as you do this all of the time. For example, we have seen many businesses post their store policy indicating "NO mask NO service". This policy is illegal. With no mention whatsoever of any medical exemptions, which you know now is discrimination under the Human Rights Code and illegal because you are in non-compliance with the mask exemptions in the bylaw. Business owners have the right to make any store policy they want, provided it is not against any law.

We realized that if business owners wrote these kinds of store policies, that the reverse could also be written.

Here is an idea we thought you might like to have if you wanted to make your own store policy that would certainly mitigate (reduce) your risk of liability. "***Please see the posted Municipal by-law or Public Health***

***recommendation on mandatory masks. We need to comply by posting this or else we could be closed down or fined. Please use at your own risk***." Want to be a hero? Add the next sentence. "***Ask us why***".

If your patrons notice this and ask about this store policy, you would be doing them a great justice if you explained to them personally why you wrote this. TO PROTECT THEM FROM HARM. Talk about customer loyalty then! This is 100% your right to do this. We are strongly encouraging ALL businesses to do this. Take your right back as a business owner!

Your ONLY legal obligation is to post the by-law or Public Health "recommendation" in your store. Your legal obligation starts and ends with this. Mitigating your risk of liability in the case of injuries related to mask-wearing is yet to be seen. Do you know why? Because forced mask-wearing for employee's and patron's have NEVER been done before in Canada. Insurance companies have no prior mask-related injuries on this scale, with which to compare and measure this risk against. Employees and patrons may be well uninformed of their rights when it comes to these injuries. Imagine IF they knew? All it takes is one patron, one employee to become injured from mask wearing and there will be mass pandemonium on lawsuits everywhere. Help mitigate your risk by not enforcing something you have no legal authority to do.

Has your business association told you any of this? If not, you might want to ask them what are you paying for?

## WHAT IS YOUR CONCLUSION?

If you've made it to the end of this document, *well done!* Not only are you a critical thinker, but an even more informed and responsible business owner. We know this was a long read and your head is probably spinning by now. Imagine ours putting all of this together for you! When you see all the information presented like this, what conclusion have you drawn for yourself? You're in business not only for profit but hopefully for something far greater that enriches your own life and the lives of all those who work for you, including the people who buy from you. For the sake of your employee's and your patron's, what is your morale compass telling you to do?

We believe that knowledge is *potential power*. But *knowledge has no power without action*. And so, our purpose has been fulfilled by giving you this knowledge - the rest is up to you.

**So now that you have this knowledge, what are you going to do with it?**

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Hello at immunization.attestation

I would like to bring to your attention that your attestation form is lacking the following information box for me to check: "I do not wish to disclose".

**I do not wish to disclose**. This is what my answer is.

Could you please send me this form again at my board email? BOARD EMAIL ADDRESS so that I can do the education required?

Today, I was put on a leave of absence without pay by the Principal, JANE DOE at ANYWHERE SCHOOL. I had sent her a picture that showed I could not access the website. I missed the 6:00pm deadline on Wednesday, Nov 10 by 2 minutes, after several trials, and was put on a leave of absence without pay.

I will point out a part of the Canada Labour Code, RSC, 1985, c. L-2, - Division XV.3, and precisely Disciplinary Action: No Employer shall dismiss, **suspend,** lay off or demote an employee, impose a **financial** or other **penalty** on an employee, or refuse **to pay an employee remuneration**……. because the employee refused a request by the employer to undergo a genetic test.."

I do not have to share my **personal medical information** in **exchange for a job** or employment, according to:

The Health Consent Act.

The Freedom of Information and Protection Act (FOIPOP) Ontario -

The Privacy Act. The Canadian Bill of Rights (CBR) S.C. 1960, c.44.

Personal Information Protection and Electronic Documents Act 2000 (PIPEDA)

OHSA OCCUPATIONAL HEALTH AND SAFETY ACT - ROS, 1990, C.0.I. (ONTARIO) SECTION 63

**The Employment Standard Act** states that only the **employee** can request a leave of absence and I did **NOT** request such a leave.

Even the **Ontario Government** is refusing to mandate vaccination for Teachers and Health Care Workers.

The **New Brunswick Labour Board** ruled last week for the government to **CEASE AND DESIST** any mandatory vaccination. The government had to call back **all essential employees** put on **leave of absence without pay**. **They got back on the job and they got paid what was owed them.**

I request a **new form of Immunization notification** and wish to **not disclose my private personal medical information** which is my **RIGHT** protected under the law as per the Personal Health Information Protection Act 2004 (PHIPA)

**Nowhere** in my contract, does it say that I have to disclose my personal information. As per the **Canada Labour Code, RSC., 1985, c.L-2-**

My contract, signed by JANE DOE, and the Superintendant, is valid until November 30th, 2021. Its terms cannot be changed, altered or broken - My contract STANDS as is -

**Criminal Code:** this action of **withholding an employment contract in exchange for personal information** that is considered **private,** is **EXTORTION**. I have not broken any law, but the Board is breaking the RULE OF LAW in Canada -

I reported to work today. I am qualified, willing and able to work - I was not permitted to work today Nov 11th, 2021.

COULD you please reinstate my wages and allow me back into ANYWHERE SCHOOL in fulfilment of OUR contract, signed by me, the Principal and the Superintendant?

I appreciate your cooperation in this matter.

SIGNED NAME

# Crimes Against Humanity and War Crimes Act

**S.C. 2000, c. 24**

Assented to 2000-06-29

An Act respecting genocide, crimes against humanity and war crimes and to implement the Rome Statute of the International Criminal Court, and to make consequential amendments to other Acts

Her Majesty, by and with the advice and consent of the Senate and House of Commons of Canada, enacts as follows:

# Short Title

**Marginal note:Short title**

**1** This Act may be cited as the *Crimes Against Humanity and War Crimes Act*.

# Interpretation

**Marginal note:Definitions**

- **2 (1)** The definitions in this subsection apply in this Act.

  ***conventional international law*** means any convention, treaty or other international agreement

  - **(a)** that is in force and to which Canada is a party; or
  - **(b)** that is in force and the provisions of which Canada has agreed to accept and apply in an armed conflict in which it is involved. (*droit international conventionnel*)

  ***International Criminal Court*** means the International Criminal Court established by the Rome Statute. (*Cour pénale internationale*)

  ***official***, in respect of the International Criminal Court, means the Prosecutor, Registrar, Deputy Prosecutor and Deputy Registrar, and the staff of the organs of the Court. (*fonctionnaire*)

  ***Rome Statute*** means the Rome Statute of the International Criminal Court adopted by the United Nations Diplomatic Conference of Plenipotentiaries on the Establishment of an International Criminal Court on July 17, 1998, as corrected by the *procès-verbaux* of November 10, 1998, July 12, 1999, November 30, 1999 and May 8, 2000, portions of which are set out in the schedule. (*Statut de Rome*)

- **Marginal note:Words and Expressions**

  **(2)** Unless otherwise provided, words and expressions used in this Act have the same meaning as in the *Criminal Code*.

# Her Majesty

**Marginal note:Binding on Her Majesty**

**3** This Act is binding on Her Majesty in right of Canada or a province.

# Offences Within Canada

**Marginal note:Genocide, etc., committed in Canada**

- **4 (1)** Every person is guilty of an indictable offence who commits
    - **(a)** genocide;
    - **(b)** a crime against humanity; or
    - **(c)** a war crime.
- **Marginal note:Conspiracy, attempt, etc.**

  **(1.1)** Every person who conspires or attempts to commit, is an accessory after the fact in relation to, or counsels in relation to, an offence referred to in subsection (1) is guilty of an indictable offence.
- **Marginal note:Punishment**

  **(2)** Every person who commits an offence under subsection (1) or (1.1)
    - **(a)** shall be sentenced to imprisonment for life, if an intentional killing forms the basis of the offence; and
    - **(b)** is liable to imprisonment for life, in any other case.
- **Marginal note:Definitions**

  **(3)** The definitions in this subsection apply in this section.

  ***crime against humanity*** means murder, extermination, enslavement, deportation, imprisonment, torture, sexual violence, persecution or any other inhumane act or omission that is committed against any civilian population or any identifiable group and that, at the time and in the place of its commission, constitutes a crime against humanity according to customary international law or conventional international law or by virtue of its being criminal according to the general principles of law recognized by the community of nations, whether or not it constitutes a contravention of the law in force at the time and in the place of its commission. (*crime contre l'humanité*)

  ***genocide*** means an act or omission committed with intent to destroy, in whole or in part, an identifiable group of persons, as such, that, at the time and in the place of its commission, constitutes genocide according to customary international law or conventional international law or by virtue of its being criminal according to the general principles of law recognized by the community of nations, whether or not it constitutes a contravention of the law in force at the time and in the place of its commission. (*génocide*)

***war crime*** means an act or omission committed during an armed conflict that, at the time and in the place of its commission, constitutes a war crime according to customary international law or conventional international law applicable to armed conflicts, whether or not it constitutes a contravention of the law in force at the time and in the place of its commission. (*crime de guerre*)

- **Marginal note:Interpretation — customary international law**

**(4)** For greater certainty, crimes described in Articles 6 and 7 and paragraph 2 of Article 8 of the Rome Statute are, as of July 17, 1998, crimes according to customary international law. This does not limit or prejudice in any way the application of existing or developing rules of international law.

**Marginal note:Breach of responsibility by military commander**

- Footnote* **5 (1)** A military commander commits an indictable offence if
    - **(a)** the military commander
        - **(i)** fails to exercise control properly over a person under their effective command and control or effective authority and control, and as a result the person commits an offence under section 4, or
        - **(ii)** fails, after the coming into force of this section, to exercise control properly over a person under their effective command and control or effective authority and control, and as a result the person commits an offence under section 6;
    - **(b)** the military commander knows, or is criminally negligent in failing to know, that the person is about to commit or is committing such an offence; and
    - **(c)** the military commander subsequently
        - **(i)** fails to take, as soon as practicable, all necessary and reasonable measures within their power to prevent or repress the commission of the offence, or the further commission of offences under section 4 or 6, or
        - **(ii)** fails to take, as soon as practicable, all necessary and reasonable measures within their power to submit the matter to the competent authorities for investigation and prosecution.
        - Return to footnote*[Note: Section 5 in force October 23, 2000, *see* SI/2000-95.]
- **Marginal note:Breach of responsibility by a superior**
  Footnote* **(2)** A superior commits an indictable offence if
    - **(a)** the superior
        - **(i)** fails to exercise control properly over a person under their effective authority and control, and as a result the person commits an offence under section 4, or

- **(ii)** fails, after the coming into force of this section, to exercise control properly over a person under their effective authority and control, and as a result the person commits an offence under section 6;

- **(b)** the superior knows that the person is about to commit or is committing such an offence, or consciously disregards information that clearly indicates that such an offence is about to be committed or is being committed by the person;

- **(c)** the offence relates to activities for which the superior has effective authority and control; and

- **(d)** the superior subsequently

  - **(i)** fails to take, as soon as practicable, all necessary and reasonable measures within their power to prevent or repress the commission of the offence, or the further commission of offences under section 4 or 6, or

  - **(ii)** fails to take, as soon as practicable, all necessary and reasonable measures within their power to submit the matter to the competent authorities for investigation and prosecution.

  - Return to footnote* [Note: Section 5 in force October 23, 2000, *see* SI/2000-95.]

- **Marginal note:Conspiracy, attempt, etc.**

  **(2.1)** Every person who conspires or attempts to commit, is an accessory after the fact in relation to, or counsels in relation to, an offence referred to in subsection (1) or (2) is guilty of an indictable offence.

- **Marginal note:Punishment**

  **(3)** Every person who commits an offence under subsection (1), (2) or (2.1) is liable to imprisonment for life.

- **Marginal note:Definitions**

  **(4)** The definitions in this subsection apply in this section.

  ***military commander*** includes a person effectively acting as a military commander and a person who commands police with a degree of authority and control comparable to a military commander. (*chef militaire*)

  ***superior*** means a person in authority, other than a military commander. (*supérieur*)

**Attempts**

- **24 (1)** Every one who, having an intent to commit an offence, does or omits to do anything for the purpose of carrying out the intention is guilty of an attempt to commit the offence whether or not it was possible under the circumstances to commit the offence.
- **Marginal note:Question of law**

  **(2)** The question whether an act or omission by a person who has an intent to commit an offence is or is not mere preparation to commit the offence, and too remote to constitute an attempt to commit the offence, is a question of law.

- R.S., c. C-34, s. 24

# Protection of Persons Administering and Enforcing the Law

**Marginal note:Protection of persons acting under authority**

- **25 (1)** Every one who is required or authorized by law to do anything in the administration or enforcement of the law
  - **(a)** as a private person,
  - **(b)** as a peace officer or public officer,
  - **(c)** in aid of a peace officer or public officer, or
  - **(d)** by virtue of his office,

  is, if he acts on reasonable grounds, justified in doing what he is required or authorized to do and in using as much force as is necessary for that purpose.
- **Marginal note:Idem**

  **(2)** Where a person is required or authorized by law to execute a process or to carry out a sentence, that person or any person who assists him is, if that person acts in good faith, justified in executing the process or in carrying out the sentence notwithstanding that the process or sentence is defective or that it was issued or imposed without jurisdiction or in excess of jurisdiction.
- **Marginal note:When not protected**

  **(3)** Subject to subsections (4) and (5), a person is not justified for the purposes of subsection (1) in using force that is intended or is likely to cause death or grievous bodily harm unless the person believes on reasonable grounds that it is necessary for the self-preservation of the person or the preservation of any one under that person's protection from death or grievous bodily harm.
- **Marginal note:When protected**

**(4)** A peace officer, and every person lawfully assisting the peace officer, is justified in using force that is intended or is likely to cause death or grievous bodily harm to a person to be arrested, if

- **(a)** the peace officer is proceeding lawfully to arrest, with or without warrant, the person to be arrested;
- **(b)** the offence for which the person is to be arrested is one for which that person may be arrested without warrant;
- **(c)** the person to be arrested takes flight to avoid arrest;
- **(d)** the peace officer or other person using the force believes on reasonable grounds that the force is necessary for the purpose of protecting the peace officer, the person lawfully assisting the peace officer or any other person from imminent or future death or grievous bodily harm; and
- **(e)** the flight cannot be prevented by reasonable means in a less violent manner.

- **Marginal note:Power in case of escape from penitentiary**

  **(5)** A peace officer is justified in using force that is intended or is likely to cause death or grievous bodily harm against an inmate who is escaping from a penitentiary within the meaning of subsection 2(1) of the *Corrections and Conditional Release Act,* if

  - **(a)** the peace officer believes on reasonable grounds that any of the inmates of the penitentiary poses a threat of death or grievous bodily harm to the peace officer or any other person; and
  - **(b)** the escape cannot be prevented by reasonable means in a less violent manner.

- R.S., 1985, c. C-46, s. 25
- 1994, c. 12, s. 1

**Marginal note:Definitions**

- **25.1 (1)** The following definitions apply in this section and sections 25.2 to 25.4.

  ***competent authority*** means, with respect to a public officer or a senior official,

  - **(a)** in the case of a member of the Royal Canadian Mounted Police, the Minister of Public Safety and Emergency Preparedness, personally;
  - **(b)** in the case of a member of a police service constituted under the laws of a province, the Minister responsible for policing in the province, personally; and

- **(c)** in the case of any other public officer or senior official, the Minister who has responsibility for the Act of Parliament that the officer or official has the power to enforce, personally. (*autorité compétente*)

***public officer*** means a peace officer, or a public officer who has the powers of a peace officer under an Act of Parliament. (*fonctionnaire public*)

***senior official*** means a senior official who is responsible for law enforcement and who is designated under subsection (5). (*fonctionnaire supérieur*)

- **Marginal note:Principle**

  **(2)** It is in the public interest to ensure that public officers may effectively carry out their law enforcement duties in accordance with the rule of law and, to that end, to expressly recognize in law a justification for public officers and other persons acting at their direction to commit acts or omissions that would otherwise constitute offences.

- **Marginal note:Designation of public officers**

  **(3)** A competent authority may designate public officers for the purposes of this section and sections 25.2 to 25.4.

- **Marginal note:Condition — civilian oversight**

  **(3.1)** A competent authority referred to in paragraph (a) or (b) of the definition of that term in subsection (1) may not designate any public officer under subsection (3) unless there is a public authority composed of persons who are not peace officers that may review the public officer's conduct.

- **Marginal note:Declaration as evidence**

  **(3.2)** The Governor in Council or the lieutenant governor in council of a province, as the case may be, may designate a person or body as a public authority for the purposes of subsection (3.1), and that designation is conclusive evidence that the person or body is a public authority described in that subsection.

- **Marginal note:Considerations**

  **(4)** The competent authority shall make designations under subsection (3) on the advice of a senior official and shall consider the nature of the duties performed by the public officer in relation to law enforcement generally, rather than in relation to any particular investigation or enforcement activity.

- **Marginal note:Designation of senior officials**

  **(5)** A competent authority may designate senior officials for the purposes of this section and sections 25.2 to 25.4.

- **Marginal note:Emergency designation**

  **(6)** A senior official may designate a public officer for the purposes of this section and sections 25.2 to 25.4 for a period of not more than 48 hours if the senior official is of the opinion that

- **(a)** by reason of exigent circumstances, it is not feasible for the competent authority to designate a public officer under subsection (3); and
- **(b)** in the circumstances of the case, the public officer would be justified in committing an act or omission that would otherwise constitute an offence.

The senior official shall without delay notify the competent authority of the designation.

- **Marginal note:Conditions**

**(7)** A designation under subsection (3) or (6) may be made subject to conditions, including conditions limiting

- **(a)** the duration of the designation;
- **(b)** the nature of the conduct in the investigation of which a public officer may be justified in committing, or directing another person to commit, acts or omissions that would otherwise constitute an offence; and
- **(c)** the acts or omissions that would otherwise constitute an offence and that a public officer may be justified in committing or directing another person to commit.

- **Marginal note:Justification for acts or omissions**

**(8)** A public officer is justified in committing an act or omission — or in directing the commission of an act or omission under subsection (10) — that would otherwise constitute an offence if the public officer

- **(a)** is engaged in the investigation of an offence under, or the enforcement of, an Act of Parliament or in the investigation of criminal activity;
- **(b)** is designated under subsection (3) or (6); and
- **(c)** believes on reasonable grounds that the commission of the act or omission, as compared to the nature of the offence or criminal activity being investigated, is reasonable and proportional in the circumstances, having regard to such matters as the nature of the act or omission, the nature of the investigation and the reasonable availability of other means for carrying out the public officer's law enforcement duties.

- **Marginal note:Requirements for certain acts**

**(9)** No public officer is justified in committing an act or omission that would otherwise constitute an offence and that would be likely to result in loss of or serious damage to property, or in directing the commission of an act or omission

under subsection (10), unless, in addition to meeting the conditions set out in paragraphs (8)(a) to (c), he or she

- **(a)** is personally authorized in writing to commit the act or omission — or direct its commission — by a senior official who believes on reasonable grounds that committing the act or omission, as compared to the nature of the offence or criminal activity being investigated, is reasonable and proportional in the circumstances, having regard to such matters as the nature of the act or omission, the nature of the investigation and the reasonable availability of other means for carrying out the public officer's law enforcement duties; or
- **(b)** believes on reasonable grounds that the grounds for obtaining an authorization under paragraph (a) exist but it is not feasible in the circumstances to obtain the authorization and that the act or omission is necessary to
  - **(i)** preserve the life or safety of any person,
  - **(ii)** prevent the compromise of the identity of a public officer acting in an undercover capacity, of a confidential informant or of a person acting covertly under the direction and control of a public officer, or
  - **(iii)** prevent the imminent loss or destruction of evidence of an indictable offence.

- **Marginal note:Person acting at direction of public officer**

  **(10)** A person who commits an act or omission that would otherwise constitute an offence is justified in committing it if

  - **(a)** a public officer directs him or her to commit that act or omission and the person believes on reasonable grounds that the public officer has the authority to give that direction; and
  - **(b)** he or she believes on reasonable grounds that the commission of that act or omission is for the purpose of assisting the public officer in the public officer's law enforcement duties.

- **Marginal note:Limitation**

  **(11)** Nothing in this section justifies

  - **(a)** the intentional or criminally negligent causing of death or bodily harm to another person;
  - **(b)** the wilful attempt in any manner to obstruct, pervert or defeat the course of justice; or
  - **(c)** conduct that would violate the sexual integrity of an individual.

- **Marginal note:Protection, defences and immunities unaffected**

**(12)** Nothing in this section affects the protection, defences and immunities of peace officers and other persons recognized under the law of Canada.

- **Marginal note:Compliance with requirements**

  **(13)** Nothing in this section relieves a public officer of criminal liability for failing to comply with any other requirements that govern the collection of evidence.

# Assaults

**Marginal note:Uttering threats**

- **264.1 (1)** Every one commits an offence who, in any manner, knowingly utters, conveys or causes any person to receive a threat
  - **(a)** to cause death or bodily harm to any person;
  - **(b)** to burn, destroy or damage real or personal property; or
  - **(c)** to kill, poison or injure an animal or bird that is the property of any person.
- **Marginal note:Punishment**

  **(2)** Every one who commits an offence under paragraph (1)(a) is guilty of
  - **(a)** an indictable offence and liable to imprisonment for a term not exceeding five years; or
  - **(b)** an offence punishable on summary conviction.
- **Marginal note:Idem**

  **(3)** Every one who commits an offence under paragraph (1)(b) or (c)
  - **(a)** is guilty of an indictable offence and liable to imprisonment for a term not exceeding two years; or
  - **(b)** is guilty of an offence punishable on summary conviction.

- R.S., 1985, c. 27 (1st Supp.), s. 38
- 1994, c. 44, s. 16
- 2019, c. 25, s. 92

# Hate Propaganda

**Marginal note:Advocating genocide**

- **318 (1)** Every person who advocates or promotes genocide is guilty of an indictable offence and liable to imprisonment for a term of not more than five years.
- **Marginal note:Definition of *genocide***

**(2)** In this section, ***genocide*** means any of the following acts committed with intent to destroy in whole or in part any identifiable group, namely,

- **(a)** killing members of the group; or
- **(b)** deliberately inflicting on the group conditions of life calculated to bring about its physical destruction.

- **Marginal note:Consent**

**(3)** No proceeding for an offence under this section shall be instituted without the consent of the Attorney General.

- **Marginal note:Definition of *identifiable group***

**(4)** In this section, ***identifiable group*** means any section of the public distinguished by colour, race, religion, national or ethnic origin, age, sex, sexual orientation, gender identity or expression, or mental or physical disability.

- R.S., 1985, c. C-46, s. 318
- 2004, c. 14, s. 1
- 2014, c. 31, s. 12
- 2017, c. 13, s. 3
- 2019, c. 25, s. 120

**Extortion**

- **346 (1)** Every one commits extortion who, without reasonable justification or excuse and with intent to obtain anything, by threats, accusations, menaces or violence induces or attempts to induce any person, whether or not he is the person threatened, accused or menaced or to whom violence is shown, to do anything or cause anything to be done.

- **Marginal note:Extortion**

**(1.1)** Every person who commits extortion is guilty of an indictable offence and liable

- **(a)** if a restricted firearm or prohibited firearm is used in the commission of the offence or if any firearm is used in the commission of the offence and the offence is committed for the benefit of, at the direction of, or in association with, a criminal organization, to imprisonment for life and to a minimum punishment of imprisonment for a term of
  - **(i)** in the case of a first offence, five years, and
  - **(ii)** in the case of a second or subsequent offence, seven years;
- **(a.1)** in any other case where a firearm is used in the commission of the offence, to imprisonment for life and to a minimum punishment of imprisonment for a term of four years; and

- **(b)** in any other case, to imprisonment for life.

- **Marginal note:Subsequent offences**

  **(1.2)** In determining, for the purpose of paragraph (1.1)(a), whether a convicted person has committed a second or subsequent offence, if the person was earlier convicted of any of the following offences, that offence is to be considered as an earlier offence:

  - **(a)** an offence under this section;
  - **(b)** an offence under subsection 85(1) or (2) or section 244 or 244.2; or
  - **(c)** an offence under section 220, 236, 239, 272 or 273, subsection 279(1) or section 279.1 or 344 if a firearm was used in the commission of the offence.

  However, an earlier offence shall not be taken into account if 10 years have elapsed between the day on which the person was convicted of the earlier offence and the day on which the person was convicted of the offence for which sentence is being imposed, not taking into account any time in custody.

- **Marginal note:Sequence of convictions only**

  **(1.3)** For the purposes of subsection (1.2), the only question to be considered is the sequence of convictions and no consideration shall be given to the sequence of commission of offences or whether any offence occurred before or after any conviction.

- **Marginal note:Saving**

  **(2)** A threat to institute civil proceedings is not a threat for the purposes of this section.

- R.S., 1985, c. C-46, s. 346
- R.S., 1985, c. 27 (1st Supp.), s. 46
- 1995, c. 39, s. 150
- 2008, c. 6, s. 33
- 2009, c. 22, s. 15

# What is Gillick competence?

Richard Griffith*



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## Abstract

This article considers the requirements for Gillick competence, it highlights the factors that must be considered when determining whether a child is competent to give consent to treatment.

**Keywords:** competence, consent, Gillick, immunization

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## Introduction

Obtaining consent for immunization becomes more complex where parental responsibility and the developmental concept of Gillick competence become intertwined as the child matures to adulthood. It is essential that health professionals are able to identify who can give consent on behalf of a child and how to determine whether a child has the competence to make a decision about receiving immunization themselves.

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## Consent

Consent is the legal expression of the moral principle of autonomy. It underpins the propriety of the treatment and furnishes a defense to the

crime of battery and civil wrong of trespass.[1] It must be obtained before an immunization can proceed.

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## Children and the Law of Consent

The United Nations Convention on Children's Rights (UNCRC; 1989) defines a child as any person under 18; however, by convention British courts refer to all persons under 18 as minors, those under 16 as children and 16 and 17 y olds as young persons.[2] The UNCRC requires that childhood is recognized as a developmental period and that our domestic laws must be developed 'in a manner consistent with the evolving capacities of the child' (United Nations 1989, Article 5).[2] As children grow and develop in maturity, their views and wishes must be given greater weight and their development toward adulthood must be respected and promoted.

This key principle is reflected in consent law applied to children. Kennedy & Grubb (1998) argue that children pass through 3 developmental stages on their journey to becoming an autonomous adult.[3]

1. The child of tender years who rely on a person with parental responsibility to consent to treatment.
2. The Gillick competent child under 16
3. Young person's 16 and 17 y old who are able to consent to treatment as if they 'were of full age'.[4]

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## The Gillick Competent Child

The right of a child under 16 to consent to medical examination and treatment, including immunization was decided by the House of Lords in *Gillick v West Norfolk and Wisbech AHA* [1986] where a mother of girls

under 16 objected to Department of Health advice that allowed doctors to give contraceptive advice and treatment to children without parental consent.[5] Their Lordships held that a child under 16 had the legal competence to consent to medical examination and treatment if they had sufficient maturity and intelligence to understand the nature and implications of that treatment.[5]

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## Gillick or Fraser an Urban Myth

Wheeler (2006) argues that something of an urban myth has emerged over the use of the term Gillick competence.[6] It suggests that Mrs Gillick wishes to disassociate her name from the assessment of children's capacity, thus carrying the implication that the objective test of a child's competence should be renamed the Fraser competence. Alteration of an established legal test would be unusual, and cause confusion and following correspondence with Victoria Gillick, Wheeler is clear that she "has never suggested to anyone, publicly or privately, that [she] disliked being associated with the term 'Gillick competent'."[6]

Gillick competence is therefore the correct term, still used by judges and health professionals, to identify children aged under 16 who have the legal competence to consent to immunization, providing they can demonstrate sufficient maturity and intelligence to understand and appraise the nature and implications of the proposed treatment, including the risks and alternative courses of actions.

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## Assessing Gillick Competence

The rule in Gillick must be applied when determining whether a child under 16 has competence to consent. The aim of Gillick competence is to reflect the transition of a child to adulthood. Legal competence to make decisions is conditional on the child gradually acquiring both:

- Maturity
- That takes account of the child's experiences and the child's ability to manage influences on their decision making such as information, peer pressure, family pressure, fear and misgivings.
- Intelligence
- That takes account of the child's understanding, ability to weigh risk and benefit, consideration of longer term factors such as effect on family life and on such things as schooling.

The degree of maturity and intelligence needed depends on the gravity of the decision. A relatively young child would have sufficient maturity and intelligence to be competent to consent to a plaster on a small cut. Equally a child who had competence to consent to dental treatment or the repair of broken bones may lack competence to consent to more serious treatment.[7] This could be because they do not understand the treatment implications or because they felt overwhelmed by the decisions they are being asked to make and so lacked the maturity to make it.

Decision making competence does not simply arrive with puberty; it depends on the maturity and intelligence of the child and the seriousness of the treatment decision to be made.

Gillick competence is a functional ability to make a decision. It is task specific so more complex procedures require greater levels of competence. When assessing Gillick competence for immunization, a health professional has to decide whether the child is or is not competent to make that particular decision. It is not just an ability to choose where the child recognizes that there is a choice to be made and is willing to make it. Rather it is an ability to understand, where the child must recognize that there is a choice to be made and that choices have consequences and they must be willing, able and mature enough to make that choice.

Health professionals must be satisfied that the child understands:

- The necessity for immunization and the reasons for it; and
- The risks, intended benefits and outcomes of the proposed immunization and alternatives to immunization, including the option of not having or delaying the immunization.

Assessment of Gillick competence requires an examination of how the child deals with the process of making a decision based on an analysis of the child's ability to understand and assess risks. It is a high test of competence that is more difficult to satisfy the more complex the treatment and its outcomes become. To date no court has found a child in need of life sustaining treatment competent to refuse that treatment.[8]

Sufficient time for the assessment must be allowed by the health professional who needs to be satisfied that a child has fully understood the nature and consequences of the proposed immunization and is mature enough to take account of broader health and social factors when making their decision.

The right to decide on competence must not be used as a license to disregard the wishes of parents whenever the health professional finds it convenient to do so. Health professionals who behave in this way would be failing to discharge their professional responsibilities and could expect to be disciplined by their professional body.[5] Where a child is considered Gillick competent then the consent is as effective as that of an adult and cannot be overruled by a parent.

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## Refusal of Treatment

If a Gillick competent child refuses medical examination or treatment then the law does allow a person with parental responsibility to consent in their place. Lord Donaldson summed up the position when he held that.[9]

*[Consent] protects the [health professional] from claims by the litigious whether they acquire it from their patient, who may be a minor over the age of 16 or a 'Gillick competent' child under that age, or from another person having parental responsibilities which include a right to consent to treatment of the minor.*

*Anyone who gives him consent may take it back, but the [health professional] only needs one and so long as they continue to have one they have the legal right to proceed.*[9]

Where a health professional accepts the consent of a Gillick competent child it cannot be overruled by the child's parent. However, where the same child refuses consent then they may obtain it from another person with parental responsibility who can consent to treatment on the child's behalf.

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## Immunization, Safeguarding or Parental Choice

Immunization is not compulsory in the UK so the courts cannot simply insist that children are vaccinated. Courts cannot treat the matter as a case of significant harm to a child that would warrant state intervention under the Children Act 1989.

However, where parents are in dispute with each other over an issue of parental responsibility, that can include disagreement over immunization, then if negotiation fails they can go to court to resolve the matter. Although a question of private law rather than state intervention into family life, the courts are still obliged to follow the provisions of the Children Act 1989 and consider the best interests of the welfare of that child.

Childhood immunization was considered by the High Court.[10] and subsequently by the Court of Appeal.[11] in a case that concerned 2 girls aged 4 and 10 y whose mothers had fundamental objections to

immunization and had refused to allow their daughters to receive any of the usual childhood vaccinations. Their fathers made an application to the court seeking the immunization of their children. The two girls lived with their respective mothers. Both fathers were in contact with their daughters and had parental responsibility through court orders. The fathers argued that the immunizations were in the children's best interests.

As the case concerned a fundamental issue of parental responsibility the High Court heard the case under the provisions of section 8 of the Children Act 1989. This provides private law remedies to settle matters of parental responsibility concerning a child. Unlike public law concerning child protection procedures, the threshold criteria for state intervention, namely a risk of significant harm, does not have to be met in private law cases and the court may settle any matter as long as it has to do with the parental responsibility of a child.

More recently the court has considered the immunization of older children. In *F v F* [2013] the High Court ordered that sisters aged 11 and 15 y must receive the MMR vaccine.[11] Mr Justice Sumner made it clear that although the case concerned a dispute between parents his only concern was for the best interests of the welfare of the children.

The judge concluded that immunization would be in the best interests of the welfare of each child. The age of the children was significant in this case. At 11 and 15 y the judge was obliged to consider whether they were Gillick competent, in that they had the maturity and intelligence to refuse the MMR vaccine. The judge concluded that neither child was competent due to the influence of the mother on their beliefs about immunization.[12]

In Re B (Child) [2003] the Court of Appeal accepted that, in general, there is wide scope for parental objection to medical intervention. Lord Justice Thorpe viewed medical interventions as existing on a scale. At one end there are the obvious cases where parental objection would have no value in child welfare terms, for example urgent lifesaving treatment

such as a blood transfusion. At the other end are cases where there is genuine scope for debate and the views of the parents are important. Immunization he held was an area where there was room for genuine debate.[11]

Immunization is voluntary and generally it is for those who have parental responsibility for a child or children who are Gillick competent to decide on immunization. It is not a question of neglect or abuse that would trigger child protection proceedings.

Although people with parental responsibility were generally free to act alone when making decisions for their children this freedom was not unfettered. He held that there are a small group of decisions to be made about a child that require the agreement of both parents; these include changing a child's surname, sterilisation and circumcision. This small group he said now included hotly disputed immunization.[11]

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## The Practicality of Enforcement

Despite the granting of an order by the High Court it is known that practical difficulties have, to date, prevented the giving of the vaccine to the children in the *F v F* [2013] case (Hickey 2013).[12,13]

A number of enforcement measures are available to the court but these are at the discretion of the judge who will again need to balance the best interests of the child against the impact of any enforcement measure. Under the Family Proceedings Rules 1991 a penal notice may be attached to a specific issues order. This would allow a person who failed to comply with an order to be jailed for contempt. Alternatively the court could direct enforcement by arranging for the removal of the child by an officer of the court for the forcible administration of the immunization. In practice both remedies are unlikely to be sanctioned as their impact on the child's welfare would be detrimental.

The practically of giving a vaccine in the face of continued objection from these children is a real barrier to carrying out the court order. Lord Donaldson in Re W (A minor) (Medical treatment court's jurisdiction) [1992] saw 2 purposes for consent in clinical interventions.[9] The first was the legal defense to an allegation of unlawful touch or trespass to the person. Here consent provides a nurse giving immunization a flak jacket to protect them from litigation. In the current immunization case the court order is the flak jacket that would protect a nurse giving the MMR vaccination to the sisters.

Lord Donaldson stressed that consent also has a second equally important clinical purpose:

*The clinical purpose (of consent) stems from the fact that in many instances the co-operation of the patient, and the patient's faith or at least confidence in the efficacy of the treatment, is a major factor contributing to the treatment's success. Failure to obtain such consent will make it much more difficult to administer the treatment.*[9]

Failure to obtain the co-operation of the children will make it very difficult to safely give the MMR. Consent is permission to touch and give the agreed treatment. It does not compel nurses to provide the treatment. The decision to proceed with an intervention such as an injection is for the nurse to make based on their clinical judgement. If the nurse's judgement is that attempting to give the immunization in the face of continued resistance from the child then it is open to the nurse to refuse to proceed at that time.

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## Conclusion

Consent is essential to the propriety of treatment and is necessary to meet the requirements of the law. Treatment cannot generally proceed without it. The United Nations Convention on the Rights of the Child requires that the evolving capacities of children are respected and this

requirement is reflected in the law of consent where a child with the necessary maturity and intelligence can give valid consent to examination or treatment.[2]

Health professionals must be confident in assessing a child's Gillick competence in order to ensure that the child's rights are respected, this requires the health professional to evaluate the child's maturity and intelligence when seeking consent to immunization. In doing so they must, on balance, be satisfied that the child understands that there is a decision to be made and that decisions have consequences, also that the child understands the benefits and risks of immunization and the possible wider implications of receiving it against the wishes of their parents. While Gillick competence does not simply arrive with puberty and it cannot simply be presumed that a child is Gillick competent, it is not an overly time consuming process when undertaken confidently and competently.

Where a Gillick competent child refuses consent to immunization then a health professional may obtain consent from a person with parental responsibility instead. Where both parents and a Gillick competent child refuse then resorting to litigation is likely to be an ineffective approach. The courts do not adopt an unquestioning recommendation of immunization but give careful consideration to each case on its facts. Immunization may not be appropriate in every case. The court views immunization as a voluntary process that both parents are entitled to be consulted on. Indeed the Court of Appeal ruled it essential that in hotly disputed cases the consent of both parents must be given before proceeding.

Yet even where, as in *F v F* [2013],[12] the courts order that children be given the immunization, the practicalities of actually doing so mean that the children remain unvaccinated. A court order is no guarantee that the vaccine will be administered.

## Disclosure of Potential Conflicts of Interest

There are no potential conflicts of interest.

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THE WORLD MEDICAL ASSOCIATION, INC.

# DECLARATION OF HELSINKI
## Ethical Principles for Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the:
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
53th WMA General Assembly, Washington, United States, October 2002
(Note of Clarification on paragraph 29 added)
55th WMA General Assembly, Tokyo, Japan, October 2004
(Note of Clarification on Paragraph 30 added)
WMA General Assembly, Seoul, Korea, October 2008

## A. INTRODUCTION

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects**,** including research on identifiable human material and data.

   The Declaration is intended to be read as a whole and each of its constituent paragraphs should not be applied without consideration of all other relevant paragraphs.

2. Although the Declaration is addressed primarily to physicians, the WMA encourages other participants in medical research involving human subjects to adopt these principles.

3. It is the duty of the physician to promote and safeguard the health of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.

4. The Declaration of Geneva of the WMA binds the physician with the words, “The health of my patient will be my first consideration,” and the International Code of Medical Ethics declares that, “A physician shall act in the patient's best interest when providing medical care.”

5. Medical progress is based on research that ultimately must include studies involving human subjects. Populations that are underrepresented in medical research should be provided appropriate access to participation in research.

6. In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests.

7. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best current

interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.

8. In medical practice and in medical research, most interventions involve risks and burdens.

9. Medical research is subject to ethical standards that promote respect for all human subjects and protect their health and rights. Some research populations are particularly vulnerable and need special protection. These include those who cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue influence.

10. Physicians should consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.

## B. PRINCIPLES FOR ALL MEDICAL RESEARCH

11. It is the duty of physicians who participate in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects.

12. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.

13. Appropriate caution must be exercised in the conduct of medical research that may harm the environment.

14. The design and performance of each research study involving human subjects must be clearly described in a research protocol. The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest, incentives for subjects and provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study. The protocol should describe arrangements for post-study access by study subjects to interventions identified as beneficial in the study or access to other appropriate care or benefits.

15. The research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins. This committee must be independent of the researcher, the sponsor and any other undue influence. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration. The committee must have the right to monitor

ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No change to the protocol may be made without consideration and approval by the committee.

16. Medical research involving human subjects must be conducted only by individuals with the appropriate scientific training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional. The responsibility for the protection of research subjects must always rest with the physician or other health care professional and never the research subjects, even though they have given consent.

17. Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research.

18. Every medical research study involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and communities involved in the research in comparison with foreseeable benefits to them and to other individuals or communities affected by the condition under investigation.

19. Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject.

20. Physicians may not participate in a research study involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians must immediately stop a study when the risks are found to outweigh the potential benefits or when there is conclusive proof of positive and beneficial results.

21. Medical research involving human subjects may only be conducted if the importance of the objective outweighs the inherent risks and burdens to the research subjects.

22. Participation by competent individuals as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no competent individual may be enrolled in a research study unless he or she freely agrees.

23. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information and to minimize the impact of the study on their physical, mental and social integrity.

24. In medical research involving competent human subjects, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information. After ensuring that

the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.

25. For medical research using identifiable human material or data, physicians must normally seek consent for the collection, analysis, storage and/or reuse. There may be situations where consent would be impossible or impractical to obtain for such research or would pose a threat to the validity of the research. In such situations the research may be done only after consideration and approval of a research ethics committee.

26. When seeking informed consent for participation in a research study the physician should be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent should be sought by an appropriately qualified individual who is completely independent of this relationship.

27. For a potential research subject who is incompetent, the physician must seek informed consent from the legally authorized representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the population represented by the potential subject, the research cannot instead be performed with competent persons, and the research entails only minimal risk and minimal burden.

28. When a potential research subject who is deemed incompetent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorized representative. The potential subject's dissent should be respected.

29. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research population. In such circumstances the physician should seek informed consent from the legally authorized representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research should be obtained as soon as possible from the subject or a legally authorized representative.

30. Authors, editors and publishers all have ethical obligations with regard to the publication of the results of research. Authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. They should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results should be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest should be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

## C. ADDITIONAL PRINCIPLES FOR MEDICAL RESEARCH COMBINED WITH MEDICAL CARE

31. The physician may combine medical research with medical care only to the extent that the research is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.

32. The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best current proven intervention, except in the following circumstances:
    - The use of placebo, or no treatment, is acceptable in studies where no current proven intervention exists; or
    - Where for compelling and scientifically sound methodological reasons the use of placebo is necessary to determine the efficacy or safety of an intervention and the patients who receive placebo or no treatment will not be subject to any risk of serious or irreversible harm. Extreme care must be taken to avoid abuse of this option.

33. At the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study and to share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits.

34. The physician must fully inform the patient which aspects of the care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never interfere with the patient-physician relationship.

35. In the treatment of a patient, where proven interventions do not exist or have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorized representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. Where possible, this intervention should be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information should be recorded and, where appropriate, made publicly available.

★★★

How To File a Human Rights Complaint:

Shared from elsewhere, in support of getting all of this overturned (source unknown, no spelling or grammar corrected):

“Here is how to defeat the vaccines & passports. Step by step.
1. Go get turned down or kicked out of an establishment, restaurant, school, etc document it.
2. Call the human rights commission. 18003879080 or file online
3. Make a complaint and get a file number.
4. Use that file number and make a statement with the human rights commission.
5. The human rights commission will serve them papers.
6. The place that rejected you will think they can win in court.
7. The judge will force them to pay because the human rights commission will remind them no business private or public can discriminate against anyone based on religion, race and yes any health reasons because it is illegal.
8. Everyone will overwhelm the places that they will also fight against the passports by allowing everyone inside and not turning anyone away.

They will have to pay for breaking the law, and they will not be able to handle more than 1 case at a time.

No protesting needed. No boycotting. There are many systems in place but no education on them.

If you truly want to be free and not feel like a victim then do these steps and share this.

No party representative is telling you this because they make money from votes and lobbyists. That's why I'm working as a public servant to actually help people wether or not I "win" any seats.

Independent 💛 ❤️ ”

# Under the Shadow of Damocles' Sword: Forcing Employers to Put Their Fingerprints on Tyranny (an update on Constable Adrienne Gilvesy's fight against mandatory vaccination)

This post is an update on Constable Adrienne Gilvesy's fight against the Toronto Police Services' mandatory vaccination requirement. As a follow-up to the letter she sent on August 28th, which I recently published on my website (An Example of Courageous Pushback For Those Facing Vaccine Mandates in the Workplace), she has now filed an official misconduct complaint with the Toronto Police Service Professional Standards Unit against her Chief of Police, Chief James Ramer, for various provincial and criminal code offences.

If found guilty, Chief Ramer could face time in prison. And, theoretically, so could any other superior with whom she lodges her complaints if they knowingly allow a criminal injustice to continue. "Just doing my job" is not a legal defense. "Just turning a blind eye" also doesn't stand up in court when it's their job to investigate a problem. Once the complaint is filed, those with the responsibility to investigate that complaint are drawn into this fight. She is forcing everyone off the sidelines by making them decide which side of the legal line they want to stand on. This is as real as it gets.

I have reproduced her complaint (with permission) for you below. But first I'd like to take a moment to explain the enormous implications of what she is doing. If enough people follow in her footsteps, NOW, to build momentum behind what she is doing, she is creating a spark that has the potential to trigger a massive institutional crisis that pits the lower levels of our institutions against the upper crust.

Simply by using all the legal tools available to her to defend her rights, and by refusing to back down, she is challenging the very core of the supportive pillars holding up this tyranny. A tyranny cannot survive without the support of its institutions. Tyranny collapses without minions.

As more people launch lawsuits and file official complaints, as Constable Gilvesy has done, employers who impose these mandates on their employees are placing themselves in legal peril. Her battle is happening at the heart of the Toronto Police Services, but the lessons of her actions apply equally to any institution, corporation, or business that is imposing these vaccine mandates on its employees.

Here's the problem for all employers: whether it takes days, months, or years, the hysteria will eventually end, but these official complaints will not just go away — those committing offenses in the name of imposing vaccine mandates are going to have to answer to these charges someday in a court of law. Constable Gilvesy is building a legal avalanche, ready and waiting for the hysteria to end. It will hang over the heads of employers like the ever-present peril of Damocles' Sword. As that avalanche grows, they will have to decide if they really trust the government to keep that sword off their own necks.

If you quit your job, you relieve your employer of the legal consequences of their decision to enforce these mandates. Do not quit. Make them fire you. By making them fire you, they have to (1) confront the difficult moral choice of firing you and (2) you put them into a position where they may face serious legal repercussions (possibly even criminal accountability) for discriminating against you based on your medical status.

Your employer cannot be sure that the government will protect them from the legal consequences of an illegal vaccine mandate. When the tyranny collapses, there won't be a Justin Trudeau or Doug Ford to shield them from the consequences of having played a role in the tyranny. And that creates a huge dilemma for employers. The larger the legal avalanche that employers face, the greater the likelihood that employers will push back against the government rather than risk crippling lawsuits and possible jail time at some point down the road. Constable Gilvesy is forcing the rats to decide if they want to go down with the government's ship. Damocles' Sword grows large and heavy indeed if tens of thousands of employees across the country start to follow in her footsteps.

It's easy for someone to get swept along by the tide of hysteria... until the day that they find themselves having to confront hard moral decisions and until the moment they find themselves at risk of facing legal consequences for having participated in the tyranny. It's one thing to be part of a baying mob. It's quite another to be the one who has to put on the jackboot to grind it into someone else's face. By refusing to quit, you shift the tyranny into their shoes. By refusing to quit, you force them to take an active role in destroying someone's career and in taking away someone's ability to feed their family. It makes them get their hands dirty.

Prime Minister Justin Trudeau has told Canadians that he will protect businesses from legal challenges like those filed by Constable Gilvesy. But a Prime Minister does not have the authority to suspend the rule of law. And that forces employers to confront the question of how long the government will pervert the rule of law in order to protect their sorry butts. The hysteria will end someday. Damocles' Sword will be waiting. If the government has shown itself to be willing to throw you under the bus to cater to fearful voters today, then it also

won't hesitate to throw your employer under the bus tomorrow, after the tide turns, in order to win back votes. At the end of the day, employee votes outnumber employer votes. Call the government's bluff. Refuse to quit. Call your employment lawyer. Make it uncomfortable. Make it real.

Constable Gilvesy is using every legal avenue available to her. Every official complaint and every legal challenge she files is going to haunt these people. For them, the end of the pandemic won't bring relief - it will bring lawsuits. They don't know if they will win. And the sheer cost of defending themselves against thousands of angry employees whose inalienable rights and freedoms have been trampled may force many of these businesses into bankruptcy long before the cases even reach a judge.

Most employers are old enough to remember that until 18 months ago we still had something called a Charter of Rights and Freedoms. It has not been invalidated; it is just being ignored. Being confronted by a lawsuit forces them to gauge their chances of winning if society rediscovers an appetite for a Charter with real teeth. The more people that follow in Constable Gilvesy's footsteps, the heavier Damocles' Sword becomes.

*"Nonviolent direct action seeks to create such a crisis & foster such a tension that a community which has constantly refused to negotiate is forced to confront the issue. It seeks so to dramatize the issue that it can no longer be ignored."* — Martin Luther King Jr.

There are many peaceful ways to create a crisis and force a community to confront an issue. Constable Gilvesy's approach is one of those ways. She, along with others who follow in her footsteps, are forcing the leaders of businesses and institutions to confront the immorality of nodding along with the government's tyranny. By

refusing to back down, Constable Gilvesy is backing her employers into a corner and asking them if they want to share the fate of the upper crust of our political and medical institutions. When this hysteria breaks, the top tier of our government will face human rights tribunals and may do hard time in prison. What they have done is not small potatoes.

For the upper crust, there is no backing down. Their goose is cooked. They cannot fall back on "we were just following orders." They gave the orders. But the Nuremberg trials after World War II established that those carrying out those orders are themselves criminally liable for human rights violations if those orders infringe upon anyone's inalienable human rights. Institutions have many layers below that upper crust. Rats don't want to go down with the ship. At some point, all the lower echelons of these institutions will begin to get nervous. Their collars will begin to feel tight as they see Damocles' Sword growing heavier above their own necks.

Constable Gilvesy is forcing them to ask themselves on which side of the legal line they want to be standing when the mood of the crowd changes. Will they find themselves in the witness stand or in the docks? Constable Gilvesy is denying them the option of neutrality by forcing them to put their fingerprints on the enforcement of these vaccine mandates.

Constable Gilvesy is following in Martin Luther King Jr.'s tradition by creating a crisis that can no longer be ignored. Every person above her in the hierarchy who is legally tasked with registering and investigating her official complaints no longer has the option of simply allowing themselves to get swept along by the tide of hysteria. They have to decide if they want to add their fingerprints to this government's tyranny and share its fate.

Sometimes crossing your arms, saying "No", and forcing others to wrestle with the consequences of not respecting your "No" is the most powerful peaceful leverage in the world. Give Constable Gilvesy a long enough lever and a fulcrum upon which to place it, and she will move the world.

So, without further ado, here is the official complaint that Constable Gilvesy's has filed against Chief Ramer. Consider sharing this article with your employer. It might save you both from having to call your lawyers.

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(This is not intended as legal advice. Contact your employment lawyer. Provided for informational purposes only. )

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TO: Supt. Christopher KIRKPATRICK
Professional Standards Unit

FROM: DC Adrienne GILVESY
[redacted] Division

DATE: 2021.09.07

**RE: MISCONDUCT**

Supt. Kirkpatrick,

I am writing you as you are the head of the Toronto Police Services Professional Standards Unit. Please see the attached notice sent to Chief James Ramer on August 28th 2021 by me. I would like to bring the attention of the Toronto Police Service's Professional Standards

Unit to the contents of that notice, Including all the referenced pieces of legislation.

I would also like to specifically draw attention to the fact that Chief Ramer has in fact committed several provincial and criminal offences, not to mention the TPS internal procedures.

The following Criminal Code of Canada offences have been committed by Chief Ramer as a result of the eUpdate regarding mandatory COVID-19 vaccination:

## 1. Uttering Threats

Uttering threats

- **264.1 (1)** Every one commits an offence who, in any manner, knowingly utters, conveys or causes any person to receive a threat
    - (a) to cause death or bodily harm to any person;

**Punishment**

**(2)** Every one who commits an offence under paragraph (1)(a) is guilty of

- **(a)** an indictable offence and liable to imprisonment for a term not exceeding five years; or
- **(b)** an offence punishable on summary conviction.

## 2. Assault

**Assault**

- **265 (1)** A person commits an assault when

- **(a)** without the consent of another person, he applies force intentionally to that other person directly or indirectly;
- **(b)** he attempts or threatens, by an act or a gesture, to apply force to another person, if he has, or causes that other person to believe on reasonable grounds that he has, present ability to effect his purpose; or

**Consent**

**(3)** For the purposes of this section, no consent is obtained where the complainant submits or does not resist by reason of

- **(a)** the application of force to the complainant or to a person other than the complainant;
- **(b)** threats or fear of the application of force to the complainant or to a person other than the complainant;
- **(c)** fraud; or
- **(d)** the exercise of authority.

**<u>3. Torture</u>**

**Torture**

- **269.1 (1)** Every official, or every person acting at the instigation of or with the consent or acquiescence of an official, who inflicts torture on any other person is guilty of an indictable offence and liable to imprisonment for a term not exceeding fourteen years.
- **Marginal note:**

**Definitions**

**(2)** For the purposes of this section,

***official*** means

- **(a)** a peace officer,
- **(b)** a public officer,
- **(c)** a member of the Canadian Forces, or
- **(d)** any person who may exercise powers, pursuant to a law in force in a foreign state, that would, in Canada, be exercised by a person referred to in paragraph (a), (b), or (c),

- whether the person exercises powers in Canada or outside Canada; (fonctionnaire)

***torture*** means any act or omission by which severe pain or suffering, whether physical or mental, is intentionally inflicted on a person

- **(a)** for a purpose including
  - **(i)** obtaining from the person or from a third person information or a statement,
  - **(ii)** punishing the person for an act that the person or a third person has committed or is suspected of having committed, and
  - **(iii)** intimidating or coercing the person or a third person, or
- **(b)** for any reason based on discrimination of any kind,

- but does not include any act or omission arising only from, inherent in or incidental to lawful sanctions. (torture)

**4. Extortion:**

**Extortion**

**346 (1)** Every one commits extortion who, without reasonable justification or excuse and with intent to obtain anything, by threats, accusations, menaces or violence induces or attempts to induce any person, whether or not he is the person threatened, accused or menaced or to whom violence is shown, to do anything or cause anything to be done.

**5. Public incitement of hatred:**

**Public incitement of hatred**

- **319 (1)** Every one who, by communicating statements in any public place, incites hatred against any identifiable group where such incitement is likely to lead to a breach of the peace is guilty of
    - **(a)** an indictable offence and is liable to imprisonment for a term not exceeding two years; or
    - **(b)** an offence punishable on summary conviction.

In light of this information, I trust that the Toronto Police Service Professional Standards Unit will adhere to their oath of office, the core values of the Service, and their position within the Service and investigate Chief Ramer for various provincial and criminal code offences, despite his rank.

I would also like to remind the Toronto Police Professional Standards of the following core value:

**Do the right thing:** by acting professionally, with integrity, and without prejudice, even in the most challenging circumstances, when no one is watching, and on and off duty; holding others accountable

to the same standards; challenging any inappropriate behavior; and asking ourselves,

***"Have I lived up to my word and values?"***

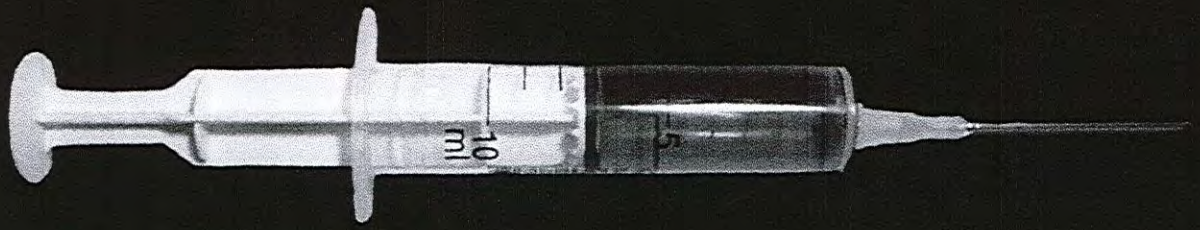
Sincerely,

DC Adrienne GILVESY

[redacted] Division

Toronto Police Service

# BEING PRESSURED TO VACCINATE?




## IN PERSON PLANNING MEETING THIS WEEK
## CALL NOW FOR DETAILS AND TO RESERVE YOUR SPOT

FOR CHRIS WEISDORF UPCOMING EVENTS, BOOKINGS AND CONSULTATIONS CONTACT
:::::::::::::::::: CINDY HARRIS 416.657.7771 ::::::::::::::::::

PUT AN END TO MANDATED VACCINATIONS | WE WILL NOT COMPLY

Concerned Constituents Of Canada

# CANADIAN CHARTER OF RIGHTS AND FREEDOMS

Whereas Canada is founded upon principles that recognize the supremacy of God and the rule of law:

## Guarantee of Rights and Freedoms

1. The *Canadian Charter of Rights and Freedoms* guarantees the rights and freedoms set out in it subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society.

## Fundamental Freedoms

2. Everyone has the following fundamental freedoms: *(a)* freedom of conscience and religion; *(b)* freedom of thought, belief, opinion and expression, including freedom of the press and other media of communication; *(c)* freedom of peaceful assembly; and *(d)* freedom of association.

## Democratic Rights

3. Every citizen of Canada has the right to vote in an election of members of the House of Commons or of a legislative assembly and to be qualified for membership therein. 4.(1) No House of Commons and no legislative assembly shall continue for longer than five years from the date fixed for the return of the writs at a general election of its members. (2) In time of real or apprehended war, invasion or insurrection, a House of Commons may be continued by Parliament and a legislative assembly may be continued by the legislature beyond five years if such continuation is not opposed by the votes of more than one-third of the members of the House of Commons or the legislative assembly, as the case may be. 5. There shall be a sitting of Parliament and of each legislature at least once every twelve months.

## Mobility Rights

6.(1) Every citizen of Canada has the right to enter, remain in and leave Canada. (2) Every citizen of Canada and every person who has the status of a permanent resident of Canada has the right *(a)* to move to and take up residence in any province; and *(b)* to pursue the gaining of a livelihood in any province. (3) The rights specified in subsection (2) are subject to *(a)* any laws or practices of general application in force in a province other than those that discriminate among persons primarily on the basis of province of present or previous residence; and *(b)* any laws providing for reasonable residency requirements as a qualification for the receipt of publicly provided social services. (4) Subsections (2) and (3) do not preclude any law, program or activity that has as its object the amelioration in a province of conditions of individuals in that province who are socially or economically disadvantaged if the rate of employment in that province is below the rate of employment in Canada.

## Legal Rights

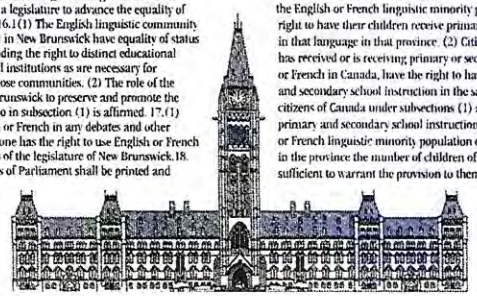
7. Everyone has the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice. 8. Everyone has the right to be secure against unreasonable search or seizure. 9. Everyone has the right not to be arbitrarily detained or imprisoned. 10. Everyone has the right on arrest or detention *(a)* to be informed promptly of the reasons therefor; *(b)* to retain and instruct counsel without delay and to be informed of that right; and *(c)* to have the validity of the detention determined by way of *habeas corpus* and to be released if the detention is not lawful. 11. Any person charged with an offence has the right *(a)* to be informed without unreasonable delay of the specific offence; *(b)* to be tried within a reasonable time; *(c)* not to be compelled to be a witness in proceedings against that person in respect of the offence; *(d)* to be presumed innocent until proven guilty according to law in a fair and public hearing by an independent and impartial tribunal; *(e)* not to be denied reasonable bail without just cause; *(f)* except in the case of an offence under military law tried before a military tribunal, to the benefit of trial by jury where the maximum punishment for the offence is imprisonment for five years or a more severe punishment; *(g)* not to be found guilty on account of any act or omission unless, at the time of the act or omission, it constituted an offence under Canadian or international law or was criminal according to the general principles of law recognized by the community of nations; *(h)* if finally acquitted of the offence, not to be tried for it again and, if finally found guilty and punished for the offence, not to be tried or punished for it again; and *(i)* if found guilty of the offence and if the punishment for the offence has been varied between the time of commission and the time of sentencing, to the benefit of the lesser punishment. 12. Everyone has the right not to be subjected to any cruel and unusual treatment or punishment. 13. A witness who testifies in any proceedings has the right not to have any incriminating evidence so given used to incriminate that witness in any other proceedings, except in a prosecution for perjury or for the giving of contradictory evidence. 14. A party or witness in any proceedings who does not understand or speak the language in which the proceedings are conducted or who is deaf has the right to the assistance of an interpreter.

## Equality Rights

15.(1) Every individual is equal before and under the law and has the right to the equal protection and equal benefit of the law without discrimination and, in particular, without discrimination based on race, national or ethnic origin, colour, religion, sex, age or mental or physical disability. (2) Subsection (1) does not preclude any law, program or activity that has as its object the amelioration of conditions of disadvantaged individuals or groups including those that are disadvantaged because of race, national or ethnic origin, colour, religion, sex, age or mental or physical disability.

## Official Languages of Canada

16.(1) English and French are the official languages of Canada and have equality of status and equal rights and privileges as to their use in all institutions of the Parliament and government of Canada. (2) English and French are the official languages of New Brunswick and have equality of status and equal rights and privileges as to their use in all institutions of the legislature and government of New Brunswick. (3) Nothing in this Charter limits the authority of Parliament or a legislature to advance the equality of status or use of English and French. 16.1(1) The English linguistic community and the French linguistic community in New Brunswick have equality of status and equal rights and privileges, including the right to distinct educational institutions and such distinct cultural institutions as are necessary for the preservation and promotion of those communities. (2) The role of the legislature and government of New Brunswick to preserve and promote the status, rights and privileges referred to in subsection (1) is affirmed. 17.(1) Everyone has the right to use English or French in any debates and other proceedings of Parliament. (2) Everyone has the right to use English or French in any debates and other proceedings of the legislature of New Brunswick. 18. (1) The statutes, records and journals of Parliament shall be printed and published in English and French and both language versions are equally authoritative. (2) The statutes, records and journals of the legislature of New Brunswick shall be printed and published in English and French and both language versions are equally authoritative. 19.(1) Either English or French may be used by any person in, or in any pleading in or process issuing from, any court established by Parliament. (2) Either English or French may be used by any person in, or in any pleading in or process issuing from, any court of New Brunswick. 20.(1) Any member of the public in Canada has the right to communicate with, and to receive available services from, any head or central office of an institution of the Parliament or government of Canada in English or French, and has the same right with respect to any other office of any such institution where *(a)* there is a significant demand for communications with and services from that office in such language; or *(b)* due to the nature of the office, it is reasonable that communications with and services from that office be available in both English and French. (2) Any member of the public in New Brunswick has the right to communicate with, and to receive available services from, any office of an institution of the legislature or government of New Brunswick in English or French. 21. Nothing in sections 16 to 20 abrogates or derogates from any right, privilege or obligation with respect to the English and French languages, or either of them, that exists or is continued by virtue of any other provision of the Constitution of Canada. 22. Nothing in sections 16 to 20 abrogates or derogates from any legal or customary right or privilege acquired or enjoyed either before or after the coming into force of this Charter with respect to any language that is not English or French.



## Minority Language Educational Rights

23.(1) Citizens of Canada *(a)* whose first language learned and still understood is that of the English or French linguistic minority population of the province in which they reside, or *(b)* who have received their primary school instruction in Canada in English or French and reside in a province where the language in which they received that instruction is the language of the English or French linguistic minority population of the province, have the right to have their children receive primary and secondary school instruction in that language in that province. (2) Citizens of Canada of whom any child has received or is receiving primary or secondary school instruction in English or French in Canada, have the right to have all their children receive primary and secondary school instruction in the same language. (3) The right of citizens of Canada under subsections (1) and (2) to have their children receive primary and secondary school instruction in the language of the English or French linguistic minority population of a province *(a)* applies wherever in the province the number of children of citizens who have such a right is sufficient to warrant the provision to them out of public funds of minority language instruction; and *(b)* includes, where the number of those children so warrants, the right to have them receive that instruction in minority language educational facilities provided out of public funds.

## Enforcement

24.(1) Anyone whose rights or freedoms, as guaranteed by this Charter, have been infringed or denied may apply to a court of competent jurisdiction to obtain such remedy as the court considers appropriate and just in the circumstances. (2) Where, in proceedings under subsection (1), a court concludes that evidence was obtained in a manner that infringed or denied any rights or freedoms guaranteed by this Charter, the evidence shall be excluded if it is established that, having regard to all the circumstances, the admission of it in the proceedings would bring the administration of justice into disrepute.

## General

25. The guarantee in this Charter of certain rights and freedoms shall not be construed so as to abrogate or derogate from any aboriginal, treaty or other rights or freedoms that pertain to the aboriginal peoples of Canada including *(a)* any rights or freedoms that have been recognized by the Royal Proclamation of October 7, 1763; and *(b)* any rights or freedoms that now exist by way of land claims agreements or may be so acquired. 26. The guarantee in this Charter of certain rights and freedoms shall not be construed as denying the existence of any other rights or freedoms that exist in Canada. 27. This Charter shall be interpreted in a manner consistent with the preservation and enhancement of the multicultural heritage of Canadians. 28. Notwithstanding anything in this Charter, the rights and freedoms referred to in it are guaranteed equally to male and female persons. 29. Nothing in this Charter abrogates or derogates from any rights or privileges guaranteed by or under the Constitution of Canada in respect of denominational, separate or dissentient schools. 30. A reference in this Charter to a province or to the legislative assembly or legislature of a province shall be deemed to include a reference to the Yukon Territory and the Northwest Territories, or to the appropriate legislative authority thereof, as the case may be. 31. Nothing in this Charter extends the legislative powers of any body or authority.

## Application of Charter

32.(1) This Charter applies (a) to the Parliament and government of Canada in respect of all matters within the authority of Parliament including all matters relating to the Yukon Territory and Northwest Territories; and (b) to the legislature and government of each province in respect of all matters within the authority of the legislature of each province. (2) Notwithstanding subsection (1), section 15 shall not have effect until three years after this section comes into force. 33.(1) Parliament or the legislature of a province may expressly declare in an Act of Parliament or of the legislature, as the case may be, that the Act or a provision thereof shall operate notwithstanding a provision included in section 2 or sections 7 to 15 of this Charter. (2) An Act or a provision of an Act in respect of which a declaration made under this section is in effect shall have such operation as it would have but for the provision of this Charter referred to in the declaration. (3) A declaration made under subsection (1) shall cease to have effect five years after it comes into force or on such earlier date as may be specified in the declaration. (4) Parliament or the legislature of a province may re-enact a declaration made under subsection (1). (5) Subsection (3) applies in respect of a re-enactment made under subsection (4).

## Citation

34. This Part may be cited as the *Canadian Charter of Rights and Freedoms.*

*" We must now establish the basic principles, the basic values and beliefs which hold us together as Canadians so that beyond our regional loyalties there is a way of life and a system of values which make us proud of the country that has given us such freedom and such immeasurable joy "*

P.E. Trudeau 1981

# Canadian Bill of Rights

## 1960, c. 44

## An Act for the Recognition and Protection of Human Rights and Fundamental Freedoms

Assented to 10th August 1960

THE Parliament of Canada, affirming that the Canadian Nation is founded upon principles that acknowledge the supremacy of God, the dignity and worth of the human person and the position of the family in a society of free men and free institutions;

Affirming also that men and institutions remain free only when freedom is founded upon respect for moral and spiritual values and the rule of law;

And being desirous of enshrining these principles and the human rights and fundamental freedoms derived from them, in a Bill of Rights which shall reflect the respect of Parliament for its constitutional authority and which shall ensure the protection of these rights and freedoms in Canada:

Therefore Her Majesty, by and with the advice and consent of the Senate and House of Commons of Canada, enacts as follows:

### PART I

### Bill of Rights

1. It is hereby recognized and declared that in Canada there have existed and shall continue to exist without discrimination by reason of race, national origin, colour, religion or sex, the following human rights and fundamental freedoms, namely,

(a) the right of the individual to life, liberty, security of the person and enjoyment of property, and the right not to be deprived thereof except by due process of law;

(b) the right of the individual to equality before the law and the protection of the law;

(c) freedom of religion;

(d) freedom of speech;

(e) freedom of assembly and association; and

(f) freedom of the press.

2. Every law of Canada shall, unless it is expressly declared by an Act of the Parliament of Canada that it shall operate notwithstanding the *Canadian Bill of Rights*, be so construed and applied as not to abrogate, abridge or infringe or to authorize the abrogation, abridgment or infringement of any of the rights or freedoms herein recognized and declared, and in particular, no law of Canada shall be construed or applied so as to

(a) authorize or effect the arbitrary detention, imprisonment or exile of any person;

(b) impose or authorize the imposition of cruel and unusual treatment or punishment;

(c) deprive a person who has been arrested or detained

(i) of the right to be informed promptly of the reason for his arrest or detention,

(ii) of the right to retain and instruct counsel without delay, or

(iii) of the remedy by way of *habeas corpus* for the determination of the validity of his detention and for his release if the detention is not lawful;

(d) authorize a court, tribunal, commission, board or other authority to compel a person to give evidence if he is denied counsel, protection against self crimination or other constitutional safeguards;

(e) deprive a person of the right to a fair hearing in accordance with the principles of fundamental justice for the determination of his rights and obligations;

(f) deprive a person charged with a criminal offence of the right to be presumed innocent until proved guilty according to law in a fair and public hearing by an independent and impartial tribunal, or of the right to reasonable bail without just cause; or

(g) deprive a person of the right to the assistance of an interpreter in any proceedings in which he is involved or in which he is a party or a witness, before a court, commission, board or other tribunal, if he does not understand or speak the language in which such proceedings are conducted.

3. (1) Subject to subsection (2), the Minister of Justice shall, in accordance with such regulations as may be prescribed by the Governor in Council, examine every regulation transmitted to the Clerk of the Privy Council for registration pursuant to the *Statutory Instruments Act* and every Bill introduced in or presented to the House of Commons by a Minister of the Crown, in order to ascertain whether any of the provisions thereof are inconsistent with the purposes and provisions of this Part and he shall report any such inconsistency to the House of Commons at the first convenient opportunity.

(2) A regulation need not be examined in accordance with subsection (1) if prior to being made it was examined as a proposed regulation in accordance with section 3 of the *Statutory Instruments Act* to ensure that it was not inconsistent with the purposes and provisions of this Part.

1960, c. 44, s. 3; 1970-71-72, c. 38, s. 29; 1985, c. 26, s. 105; 1992, c. 1, s. 144(F).

4. The provisions of this Part shall be known as the *Canadian Bill of Rights*.

### PART II

5. (1) Nothing in Part I shall be construed to abrogate or abridge any human right or fundamental freedom not enumerated therein that may have existed in Canada at the commencement of this Act.

(2) The expression "law of Canada" in Part I means an Act of the Parliament of Canada enacted before or after the coming into force of this Act, any order, rule or regulation thereunder, and any law in force in Canada or in any part of Canada at the commencement of this Act that is subject to be repealed, abolished or altered by the Parliament of Canada.

(3) The provisions of Part I shall be construed as extending only to matters coming within the legislative authority of the Parliament of Canada.


*"I am a Canadian, a free Canadian, free to speak without fear, free to worship God in my own way, free to stand for what I think right, free to oppose what I believe wrong, free to choose those who shall govern my country. This heritage of freedom I pledge to uphold for myself and all mankind."*

The Right Honourable John G. Diefenbaker, Prime Minister of Canada,
House of Commons Debates, July 1, 1960.

*Roger Duhamel, F.R.S.C., Queen's Printer, Ottawa, Canada.*

(i) is a person who is entitled to consent to the collection, use or disclosure of personal health information about another individual,

(ii) meets the requirement of clauses 26 (2) (b) and (c),

(iii) holds the beliefs described in subsection 26 (5), or

(iv) is a person entitled to access to a record of personal health information under section 52;

(d) disposes of a record of personal health information in the custody or under the control of the custodian with an intent to evade a request for access to the record that the custodian has received under subsection 53 (1);

(e) wilfully disposes of a record of personal health information in contravention of section 13;

(f) contravenes subsection 34 (2), (3) or (4) or clause 47 (15) (a), (e) or (f);

(g) wilfully obstructs the Commissioner or a person known to be acting under the authority of the Commissioner in the performance of his or her functions under this Act;

(h) wilfully makes a false statement to mislead or attempt to mislead the Commissioner or a person known to be acting under the authority of the Commissioner in the performance of his or her functions under this Act;

(i) wilfully fails to comply with an order made by the Commissioner or a person known to be acting under the authority of the Commissioner under this Act; or

(j) contravenes section 70. 2004, c. 3, Sched. A, s. 72 (1); 2019, c. 15, Sched. 30, s. 7 (1).

**Penalty**

(2) A person who is guilty of an offence under subsection (1) is liable, on conviction,

(a) if the person is a natural person, to a fine of not more than $200,000 or to a term of imprisonment of not more than 1 year, or to both; or

(b) if the person is not a natural person, to a fine of not more than $1,000,000. 2004, c. 3, Sched. A, s. 72 (2); 2016, c. 6, Sched. 1, s. 1 (26); 2020, c. 5, Sched. 6, s. 23.

**Officers, etc.**

(3) If a corporation commits an offence under this Act, every officer, member, employee or other agent of the corporation who authorized the offence, or who had the authority to prevent the offence from being committed but knowingly refrained from doing so, is a party to and guilty of the offence and is liable, on conviction, to the penalty for the offence, whether or not the corporation has been prosecuted or convicted. 2004, c. 3, Sched. A, s. 72 (3).

## *Human Rights Code*, RSO 1990, c H.19

**Preamble**

Whereas recognition of the inherent dignity and the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world and is in accord with the Universal Declaration of Human Rights as proclaimed by the United Nations;

And Whereas it is public policy in Ontario to recognize the dignity and worth of every person and to

provide for equal rights and opportunities without discrimination that is contrary to law, and having as its aim the creation of a climate of understanding and mutual respect for the dignity and worth of each person so that each person feels a part of the community and able to contribute fully to the development and well-being of the community and the Province;

And Whereas these principles have been confirmed in Ontario by a number of enactments of the Legislature and it is desirable to revise and extend the protection of human rights in Ontario;

Therefore, Her Majesty, by and with the advice and consent of the Legislative Assembly of the Province of Ontario, enacts as follows:

## PART I
## FREEDOM FROM DISCRIMINATION

**Services**

**1** Every person has a right to equal treatment with respect to services, goods and facilities, without discrimination because of race, ancestry, place of origin, colour, ethnic origin, citizenship, creed, sex, sexual orientation, gender identity, gender expression, age, marital status, family status or disability. R.S.O. 1990, c. H.19, s. 1; 1999, c. 6, s. 28 (1); 2001, c. 32, s. 27 (1); 2005, c. 5, s. 32 (1); 2012, c. 7, s. 1.

**Accommodation**

**2** (1) Every person has a right to equal treatment with respect to the occupancy of accommodation, without discrimination because of race, ancestry, place of origin, colour, ethnic origin, citizenship, creed, sex, sexual orientation, gender identity, gender expression, age, marital status, family status, disability or the receipt of public assistance. R.S.O. 1990, c. H.19, s. 2 (1); 1999, c. 6, s. 28 (2); 2001, c. 32, s. 27 (1); 2005, c. 5, s. 32 (2); 2012, c. 7, s. 2 (1).

**Harassment in accommodation**

(2) Every person who occupies accommodation has a right to freedom from harassment by the landlord or agent of the landlord or by an occupant of the same building because of race, ancestry, place of origin, colour, ethnic origin, citizenship, creed, sexual orientation, gender identity, gender expression, age, marital status, family status, disability or the receipt of public assistance. R.S.O. 1990, c. H.19, s. 2 (2); 1999, c. 6, s. 28 (3); 2001, c. 32, s. 27 (1); 2005, c. 5, s. 32 (3); 2012, c. 7, s. 2 (2).

**Contracts**

**3** Every person having legal capacity has a right to contract on equal terms without discrimination because of race, ancestry, place of origin, colour, ethnic origin, citizenship, creed, sex, sexual orientation, gender identity, gender expression, age, marital status, family status or disability. R.S.O. 1990, c. H.19, s. 3; 1999, c. 6, s. 28 (4); 2001, c. 32, s. 27 (1); 2005, c. 5, s. 32 (4); 2012, c. 7, s. 3.

**Employment**

**5** (1) Every person has a right to equal treatment with respect to employment without discrimination because of race, ancestry, place of origin, colour, ethnic origin, citizenship, creed, sex, sexual orientation, gender identity, gender expression, age, record of offences, marital status, family status or disability. R.S.O. 1990, c. H.19, s. 5 (1); 1999, c. 6, s. 28 (5); 2001, c. 32, s. 27 (1); 2005, c. 5, s. 32 (5); 2012, c. 7, s. 4 (1).

**Harassment in employment**

(2) Every person who is an employee has a right to freedom from harassment in the workplace by the employer or agent of the employer or by another employee because of race, ancestry, place of origin, colour, ethnic origin, citizenship, creed, sexual orientation, gender identity, gender expression, age, record of offences, marital status, family status or disability. R.S.O. 1990, c. H.19, s. 5 (2); 1999, c. 6, s. 28 (6); 2001, c. 32, s. 27 (1); 2005, c. 5, s. 32 (6); 2012, c. 7, s. 4 (2).

**Announced intention to discriminate**

**13** (1) A right under Part I is infringed by a person who publishes or displays before the public or causes the publication or display before the public of any notice, sign, symbol, emblem, or other similar representation that indicates the intention of the person to infringe a right under Part I or that is intended by the person to incite the infringement of a right under Part I. R.S.O. 1990, c. H.19, s. 13 (1).

**Opinion**

(2) Subsection (1) shall not interfere with freedom of expression of opinion. R.S.O. 1990, c. H.19, s. 13 (2).

***Hopp v. Lepp*, 1980 CanLII 14 (SCC), [1980] 2 SCR 192**

Informed consent:

Whether there was informed consent was the main issue argued in this Court. It is an issue that comes before this Court for the first time. The

[Page 196]

term "informed consent", frequently used in American cases, reflects the fact that although there is, generally, prior consent by a patient to proposed surgery or therapy, this does not immunize a surgeon or physician from liability for battery or for negligence if he has failed in a duty to disclose risks of the surgery or treatment, known or which should be known to him, and which are unknown to the patient. The underlying principle is the right of a patient to decide what, if anything, should be done with his body: see Parmley v. Parmley and Yule[2], at pp. 645-46. (I leave aside any question of emergency or of mental incompetency and, also, situations where the operation or treatment performed or given is different from that to which the patient consented.) It follows, therefore, that a patient's consent, whether to surgery or to therapy, will give protection to his surgeon or physician only if the patient has been sufficiently informed to enable him to make a choice whether or not to submit to the surgery or therapy. The issue of informed consent is at bottom a question whether there is a duty of disclosure, a duty by the surgeon or physician to provide information and, if so, the extent or scope of the duty.

***Parmley v. Parmley*, 1945 CanLII 13 (SCC), [1945] SCR 635**

Consent and assault:

Force to the person is rendered lawful by consent in such matters as surgical operations. The

# COVID-19 CANADIAN BORDER RIGHTS – AUTHORITIES CITED



## *The Constitution Act, 1982*

### PART I
### CANADIAN CHARTER OF RIGHTS AND FREEDOMS

Whereas Canada is founded upon principles that recognize the supremacy of God and the rule of law:

**Mobility of citizens** **6.** (1) Every citizen of Canada has the right to enter, remain in and leave Canada.

**Life, liberty and security of person** **7.** Everyone has the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice.

**Detention or imprisonment** **9.** Everyone has the right not to be arbitrarily detained or imprisoned.

### PART VII
### GENERAL

**Primacy of Constitution of Canada** **52.** (1) The Constitution of Canada is the supreme law of Canada, and any law that is inconsistent with the provisions of the Constitution is, to the extent of the inconsistency, of no force or effect.

## *Quarantine Act*, SC 2005, c 20

**Screening technology**

**14** (1) Any qualified person authorized by the Minister may, to determine whether a traveller has a communicable disease or symptoms of one, use any screening technology authorized by the Minister that does not involve the entry into the traveller's body of any instrument or other foreign body.

**Refusal to be screened**

(2) If a traveller refuses to be screened with the screening technology and the person using it is not a screening officer or quarantine officer, the person shall immediately inform a screening officer or quarantine officer of the refusal.

**Release**

**32** A quarantine officer shall not detain a traveller if

(a) the quarantine officer has reasonable grounds to believe that the traveller does not pose a risk of significant harm to public health;

***Canadian Bill of Rights*, SC 1960, c 44**

An Act for the Recognition and Protection of Human Rights and Fundamental Freedoms

**Preamble**

The Parliament of Canada, affirming that the Canadian Nation is founded upon principles that acknowledge the supremacy of God, the dignity and worth of the human person and the position of the family in a society of free men and free institutions;

Affirming also that men and institutions remain free only when freedom is founded upon respect for moral and spiritual values and the rule of law;

And being desirous of enshrining these principles and the human rights and fundamental freedoms derived from them, in a Bill of Rights which shall reflect the respect of Parliament for its constitutional authority and which shall ensure the protection of these rights and freedoms in Canada:

Therefore Her Majesty, by and with the advice and consent of the Senate and House of Commons of Canada, enacts as follows:

## PART I

## Bill of Rights

**Recognition and declaration of rights and freedoms**

**1** It is hereby recognized and declared that in Canada there have existed and shall continue to exist without discrimination by reason of race, national origin, colour, religion or sex, the following human rights and fundamental freedoms, namely,

(a) the right of the individual to life, liberty, security of the person and enjoyment of property, and the right not to be deprived thereof except by due process of law;

...

**Construction of law**

**2** Every law of Canada shall, unless it is expressly declared by an Act of the Parliament of Canada that it shall operate notwithstanding the *Canadian Bill of Rights*, be so construed and applied as not to abrogate, abridge or infringe or to authorize the abrogation, abridgment or infringement of any of the

rights or freedoms herein recognized and declared, and in particular, no law of Canada shall be construed or applied so as to

(a) authorize or effect the arbitrary detention, imprisonment or exile of any person;

(b) impose or authorize the imposition of cruel and unusual treatment or punishment;

(c) deprive a person who has been arrested or detained

(i) of the right to be informed promptly of the reason for his arrest or detention,

(ii) of the right to retain and instruct counsel without delay, or

(iii) of the remedy by way of habeas corpus for the determination of the validity of his detention and for his release if the detention is not lawful;

(d) authorize a court, tribunal, commission, board or other authority to compel a person to give evidence if he is denied counsel, protection against self crimination or other constitutional safeguards;

(e) deprive a person of the right to a fair hearing in accordance with the principles of fundamental justice for the determination of his rights and obligations;

## Part II

**Savings**

**5** (1) Nothing in Part I shall be construed to abrogate or abridge any human right or fundamental freedom not enumerated therein that may have existed in Canada at the commencement of this Act.

**"Law of Canada" defined**

(2) The expression "law of Canada" in Part I means an Act of the Parliament of Canada enacted before or after the coming into force of this Act, any order, rule or regulation thereunder, and any law in force in Canada or in any part of Canada at the commencement of this Act that is subject to be repealed, abolished or altered by the Parliament of Canada.

**Jurisdiction of Parliament**

(3) The provisions of Part I shall be construed as extending only to matters coming within the legislative authority of the Parliament of Canada.

# How to deal with an employer who pressures you to get "vaccinated"

BY GREATREJECT · 13/08/2021

## If you are being forced to Vax in order to keep your job, here's a great way to handle it. The secret is NOT to refuse it…

A friend in the NHS is being pressured to take the jab: he wrote to his senior, "I write with regard to the matter of potential covid vaccine and my desire to be fully informed and appraised of ALL facts before going ahead. I'd be most grateful if you could please provide the following information, in accordance with statutory legal requirements.":

1. Can you please advise the approved legal status of any vaccine and if it is experimental?

2. Can you please provide details and assurances that the vaccine has been fully, independently and rigorously tested against control groups and the subsequent outcomes of those tests?

3. Can you please advise the entire list of contents of the vaccine I am to receive and if any are toxic to the body?

4. Can you please fully advise of all the adverse reactions associated with this vaccine since it's introduction?

5. Can you please confirm that the vaccine you are advocating is NOT 'experimental mRNA gene altering therapy'?

6. Can you please confirm that I will not be under any duress from yourselves as my employers, in compliance with the Nuremberg Code?

7. Can you please advise me of the likely risk of fatality, should I be unfortunate to contract Covid 19 and the likelihood of recovery?

in my sole and absolute discretion,

Once I have received the above information in full and I am satisfied, that there is NO threat to my health, I will be happy to accept your offer to receive the treatment, but with certain conditions – namely that:

1. You confirm in writing that I will suffer no harm.

2. Following acceptance of this, the offer must be signed by a fully qualified doctor who will take full legal and financial responsibility for any injuries occurring to myself, and/or from any interactions by authorized personnel regarding these procedures.

3. In the event that I should have to decline the offer of vaccination, please confirm that it will not compromise my position and that I will not suffer prejudice and discrimination as a result?

I would also advise that my inalienable rights are reserved.'

The point is that if they CANNOT provide that information you've NOT refused…

Source: World Doctors Alliance

Please share widely.

If your government regulated employers such as airlines, trains, hospitals, and many others goes to implement this, you simply say, you are willing to get the vaccine if they can provide you with the following information.

1. Are there any of the vaccines that are approved for clinical use, and if so what are they?
2. Can you provide me with a detailed list of adverse reactions, deaths, and other risks of injury that are required in order for you to have informed consent?
3. Since the vaccine manufacturers are indemnified from liability if there is injury, death, or long or shorterm adverse reactions, are you willing to accept liability?

**BRITISH MEDICAL JOURNAL No 7070 Volume 313: Page 1448,**
**7 December 1996.**

## Introduction

The judgment by the war crimes tribunal at Nuremberg laid down 10 standards to which physicians must conform when carrying out experiments on human subjects in a new code that is now accepted worldwide.

This judgment established a new standard of ethical medical behaviour for the post World War II human rights era. Amongst other requirements, this document enunciates the requirement of *voluntary informed consent* of the human subject. The principle of voluntary informed consent protects the right of the individual to control his own body.

This code also recognizes that the risk must be weighed against the expected benefit, and that unnecessary pain and suffering must be avoided.

This code recognizes that doctors should avoid actions that injure human patients.

The principles established by this code for medical practice now have been extended into general codes of medical ethics.

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# The Nuremberg Code (1947)

## Permissible Medical Experiments

The great weight of the evidence before us to effect that certain types of medical experiments on human beings, when kept within reasonably well-defined bounds, conform to the ethics of the medical profession generally. The protagonists of the practice of human experimentation justify their views on the basis that such experiments yield results for the good of society that are unprocurable by other methods or means of study. All agree, however, that certain basic principles must be observed in order to satisfy moral, ethical and legal concepts:

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

   The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is

a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results justify the performance of the experiment.

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability or death.

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

For more information see Nuremberg Doctor's Trial, *BMJ* 1996;313(7070):1445-75.

Health Care Consent Act, 1996, SO 1996, c 2, Shc A

(i) allowing those who have been found to be incapable to apply to a tribunal for a review of the finding,

(ii) allowing incapable persons to request that a representative of their choice be appointed by the tribunal for the purpose of making decisions on their behalf concerning treatment, admission to a care facility or personal assistance services, and

(iii) requiring that wishes with respect to treatment, admission to a care facility or personal assistance services, expressed by persons while capable and after attaining 16 years of age, be adhered to

Consent to Treatment

**No treatment without consent**

**10** (1) A health practitioner who proposes a treatment for a person shall not administer the treatment, and shall take reasonable steps to ensure that it is not administered, unless,

(a) he or she is of the opinion that the person is capable with respect to the treatment, and the person has given consent; or

(b) he or she is of the opinion that the person is incapable with respect to the treatment, and the person's substitute decision-maker has given consent on the person's behalf in accordance with this Act. 1996, c. 2, Sched. A, s. 10 (1).

**Elements of consent**

**11** (1) The following are the elements required for consent to treatment:

1. The consent must relate to the treatment.
2. The consent must be informed.
3. The consent must be given voluntarily.
4. The consent must not be obtained through misrepresentation or fraud. 1996, c. 2, Sched. A, s. 11 (1).

**Informed consent**

(2) A consent to treatment is informed if, before giving it,

(a) the person received the information about the matters set out in subsection (3) that a reasonable person in the same circumstances would require in order to make a decision about the treatment; and

(b) the person received responses to his or her requests for additional information about those matters. 1996, c. 2, Sched. A, s. 11 (2).

**Same**

(3) The matters referred to in subsection (2) are:

1. The nature of the treatment.
2. The expected benefits of the treatment.
3. The material risks of the treatment.
4. The material side effects of the treatment.

5. Alternative courses of action.

6. The likely consequences of not having the treatment. 1996, c. 2, Sched. A, s. 11 (3).

**Express or implied**

(4) Consent to treatment may be express or implied. 1996, c. 2, Sched. A, s. 11 (4).

**Included consent**

**12** Unless it is not reasonable to do so in the circumstances, a health practitioner is entitled to presume that consent to a treatment includes,

(a) consent to variations or adjustments in the treatment, if the nature, expected benefits, material risks and material side effects of the changed treatment are not significantly different from the nature, expected benefits, material risks and material side effects of the original treatment; and

(b) consent to the continuation of the same treatment in a different setting, if there is no significant change in the expected benefits, material risks or material side effects of the treatment as a result of the change in the setting in which it is administered. 1996, c. 2, Sched. A, s. 12.

**Withdrawal of consent**

**14** A consent that has been given by or on behalf of the person for whom the treatment was proposed may be withdrawn at any time,

(a) by the person, if the person is capable with respect to the treatment at the time of the withdrawal;

(b) by the person's substitute decision-maker, if the person is incapable with respect to the treatment at the time of the withdrawal. 1996, c. 2, Sched. A, s. 14.

Consent on Incapable Person's Behalf

**Consent**

**List of persons who may give or refuse consent**

**20** (1) If a person is incapable with respect to a treatment, consent may be given or refused on his or her behalf by a person described in one of the following paragraphs:

1. The incapable person's guardian of the person, if the guardian has authority to give or refuse consent to the treatment.

2. The incapable person's attorney for personal care, if the power of attorney confers authority to give or refuse consent to the treatment.

3. The incapable person's representative appointed by the Board under section 33, if the representative has authority to give or refuse consent to the treatment.

4. The incapable person's spouse or partner.

5. A child or parent of the incapable person, or a children's aid society or other person who is lawfully entitled to give or refuse consent to the treatment in the place of the parent. This

2. Whether the incapable person's condition or well-being is likely to improve, remain the same or deteriorate without the treatment.

3. Whether the benefit the incapable person is expected to obtain from the treatment outweighs the risk of harm to him or her.

4. Whether a less restrictive or less intrusive treatment would be as beneficial as the treatment that is proposed. 1996, c. 2, Sched. A, s. 21 (2).

**Offence: decision contrary to wishes**

**84** (1) A person who knowingly contravenes paragraph 1 of subsection 21 (1), paragraph 1 of subsection 42 (1) or paragraph 1 of subsection 59 (1) is guilty of an offence and is liable, on conviction, to a fine not exceeding $10,000. 1996, c. 2, Sched. A, s. 84 (1).

***Freedom of Information and Protection of Privacy Act*, RSO 1990, c F.31**

**Definitions**

**2** (1) In this Act,

...

"personal information" means recorded information about an identifiable individual, including,

(a) information relating to the race, national or ethnic origin, colour, religion, age, sex, sexual orientation or marital or family status of the individual,

(b) information relating to the education or the medical, psychiatric, psychological, criminal or employment history of the individual or information relating to financial transactions in which the individual has been involved,

(c) any identifying number, symbol or other particular assigned to the individual,

(d) the address, telephone number, fingerprints or blood type of the individual,

(e) the personal opinions or views of the individual except where they relate to another individual,

(f) correspondence sent to an institution by the individual that is implicitly or explicitly of a private or confidential nature, and replies to that correspondence that would reveal the contents of the original correspondence,

(g) the views or opinions of another individual about the individual, and

(h) the individual's name where it appears with other personal information relating to the individual or where the disclosure of the name would reveal other personal information about the individual; ("renseignements personnels")

**Personal information**

**38** (1) In this section and in section 39,

"personal information" includes information that is not recorded and that is otherwise defined as

"personal information" under this Act. R.S.O. 1990, c. F.31, s. 38 (1).

**Collection of personal information**

(2) No person shall collect personal information on behalf of an institution unless the collection is expressly authorized by statute, used for the purposes of law enforcement or necessary to the proper administration of a lawfully authorized activity. R.S.O. 1990, c. F.31, s. 38 (2).

**Manner of collection**

**39** (1) Personal information shall only be collected by an institution directly from the individual to whom the information relates unless,

(a) the individual authorizes another manner of collection;

(b) the personal information may be disclosed to the institution concerned under section 42 or under section 32 of the *Municipal Freedom of Information and Protection of Privacy Act*;

(c) the Commissioner has authorized the manner of collection under clause 59 (c);

(d) the information is in a report from a reporting agency in accordance with the *Consumer Reporting Act*;

(e) the information is collected for the purpose of determining suitability for an honour or award to recognize outstanding achievement or distinguished service;

(f) the information is collected for the purpose of the conduct of a proceeding or a possible proceeding before a court or tribunal;

(g) the information is collected for the purpose of law enforcement; or

(h) another manner of collection is authorized by or under a statute. R.S.O. 1990, c. F.31, s. 39 (1).

**Notice to individual**

(2) Where personal information is collected on behalf of an institution, the head shall, unless notice is waived by the responsible minister, inform the individual to whom the information relates of,

(a) the legal authority for the collection;

(b) the principal purpose or purposes for which the personal information is intended to be used; and

(c) the title, business address and business telephone number of a public official who can answer the individual's questions about the collection. R.S.O. 1990, c. F.31, s. 39 (2).

**Offences**

**61** (1) No person shall,

(a) wilfully disclose personal information in contravention of this Act;

(b) wilfully maintain a personal information bank that contravenes this Act;

(b.1) wilfully contravene section 49.8;

(c) make a request under this Act for access to or correction of personal information under false pretenses;

(c.1) alter, conceal or destroy a record, or cause any other person to do so, with the intention of

denying a right under this Act to access the record or the information contained in the record;

(d) wilfully obstruct the Commissioner in the performance of his or her functions under this Act;

(e) wilfully make a false statement to, mislead or attempt to mislead the Commissioner in the performance of his or her functions under this Act; or

(f) wilfully fail to comply with an order of the Commissioner. R.S.O. 1990, c. F.31, s. 61 (1); 2014, c. 13, Sched. 6, s. 2 (1); 2019, c. 7, Sched. 31, s. 8.

**Penalty**

(2) Every person who contravenes subsection (1) is guilty of an offence and on conviction is liable to a fine not exceeding $5,000. R.S.O. 1990, c. F.31, s. 61 (2).

**Consent of Attorney General**

(3) A prosecution shall not be commenced under clause (1) (c.1), (d), (e) or (f) without the consent of the Attorney General. R.S.O. 1990, c. F.31, s. 61 (3); 2014, c. 13, Sched. 6, s. 2 (2).

## *Personal Health Information Protection Act*, 2004, SO 2004, c 3, Sch A

**Personal health information**

4 (1) In this Act,

"personal health information", subject to subsections (3) and (4), means identifying information about an individual in oral or recorded form, if the information,

(a) relates to the physical or mental health of the individual, including information that consists of the health history of the individual's family,

(b) relates to the providing of health care to the individual, including the identification of a person as a provider of health care to the individual,

(c) is a plan of service within the meaning of the *Home Care and Community Services Act, 1994* for the individual,

(d) relates to payments or eligibility for health care, or eligibility for coverage for health care, in respect of the individual,

(e) relates to the donation by the individual of any body part or bodily substance of the individual or is derived from the testing or examination of any such body part or bodily substance,

(f) is the individual's health number, or

(g) identifies an individual's substitute decision-maker. 2004, c. 3, Sched. A, s. 4 (1); 2007, c. 8, s. 224 (6); 2007, c. 10, Sched. H, s. 2.

**Identifying information**

(2) In this section,

"identifying information" means information that identifies an individual or for which it is reasonably foreseeable in the circumstances that it could be utilized, either alone or with other information, to identify an individual. 2004, c. 3, Sched. A, s. 4 (2).

**Elements of consent**

**18** (1) If this Act or any other Act requires the consent of an individual for the collection, use or disclosure of personal health information by a health information custodian, the consent,

(a) must be a consent of the individual;

(b) must be knowledgeable;

(c) must relate to the information; and

(d) must not be obtained through deception or coercion. 2004, c. 3, Sched. A, s. 18 (1).

**Implied consent**

(2) Subject to subsection (3), a consent to the collection, use or disclosure of personal health information about an individual may be express or implied. 2004, c. 3, Sched. A, s. 18 (2).

**Exception**

(3) A consent to the disclosure of personal health information about an individual must be express, and not implied, if,

(a) a health information custodian makes the disclosure to a person that is not a health information custodian; or

(b) a health information custodian makes the disclosure to another health information custodian and the disclosure is not for the purposes of providing health care or assisting in providing health care. 2004, c. 3, Sched. A, s. 18 (3).

**Same**

(4) Subsection (3) does not apply to,

(a) a disclosure pursuant to an implied consent described in subsection 20 (4);

(b) a disclosure pursuant to clause 32 (1) (b); or

(c) a prescribed type of disclosure that does not include information about an individual's state of health. 2004, c. 3, Sched. A, s. 18 (4).

**Knowledgeable consent**

(5) A consent to the collection, use or disclosure of personal health information about an individual is knowledgeable if it is reasonable in the circumstances to believe that the individual knows,

(a) the purposes of the collection, use or disclosure, as the case may be; and

(b) that the individual may give or withhold consent. 2004, c. 3, Sched. A, s. 18 (5).

**Notice of purposes**

(6) Unless it is not reasonable in the circumstances, it is reasonable to believe that an individual knows the purposes of the collection, use or disclosure of personal health information about the individual by a health information custodian if the custodian posts or makes readily available a notice describing the purposes where it is likely to come to the individual's attention or provides the individual with such a notice. 2004, c. 3, Sched. A, s. 18 (6).

**Transition**

(7) A consent that an individual gives, before the day that subsection (1) comes into force, to a collection, use or disclosure of information that is personal health information is a valid consent if it

meets the requirements of this Act for consent. 2004, c. 3, Sched. A, s. 18 (7).

**Withdrawal of consent**

**19** (1) If an individual consents to have a health information custodian collect, use or disclose personal health information about the individual, the individual may withdraw the consent, whether the consent is express or implied, by providing notice to the health information custodian, but the withdrawal of the consent shall not have retroactive effect. 2004, c. 3, Sched. A, s. 19 (1).

**Conditional consent**

(2) If an individual places a condition on his or her consent to have a health information custodian collect, use or disclose personal health information about the individual, the condition is not effective to the extent that it purports to prohibit or restrict any recording of personal health information by a health information custodian that is required by law or by established standards of professional practice or institutional practice. 2004, c. 3, Sched. A, s. 19 (2).

**Persons who may consent**

**23** (1) If this Act or any other Act refers to a consent required of an individual to a collection, use or disclosure by a health information custodian of personal health information about the individual, a person described in one of the following paragraphs may give, withhold or withdraw the consent:

1. If the individual is capable of consenting to the collection, use or disclosure of the information,

   i. the individual, or

   ii. if the individual is at least 16 years of age, any person who is capable of consenting, whom the individual has authorized in writing to act on his or her behalf and who, if a natural person, is at least 16 years of age.

2. If the individual is a child who is less than 16 years of age, a parent of the child or a children's aid society or other person who is lawfully entitled to give or refuse consent in the place of the parent unless the information relates to,

   i. treatment within the meaning of the *Health Care Consent Act, 1996*, about which the child has made a decision on his or her own in accordance with that Act, or

   ii. counselling in which the child has participated on his or her own under the *Child, Youth and Family Services Act, 2017*.

3. If the individual is incapable of consenting to the collection, use or disclosure of the information, a person who is authorized under subsection 5 (2), (3) or (4) or section 26 to consent on behalf of the individual.

**Incapable individual: persons who may consent**

**26** (1) If an individual is determined to be incapable of consenting to the collection, use or disclosure of personal health information by a health information custodian, a person described in one of the following paragraphs may, on the individual's behalf and in the place of the individual, give, withhold or withdraw the consent:

## Interpretation

### Definitions

**2** The following definitions apply in this Act.

disclose includes to authorize disclosure. (communiquer)

genetic test means a test that analyzes DNA, RNA or chromosomes for purposes such as the prediction of disease or vertical transmission risks, or monitoring, diagnosis or prognosis. (test génétique)

health care practitioner means a person lawfully entitled under the law of a province to provide health services in the place in which the services are provided by that person. (professionnel de la santé)

## Prohibitions

### Genetic test

**3 (1)** It is prohibited for any person to require an individual to undergo a genetic test as a condition of

(a) providing goods or services to that individual;

(b) entering into or continuing a contract or agreement with that individual; or

(c) offering or continuing specific terms or conditions in a contract or agreement with that individual.

### Refusal to undergo genetic test

**(2)** It is prohibited for any person to refuse to engage in an activity described in any of paragraphs (1)(a) to (c) in respect of an individual on the grounds that the individual has refused to undergo a genetic test.

### Disclosure of results

**4 (1)** It is prohibited for any person to require an individual to disclose the results of a genetic test as a condition of engaging in an activity described in any of paragraphs 3(1)(a) to (c).

### Refusal to disclose results

**(2)** It is prohibited for any person to refuse to engage in an activity described in any of paragraphs 3(1)(a) to (c) in respect of an individual on the grounds that the individual has refused to disclose the results of a genetic test.

### Written consent

**5** It is prohibited for any person who is engaged in an activity described in any of paragraphs 3(1)(a) to (c) in respect of an individual to collect, use or disclose the results of a genetic test of the individual without the individual's written consent.

## Offences and Punishment

Contravention of sections 3 to 5

7 Every person who contravenes any of sections 3 to 5 is guilty of an offence and is liable

**(a)** on conviction on indictment, to a fine not exceeding $1,000,000 or to imprisonment for a term not exceeding five years, or to both; or

**(b)** on summary conviction, to a fine not exceeding $300,000 or to imprisonment for a term not exceeding twelve months, or to both.

***Criminal Code*, RSC 1985, c C-46**

## Parties to Offences

### Parties to offence

**21 (1)** Every one is a party to an offence who

**(a)** actually commits it;

**(b)** does or omits to do anything for the purpose of aiding any person to commit it; or

**(c)** abets any person in committing it.

### Common intention

**(2)** Where two or more persons form an intention in common to carry out an unlawful purpose and to assist each other therein and any one of them, in carrying out the common purpose, commits an offence, each of them who knew or ought to have known that the commission of the offence would be a probable consequence of carrying out the common purpose is a party to that offence.

### Person counselling offence

**22 (1)** Where a person counsels another person to be a party to an offence and that other person is afterwards a party to that offence, the person who counselled is a party to that offence, notwithstanding that the offence was committed in a way different from that which was counselled.

### Idem

**(2)** Every one who counsels another person to be a party to an offence is a party to every offence that the other commits in consequence of the counselling that the person who counselled knew or ought to have known was likely to be committed in consequence of the counselling.

### Definition of counsel

**(3)** For the purposes of this Act, counsel includes procure, solicit or incite.

### Offences of negligence — organizations

**22.1** In respect of an offence that requires the prosecution to prove negligence, an organization is a

party to the offence if

**(a)** acting within the scope of their authority

**(i)** one of its representatives is a party to the offence, or

**(ii)** two or more of its representatives engage in conduct, whether by act or omission, such that, if it had been the conduct of only one representative, that representative would have been a party to the offence; and

**(b)** the senior officer who is responsible for the aspect of the organization's activities that is relevant to the offence departs — or the senior officers, collectively, depart — markedly from the standard of care that, in the circumstances, could reasonably be expected to prevent a representative of the organization from being a party to the offence.

**Other offences — organizations**

**22.2** In respect of an offence that requires the prosecution to prove fault — other than negligence — an organization is a party to the offence if, with the intent at least in part to benefit the organization, one of its senior officers

**(a)** acting within the scope of their authority, is a party to the offence;

**(b)** having the mental state required to be a party to the offence and acting within the scope of their authority, directs the work of other representatives of the organization so that they do the act or make the omission specified in the offence; or

**(c)** knowing that a representative of the organization is or is about to be a party to the offence, does not take all reasonable measures to stop them from being a party to the offence.

**Accessory after the fact**

**23 (1)** An accessory after the fact to an offence is one who, knowing that a person has been a party to the offence, receives, comforts or assists that person for the purpose of enabling that person to escape.

**(2)** [Repealed, 2000, c. 12, s. 92]

**Where one party cannot be convicted**

**23.1** For greater certainty, sections 21 to 23 apply in respect of an accused notwithstanding the fact that the person whom the accused aids or abets, counsels or procures or receives, comforts or assists cannot be convicted of the offence.

**Assault**

**265 (1)** A person commits an assault when

**(a)** without the consent of another person, he applies force intentionally to that other person, directly or indirectly;

...

**Consent**

**(3)** For the purposes of this section, no consent is obtained where the complainant submits or does not resist by reason of

**(a)** the application of force to the complainant or to a person other than the complainant;

**(b)** threats or fear of the application of force to the complainant or to a person other than the complainant;

**(c)** fraud; or

**(d)** the exercise of authority.

**Assault**

**266** Every one who commits an assault is guilty of

**(a)** an indictable offence and is liable to imprisonment for a term not exceeding five years; or

**(b)** an offence punishable on summary conviction.

**Unlawfully causing bodily harm**

**269** Every one who unlawfully causes bodily harm to any person is guilty of

**(a)** an indictable offence and liable to imprisonment for a term not exceeding ten years; or

**(b)** an offence punishable on summary conviction.

**Torture**

**269.1 (1)** Every official, or every person acting at the instigation of or with the consent or acquiescence of an official, who inflicts torture on any other person is guilty of an indictable offence and liable to imprisonment for a term not exceeding fourteen years.

**Definitions**

**(2)** For the purposes of this section,

official means

**(a)** a peace officer,

**(b)** a public officer,

**(c)** a member of the Canadian Forces, or

**(d)** any person who may exercise powers, pursuant to a law in force in a foreign state, that would, in Canada, be exercised by a person referred to in paragraph (a), (b), or (c),

whether the person exercises powers in Canada or outside Canada; (fonctionnaire)

torture means any act or omission by which severe pain or suffering, whether physical or mental, is intentionally inflicted on a person

**(a)** for a purpose including

**(i)** obtaining from the person or from a third person information or a statement,

**(ii)** punishing the person for an act that the person or a third person has committed or is suspected of having committed, and

**(iii)** intimidating or coercing the person or a third person, or

**(b)** for any reason based on discrimination of any kind,

but does not include any act or omission arising only from, inherent in or incidental to lawful sanctions. (torture)

**No defence**

**(3)** It is no defence to a charge under this section that the accused was ordered by a superior or a public authority to perform the act or omission that forms the subject-matter of the charge or that the act or omission is alleged to have been justified by exceptional circumstances, including a state of war, a threat of war, internal political instability or any other public emergency.

**Fraud**

**380 (1)** Every one who, by deceit, falsehood or other fraudulent means, whether or not it is a false pretence within the meaning of this Act, defrauds the public or any person, whether ascertained or not, of any property, money or valuable security or any service,

**(a)** is guilty of an indictable offence and liable to a term of imprisonment not exceeding fourteen years, where the subject-matter of the offence is a testamentary instrument or the value of the subject-matter of the offence exceeds five thousand dollars; or

**(b)** is guilty

**(i)** of an indictable offence and is liable to imprisonment for a term not exceeding two years, or

**(ii)** of an offence punishable on summary conviction,

where the value of the subject-matter of the offence does not exceed five thousand dollars.

**Minimum punishment**

**(1.1)** When a person is prosecuted on indictment and convicted of one or more offences referred to in subsection (1), the court that imposes the sentence shall impose a minimum punishment of imprisonment for a term of two years if the total value of the subject-matter of the offences exceeds one million dollars.

...

**Sentencing — aggravating circumstances**

**380.1 (1)** Without limiting the generality of section 718.2, where a court imposes a sentence for an offence referred to in section 380, 382, 382.1 or 400, it shall consider the following as aggravating circumstances:

**(a)** the magnitude, complexity, duration or degree of planning of the fraud committed was significant;

**(b)** the offence adversely affected, or had the potential to adversely affect, the stability of the Canadian economy or financial system or any financial market in Canada or investor confidence in such a financial market;

**(c)** the offence involved a large number of victims;

**(c.1)** the offence had a significant impact on the victims given their personal circumstances including their age, health and financial situation;

**(d)** in committing the offence, the offender took advantage of the high regard in which the offender was held in the community;

**(e)** the offender did not comply with a licensing requirement, or professional standard, that is normally applicable to the activity or conduct that forms the subject-matter of the offence; and

**(f)** the offender concealed or destroyed records related to the fraud or to the disbursement of the proceeds of the fraud.

**Intimidation**

**423 (1)** Every one is guilty of an indictable offence and liable to imprisonment for a term of not more than five years or is guilty of an offence punishable on summary conviction who, wrongfully and without lawful authority, for the purpose of compelling another person to abstain from doing anything that he or she has a lawful right to do, or to do anything that he or she has a lawful right to abstain from doing,

**(a)** uses violence or threats of violence to that person or their intimate partner or children, or injures the person's property;

**(b)** intimidates or attempts to intimidate that person or a relative of that person by threats that, in Canada or elsewhere, violence or other injury will be done to or punishment inflicted on him or her or a relative of his or hers, or that the property of any of them will be damaged;

...

**Punishment**

**(3)** Every person who contravenes this section is guilty of an indictable offence and is liable to imprisonment for a term of not more than fourteen years.

**Vaccine Notice of Liability**
**Employer**

Employer: _____

Attn: _____

**Re: COVID-19 injections recommended or administered to employees**

**This is an official and personal Notice of Liability.**

**As my employer you are not a medical professional and, therefore, you are unlawfully practising medicine by prescribing, recommending, and/or using coercion to insist employees submit to the experimental medical treatment for Covid-19, namely being injected with one of the experimental gene therapies commonly referred to as a "vaccine".**

To begin with, the emergency measures are based on the claim that we are experiencing a "public health emergency." There is no evidence to substantiate this claim. In fact, the evidence indicates that we are experiencing a rate of infection consistent with a normal influenza season.[1]

The purported increase in "cases" is a direct consequence of increased testing through the inappropriate use of the PCR instrument to diagnose so-called COVID-19. It has been well established that the PCR test was never designed or intended as a diagnostic tool and is not an acceptable instrument to measure this so-called pandemic. Its inventor, Kary Mullis, has clearly indicated that the PCR testing device was never created to test for coronavirus[2]. Mullis warns that, "the PCR Test can be used to find almost anything, in anybody. If you can amplify one single molecule, then you can find it because that molecule is nearly in every single person."

In light of this warning, the current PCR test utilization, set at higher amplifications, is producing up to 97% false positives[3]. Therefore, any imposed emergency measures that are based on PCR testing are unwarranted, unscientific, and quite possibly fraudulent. An international consortium of life science scientists has detected 10 major scientific flaws at the molecular and methodological level in a 3-peer review of the RTPCR test to detect SARS-CoV-2[4].

In November 2020, a Portuguese court ruled that PCR tests are unreliable.[5] On December 14, 2020, the WHO admitted the PCR Test has a 'problem' at high amplifications as it detects dead cells from old viruses, giving a false positive[6]. Feb 16, 2021, BC Health Officer, Bonnie Henry, admitted PCR tests are unreliable[7]. On April 8, 2021, the Austrian court ruled the PCR was unsuited for COVID testing[8]. On April 8, 2021, a German Court ruled against PCR testing stating, "the test cannot provide any information on whether a person is infected with an active pathogen or not, because the test cannot distinguish between "dead" matter and living matter." [9]On May 8, 2021, the Swedish Public Health Agency stopped PCR Testing for the same reason[10]. On May 10th, 2021, Manitoba's Chief Microbiologist and Laboratory Specialist, Dr. Jared Bullard testified under cross examination in a trial before the court of Queen's Bench in Manitoba, that PCR test results do not verify infectiousness and were never intended to be used to diagnose respiratory illnesses.[11]

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1 https://www.bitchute.com/video/nQgq0BxXfZ4f

2 https://rumble.com/vhu4rz-kary-mullis-inventor-of-the-pcr-test.html

3 https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1491/5912603

4 https://cormandrostenreview.com/report/

5 https://unitynewsnetwork.co.uk/portuguese-court-rules-pcr-tests-unreliable-quarantines-unlawful-media-blackout/

6 https://principia-scientific.com/who-finally-admits-covid19-pcr-test-has-a-problem/

7 https://rumble.com/vhww4d-bc-health-officer-admits-pcr-test-is-unreliable.html

8 https://greatgameindia.com/austria-court-pcr-test/

9 https://2020news.de/sensationsurteil-aus-weimar-keine-masken-kein-abstand-keine-tests-mehr-fuer-schueler/

10 https://tapnewswire.com/2021/05/sweden-stops-pcr-tests-as-covid19-diagnosis/

11 https://www.jccf.ca/Manitoba-chief-microbiologist-and-laboratory-specialist-56-of-positive-cases-are-not-infectious/

Based on this compelling and factual information, the emergency use of the COVID-19 experimental injection is not required or recommended.

1. The Nuremberg Code,[12] to which Canada is a signatory, states that it is essential before performing medical experiments on human beings, there is voluntary informed consent. It also confirms, a person involved should have legal capacity to give consent, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him/her to make an understanding and enlightened decision. This requires, before the acceptance of an affirmative decision by the experimental subject, that there should be made known to him/her the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon his/her health or person which may possibly come from participation in the experiment;

2. All the treatments being marketed as COVID-19 "vaccines", are still in Phase III clinical trials until 2023,[13] and hence, qualify as a medical experiment. People taking these treatments are enrolled as test-subjects and are further unaware that the injections are not actual vaccines as they do not contain a virus but instead an experimental gene therapy;

3. None of these treatments have been fully approved; only granted emergency use authorization by the FDA, which Health Canada, [14] [15] [16] is using as the basis for approval under the interim-order, therefore, fully informed consent is not possible;

4. Most vaccines are trialed for at least 5-10 years,[17] and COVID-19 treatments have been in trials for one year;

5. No other coronavirus vaccine (i.e., MERS, SARS-1) has been approved for market, due to antibody-dependent enhancement, resulting in severe illness and deaths in animal models;[18]

6. Numerous doctors, scientists, and medical experts are issuing dire warnings about the short and long-term effects of COVID-19 injections, including, but not limited to death, blood clots, infertility, miscarriages, Bell's Palsy, cancer, inflammatory conditions, autoimmune disease, early-onset dementia, convulsions, anaphylaxis, inflammation of the heart[19], and antibody dependent enhancement leading to death; this includes children ages 12-17 years old.[20]

   Dr. Byram Bridle, a pro-vaccine Associate Professor on Viral Immunology at the University of Guelph, gives a terrifying warning of the harms of the experimental treatments in a new peer reviewed scientifically published research study[21] on COVID-19 shots. The added Spike Protein to the "vaccine" gets into the blood, circulates through the blood in individuals over several days post-vaccination, it accumulates in the tissues such as the spleen, bone marrow, the liver, the adrenal glands, testes, and of great concern, it accumulates high concentrations into the ovaries. Dr. Bridle notes that they "have known for a long time that the Spike Protein is a pathogenic protein, it is a toxin, and can cause damage if it gets into blood circulation." The study confirms the combination is causing clotting, neurological damage, bleeding, heart problems, etc. There is a high concentration of the Spike Protein getting into breast milk and reports of suckling infants developing bleeding disorders in the gastrointestinal tract. There are further warnings that this injection will render children infertile, and that people who have been vaccinated should NOT donate blood;

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[12] https://media.tghn.org/medialibrary/2011/04/BMJ_No_7070_Volume_313_The_Nuremberg_Code.pdf

[13] https://clinicaltrials.gov/ct2/show/NCT04368728?term=NCT04368728&draw=2&rank=1

[14] https://action4canada.com/wp-content/uploads/Summary-Basis-of-Decision-COVID-19-Vaccine-Moderna-Health-Canada.pdf

[15] https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-_treatments/authorization/applications.html

[16] https://www.pfizer.com/news/hot-topics/the_facts_about_pfizer_and_biontech_s_covid_19_vaccine

[17] https://hillnotes.ca/2020/06/23/covid-19-vaccine-research-and-development/

[18] https://www.tandfonline.com/doi/full/10.1080/21645515.2016.1177688

[19] https://www.nbcconnecticut.com/news/coronavirus/connecticut-confirms-at-least-18-cases-of-apparent-heart-problems-in-young-people-after-covid-19-vaccination/2494534/

[20] https://childrenshealthdefense.org/defender/vaers-data-reports-injuries-12-to-17-year-olds-more-than-triple/

[21] https://omny.fm/shows/on-point-with-alex-pierson/new-peer-reviewed-study-on-covid-19-vaccines-sugg

7. Minors are at nearly zero percent risk of contracting or transmitting this respiratory illness and are, instead, buffers which help others build their immune system. The overall survival rate of minors is 99.997%.[22] In spite of these facts, the government is pushing the experimental treatment with the tragic outcome of a high incidence of injury and death;

8. According to Health Canada's Summary Basis of Decision, updated May 20, 2021, the trials have not proven that the COVID-19 treatments prevent infection or transmission. The Summary also reports that both Moderna and Pfizer identified that there are six areas of missing (limited/no clinical data) information: "use in paediatric (age 0-18)", "use in pregnant and breastfeeding women", "long-term safety", "long-term efficacy" including "real-world use", "safety and immunogenicity in subjects with immune-suppression", and concomitant administration of non-COVID vaccines."

   Under the Risk Management plan section of the Summary Basis of Decision,[23] it includes a statement based on clinical and non-clinical studies that "one important potential risk was identified being vaccine-associated enhanced disease, including VAERD (vaccine-associated enhanced respiratory disease)." In other words, the shot increases the risk of disease and side-effects, and weakens immunity toward future SARS related illness.

   The report specifically states, "the possibility of vaccine-induced disease enhancement after vaccination against SARS-CoV-2 has been flagged as a potential safety concern that requires particular attention by the scientific community, including The World Health Organization (WHO), the Coalition for Epidemic Preparedness Innovations (CEPI) and the International Coalition of Medicines Regulatory Authorities (ICMRA)[24];"

9. As reported in the United States to the Vaccine Adverse Events Reporting System (VAERS), there have been more deaths from the COVID-19 injections in five months (Dec. 2020 – May 2021) than deaths recorded in the last 23 years from all vaccines combined[25].

   It is further reported that only one percent of vaccine injuries are reported to VAERS,[26] compounded by several months delay in uploading the adverse events to the VAERS database[27].

   On May 21, 2021, VAERS data release (in the USA alone) showed 262,521 reports of adverse events following COVID-19 injections, including 4,406 deaths and 21,537 serious injuries, between December 14, 2020, and May 21, 2021, and that adverse injury reports among 12-17-year old's more than tripled in one week[28].

   Dr. McCullough, a highly cited Covid doctor, came to the stunning conclusion that the government was "...scrubbing unprecedented numbers of injection-related-deaths." He further added, "...a typical new drug at about five deaths, unexplained deaths, we get a black-box warning, your listeners would see it on TV, saying it may cause death. And then at about 50 deaths it's pulled off the market[29];"

10. Canada's Adverse Events Following Immunization (AEFI) is a passive reporting system and is not widely promoted to the public, hence, many adverse events are going unreported;

11. **Safe and effective treatments and preventive measures exist for COVID-19, apart from the experimental shots, yet the government is prohibiting their use.**[30] [31]

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22 https://online.anyflip.com/inblw/ufbs/mobile/index.html?s=08

23 https://action4canada.com/wp-content/uploads/Summary-Basis-of-Decision-COVID-19-Vaccine-Moderna-Health-Canada.pdf

24 https://www.tandfonline.com/doi/full/10.1080/14760584.2020.1800463

25 https://vaccineimpact.com/2021/cdc-death-toll-following-experimental-covid-injections-now-at-4863-more-than-23-previous-years-of-recorded-vaccine-deaths-according-to-vaers/

26 https://www.lewrockwell.com/2019/10/no_author/harvard-medical-school-professors-uncover-a-hard-to-swallow-truth-about-vaccines/

27 http://vaxoutcomes.com/thelatestreport/

28 https://childrenshealthdefense.org/defender/vaers-data-reports-injuries-12-to-17-year-olds-more-than-triple/

29 https://leohohmann.com/2021/04/30/highly-cited-covid-doctor-comes-to-stunning-conclusion-govt-scrubbing-unprecedented-numbers-of-injection-related-deaths/

30 https://www.washingtonexaminer.com/news/study-finds-84-fewer-hospitalizations-for-patients-treated-with-controversial-drug-hydroxychloroquine?

31 https://alethonews.com/2021/05/26/five-recently-published-randomized-controlled-trials-confirm-major-statistically-significant-benefits-of-ivermectin-against-covid-19/

Under the *Crimes Against Humanity and War Crimes Act of Canada*[32], a crime against humanity means, among other things, murder, any other inhumane act or omission that is committed against any civilian population or any identifiable group and that, at the time and in the place of its commission, constitutes a crime against humanity according to customary international law, conventional international law, or by virtue of its being criminal according to the general principles of law are recognized by the community of nations, whether or not it constitutes a contravention of the law in force at the time and in the place of its commission. The *Act* also confirms that every person who conspires or attempts to commit, **is an accessory after the fact**, in relation to, or councils in relation to, a crime against humanity, is guilty of an offence and liable to imprisonment for life.

Under sections 265 and 266 of the Criminal Code of Canada,[33] a person commits an assault when, without the consent of another person, he applies force intentionally to that other person, directly or indirectly. Everyone who commits an assault is guilty of an indictable offence and liable to imprisonment for a term not exceeding five years, or an offence punishable on summary conviction.

It is a further violation of the Canadian Criminal Code,[34] to endanger the life of another person. Sections 216, 217, 217.1 and 221.

> **Duty of persons undertaking acts dangerous to life**
>
> **Sec. 216:** Everyone who undertakes to administer surgical or medical treatment to another person or to do any other lawful act that may endanger the life of another person is, except in cases of necessity, under a legal duty to have and to use reasonable knowledge, skill and care in so doing.
>
> R.S., c. C-34, s. 198
>
> **Duty of persons undertaking acts**
>
> **Sec. 217:** Everyone who undertakes to do an act is under a legal duty to do it if an omission to do the act is or may be dangerous to life.
>
> **Duty of persons directing work**
>
> **Sec. 217.1:** Everyone who undertakes, or has the authority, to direct how another person does work or performs a task is under a legal duty to take reasonable steps to prevent bodily harm to that person, or any other person, arising from that work or task.
>
> **Causing bodily harm by criminal negligence**
>
> **Sec. 221**: Every person who by criminal negligence causes bodily harm to another person is guilty of
> (a) an indictable offence and liable to imprisonment for a term of not more than 10 years; or,
> (b) an offence punishable on summary conviction.

Domestically, in the seminal decision of Hopp v Lepp, [1980] 2 SCR 192,[35] the Supreme Court of Canada determined that cases of non-disclosure of risks and medical information fall under the law of negligence. Hopp also clarified the standard of informed consent and held that, even if a certain risk is only a slight possibility which ordinarily would not be disclosed, but which carries serious consequences, such as paralysis or death, the material risk must be revealed to the patient.

The duty of disclosure for informed consent is rooted in an individual's right to bodily integrity and respect for patient autonomy. In other words, a patient has the right to understand the consequences of medical treatment regardless of whether those consequences are deemed improbable, and have determined that, although medical opinion can be divided as to the level of disclosure required, the standard is simple, "A Reasonable Person Would Want to Know the Serious Risks, Even if Remote." Hopp v Lepp, supra; Bryan v Hicks, 1995 CanLII 172 (BCCA); British Columbia Women's Hospital Center, 2013 SCC 30.[36]

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[32] https://laws-lois.justice.gc.ca/eng/acts/c-45.9/page-1.html

[33] https://laws-lois.justice.gc.ca/eng/acts/c-46/page-57.html#docCont

[34] https://laws-lois.justice.gc.ca/eng/acts/c-46/page-51.html#docCont

[35] https://scc-csc.lexum.com/scc-csc/scc-csc/en/item/2553/index.do

[36] https://www.canlii.org/en/ca/scc/doc/2013/2013scc30/2013scc30.html?resultIndex=1

Vaccination is voluntary in Canada. The federal and provincial governments have made it clear that getting the COVID-19 injections will not be mandatory. Employers are infringing on human rights and putting themselves personally at risk of a civil lawsuit for damages, and potential imprisonment, by attempting to impose this experimental medical treatment upon their employees. Canadian law has long recognized that individuals have the right to control what happens to their bodies.

The citizens of Canada are protected under the medical and legal ethics of express informed consent, and are entitled to the full protections guaranteed under:

- **Canadian Charter of Rights and Freedoms**[37] **(1982)** Section 2a, 2b, 7, 8, 9, 15.
- **Universal Declaration on Bioethics and Human Rights**[38] **(2005)**
- **Nuremberg Code**[39] **(1947)**
- **Helsinki Declaration**[40] **(1964, Revised 2013) Article 25, 26**

According to top constitutional lawyer, Rocco Galati, "both government and private businesses cannot impose mandatory vaccinations...mandatory vaccination in all employment context would be unconstitutional and/or illegal and unenforceable."[41]

There is no legislation that allows an employer to terminate an employee for not getting a COVID-19 shot. If an employer does so, they are inviting a wrongful dismissal claim, as well as a claim for a human rights code violation[42]. For those employees who are influenced, pressured or coerced by their employer to have the COVID-19 shot, and suffer any adverse consequences as a result of the injection, the employer, and its directors, officers, and those in positions carrying out these measures on behalf of the employer, will be opening themselves up to personal civil liability, and potential personal criminal liability, under the Nuremberg Code, the Criminal Code of Canada, and the *Crimes Against Humanity and War Crimes Act of Canada*, all referenced above.

In conclusion, administration of vaccines is defined as a " medical procedure". In what other medical context could non-doctors and non-pharmacists prescribe, promote and help distribute pharmaceutical drugs? This is unauthorized practice of medicine.

Therefore, I hereby notify you that I will hold you personally liable for any financial injury and/or loss of my personal income and my ability to provide food and shelter for my family if you use coercion or discrimination against me based on my decision not to participate in the COVID-19 experimental treatments.

Name: _____

Signature: _____

Date: _____

Source: Action4Canada.com

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[37] https://www.canada.ca/en/canadian-heritage/services/how-rights-protected/guide-canadian-charter-rights-freedoms.html

[38] https://en.unesco.org/themes/ethics-science-and-technology/bioethics-and-human-rights

[39] http://www.cirp.org/library/ethics/nuremberg

[40] https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/

[41] https://www.constitutionalrightscentre.ca/employee-rights-the-covid-19-vaccine/

[42] https://www.chrc-ccdp.gc.ca/en/about-human-rights/what-discrimination

Français

# Reopening Ontario (A Flexible Response to COVID-19) Act, 2020

## ONTARIO REGULATION 364/20

*formerly under Emergency Management and Civil Protection Act*

## RULES FOR AREAS IN STAGE 3

Consolidation Period: From November 27, 2020 to the e-Laws currency date.

Last amendment: 687/20.

Legislative History: 415/20, 428/20, 453/20, 456/20, 501/20, 519/20, 529/20, 530/20, 531/20, 546/20, 574/20, 579/20, 588/20, 642/20, 655/20, 687/20.

***This is the English version of a bilingual regulation.***

**Terms of Order**

**1.** The terms of this Order are set out in Schedules 1, 2 and 3.

**2.** REVOKED: O. Reg. 574/20, s. 1.

**Application**

**3.** (1) This Order applies to the areas listed in Schedule 3 to Ontario Regulation 363/20 (Stages of Reopening). O. Reg. 364/20, s. 3.

(2) This Order applies throughout the Green Zone, the Yellow Zone and the Orange Zone. O. Reg. 642/20, s. 1.

(3) Despite subsection (2),

(a) if this Order specifies that a particular requirement, condition, rule or other restriction applies in the Yellow Zone only, then the requirement, condition, rule or other restriction does not apply in the Green Zone or the Orange Zone;

(b) if this Order specifies that a particular requirement, condition, rule or other restriction applies in the Orange Zone only, then the requirement, condition, rule or other restriction does not apply in the Green Zone or the Yellow Zone; and

(c) if this Order specifies that a particular requirement, condition, rule or other restriction applies in both the Yellow Zone and the Orange Zone, then the requirement, condition, rule or other restriction does not apply in the Green Zone. O. Reg. 642/20, s. 1.

**Green Zone**

**3.1** In this Order, a reference to the Green Zone is a reference to all areas listed as being in the Green Zone of Stage 3 in section 1 of Schedule 3 to Ontario Regulation 363/20 (Stages of Reopening) made under the Act. O. Reg. 642/20, s. 2.

**Yellow Zone**

**3.2** In this Order, a reference to the Yellow Zone is a reference to all areas listed as being in the Yellow Zone of Stage 3 in section 2 of Schedule 3 to Ontario Regulation 363/20 (Stages of Reopening) made under the Act. O. Reg. 642/20, s. 2.

**Orange Zone**

**3.3** In this Order, a reference to the Orange Zone is a reference to all areas listed as being in the Orange Zone of Stage 3 in section 3 of Schedule 3 to Ontario Regulation 363/20 (Stages of Reopening) made under the Act. O. Reg. 642/20, s. 2.

**Indoor vs. outdoor**

**4.** (1) The outdoor capacity limits set out in this Order apply to a business, place, event or gathering if the people attending it are only permitted to access an indoor area,

(a) to use a washroom;

(b) to access an outdoor area that can only be accessed through an indoor route; or

(c) as may be necessary for the purposes of health and safety.

(2) The indoor capacity limits set out in this Order apply to a business, place, event or gathering if the business, place, event or gathering is fully or partially indoors.

(3) An indoor event or gathering cannot be combined with an outdoor event or gathering so as to increase the applicable limit on the number of people at the event or gathering.

**Safety plan**

**5.** (1) A person who is required under this Order to prepare and make available a safety plan in accordance with this section, or to ensure that one is prepared and made available, shall comply with the requirement no later than seven days after the requirement first applies to the person. O. Reg. 642/20, s. 3.

(2) The safety plan shall describe the measures and procedures which have been implemented or will be implemented in the business, place, facility or establishment to reduce the transmission risk of COVID-19. O. Reg. 642/20, s. 3.

(3) Without limiting the generality of subsection (2), the safety plan shall describe how the requirements of this Order will be implemented in the location including by screening, physical distancing, masks or face coverings, cleaning and disinfecting of surfaces and objects, and the wearing of personal protective equipment. O. Reg. 642/20, s. 3.

(4) The safety plan shall be in writing and shall be made available to any person for review on request. O. Reg. 642/20, s. 3.

(5) The person responsible for the business, place, facility or establishment shall ensure that a copy of the safety plan is posted in a conspicuous place where it is most likely to come to the attention of individuals working in or attending the location. O. Reg. 642/20, s. 3.

## SCHEDULE 1
## BUSINESSES AND PLACES

**Closures**

**1.** (1) Each person responsible for a business or place, or part of a business or place, that is required to be closed by Schedule 2 shall ensure that the business or place, or part of the business or place, is closed in accordance with that Schedule.

(2) Each person responsible for a business or place, or part of a business or place, that Schedule 2 describes as being permitted to open if certain conditions set out in that Schedule are met shall ensure that the business or place, or part of the business or place, either meets those conditions or is closed.

(3) Each person responsible for a business or place, or part of a business or place, that does not comply with sections 2 to 6 of this Schedule shall ensure that it is closed.

(4) Despite subsections (1), (2) and (3), temporary access to a business or place, or part of a business or place, that is required to be closed by Schedule 2 is authorized, unless otherwise prohibited by any applicable law, for the purposes of,

(a) performing work at the business or place in order to comply with any applicable law;

(b) preparing the business or place to be reopened;

(c) allowing for inspections, maintenance or repairs to be carried out at the business or place;

(d) allowing for security services to be provided at the business or place; and

(e) attending at the business or place temporarily,

(i) to deal with other critical matters relating to the closure of the business or place, if the critical matters cannot be attended to remotely, or

(ii) to access materials, goods or supplies that may be necessary for the business or place to be operated remotely.

(5) Nothing in this Order precludes a business or organization from operating remotely for the purpose of,

(a) providing goods by mail or other forms of delivery, or making goods available for pick-up; and

(b) providing services online, by telephone or other remote means.

**General compliance**

**2.** (1) The person responsible for a business or organization that is open shall ensure that the business or organization operates in accordance with all applicable laws, including the *Occupational Health and Safety Act* and the regulations made under it.

(2) The person responsible for a business or organization that is open shall operate the business or organization in compliance with the advice, recommendations and instructions of public health officials, including any advice, recommendations or instructions on physical distancing, cleaning or disinfecting.

(3) The person responsible for a business or organization that is open shall operate the business or organization in compliance with the advice, recommendations and instructions issued by the Office of the Chief Medical Officer of Health on screening individuals.

(4) The person responsible for a business or organization that is open shall ensure that any person in the indoor area of the premises of the business or organization, or in a vehicle that is operating as part of the business or organization, wears a mask

or face covering in a manner that covers their mouth, nose and chin during any period when they are in the indoor area unless the person in the indoor area,

(a) is a child who is younger than two years of age;

(b) is attending a school or private school within the meaning of the *Education Act* that is operated in accordance with a return to school direction issued by the Ministry of Education and approved by the Office of the Chief Medical Officer of Health;

(c) is attending a child care program at a place that is in compliance with the child care re-opening guidance issued by the Ministry of Education;

(d) is receiving residential services and supports in a residence listed in the definition of "residential services and supports" in subsection 4 (2) of the *Services and Supports to Promote the Social Inclusion of Persons with Developmental Disabilities Act, 2008*;

(e) is in a correctional institution or in a custody and detention program for young persons in conflict with the law;

(f) is performing or rehearsing in a film or television production or in a concert, artistic event, theatrical performance or other performance;

(g) has a medical condition that inhibits their ability to wear a mask or face covering;

(h) is unable to put on or remove their mask or face covering without the assistance of another person;

(i) needs to temporarily remove their mask or face covering while in the indoor area,

(i) to receive services that require the removal of their mask or face covering,

(ii) to engage in an athletic or fitness activity,

(iii) to consume food or drink, or

(iv) as may be necessary for the purposes of health and safety;

(j) is being accommodated in accordance with the *Accessibility for Ontarians with Disabilities Act, 2005*;

(k) is being reasonably accommodated in accordance with the *Human Rights Code*; or

(l) performs work for the business or organization, is in an area that is not accessible to members of the public and is able to maintain a physical distance of at least two metres from every other person while in the indoor area.

(5) Subsection (4) does not apply with respect to premises that are used as a dwelling if the person responsible for the business or organization ensures that persons in the premises who are not entitled to an exception set out in subsection (4) wear a mask or face covering in a manner that covers their mouth, nose and chin in any common areas of the premises in which persons are unable to maintain a physical distance of at least two metres from other persons.

(6) For greater certainty, it is not necessary for a person to present evidence to the person responsible for a business or place that they are entitled to any of the exceptions set out in subsection (4).

(7) A person shall wear appropriate personal protective equipment that provides protection of the person's eyes, nose and mouth if, in the course of providing services, the person,

(a) is required to come within 2 metres of another person who is not wearing a mask or face covering in a manner that covers that person's mouth, nose and chin during any period when that person is in an indoor area; and

(b) is not separated by plexiglass or some other impermeable barrier from a person described in clause (a).

**Capacity limits for businesses or facilities open to the public**

**3.** (1) The person responsible for a place of business or facility that is open to the public shall limit the number of persons in the place of business or facility so that every member of the public is able to maintain a physical distance of at least two metres from every other person in the business or facility, except where Schedule 2 allows persons to be closer together.

(2) For greater certainty, subsection (1) does not require persons who are in compliance with public health guidance on households to maintain a physical distance of at least two metres from each other while in a place of business or facility.

**Meeting or event space**

**4.** (1) The person responsible for a business or place that is open may only rent out meeting or event space if the total number of members of the public permitted to be in all of the rentable meeting or event space in the business or place at any one time is limited to the number that can maintain a physical distance of at least two metres from every other person in the business or place, and in any event is not permitted to exceed,

(a) 50 persons, if the meeting or event is indoors; or

(b) 100 persons, if the meeting or event is outdoors.

Ontario

Français

# Trespass to Property Act

R.S.O. 1990, CHAPTER T.21

**Consolidation Period:** From September 1, 2016 to the e-Laws currency date.

Last amendment: 2016, c. 8, Sched. 6.

Legislative History: [ + ]

**Definitions**

**1** (1) In this Act,

"occupier" includes,

(a) a person who is in physical possession of premises, or

(b) a person who has responsibility for and control over the condition of premises or the activities there carried on, or control over persons allowed to enter the premises,

even if there is more than one occupier of the same premises; ("occupant")

"premises" means lands and structures, or either of them, and includes,

(a) water,

(b) ships and vessels,

(c) trailers and portable structures designed or used for residence, business or shelter,

(d) trains, railway cars, vehicles and aircraft, except while in operation. ("lieux") R.S.O. 1990, c. T.21, s. 1 (1).

**School boards**

(2) A school board has all the rights and duties of an occupier in respect of its school sites as defined in the *Education Act*. R.S.O. 1990, c. T.21, s. 1 (2).

**Trespass an offence**

**2** (1) Every person who is not acting under a right or authority conferred by law and who,

(a) without the express permission of the occupier, the proof of which rests on the defendant,

(i) enters on premises when entry is prohibited under this Act, or

(ii) engages in an activity on premises when the activity is prohibited under this Act; or

(b) does not leave the premises immediately after he or she is directed to do so by the occupier of the premises or a person authorized by the occupier,

is guilty of an offence and on conviction is liable to a fine of not more than $10,000. R.S.O. 1990, c. T.21, s. 2 (1); 2016, c. 8, Sched. 6, s. 1.

**Colour of right as a defence**

(2) It is a defence to a charge under subsection (1) in respect of premises that is land that the person charged reasonably believed that he or she had title to or an interest in the land that entitled him or her to do the act complained of. R.S.O. 1990, c. T.21, s. 2 (2).

**Section Amendments with date in force (d/m/y)** [+]

**Prohibition of entry**

**3** (1) Entry on premises may be prohibited by notice to that effect and entry is prohibited without any notice on premises,

(a) that is a garden, field or other land that is under cultivation, including a lawn, orchard, vineyard and premises on which trees have been planted and have not attained an average height of more than two metres and woodlots on land used primarily for agricultural purposes; or

(b) that is enclosed in a manner that indicates the occupier's intention to keep persons off the premises or to keep animals on the premises. R.S.O. 1990, c. T.21, s. 3 (1).

**Implied permission to use approach to door**

(2) There is a presumption that access for lawful purposes to the door of a building on premises by a means apparently provided and used for the purpose of access is not prohibited. R.S.O. 1990, c. T.21, s. 3 (2).

**Limited permission**

**4** (1) Where notice is given that one or more particular activities are permitted, all other activities and entry for the purpose are prohibited and any additional notice that entry is prohibited or a particular activity is prohibited on the same premises shall be construed to be for greater certainty only. R.S.O. 1990, c. T.21, s. 4 (1).

**Limited prohibition**

(2) Where entry on premises is not prohibited under section 3 or by notice that one or more particular activities are permitted under subsection (1), and notice is given that a particular activity is prohibited, that activity and entry for the purpose is prohibited and all other activities and entry for the purpose are not prohibited. R.S.O. 1990, c. T.21, s. 4 (2).

**Method of giving notice**

**5** (1) A notice under this Act may be given,

(a) orally or in writing;

(b) by means of signs posted so that a sign is clearly visible in daylight under normal conditions from the approach to each ordinary point of access to the premises to which it applies; or

(c) by means of the marking system set out in section 7. R.S.O. 1990, c. T.21, s. 5 (1).

**Substantial compliance**

(2) Substantial compliance with clause (1) (b) or (c) is sufficient notice. R.S.O. 1990, c. T.21, s. 5 (2).

**Form of sign**

**6** (1) A sign naming an activity or showing a graphic representation of an activity is sufficient for the purpose of giving notice that the activity is permitted. R.S.O. 1990, c. T.21, s. 6 (1).

**Idem**

(2) A sign naming an activity with an oblique line drawn through the name or showing a graphic representation of an activity with an oblique line drawn through the representation is sufficient for the purpose of giving notice that the activity is prohibited. R.S.O. 1990, c. T.21, s. 6 (2).

**Red markings**

**7** (1) Red markings made and posted in accordance with subsections (3) and (4) are sufficient for the purpose of giving notice that entry on the premises is prohibited. R.S.O. 1990, c. T.21, s. 7 (1).

**Yellow markings**

(2) Yellow markings made and posted in accordance with subsections (3) and (4) are sufficient for the purpose of giving notice that entry is prohibited except for the purpose of certain activities and shall be deemed to be notice of the activities permitted. R.S.O. 1990, c. T.21, s. 7 (2).

**Size**

(3) A marking under this section shall be of such a size that a circle ten centimetres in diameter can be contained wholly within it. R.S.O. 1990, c. T.21, s. 7 (3).

**Posting**

(4) Markings under this section shall be so placed that a marking is clearly visible in daylight under normal conditions from the approach to each ordinary point of access to the premises to which it applies. R.S.O. 1990, c. T.21, s. 7 (4).

**Notice applicable to part of premises**

**8** A notice or permission under this Act may be given in respect of any part of the premises of an occupier. R.S.O. 1990, c. T.21, s. 8.

**Arrest without warrant on premises**

**9** (1) A police officer, or the occupier of premises, or a person authorized by the occupier may arrest without warrant any person he or she believes on reasonable and probable grounds to be on the premises in contravention of section 2. R.S.O. 1990, c. T.21, s. 9 (1).

**Delivery to police officer**

(2) Where the person who makes an arrest under subsection (1) is not a police officer, he or she shall promptly call for the assistance of a police officer and give the person arrested into the custody of the police officer. R.S.O. 1990, c. T.21, s. 9 (2).

**Deemed arrest**

(3) A police officer to whom the custody of a person is given under subsection (2) shall be deemed to have arrested the person for the purposes of the provisions of the *Provincial Offences Act* applying to his or her release or continued detention and bail. R.S.O. 1990, c. T.21, s. 9 (3).

**Arrest without warrant off premises**

IMPORTANT VACCINE FACTS

- This is an Experimental Gene Altering Technology treatment
- Experimental trial is not over until 2023
- YOU are the volunteer experimental subject
- You can still catch, transmit and spread Covid-19
- You can still suffer from symptoms; mild, medium, severe & death
- Have you weighed the negative risks of the experimental technology by researching the negative side effects reported on the VAERS or AEFI or MHRA websites
- The experimental gene altering technology treatment was not tested on animals; you are the animal
- All 34 previous MRNA gene altering technology experiments failed in the previous 20 years in the animal studies (immediately following and up to several months after receiving the doses & usually after being exposed to a/the wild virus)
- If you experience a negative effect from the MRNA experimental gene altering technology, there may be no treatment to correct the effect as this is a gene altering therapy. There are no returns nor refunds nor reversals for what may happen to you
- Your health, life or death insurance company may not cover you if you suffer negative effects or death by taking part as a volunteer in the experimental trials; please contact your insurance provider
- This experimental gene altering technology treatment has NOT been approved by the FDA as it has not completed the experimental phases of the trial which is to end in 2023
- Vaccine manufacturers have absolute immunity from any liability side effects you may suffer from by consenting to be a volunteer in the experimental trials
- The only benefit you may receive is a 95% chance of suffering only mild symptoms from the virus (the virus itself has affected only 1.4% of the population as per the PCR cases, and 99.9% of those cases survived and over 95% survived without treatment)

***Important Websites for Research!***

Canada Health Alliance – canadahealthalliance.org

Canadian Frontline Nurses – canadianfrontlinenurses.ca

Global Frontline Nurses – globalfrontlinenurses.com

Covid 19 Critical Care – covid19criticalcare.com

World Doctors Alliance – worlddoctorsalliance.com

America's Frontline Doctors – americasfrontlinedoctors.com

***Mask Studies – Recent to oldest.....The consensus, more damage than good***

https://www.scientificamerican.com/article/masks-can-be-detrimental-to-babies-speech-and-language-development1/

https://www.researchsquare.com/article/rs-124394/v2

https://headachejournal.onlinelibrary.wiley.com/doi/10.1111/head.14038

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7680614/

https://www.acpjournals.org/doi/10.7326/M20-6817

https://pdmj.org/

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7598570/

https://www.sott.net/article/442455-German-Neurologist-Warns-Against-Wearing-Facemasks-Oxygen-Deprivation-Causes-Permanent-Neurological-Damage

https://eurjmedres.biomedcentral.com/articles/10.1186/s40001-020-00430-5

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7417296/

https://link.springer.com/article/10.1007/s00392-020-01704-y

https://pdmj.org/papers/masks_are_neither_effective_nor_safe/index.html

https://www.medrxiv.org/content/10.1101/2020.06.16.20133207v1

https://link.springer.com/article/10.1007/s00266-020-01833-9

https://www.sciencedirect.com/science/article/pii/S0306987720317126?via%3Dihub

https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/steps-when-sick.html

https://www.acpjournals.org/doi/10.7326/M20-1342

http://www.upmc-biosecurity.org/website/resources/publications/2006/2006-09-15-diseasemitigationcontrolpandemicflu.html

*Here are 30 studies from various medical journals showing that lockdowns do not work.*

1. https://onlinelibrary.wiley.com/doi/abs/10.1111/eci.13484
2. https://www.medrxiv.org/content/10.1101/2020.07.22.20160341v3
3. https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(20)30208-X/fulltext
4. https://advance.sagepub.com/articles/preprint/Comment_on_Dehning_et_al_Science_15_May_2020_eabb9789_Inferring_change_points_in_the_spread_of_COVID-19_reveals_the_effectiveness_of_interventions_/12362645
5. https://arxiv.org/pdf/2005.02090.pdf
6. https://www.datascienceassn.org/sites/default/files/Illusory%20Effects%20of%20Non-pharmaceutical%20Interventions%20on%20COVID19%20in%20Europe.pdf
7. https://www.timesofisrael.com/the-end-of-exponential-growth-the-decline-in-the-spread-of-coronavirus/
8. https://www.medrxiv.org/content/10.1101/2020.05.01.20088260v2
9. https://www.medrxiv.org/content/10.1101/2020.04.24.20078717v1
10. https://www.medrxiv.org/content/10.1101/2020.09.26.20202267v1
11. https://www.nicholaslewis.org/did-lockdowns-really-save-3-million-covid-19-deaths-as-flaxman-et-al-claim/
12. https://www.bmj.com/content/371/bmj.m3588
13. https://www.medrxiv.org/content/10.1101/2020.03.30.20047860v3
14. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2652751/
15. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3607803
16. https://imgcdn.larepublica.co/cms/2020/05/21180548/JP-Morgan.pdf
17. https://jamanetwork.com/journals/jama/fullarticle/2768086
18. https://www.medrxiv.org/content/10.1101/2020.10.09.20210146v3
19. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3665588
20. https://www.nber.org/papers/w27719
21. https://www.bmj.com/content/370/bmj.m3543
22. https://www.medrxiv.org/content/10.1101/2020.11.01.20222315v1
23. https://pandata.org/wp-content/uploads/2020/07/Exploring-inter-country-variation.pdf
24. https://www.nejm.org/doi/full/10.1056/NEJMoa2029717

25. https://www.medrxiv.org/content/10.1101/2020.08.04.20168112v1#:~:text=The%20seroprevalence%20of%20COVID%2D19,care%20workers%20in%20Niger%20State
26. https://www.frontiersin.org/articles/10.3389/fpubh.2020.604339/full
27. https://www.tandfonline.com/doi/abs/10.1080/00779954.2020.1844786?journalCode=rnzp20
28. http://www.upmc-biosecurity.org/website/resources/publications/2006/2006-09-15-diseasemitigationcontrolpandemicflu.html
29. https://www.medrxiv.org/content/10.1101/2020.12.25.20248853v1
30. https://www.medrxiv.org/content/10.1101/2020.12.28.20248936v1

***Non-Pharmaceutical Interventions (NPI) for Lockdown Actions***

1.PPE (hand hygiene, respiratory etiquette, face masks)

2. Environmental Measures (surface/object cleaning, ultra-violet light, increased ventilation, modifying humidity)

3. Social Distancing (contact tracing, isolation of the sick, quarantine of the exposed, school measures/closures, workplace closures/measures, avoiding crowding)

4. Travel -related Measures (travel advice, entry & exit screening, internal travel existence, border closure)

Transport Canada Transports Canada

**Protected B when completed**

# MEDICAL CERTIFICATE FOR PERSONS WITH PHYSICAL OR MEDICAL CONDITIONS THAT PREVENT THE USE OF A NON-MEDICAL MASK OR FACE COVERING FOR CIVIL AVIATION

**The holder of this medical certificate is unable to wear a non-medical mask or face covering due to a medical or physical condition. This condition is not related to COVID-19 or any other infectious condition.**

This form may only be signed by a healthcare provider who is a physician, nurse practitioner, dentist, or physician assistant.

| **CERTIFICATE HOLDER INFORMATION** | |
|---|---|
| Surname | |
| Given Name(s) | |
| Date of Birth (yyyy-mm-dd) | |
| **HEALTHCARE PROVIDER INFORMATION** | |
| Healthcare Provider Full Name | |
| Healthcare Provider License Number | Healthcare Provider Telephone Number (999-999-9999) |

Signature of Healthcare Provider

Date (yyyy-mm-dd)



Canada

# What To Do If You Get A Ticket

Bylaw and other enforcement agencies may not lawfully issue fines for violations of laws and bylaws which are themselves illegal. Many fines have already been thrown out of court as unconstitutional.

In Ontario, the courts have been backlogged for 9 years and currently have more than 400,000 unheard claims. They only have 18 months to hear any claim in court so the odds of any of these ReOpening Ontario Act tickets being heard is very unlikely.

If you receive a "blue" ticket, file it to court within 30 days like you would a parking ticket.

If you get a summons to court (yellow), send both an email and registered mail to your local court house requesting disclosure as well as a pre-trial meeting. (we can provide a template) They must give you these two things before they can proceed in court.

**DO NOT PAY FINES, FIGHT THEM.**

Contact the Justice Center for Constitutional Freedoms (JCCF). They can advise and defend you at no cost. Or contact Rebel News. They also have a team of lawyers dedicated to fighting lockdown fines at no cost.

**Contact JCCF**
https://www.jccf.ca/contact-information/

**Contact Rebel News**
https://www.rebelnews.com/fight_the_fines_canada

# Additional Support

JOIN WeAreAllEssential.ca as a member for additional training and support to confidently open your business with the support of over 900 businesses and growing exponentially.

You can join privately or publicly. The key is to join so that we can help empower you and help you organize with other businesses locally. United Non-Compliance is KEY. We are coordinating mass re-opening dates in the coming weeks. You do not want to miss out. Strength in numbers!

Once you've registered and your account is approved (less than 24hr), login to your account here: www.WeAreAllEssential.ca/account to access more videos and support docs.

Create a telegram account if you do not already have one. Install this free app on your phone and on your computer too. Inside of your user account, you will see a link to join our private network chat on telegram which is incredible for day-to-day support.

Inside of your user account, you will also see a link to join our network zoom calls. Install zoom software on your computer and click link. (Software available here www.zoom.us) We meet to strategize and support face-to-face on Mondays at 5pm EST and Wednesdays at 9pm EST.

1. Will you please educate me on Section 1 of the Police services Act? (police oath to protect our Human Rights)
2. How confident are you in your indemnity insurance? You know you can be sued personally and held criminally responsible for not upholding Section 1 of the Police Services Act? Typically insurance companies will not cover your legal expenses or damages when you are breaking the law (PSA, section 1)
3. I do not answer questions.
4. Am I being Detained?
5. I will not talk to you without my lawyer present.
6. I will not talk to you without immunity.
7. I will not let you in without a warrant.
8. I now assert my right to remain silent.

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This document is currently offline since the start of the Covid-19 Pandemic

**Volume: 23S4 - May 1997**

**Canadian National Report on Immunization, 1996**

# 1. Immunization in Canada

Vaccines are licensed for use in Canada by the Bureau of Biologics and Radiopharmaceuticals, Health Protection Branch, Health Canada. Licensing is conditional to an application being filed by the manufacturer and a favourable review of the supporting information submitted by the company. Provincial and territorial ministries of health then buy vaccines from available licensed products on the market, which are then provided to the public free of charge. Each province and territory is responsible for the delivery of immunization programs to its populations; vaccines and schedules are selected to suit the goals of their public-health programs. Nevertheless, general Canadian recommendations on the use of vaccines exist. They are formulated by the National Advisory Committee on Immunization (NACI) - a committee of members from across the country who are experts in areas, such as public health, infectious diseases, and pediatrics.

NACI has reported to the Assistant Deputy Minister of the Health Protection Branch since 1975. Its mandate is to provide Health Canada with ongoing and timely medical, scientific, and public-health advice relating to vaccines and certain prophylactic agents generally and, more specifically, to their use in humans, their evaluation, and the monitoring of vaccine-associated adverse events (VAAEs). In addition to updating the Canadian Immunization Guide, NACI also issues regular statements on the use of vaccines. Currently, all NACI statements are published in the Canada Communicable Disease Report (CCDR) which is available by subscription, from an automated fax delivery service at LCDC, and from the LCDC web site (http://www.hc-sc.gc.ca/hpb/lcdc). Provinces and territories will adjust their recommended schedules and selection of vaccines, based on NACI recommendations as well as on local epidemiologic, program, and financial considerations.

Vaccines Not Mandatory In Canada =====>

***Unlike some countries, immunization is not mandatory in Canada; it cannot be made mandatory because of the Canadian Constitution. Only three provinces have legislation or regulations under their health-protection acts to require proof of immunization for school entrance. Ontario and New Brunswick require proof for diphtheria, tetanus, polio, measles, mumps, and rubella immunization. In Manitoba, only measles vaccination is covered. It must be emphasized that, in these three provinces, exceptions are permitted for medical or religious grounds and reasons of conscience; legislation and regulations must not be interpreted to imply compulsory immunization. Requiring proof of immunization for school entrance serves two main purposes. First, parents who have forgotten to have their children properly immunized will be reminded and can rectify the situation. Second, parents who do not wish to have their children immunized must actively refuse and sign documents attesting to that fact. Also, all provinces and territories have regulations that allow for the exclusion of unvaccinated children from school during outbreaks of vaccine-preventable diseases. Currently, Quebec is the only jurisdiction in Canada to have a compensation plan for VAAEs.***

In some provinces and territories, the public health-care system administers immunization programs; infants and children receive their vaccinations at public-health clinics. In other provinces and territories, vaccinations are primarily given by private physicians who order vaccines from local public-health units. Figure 1 indicates the estimated percentage of immunization provided by both ways in each jurisdiction. Generally, in provinces and territories with a dual system, the public health-care system serves rural areas while private practice predominates in urban settings. Private physicians generally administer recommended vaccines for non-institutionalized adults.

# Resources

## Advisor Resources

Jonathon Wakelin, Barrister & Solicitor – 416-227-3444, jwakelin@wakelinlaw.com

Vladimir Reznik, Paralegal, Notary Public – 416-222-9906, rezniklegal@gmail.com

Chris Weisdorf, part of Adam Skelly 's Legal Team, advisor
Assistant - Cindy Harris 416-657-7771

Jody Ledgerwood, realtor, researcher, Take Action Canada/The Fringe Majority/Freedom Fighters Canada/NAUT/WAAE – 905-269-7653, jledgerwood@nhrealty.ca

## Helpful Websites

www.tfmcast.com

www.TakeActionCanada.ca

www.GameOnCanada.org

www.WeAreAllEssential.ca

www.FreedomFightersCan.ca

www.drtrozzi.org

www.CanadianCovidCareAlliance.org

www.PoliceOnGuard.ca

www.Action4Canada.com

www.Jccf.ca

www.VaccineChoiceCanada.com

www.CanadianFrontLineNurses.ca

www.StandUpCanada.solutions

www.ChildrensHealthDefense.ca

www.Stand4Thee.com

https://enableair.com

https://Doctors4CovidEthics.org/resources-2/

https://iamhassentmetoyou.com/mdocuments-library/

https://yummy.doctor/blog/if-your-doctor-insists-that-vaccines-are-safe-then-have-them-sign-this-form/

https://AwakeCanada.org/say-no/

https://pandemic.solari.com/form-for-employees-whose-employers-are-requiring-covid-19-injections/

https://twitter.com/denisrancourt/status/1437110855234097161

www.rebelnews.com

# Resources

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www.CanadianFrontLineNurses.ca

www.StandUpCanada.solutions

www.ChildrensHealthDefense.ca

www.Stand4Thee.com

https://enableair.com

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https://iamhassentmetoyou.com/mdocuments-library/

https://yummy.doctor/blog/if-your-doctor-insists-that-vaccines-are-safe-then-have-them-sign-this-form/

https://AwakeCanada.org/say-no/

https://pandemic.solari.com/form-for-employees-whose-employers-are-requiring-covid-19-injections/

https://twitter.com/denisrancourt/status/1437110855234097161

www.rebelnews.com

**A SHORT SUMMARY OF LAWS THAT PROTECT YOUR LEGAL RIGHTS**

RSO 1990 c. F31 – Freedom of Information and Protection of Privacy Act

RSO 1990 c. 0.1 – Occupational Health & Safety Act

SO 1996 c.2 – The Health Care Consent Act

SO 2004 c.3 – Personal Health Information Protection Act

C 44 - Canadian Bill of Rights 1960

The Canadian Constitution 1867

The Canadian Charter of Rights & Freedoms – The Constitution Act 1982

RSO 1990 ch 19 - Human Rights Code

The Canadian Immunization Act 1997

Bill S-201 – Genetic Non-Discrimination Act - 2017

The Canadian Criminal Code – S. 265 (1) Assault, S. 264 (1) Uttering Threats, S. 269 (1) Unlawfully Causing Bodily Harm, S 269 1 (1) Torture (definition: any act or omission by which severe pain or suffering, whether physical or mental, is intentionally inflicted upon a person), S. 346 (1) Extortion, S. 423 (1) Intimidation S. 318 (1) Inciting Hate Propaganda (genocide)

The Nuremberg Code 1947 – informed voluntary consent, ingredients list, animal testing, risks involved, length of experiment, expected outcomes

Sc 2005, c 20 - The Quarantine Act (S. 14(1), (2), S 32

Ontario Regulation 364/20 – Reopening Ontario (A Flexible Response to COVID-19) Act, 2020 – Formerly under Emergency Management & Civil Protection Act (was revoked June 9, 2021) – Mask Exemptions Schedule 1 – s 2 (4), (6)

RSO 1990 - Trespass to Property Act

August 18, 2021

**VIA EMAIL / OPEN LETTER**

**TO:** Presidents of Universities and Colleges that are mandating COVID vaccines

**RE: Demand to cease the use of unlawful "vaccine passports"**

I write as litigation counsel with Liberty Coalition Canada ("Liberty Coalition"). Liberty Coalition advocates for the liberty of Canadians, such as freedom of conscience and religion, the right to bodily autonomy, and the right to make personal health choices free of coercion. We represent the interests of students who have expressed to Liberty Coalition their deep concern regarding the recent move by your institution to demand all those on campus receive COVID vaccinations under the threat of penalization should they exercise their right to decline.

**The Scientific Reality of COVID Vaccinations**

The COVID vaccines available in Canada are "experimental" insofar as they have not been properly tested, are the result of accelerated development, use novel technology, and have only received "interim authorization" by various governments, not "approval". This necessarily implies a degree of long-term risk associated with receiving a COVID vaccine, and, indeed, the long-term risks of the available COVID vaccines are entirely unknown.

Further, it has recently come to light that the COVID vaccines carry an alarming degree of short-term risks, up to and including serious cardiovascular harm, neurological harm, and even death. Unfortunately, like so many things regarding COVID, the COVID vaccines have become politicized and information regarding their potentially dangerous side effects is being suppressed.

However inconvenient, the fact is the COVID vaccines are ***not*** "safe". As just one example of how the effects of some of the COVID vaccines (Pfizer and Moderna's mRNA vaccines) are not what was initially promulgated, it is now known the spike protein does not stay within the area of the vaccine injection site, but rather travels to every part of the body, and that the spike protein may act as a toxin and collect in certain areas of the body (such as the ovaries), potentially causing permanent damage. The recent report by viral immunologist and Guelph University Professor, Dr. Byram Bridle explains how the COVID vaccines work, their experimental nature, and why they can be dangerous, among other things.

**COVID-19 is Not Serious Enough to Outweigh the Risks of the COVID Vaccinations**

COVID-19 is not an extremely severe or uncommonly deadly respiratory illness. Despite media fear-mongering and government propaganda, COVID-19, including any of its so-called variants, is not of "pandemic proportions". The reality is COVID poses no credible threat to anybody under the age of retirement, except the very few who are significantly immunocompromised or have serious health

conditions such as obesity. Further, asymptomatic people, otherwise known as "healthy" individuals, do not meaningfully contribute to the transmission of COVID-19, regardless of their vaccination status.

Further still, it is now known (if not widely, due to the suppression of inconvenient information) that natural immunity is both widespread and provides even more effective protection than the vaccines against both the original strain of COVID and its subsequent variants.[1]

In short, COVID vaccinations are not required to protect the "health and safety" of students, faculty, staff, or visitors to the reasonable degree required by law. Any reasonable accommodation or duty of care obligation on universities and colleges to the few individuals with physical disabilities or medical conditions that actually put them at any measurable degree of risk from COVID-19 can be discharged without incurring the incredibly undue hardship of mandating all students receive COVID vaccinations, even the ones who do not consent.

**Legal Obligations of Public Universities and Colleges**

Any requirement that students unwillingly receive a COVID vaccination in order to attend classes, live on campus, or participate in athletics is unreasonable in light of the above. Any attempt to penalize a student for the reasonable decision to not receive a COVID vaccine will be unlawful.

As recently noted by the Court of Appeal of Alberta, public universities and colleges are bound by the *Canadian Charter of Rights and Freedoms* regarding certain aspects of the institution's relationship with its students.[2] In addition to being unlawful due to its unreasonableness,[3] excluding students from full participation in all academic or extracurricular activities due to their unvaccinated status will infringe their rights to liberty and security of the person as guaranteed by section 7 in a manner not in accordance with the principles of fundamental justice. These rights limitations are incapable of being demonstrably justified in a free and democratic society.

Security of the person protects the right of students to be free from action by their institution that threatens physical harm to their bodies. As already detailed, the available COVID vaccinations are potentially dangerous and unnecessary. Any coercion to accept a high risk and low benefit medical intervention such as the COVID vaccines implicates security of the person.

Liberty under section 7 of the *Charter* protects students' right to bodily autonomy. Ownership and autonomy over the body and the ability to freely choose what does or does not enter one's body is a critical aspect of individual liberty. Universities and colleges do not own or control students' bodies and must never be permitted to act as if they do by coercing students to take COVID vaccines without their consent by penalizing them if they don't. Liberty is egregiously interfered with by the threat of being

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8253687/; https://www.medrxiv.org/content/10.1101/2021.04.20.21255670v1.full.
[2] *UAlberta Pro-Life v. Governors of the University of Alberta*, 2020 ABCA 1 (not appealed to the Supreme Court of Canada).
[3] *Pridgen v. University of Calgary*, 2012 ABCA 139.

excluded from classes, varsity athletics, or other programs and services if students decline to be unnecessarily injected with foreign, experimental substances that carry serious risks and limited benefits.

Requiring the testing or masking of students who decline COVID vaccines does nothing to justify the above rights violations. COVID testing is notoriously inaccurate and entirely useless in the face of the scientific reality that natural immunity is effective and widespread. Such an approach will only result in further rights violations when students are inevitably excluded following a "positive" test result. Masking is also utterly ineffective and unnecessary and itself a violation of multiple *Charter* rights. The imposition of these or other extra hurdles or any exclusion as a result of a student's refusal to receive COVID vaccines is also an unjustified infringement of section 8 of the *Charter*, which protects students' right to privacy regarding personal health decisions.

Ostensibly offering exemptions based on statutory human rights misses the point because it presumes the mandate from which exemptions may be provided is otherwise lawful. It is not—mandatory COVID vaccination is not constitutional and therefore not lawful.

**Conclusion**

The decision to receive a vaccine, particularly the potentially dangerous and experimental COVID vaccines, is a deeply personal health decision. Any student's decision to decline the COVID vaccines is eminently reasonable given the lack of necessity for the vaccines, the risks of severe harm and death associated, and the COVID vaccines' questionable efficacy, especially when compared to natural immunity.

Mandating COVID vaccines as a condition to receiving an education at a public university or college, or to participate in extracurricular activities, is not about "health and safety", it is about an irrational fear of liability and political expediency.

Liberty Coalition demands your institution abandon this reckless, unnecessary attack on the rights of its students. Liberty Coalition and the students whose interests it represents expect universities and colleges to adhere to their legal obligations and prioritize the rights of their students above any desire to engage in "woke" virtual signalling regarding COVID vaccines.

Liberty Coalition is prepared to take whatever steps necessary to defend the rights of students to assert their bodily autonomy and decline potentially dangerous, unnecessary, and experimental injections. If your institution proceeds to enforce its vaccine passport policy, litigation will ensue.

Regards,

James S. M. Kitchen
Chief Litigator
Liberty Coalition Canada

**Notice of Liability**
**COVID-19 Testing**

Attn: _____

Re: Any COVID-19 testing forcibly required, mandated or administered to Canadian citizens, including children, by the government, appointed officials, employers, educators, and the like.

**This is an official and personal Notice of Liability.**

**You are not my physician or a medical professional and, therefore, you are unlawfully practicing medicine by prescribing, recommending, and/or using coercion to insist I submit to testing for COVID-19, such as but not limited to, PCR testing which includes rapid tests, blood tests, or any medical intervention to determine any communicable disease known through proof of a genome report.**

To begin with, the emergency measures are based on the claim that we are experiencing a "public health emergency." There is no evidence to substantiate this claim. In fact, the evidence indicates that we are experiencing a rate of infection consistent with a normal influenza season[1].

The purported increase in "cases" is a direct consequence of increased testing through the inappropriate use of the PCR instrument to diagnose alleged COVID-19. It has been well established that the PCR test was never designed or intended as a diagnostic tool and is not an acceptable instrument to measure this alleged pandemic. Its inventor, Kary Mullis, has clearly indicated that the PCR testing device was never created to test for coronavirus[2]. Mullis warns that, ***"the PCR Test can be used to find almost anything, in anybody. If you can amplify one single molecule, then you can find it because that molecule is nearly in every single person."***

In light of this warning, the current PCR test utilization, set at higher amplifications (+35), is producing up to 97% false positives[3]. Therefore, any imposed emergency measures that are based on PCR testing are unwarranted, unscientific, and quite possibly fraudulent. An international consortium of life science scientists has detected 10 major scientific flaws at the molecular and methodological level in a 3-peer review of the RTPCR test to detect SARS-CoV-2[4].

In November 2020, a Portuguese court ruled that PCR tests are unreliable[5].

On November 20, 2020 a study from Wuhan, of nearly 10 million residents, revealed that the detection of asymptomatic positive cases was very low and there was no evidence of transmission from asymptomatic people. A nucleic acid test was used rather than the unreliable PCR testing[6].

On December 14, 2020, the WHO admitted the PCR Test has a 'problem' at high amplifications as it detects dead cells from old viruses, giving a false positive[7].

Feb 16, 2021, BC Health Officer, Bonnie Henry, admitted PCR tests are unreliable[8].

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1 https://www.bitchute.com/video/nQgq0BxXfZ4f
2 https://rumble.com/vhu4rz-kary-mullis-inventor-of-the-pcr-test.html
3 https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1491/5912603
4 https://cormandrostenreview.com/report/
5 https://unitynewsnetwork.co.uk/portuguese-court-rules-pcr-tests-unreliable-quarantines-unlawful-media-blackout/
6 https://www.nature.com/articles/s41467-020-19802-w
7 https://principia-scientific.com/who-finally-admits-covid19-pcr-test-has-a-problem/
8 https://rumble.com/vhww4d-bc-health-officer-admits-pcr-test-is-unreliable.html

On April 8, 2021, the Austrian court ruled the PCR was unsuited for COVID testing[9].

On April 8, 2021, a German Court ruled against PCR testing stating, ***"the test cannot provide any information on whether a person is infected with an active pathogen or not, because the test cannot distinguish between "dead" matter and living matter."*** [10]

On May 8, 2021, the Swedish Public Health Agency stopped PCR Testing for the same reason[11].

On May 10th, 2021, Manitoba's Chief Microbiologist and Laboratory Specialist, Dr. Jared Bullard testified under cross examination in a trial before the court of Queen's Bench in Manitoba, that PCR test results do not verify infectiousness and were never intended to be used to diagnose respiratory illnesses.[12]

**On July 21, 2021 - Innova Medical Group Recalled Unauthorized SARS-CoV-2 Antigen Rapid Qualitative Test with Risk of False Test Results.** The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death[13].

On July 21, 2021 the CDC sent out a "Lab Alert revoking the emergency use authorization to RT-PCR for COVDI-19 testing and encourages laboratories to adopt a multiplexed method that can facilitate detection and differentiation of SARS-CoV-2 and influenza viruses" [14].

The Nuremberg Code[15], to which Canada is a signatory, states that it is essential before performing a medical procedure on human beings, that there is voluntary informed consent. It also confirms, a person involved should have legal capacity to give consent, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him/her to make an understanding and enlightened decision.

> Nuremberg Code: Article 6, section 1:
>
> Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be expressed and may be withdrawn by the person concerned at any time and for any reason WITHOUT DISADVANTAGE or prejudice.
>
> Nuremberg Code: Article 6, section 3:
>
> In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual's informed consent.

Under the *Crimes Against Humanity and War Crimes Act of Canada*[16], a crime against humanity means, among other things, murder, any other inhumane act or omission that is committed against any civilian population or any identifiable group and that, at the time and in the place of its commission, constitutes a crime against humanity according to customary international law, conventional international law, or by virtue of its being criminal according to the general principles of law are recognized by the community of nations, whether or not it constitutes a contravention of the law in force at the time and in the place of its commission. The Act also confirms that every person **who conspires or attempts to commit, is an**

9 https://greatgameindia.com/austria-court-pcr-tes

10 https://2020news.de/sensationsurteil-aus-weimar-keine-masken-kein-abstand-keine-tests-mehr-fuer-schueler

11 https://tapnewswire.com/2021/05/sweden-stops-pcr-tests-as-covid19-diagnosis/

12 https://www.jccf.ca/Manitoba-chief-microbiologist-and-laboratory-specialist-56-of-positive-cases-are-not-infectious/

13 https://www.fda.gov/medical-devices/medical-device-recalls/innova-medical-group-recalls-unauthorized-sars-cov-2-antigen-rapid-qualitative-test-risk-false-test

14 https://www.cdc.gov/csels/dls/locs/2021/07-21-2021-lab-alert-Changes_CDC_RT-PCR_SARS-CoV-2_Testing_1.html

15 https://media.tghn.org/medialibrary/2011/04/BMJ_No_7070_Volume_313_The_Nuremberg_Code.pdf

16 https://laws-lois.justice.gc.ca/eng/acts/c-45.9/page-1.html

**accessory after the fact**, in relation to, or councils in relation to, a crime against humanity, is guilty of an offence and liable to imprisonment for life.

Under sections 265 and 266 of the *Criminal Code of Canada*[17], a person commits an assault when, **without the consent of another person, he applies force intentionally to that other person, directly or indirectly**. Everyone who commits an assault is guilty of an indictable offence and liable to imprisonment for a term not exceeding five years, or an offence punishable on summary conviction.

According to Section 14(1) of the *Quarantine Act*, screening cannot "involve the entry into the traveler's body of any instrument or other foreign body" [18].

There is no legislation that allows an employer, business owner, educator, government entity, or any individual in any other capacity, to discriminate against, force, coerce, prescribe, recommend or mandate that any person, including children, submit to a medical procedure, especially with the threat of loss of guaranteed rights such as, but not limited to, employment, education, goods and services, travel, or respect for bodily autonomy.

Anyone involved in pressuring, influencing, or coercing others to submit to a COVID-19 test, and that individual suffers any adverse consequences, including but not limited to emotional duress as a result of the test, will be opening themselves up to personal civil liability, and potential personal criminal liability, according to the Canadian Criminal Code, the Privacy Act, the Nuremberg Code, and the Crimes Against Humanity and War Crimes Act of Canada.

Administration of a COVID-19 test is defined as a "medical procedure". In what other medical context could non-doctors and non-pharmacists prescribe or promote medical testing? This is unauthorized practice of medicine.

Bodily integrity is the inviolability of the physical body and emphasizes the importance of personal autonomy, self-ownership, and self-determination of human beings over their own bodies. In the field of human rights, violation of the bodily integrity of another is regarded as an unethical infringement, intrusive, and possibly criminal.

Therefore, I hereby notify you that I will hold you personally liable for any harm I may suffer, financial injury and/or loss of my personal income and my ability to provide food and shelter for myself or my family if you use coercion, force or discriminate against me based on my decision not to participate in COVID-19 testing of any kind, not limited to rapid testing, internal swabbing or blood tests.

Name: _____

Signature: _____

Date: _____

Source: Action4Canada.com

17 https://laws-lois.justice.gc.ca/eng/acts/c-46/page-57.html#docCont
18 https://laws-lois.justice.gc.ca/eng/acts/Q-1.1/page-1.html

# Personal Information Protection and Electronic Documents Act

**S.C. 2000, c. 5**

Assented to 2000-04-13

An Act to support and promote electronic commerce by protecting personal information that is collected, used or disclosed in certain circumstances, by providing for the use of electronic means to communicate or record information or transactions and by amending the Canada Evidence Act, the Statutory Instruments Act and the Statute Revision Act

Her Majesty, by and with the advice and consent of the Senate and House of Commons of Canada, enacts as follows:

# Short Title

**Marginal note:Short title**

**1** This Act may be cited as the *Personal Information Protection and Electronic Documents Act*.

# PART 1 Protection of Personal Information in the Private Sector

## Interpretation

**Marginal note:Definitions**

- **2 (1)** The definitions in this subsection apply in this Part.

  ***alternative format***, with respect to personal information, means a format that allows a person with a sensory disability to read or listen to the personal information. (*support de substitution*)

  ***breach of security safeguards*** means the loss of, unauthorized access to or unauthorized disclosure of personal information resulting from a breach of an organization's security safeguards that are referred to in clause 4.7 of Schedule 1 or from a failure to establish those safeguards. (*atteinte aux mesures de sécurité*)

  ***business contact information*** means any information that is used for the purpose of communicating or facilitating communication with an individual in relation to their employment, business or profession such as the individual's name, position name or title, work address, work telephone number, work fax number or work electronic address. (*coordonnées d'affaires*)

  ***business transaction*** includes

- **(a)** the purchase, sale or other acquisition or disposition of an organization or a part of an organization, or any of its assets;
- **(b)** the merger or amalgamation of two or more organizations;
- **(c)** the making of a loan or provision of other financing to an organization or a part of an organization;
- **(d)** the creating of a charge on, or the taking of a security interest in or a security on, any assets or securities of an organization;
- **(e)** the lease or licensing of any of an organization's assets; and
- **(f)** any other prescribed arrangement between two or more organizations to conduct a business activity. (*transaction commerciale*)

***commercial activity*** means any particular transaction, act or conduct or any regular course of conduct that is of a commercial character, including the selling, bartering or leasing of donor, membership or other fundraising lists. (*activité commerciale*)

***Commissioner*** means the Privacy Commissioner appointed under section 53 of the *Privacy Act*. (*commissaire*)

***Court*** means the Federal Court. (*Cour*)

***federal work, undertaking or business*** means any work, undertaking or business that is within the legislative authority of Parliament. It includes

- **(a)** a work, undertaking or business that is operated or carried on for or in connection with navigation and shipping, whether inland or maritime, including the operation of ships and transportation by ship anywhere in Canada;
- **(b)** a railway, canal, telegraph or other work or undertaking that connects a province with another province, or that extends beyond the limits of a province;
- **(c)** a line of ships that connects a province with another province, or that extends beyond the limits of a province;
- **(d)** a ferry between a province and another province or between a province and a country other than Canada;
- **(e)** aerodromes, aircraft or a line of air transportation;
- **(f)** a radio broadcasting station;
- **(g)** a bank or an authorized foreign bank as defined in section 2 of the *Bank Act*;
- **(h)** a work that, although wholly situated within a province, is before or after its execution declared by Parliament to be for the general advantage of Canada or for the advantage of two or more provinces;

- **(i)** a work, undertaking or business outside the exclusive legislative authority of the legislatures of the provinces; and
- **(j)** a work, undertaking or business to which federal laws, within the meaning of section 2 of the *Oceans Act*, apply under section 20 of that Act and any regulations made under paragraph 26(1)(k) of that Act. (*entreprises fédérales*)

***organization*** includes an association, a partnership, a person and a trade union. (*organisation*)

***personal health information***, with respect to an individual, whether living or deceased, means

- **(a)** information concerning the physical or mental health of the individual;
- **(b)** information concerning any health service provided to the individual;
- **(c)** information concerning the donation by the individual of any body part or any bodily substance of the individual or information derived from the testing or examination of a body part or bodily substance of the individual;
- **(d)** information that is collected in the course of providing health services to the individual; or
- **(e)** information that is collected incidentally to the provision of health services to the individual. (*renseignement personnel sur la santé*)

***personal information*** means information about an identifiable individual. (*renseignement personnel*)

***prescribed*** means prescribed by regulation. (*Version anglaise seulement*)

***record*** includes any correspondence, memorandum, book, plan, map, drawing, diagram, pictorial or graphic work, photograph, film, microform, sound recording, videotape, machine-readable record and any other documentary material, regardless of physical form or characteristics, and any copy of any of those things. (*document*)

- **Marginal note:Notes in Schedule 1**

**(2)** In this Part, a reference to clause 4.3 or 4.9 of Schedule 1 does not include a reference to the note that accompanies that clause.

- 2000, c. 5, s. 2
- 2002, c. 8, s. 183
- 2015, c. 32, s. 2

Previous Version

# Purpose

**Marginal note:Purpose**

**3** The purpose of this Part is to establish, in an era in which technology increasingly facilitates the circulation and exchange of information, rules to govern the collection, use and disclosure of personal information in a manner that recognizes the right of privacy of individuals with respect to their personal information and the need of organizations to collect, use or disclose personal information for purposes that a reasonable person would consider appropriate in the circumstances.

# Application

**Marginal note:Application**

- **4 (1)** This Part applies to every organization in respect of personal information that
    - **(a)** the organization collects, uses or discloses in the course of commercial activities; or
    - **(b)** is about an employee of, or an applicant for employment with, the organization and that the organization collects, uses or discloses in connection with the operation of a federal work, undertaking or business.
- **Marginal note:Application**

  **(1.1)** This Part applies to an organization set out in column 1 of Schedule 4 in respect of personal information set out in column 2.
- **Marginal note:Limit**

  **(2)** This Part does not apply to
    - **(a)** any government institution to which the *Privacy Act* applies;
    - **(b)** any individual in respect of personal information that the individual collects, uses or discloses for personal or domestic purposes and does not collect, use or disclose for any other purpose; or
    - **(c)** any organization in respect of personal information that the organization collects, uses or discloses for journalistic, artistic or literary purposes and does not collect, use or disclose for any other purpose.
- **Marginal note:Other Acts**
  Footnote* **(3)** Every provision of this Part applies despite any provision, enacted after this subsection comes into force, of any other Act of Parliament, unless the other Act expressly declares that that provision operates despite the provision of this Part.

# Protect Your Rights

CANADA RISING
STAND UP STAND FREE

If you are pulled over by the police, your rights are indicated below. My narrative would be the following. I will be keeping copies of this on my person and in my car:

“Why have you pulled me over officer (on foot or in a car)” If the answer is not related to a moving offence or crime and they are just asking for identification and questions related to where you are going…

“I understand how difficult this must be for you officer. You are in conflict between your oath of office, which clearly states in Section 1 of the Police Services Act that you are sworn to uphold the Constitution of Canada AND these unlawful emergency mandates being put on you and your colleagues. I don’t envy your position.

My rights on the other hand, are clearly spelled out by the Ministry of the Solicitor general on their own website and in the Police Services Act. You cannot pull me over in an arbitrary fashion and ask me personal questions and I am not required to answer them if you do. In fact, you are **REQUIRED to tell me directly that I can refuse to provide my personal information when you ask. The Act also REQUIRES you to provide me with a receipt of the incident that includes your name, badge number and the complaint process.**

In order to ensure complete clarity, **Regulation 58/16 of the *Police Services Act*** clearly states that you are not permitted to ask for anybody’s personal information unless you suspect that there is a crime being committed or the person is being questioned regarding a crime. The term “crime” is interpreted narrowly in the Act. It goes further to state explicitly that unless there is a crime being committed, you CANNOT ask for my personal information and you CANNOT charge me in any way for non compliance.

If you do not follow the law, I will be forced to file a complaint with the Office of the Independent Police Review Director. The process for filing a complaint are stated in the Police Services Act. This will lead to a code of conduct violation and will be a blemish on your service record.

I know my rights. I will not be answering any more personal questions. I am providing this in writing to ensure that I am being clear and to indicate that I am not being belligerent or confrontational. Just a citizen who knows and understands my rights.

## Supporting Excerpts:

https://www.ontario.ca/page/street-checks

Ontario
Ministry of the Solicitor General

The Ministry of the Solicitor General is committed to ensuring that Ontario’s communities are supported and protected by law enforcement and public safety systems that are safe, secure, effective, efficient and accountable.

## The rules and what they mean for you

If a police officer asks you for ID in a situation when the rules apply, they must:

- **have a reason**, which cannot be:
  - based on race
  - arbitrary (not meaningful)
  - only because you are in a high-crime area
  - because you refused to answer a question or walked away
- **tell you why** they want your identifying information
- **tell you that you can refuse** to give identifying information
- **offer you a receipt** – even if you refuse to share information – that includes:
  - the officer's name
  - the officer's badge number
  - how to contact the Office of the Independent Police Review Director, which handles complaints about police in Ontario
  - who to contact to access personal information about you that the police service has on file
- **keep detailed records** of their interaction with you – even if you refuse to share information

If a police officer does not follow these rules, it is a Code of Conduct violation under the Police Services Act and they may be disciplined.

## *Police Services Act*

ONTARIO REGULATION 268/10

**General**

**Consolidation Period:** From December 1, 2020 to the e-Laws currency date.

**Part I**
**Oaths and affirmations**

### *Member of the board*

**1.** The oath or affirmation of office to be taken by a member of the board shall be in one of the following forms set out in the English or French version of this section:

I solemnly swear (affirm) that I will be loyal to Her Majesty the Queen and to Canada, and that I will uphold the Constitution of Canada and that I will, to the best of my ability, discharge my duties as a member of the (insert name of municipality) Police Services Board faithfully, impartially and according to the Police Services Act, any other Act, and any regulation, rule or by-law.

**Schedule**
**CODE OF CONDUCT**

**2.** (1) Any chief of police or other police officer commits misconduct if he or she engages in,

(a) Discreditable Conduct, in that he or she,

(i) fails to treat or protect persons equally without discrimination with respect to police services because of race, ancestry, place of origin, colour, ethnic origin, citizenship, creed, sex, sexual orientation, age, marital status, family status or disability,

(ii) uses profane, abusive or insulting language that relates to a person's race, ancestry, place of origin, colour, ethnic origin, citizenship, creed, sex, sexual orientation, age, marital status, family status or disability,

(iii) is guilty of oppressive or tyrannical conduct towards an inferior in rank,

(iv) uses profane, abusive or insulting language to any other member of a police force,

(v) **uses profane, abusive or insulting language or is otherwise uncivil to a member of the public,**

(vi) willfully or negligently makes any false complaint or statement against any member of a police force,

(vii) assaults any other member of a police force,

(viii) withholds or suppresses a complaint or report against a member of a police force or about the policies of or services provided by the police force of which the officer is a member,

(ix) is guilty of a criminal offence that is an indictable offence or an offence punishable upon summary conviction,

(x) contravenes any provision of the Act or the regulations, or

(xi) acts in a disorderly manner or in a manner prejudicial to discipline or likely to bring discredit upon the reputation of the police force of which the officer is a member;

**Unlawful or Unnecessary Exercise of Authority, in that he or she,**

(i) without good and sufficient cause makes an unlawful or unnecessary arrest,

(i.1) **without good and sufficient cause makes an unlawful or unnecessary physical or psychological detention,**

(ii) uses any unnecessary force against a prisoner or other person contacted in the execution of duty, or

(iii) **collects or attempts to collect identifying information about an individual from the individual in the circumstances to which Ontario Regulation 58/16 (Collection of Identifying Information in Certain Circumstances – Prohibition and Duties) made under the Act applies, other than as permitted by that regulation;**

# *Police Services Act*

ONTARIO REGULATION 58/16

**COLLECTION OF IDENTIFYING INFORMATION IN CERTAIN CIRCUMSTANCES – PROHIBITION AND DUTIES**

For the purpose of clause (1) (b), an attempted collection by a police officer from an individual is done in an arbitrary way unless the officer has a reason that the officer can articulate that complies with **all** of the following:

**1.** The reason includes details about the individual that cause the officer to reasonably suspect that identifying the individual may contribute to or assist in an inquiry described in clause 1 (1) (a) or (b) or the gathering of information described in clause 1 (1) (c).

**2. The reason does not include either of the following:**

i. that the individual has declined to answer a question from the officer which the individual is not legally required to answer, or

ii. that the individual has attempted or is attempting to discontinue interaction with the officer in circumstances in which the individual has the legal right to do so.

**3.** The reason is not only that the individual is present in a high crime location.

CANADA

A Consolidation of

# THE CONSTITUTION ACTS 1867 to 1982

**DEPARTMENT OF JUSTICE**
**CANADA**

**Consolidated as of January 1, 2013**

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## FOREWORD

### Consolidation of the Constitution Acts, 1867 to 1982

This consolidation contains the text of the *Constitution Act, 1867* (formerly the *British North America Act, 1867*), together with amendments made to it since its enactment, and the text of the *Constitution Act, 1982*, as amended since its enactment. The *Constitution Act, 1982* contains the *Canadian Charter of Rights and Freedoms* and other provisions, including the procedure for amending the Constitution of Canada.

The *Constitution Act, 1982* also contains a schedule of repeals of certain constitutional enactments and provides for the renaming of others. The *British North America Act, 1949*, for example, is renamed as the *Newfoundland Act*. The new names of these enactments are used in this consolidation, but their former names may be found in the schedule.

The *Constitution Act, 1982* was enacted as Schedule B to the *Canada Act 1982*, 1982, c. 11 (U.K.). It is set out in this consolidation as a separate Act after the *Constitution Act, 1867*.

### Amendment of the Constitution Act, 1867

The law embodied in the *Constitution Act, 1867* has been altered many times otherwise than by textual amendment, not only by the Parliament of the United Kingdom but also by the Parliament of Canada and the legislatures of the provinces in those cases where provisions of that Act are expressed to be subject to alteration by Parliament or the legislatures. A consolidation of the Constitution Acts including only those subsequent enactments that alter the text of the Act would therefore not produce a true statement of the law. In preparing this consolidation, an attempt has been made to reflect accurately the substance of the law contained in enactments modifying the provisions of the *Constitution Act, 1867*, whether by textual amendment or otherwise.

The various classes of enactments modifying the *Constitution Act, 1867* have been dealt with as follows:

#### I. Textual Amendments

**1. *Repeals***

Repealed provisions (*e.g.* section 2) have been deleted from the text and quoted in a footnote.

**2.** ***Amendments***

Amended provisions (*e.g.* section 4) are reproduced in the text in their amended form and the original provisions are quoted in a footnote.

**3.** ***Additions***

Added provisions (*e.g.* section 51A) are included in the text.

**4.** ***Substitutions***

Substituted provisions (*e.g.* section 18) are included in the text and the former provision is quoted in a footnote.

## II. Non-textual Amendments

**1.** ***Alterations by United Kingdom Parliament***

Provisions altered by the United Kingdom Parliament otherwise than by textual amendment (*e.g.* section 21) are included in the text in their altered form and the original provision is quoted in a footnote.

**2.** ***Additions by United Kingdom Parliament***

Constitutional provisions added otherwise than by the insertion of additional provisions in the *Constitution Act, 1867* (*e.g.* provisions of the *Constitution Act, 1871* authorizing Parliament to legislate for any territory not included in a province) are not incorporated in the text but the additional provisions are quoted in an appropriate footnote.

**3.** ***Alterations by Parliament of Canada***

Provisions subject to alteration by the Parliament of Canada (*e.g.* section 37) have been included in the text in their altered form, wherever possible, but where this was not feasible (*e.g.* section 40) the original section has been retained in the text and a footnote reference made to the Act of the Parliament of Canada effecting the alteration.

**4.** ***Alterations by the Legislatures***

Provisions subject to alteration by the legislatures of the provinces, either by virtue of specific authority (*e.g.* sections 83 and 84) or by virtue of head 1 of section 92 (*e.g.* sections 70 and 72), have been included in the text in their original form but the footnotes refer to the provincial enactments effecting the alteration. Amendments to the provincial enactments are not noted; these may be found by consulting the provincial statutes. In addition, only the enactments of the original provinces are

referred to; corresponding enactments by the provinces that were created at a later date are not noted.

## Spent Provisions

Footnote references are made to those sections that are spent or probably spent. For example, section 119 became spent by lapse of time and the footnote reference indicates this. In turn, section 140 is probably spent, but short of examining all statutes passed before Confederation there would be no way of ascertaining definitely whether or not the section is spent; the footnote reference therefore indicates that the section is probably spent.

## General

The enactments of the United Kingdom Parliament and the Parliament of Canada, and Orders in Council admitting territories, that are referred to in the footnotes may be found in Appendix II of the Appendices to the Revised Statutes of Canada, 1985 and in the annual volumes of the Statutes of Canada.

There are some inconsistencies in the capitalization of nouns. It was originally the practice to capitalize the first letter of all nouns in British statutes and the *Constitution Act, 1867* was so written, but this practice was discontinued and was never followed in Canadian statutes. In the original provisions included in this consolidation, nouns are written as they were enacted.

## French Version

The French version of the *Constitution Act, 1867* is the conventional translation. It does not have the force of law since this Act was enacted by the Parliament of the United Kingdom in English only.

Section 55 of the *Constitution Act, 1982* provides that a "French version of the portions of the Constitution of Canada referred to in the schedule [to that Act] shall be prepared by the Minister of Justice of Canada as expeditiously as possible". The French Constitutional Drafting Committee was established in 1984 with a mandate to assist the Minister of Justice in that task. The Committee's Final Report, which contains forty-two constitutional enactments, was tabled in Parliament in December 1990. The French version of the Final Report is available on the Justice Canada Website at the following URL: http://canada.justice.gc.ca/fra/pi/const/index.html.

## Acknowledgement

This consolidation of the *Constitution Acts, 1867 to 1982* contains material prepared by the late Dr. E. A. Driedger, Q.C. The material has been updated where necessary. The Department of Justice gratefully acknowledges Dr. Driedger's earlier work.

TABLE OF PROVISIONS

# CONSTITUTION ACT, 1867

30 & 31 Victoria, c. 3 (U.K.)

An Act for the Union of Canada, Nova Scotia, and New Brunswick, and the Government thereof; and for Purposes connected therewith

(*29th March 1867*)

WHEREAS the Provinces of Canada, Nova Scotia, and New Brunswick have expressed their Desire to be federally united into One Dominion under the Crown of the United Kingdom of Great Britain and Ireland, with a Constitution similar in Principle to that of the United Kingdom:

And whereas such a Union would conduce to the Welfare of the Provinces and promote the Interests of the British Empire:

And whereas on the Establishment of the Union by Authority of Parliament it is expedient, not only that the Constitution of the Legislative Authority in the Dominion be provided for, but also that the Nature of the Executive Government therein be declared:

And whereas it is expedient that Provision be made for the eventual Admission into the Union of other Parts of British North America: [(1)]

## I. PRELIMINARY

Short title

**1.** This Act may be cited as the *Constitution Act, 1867*. [(2)]

**2.** Repealed. [(3)]

---

**[(1)] The enacting clause was repealed by the *Statute Law Revision Act, 1893*, 56-57 Vict., c. 14 (U.K.). It read as follows:**

Be it therefore enacted and declared by the Queen's most Excellent Majesty, by and with the Advice and Consent of the Lords Spiritual and Temporal, and Commons, in this present Parliament assembled, and by the Authority of the same, as follows:

**[(2)] As amended by the *Constitution Act, 1982*, which came into force on April 17, 1982. The section originally read as follows:**

**1.** This Act may be cited as *The British North America Act, 1867*.

**[(3)] Section 2, repealed by the *Statute Law Revision Act, 1893*, 56-57 Vict., c. 14 (U.K.), read as follows:**

**2.** The Provisions of this Act referring to Her Majesty the Queen extend also to the Heirs and Successors of Her Majesty, Kings and Queens of the United Kingdom of Great Britain and Ireland.

## II. UNION

Declaration of Union

**3.** It shall be lawful for the Queen, by and with the Advice of Her Majesty's Most Honourable Privy Council, to declare by Proclamation that, on and after a Day therein appointed, not being more than Six Months after the passing of this Act, the Provinces of Canada, Nova Scotia, and New Brunswick shall form and be One Dominion under the Name of Canada; and on and after that Day those Three Provinces shall form and be One Dominion under that Name accordingly. [(4)]

Construction of subsequent Provisions of Act

**4.** Unless it is otherwise expressed or implied, the Name Canada shall be taken to mean Canada as constituted under this Act. [(5)]

Four Provinces

**5.** Canada shall be divided into Four Provinces, named Ontario, Quebec, Nova Scotia, and New Brunswick. [(6)]

Provinces of Ontario and Quebec

**6.** The Parts of the Province of Canada (as it exists at the passing of this Act) which formerly constituted respectively the Provinces of Upper Canada and Lower Canada shall be deemed to be severed, and shall form Two separate Provinces. The Part which formerly constituted the Province of Upper Canada shall constitute the Province of Ontario; and the Part which formerly constituted the Province of Lower Canada shall constitute the Province of Quebec.

Provinces of Nova Scotia and New Brunswick

**7.** The Provinces of Nova Scotia and New Brunswick shall have the same Limits as at the passing of this Act.

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**[(4)] The first day of July, 1867, was fixed by proclamation dated May 22, 1867.**

**[(5)] Partially repealed by the *Statute Law Revision Act, 1893*, 56-57 Vict., c. 14 (U.K.). The section originally read as follows:**

> **4.** The subsequent Provisions of this Act shall, unless it is otherwise expressed or implied, commence and have effect on and after the Union, that is to say, on and after the Day appointed for the Union taking effect in the Queen's Proclamation; and in the same Provisions, unless it is otherwise expressed or implied, the Name Canada shall be taken to mean Canada as constituted under this Act.

**[(6)] Canada now consists of ten provinces (Ontario, Quebec, Nova Scotia, New Brunswick, Manitoba, British Columbia, Prince Edward Island, Alberta, Saskatchewan and Newfoundland and Labrador) and three territories (Yukon, the Northwest Territories and Nunavut).**

**For further details, see endnote 1.**

Decennial Census

**8.** In the general Census of the Population of Canada which is hereby required to be taken in the Year One thousand eight hundred and seventy-one, and in every Tenth Year thereafter, the respective Populations of the Four Provinces shall be distinguished.

## III. EXECUTIVE POWER

Declaration of Executive Power in the Queen

**9.** The Executive Government and Authority of and over Canada is hereby declared to continue and be vested in the Queen.

Application of Provisions referring to Governor General

**10.** The Provisions of this Act referring to the Governor General extend and apply to the Governor General for the Time being of Canada, or other the Chief Executive Officer or Administrator for the Time being carrying on the Government of Canada on behalf and in the Name of the Queen, by whatever Title he is designated.

Constitution of Privy Council for Canada

**11.** There shall be a Council to aid and advise in the Government of Canada, to be styled the Queen's Privy Council for Canada; and the Persons who are to be Members of that Council shall be from Time to Time chosen and summoned by the Governor General and sworn in as Privy Councillors, and Members thereof may be from Time to Time removed by the Governor General.

All Powers under Acts to be exercised by Governor General with Advice of Privy Council, or alone

**12.** All Powers, Authorities, and Functions which under any Act of the Parliament of Great Britain, or of the Parliament of the United Kingdom of Great Britain and Ireland, or of the Legislature of Upper Canada, Lower Canada, Canada, Nova Scotia, or New Brunswick, are at the Union vested in or exerciseable by the respective Governors or Lieutenant Governors of those Provinces, with the Advice, or with the Advice and Consent, of the respective Executive Councils thereof, or in conjunction with those Councils, or with any Number of Members thereof, or by those Governors or Lieutenant Governors individually, shall, as far as the same continue in existence and capable of being exercised after the Union in relation to the Government of Canada, be vested in and exerciseable by the Governor General, with the Advice or with the Advice and Consent of or in conjunction with the Queen's Privy Council for Canada, or any Members thereof, or by the Governor General individually, as the Case requires, subject nevertheless (except with respect to such as exist under Acts of the Parliament of Great Britain or of the Parliament of

the United Kingdom of Great Britain and Ireland) to be abolished or altered by the Parliament of Canada. [7]

Application of Provisions referring to Governor General in Council

**13.** The Provisions of this Act referring to the Governor General in Council shall be construed as referring to the Governor General acting by and with the Advice of the Queen's Privy Council for Canada.

Power to Her Majesty to authorize Governor General to appoint Deputies

**14.** It shall be lawful for the Queen, if Her Majesty thinks fit, to authorize the Governor General from Time to Time to appoint any Person or any Persons jointly or severally to be his Deputy or Deputies within any Part or Parts of Canada, and in that Capacity to exercise during the Pleasure of the Governor General such of the Powers, Authorities, and Functions of the Governor General as the Governor General deems it necessary or expedient to assign to him or them, subject to any Limitations or Directions expressed or given by the Queen; but the Appointment of such a Deputy or Deputies shall not affect the Exercise by the Governor General himself of any Power, Authority, or Function.

Command of Armed Forces to continue to be vested in the Queen

**15.** The Command-in-Chief of the Land and Naval Militia, and of all Naval and Military Forces, of and in Canada, is hereby declared to continue and be vested in the Queen.

Seat of Government of Canada

**16.** Until the Queen otherwise directs, the Seat of Government of Canada shall be Ottawa.

## IV. LEGISLATIVE POWER

Constitution of Parliament of Canada

**17.** There shall be One Parliament for Canada, consisting of the Queen, an Upper House styled the Senate, and the House of Commons.

Privileges, etc., of Houses

**18.** The privileges, immunities, and powers to be held, enjoyed, and exercised by the Senate and by the House of Commons, and by the members thereof respectively, shall be such as are from time to time defined by Act of the Parliament of Canada, but so that any Act of the Parliament of Canada defining such privileges, immunities, and powers shall not confer any privileges, immunities, or powers exceeding those at the passing of such Act held, enjoyed, and exercised by the Commons

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[7] **See footnote (65) to section 129, below.**

House of Parliament of the United Kingdom of Great Britain and Ireland, and by the members thereof. [8]

First Session of the Parliament of Canada

**19.** The Parliament of Canada shall be called together not later than Six Months after the Union. [9]

**20.** Repealed. [10]

## The Senate

Number of Senators

**21.** The Senate shall, subject to the Provisions of this Act, consist of One Hundred and five Members, who shall be styled Senators. [11]

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**[8] Repealed and re-enacted by the *Parliament of Canada Act, 1875*, 38-39 Vict., c. 38 (U.K.). The original section read as follows:**

**18.** The Privileges, Immunities, and Powers to be held, enjoyed, and exercised by the Senate and by the House of Commons and by the Members thereof respectively shall be such as are from Time to Time defined by Act of the Parliament of Canada, but so that the same shall never exceed those at the passing of this Act held, enjoyed, and exercised by the Commons House of Parliament of the United Kingdom of Great Britain and Ireland and by the Members thereof.

**[9] Spent. The first session of the first Parliament began on November 6, 1867.**

**[10] Section 20, repealed by the *Constitution Act, 1982*, read as follows:**

**20.** There shall be a Session of the Parliament of Canada once at least in every Year, so that Twelve Months shall not intervene between the last Sitting of the Parliament in one Session and its first sitting in the next Session.

**Section 20 has been replaced by section 5 of the *Constitution Act, 1982*, which provides that there shall be a sitting of Parliament at least once every twelve months.**

**[11] As amended by the *Constitution Act, 1915*, 5-6 Geo. V, c. 45 (U.K.) and modified by the *Newfoundland Act*, 12-13 Geo. VI, c. 22 (U.K.), the *Constitution Act (No. 2), 1975*, S.C. 1974-75-76, c. 53, and the *Constitution Act, 1999 (Nunavut)*, S.C. 1998, c. 15, Part 2. The original section read as follows:**

**21.** The Senate shall, subject to the Provisions of this Act, consist of Seventy-two Members, who shall be styled Senators.

**The *Manitoba Act, 1870*, added two senators for Manitoba; the *British Columbia Terms of Union* added three; upon admission of Prince Edward Island four more were provided by section 147 of the *Constitution Act, 1867*; the *Alberta Act* and the *Saskatchewan Act* each added four. The Senate was reconstituted at 96 by the *Constitution Act, 1915*. Six more senators were added upon union with Newfoundland, and one senator each was added for Yukon and the Northwest Territories by the *Constitution Act (No. 2), 1975*. One senator was added for Nunavut by the *Constitution Act, 1999 (Nunavut)*.**

Representation of Provinces in Senate

**22.** In relation to the Constitution of the Senate Canada shall be deemed to consist of Four Divisions:

1. Ontario;
2. Quebec;
3. The Maritime Provinces, Nova Scotia and New Brunswick, and Prince Edward Island;
4. The Western Provinces of Manitoba, British Columbia, Saskatchewan, and Alberta;

which Four Divisions shall (subject to the Provisions of this Act) be equally represented in the Senate as follows: Ontario by twenty-four senators; Quebec by twenty-four senators; the Maritime Provinces and Prince Edward Island by twenty-four senators, ten thereof representing Nova Scotia, ten thereof representing New Brunswick, and four thereof representing Prince Edward Island; the Western Provinces by twenty-four senators, six thereof representing Manitoba, six thereof representing British Columbia, six thereof representing Saskatchewan, and six thereof representing Alberta; Newfoundland shall be entitled to be represented in the Senate by six members; the Yukon Territory, the Northwest Territories and Nunavut shall be entitled to be represented in the Senate by one member each.

In the Case of Quebec each of the Twenty-four Senators representing that Province shall be appointed for One of the Twenty-four Electoral Divisions of Lower Canada specified in Schedule A. to Chapter One of the Consolidated Statutes of Canada. **(12)**

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**(12) As amended by the *Constitution Act, 1915*, 5-6 Geo. V, c. 45 (U.K.), the *Newfoundland Act*, 12-13 Geo. VI, c. 22 (U.K.), the *Constitution Act (No. 2), 1975*, S.C. 1974-75-76, c. 53 and the *Constitution Act, 1999 (Nunavut)*, S.C. 1998, c. 15, Part 2. The original section read as follows:**

**22.** In relation to the Constitution of the Senate, Canada shall be deemed to consist of Three Divisions:

1. Ontario;

2. Quebec;

3. The Maritime Provinces, Nova Scotia and New Brunswick;

which Three Divisions shall (subject to the Provisions of this Act) be equally represented in the Senate as follows: Ontario by Twenty-four Senators; Quebec by Twenty-four Senators; and the Maritime Provinces by Twenty-four Senators, Twelve thereof representing Nova Scotia, and Twelve thereof representing New Brunswick.

In the case of Quebec each of the Twenty-four Senators representing that Province shall be appointed for One of the Twenty-four Electoral Divisions of Lower Canada specified in Schedule A. to Chapter One of the Consolidated Statutes of Canada.

**The reference in section 22 to the Consolidated Statutes of Canada is a reference to the Consolidated Statutes of 1859.**

Qualifications of Senator

**23.** The Qualifications of a Senator shall be as follows:

(1) He shall be of the full age of Thirty Years;

(2) He shall be either a natural-born Subject of the Queen, or a Subject of the Queen naturalized by an Act of the Parliament of Great Britain, or of the Parliament of the United Kingdom of Great Britain and Ireland, or of the Legislature of One of the Provinces of Upper Canada, Lower Canada, Canada, Nova Scotia, or New Brunswick, before the Union, or of the Parliament of Canada after the Union;

(3) He shall be legally or equitably seised as of Freehold for his own Use and Benefit of Lands or Tenements held in Free and Common Socage, or seised or possessed for his own Use and Benefit of Lands or Tenements held in Franc-alleu or in Roture, within the Province for which he is appointed, of the Value of Four thousand Dollars, over and above all Rents, Dues, Debts, Charges, Mortgages, and Incumbrances due or payable out of or charged on or affecting the same;

(4) His Real and Personal Property shall be together worth Four thousand Dollars over and above his Debts and Liabilities;

(5) He shall be resident in the Province for which he is appointed;

(6) In the Case of Quebec he shall have his Real Property Qualification in the Electoral Division for which he is appointed, or shall be resident in that Division. [13]

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**[13] Section 44 of the *Constitution Act, 1999 (Nunavut)*, S.C. 1998, c. 15, Part 2, provided that, for the purposes of that Part (which added one senator for Nunavut), the word "Province" in section 23 of the *Constitution Act, 1867* has the same meaning as is assigned to the word "province" by section 35 of the *Interpretation Act*, R.S.C. 1985, c. I-21, as amended, which provides that the term "province" means "a province of Canada, and includes Yukon, the Northwest Territories and Nunavut".**

**Section 2 of the *Constitution Act (No. 2), 1975*, S.C. 1974-75-76, c. 53, provided that for the purposes of that Act (which added one senator each for the Yukon Territory and the Northwest Territories) the term "Province" in section 23 of the *Constitution Act, 1867* has the same meaning as is assigned to the term "province" by section 28 of the *Interpretation Act*, R.S.C. 1970, c. I-23, which provides that the term "province" means "a province of Canada, and includes the Yukon Territory and the Northwest Territories".**

Summons of Senator

**24.** The Governor General shall from Time to Time, in the Queen's Name, by Instrument under the Great Seal of Canada, summon qualified Persons to the Senate; and, subject to the Provisions of this Act, every Person so summoned shall become and be a Member of the Senate and a Senator.

**25.** Repealed. [(14)]

Addition of Senators in certain cases

**26.** If at any Time on the Recommendation of the Governor General the Queen thinks fit to direct that Four or Eight Members be added to the Senate, the Governor General may by Summons to Four or Eight qualified Persons (as the Case may be), representing equally the Four Divisions of Canada, add to the Senate accordingly. [(15)]

Reduction of Senate to normal Number

**27.** In case of such Addition being at any Time made, the Governor General shall not summon any Person to the Senate, except on a further like Direction by the Queen on the like Recommendation, to represent one of the Four Divisions until such Division is represented by Twenty-four Senators and no more. [(16)]

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**(14) Repealed by the *Statute Law Revision Act, 1893*, 56-57 Vict., c. 14 (U.K.). The section read as follows:**

**25.** Such Persons shall be first summoned to the Senate as the Queen by Warrant under Her Majesty's Royal Sign Manual thinks fit to approve, and their Names shall be inserted in the Queen's Proclamation of Union.

**(15) As amended by the *Constitution Act, 1915*, 5-6 Geo. V, c. 45 (U.K.). The original section read as follows:**

**26.** If at any Time on the Recommendation of the Governor General the Queen thinks fit to direct that Three or Six Members be added to the Senate, the Governor General may by Summons to Three or Six qualified Persons (as the Case may be), representing equally the Three Divisions of Canada, add to the Senate accordingly.

**(16) As amended by the *Constitution Act, 1915*, 5-6 Geo. V, c. 45 (U.K.). The original section read as follows:**

**27.** In case of such Addition being at any Time made the Governor General shall not summon any Person to the Senate except on a further like Direction by the Queen on the like Recommendation, until each of the Three Divisions of Canada is represented by Twenty-four Senators and no more.

Maximum Number of Senators

**28.** The Number of Senators shall not at any Time exceed One Hundred and thirteen. [17]

Tenure of Place in Senate

**29.** (1) Subject to subsection (2), a Senator shall, subject to the provisions of this Act, hold his place in the Senate for life.

Retirement upon attaining age of seventy-five years

(2) A Senator who is summoned to the Senate after the coming into force of this subsection shall, subject to this Act, hold his place in the Senate until he attains the age of seventy-five years. [18]

Resignation of Place in Senate

**30.** A Senator may by Writing under his Hand addressed to the Governor General resign his Place in the Senate, and thereupon the same shall be vacant.

Disqualification of Senators

**31.** The Place of a Senator shall become vacant in any of the following Cases:

(1) If for Two consecutive Sessions of the Parliament he fails to give his Attendance in the Senate;

(2) If he takes an Oath or makes a Declaration or Acknowledgment of Allegiance, Obedience, or Adherence to a Foreign Power, or does an Act whereby he becomes a Subject or Citizen, or entitled to the Rights or Privileges of a Subject or Citizen, of a Foreign Power;

(3) If he is adjudged Bankrupt or Insolvent, or applies for the Benefit of any Law relating to Insolvent Debtors, or becomes a public Defaulter;

(4) If he is attainted of Treason or convicted of Felony or of any infamous Crime;

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**[17] As amended by the *Constitution Act, 1915*, 5-6 Geo. V, c. 45 (U.K.), the *Constitution Act (No. 2), 1975*, S.C. 1974-75-76, c. 53, and the *Constitution Act, 1999 (Nunavut)*, S.C. 1998, c. 15, Part 2. The original section read as follows:**

**28.** The Number of Senators shall not at any Time exceed Seventy-eight.

**[18] As enacted by the *Constitution Act, 1965*, S.C. 1965, c. 4, which came into force on June 2, 1965. The original section read as follows:**

**29.** A Senator shall, subject to the Provisions of this Act, hold his Place in the Senate for Life.

(5) If he ceases to be qualified in respect of Property or of Residence; provided, that a Senator shall not be deemed to have ceased to be qualified in respect of Residence by reason only of his residing at the Seat of the Government of Canada while holding an Office under that Government requiring his Presence there.

Summons on Vacancy in Senate

**32.** When a Vacancy happens in the Senate by Resignation, Death, or otherwise, the Governor General shall by Summons to a fit and qualified Person fill the Vacancy.

Questions as to Qualifications and Vacancies in Senate

**33.** If any Question arises respecting the Qualification of a Senator or a Vacancy in the Senate the same shall be heard and determined by the Senate.

Appointment of Speaker of Senate

**34.** The Governor General may from Time to Time, by Instrument under the Great Seal of Canada, appoint a Senator to be Speaker of the Senate, and may remove him and appoint another in his Stead. **(19)**

Quorum of Senate

**35.** Until the Parliament of Canada otherwise provides, the Presence of at least Fifteen Senators, including the Speaker, shall be necessary to constitute a Meeting of the Senate for the Exercise of its Powers.

Voting in Senate

**36.** Questions arising in the Senate shall be decided by a Majority of Voices, and the Speaker shall in all Cases have a Vote, and when the Voices are equal the Decision shall be deemed to be in the Negative.

## The House of Commons

Constitution of House of Commons in Canada

**37.** The House of Commons shall, subject to the Provisions of this Act, consist of three hundred and eight members of whom one hundred and six shall be elected for Ontario, seventy-five for Quebec, eleven for Nova Scotia, ten for New

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**(19) Provision for exercising the functions of Speaker during his or her absence is made by Part II of the *Parliament of Canada Act*, R.S.C. 1985, c. P-1 (formerly the *Speaker of the Senate Act*, R.S.C. 1970, c. S-14). Doubts as to the power of Parliament to enact the *Speaker of the Senate Act* were removed by the *Canadian Speaker (Appointment of Deputy) Act, 1895*, 2nd Sess., 59 Vict., c. 3 (U.K.), which was repealed by the *Constitution Act, 1982*.**

Brunswick, fourteen for Manitoba, thirty-six for British Columbia, four for Prince Edward Island, twenty-eight for Alberta, fourteen for Saskatchewan, seven for Newfoundland, one for the Yukon Territory, one for the Northwest Territories and one for Nunavut. [(20)]

Summoning of House of Commons

**38.** The Governor General shall from Time to Time, in the Queen's Name, by Instrument under the Great Seal of Canada, summon and call together the House of Commons.

Senators not to sit in House of Commons

**39.** A Senator shall not be capable of being elected or of sitting or voting as a Member of the House of Commons.

Electoral districts of the four Provinces

**40.** Until the Parliament of Canada otherwise provides, Ontario, Quebec, Nova Scotia, and New Brunswick shall, for the Purposes of the Election of Members to serve in the House of Commons, be divided into Electoral Districts as follows:

1. Ontario

Ontario shall be divided into the Counties, Ridings of Counties, Cities, Parts of Cities, and Towns enumerated in the First Schedule to this Act, each whereof shall be an Electoral District, each such District as numbered in that Schedule being entitled to return One Member.

2. Quebec

Quebec shall be divided into Sixty-five Electoral Districts, composed of the Sixty-five Electoral Divisions into which Lower Canada is at the passing of this Act divided under Chapter Two of the Consolidated Statutes of Canada, Chapter Seventy-five of the Consolidated Statutes for Lower Canada, and the Act of the Province of Canada of the Twenty-third Year of the Queen, Chapter One, or any other Act amending the same in force at the Union, so that each such Electoral Division shall be for the Purposes of this Act an Electoral District entitled to return One Member.

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**[(20)] The figures given here result from the application of section 51, as enacted by the *Constitution Act, 1985 (Representation)*, S.C. 1986, c. 8, Part I, and amended by the *Constitution Act, 1999 (Nunavut)*, S.C. 1998, c. 15, Part 2, and readjustments made pursuant to the *Electoral Boundaries Readjustment Act*, R.S.C. 1985, c. E-3. The original section (which was altered from time to time as the result of the addition of new provinces and changes in population) read as follows:**

**37.** The House of Commons shall, subject to the Provisions of this Act, consist of one hundred and eighty-one members, of whom Eighty-two shall be elected for Ontario, Sixty-five for Quebec, Nineteen for Nova Scotia, and Fifteen for New Brunswick.

### 3. Nova Scotia

Each of the Eighteen Counties of Nova Scotia shall be an Electoral District. The County of Halifax shall be entitled to return Two Members, and each of the other Counties One Member.

### 4. New Brunswick

Each of the Fourteen Counties into which New Brunswick is divided, including the City and County of St. John, shall be an Electoral District. The City of St. John shall also be a separate Electoral District. Each of those Fifteen Electoral Districts shall be entitled to return One Member. [21]

Continuance of existing Election Laws until Parliament of Canada otherwise provides

**41.** Until the Parliament of Canada otherwise provides, all Laws in force in the several Provinces at the Union relative to the following Matters or any of them, namely, — the Qualifications and Disqualifications of Persons to be elected or to sit or vote as Members of the House of Assembly or Legislative Assembly in the several Provinces, the Voters at Elections of such Members, the Oaths to be taken by Voters, the Returning Officers, their Powers and Duties, the Proceedings at Elections, the Periods during which Elections may be continued, the Trial of controverted Elections, and Proceedings incident thereto, the vacating of Seats of Members, and the Execution of new Writs in case of Seats vacated otherwise than by Dissolution, — shall respectively apply to Elections of Members to serve in the House of Commons for the same several Provinces.

Provided that, until the Parliament of Canada otherwise provides, at any Election for a Member of the House of Commons for the District of Algoma, in addition to Persons qualified by the Law of the Province of Canada to vote, every Male British Subject, aged Twenty-one Years or upwards, being a Householder, shall have a Vote. [22]

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**[21] Spent. The electoral districts are now established by proclamations issued from time to time under the *Electoral Boundaries Readjustment Act*, R.S.C. 1985, c. E-3, as amended for particular districts by Acts of Parliament (see the most recent *Table of Public Statutes and Responsible Ministers*).**

**[22] Spent. Elections are now provided for by the *Canada Elections Act*, S.C. 2000, c. 9; qualifications and disqualifications of members by the *Parliament of Canada Act*, R.S.C. 1985, c. P-1. The right of citizens to vote and hold office is provided for in section 3 of the *Constitution Act, 1982*.**

**42.** Repealed. [(23)]

**43.** Repealed. [(24)]

As to Election of Speaker of House of Commons

**44.** The House of Commons on its first assembling after a General Election shall proceed with all practicable Speed to elect One of its Members to be Speaker.

As to filling up Vacancy in Office of Speaker

**45.** In case of a Vacancy happening in the Office of Speaker by Death, Resignation, or otherwise, the House of Commons shall with all practicable Speed proceed to elect another of its Members to be Speaker.

Speaker to preside

**46.** The Speaker shall preside at all Meetings of the House of Commons.

Provision in case of Absence of Speaker

**47.** Until the Parliament of Canada otherwise provides, in case of the Absence for any Reason of the Speaker from the Chair of the House of Commons for a Period of Forty-eight consecutive Hours, the House may elect another of its Members to act as Speaker, and the Member so elected shall during the Continuance of such Absence of the Speaker have and execute all the Powers, Privileges, and Duties of Speaker. [(25)]

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**[(23)] Repealed by the *Statute Law Revision Act, 1893*, 56-57 Vict., c. 14 (U.K.). The section read as follows:**

**42.** For the First Election of Members to serve in the House of Commons the Governor General shall cause Writs to be issued by such Person, in such Form, and addressed to such Returning Officers as he thinks fit.

The Person issuing Writs under this Section shall have the like Powers as are possessed at the Union by the Officers charged with the issuing of Writs for the Election of Members to serve in the respective House of Assembly or Legislative Assembly of the Province of Canada, Nova Scotia, or New Brunswick; and the Returning Officers to whom Writs are directed under this Section shall have the like Powers as are possessed at the Union by the Officers charged with the returning of Writs for the Election of Members to serve in the same respective House of Assembly or Legislative Assembly.

**[(24)] Repealed by the *Statute Law Revision Act, 1893*, 56-57 Vict., c. 14 (U.K.). The section read as follows:**

**43.** In case a Vacancy in the Representation in the House of Commons of any Electoral District happens before the Meeting of the Parliament, or after the Meeting of the Parliament before Provision is made by the Parliament in this Behalf, the Provisions of the last foregoing Section of this Act shall extend and apply to the issuing and returning of a Writ in respect of such Vacant District.

**[(25)] Provision for exercising the functions of Speaker during his or her absence is now made by Part III of the *Parliament of Canada Act*, R.S.C. 1985, c. P-1.**

Quorum of House of Commons

**48.** The Presence of at least Twenty Members of the House of Commons shall be necessary to constitute a Meeting of the House for the Exercise of its Powers, and for that Purpose the Speaker shall be reckoned as a Member.

Voting in House of Commons

**49.** Questions arising in the House of Commons shall be decided by a Majority of Voices other than that of the Speaker, and when the Voices are equal, but not otherwise, the Speaker shall have a Vote.

Duration of House of Commons

**50.** Every House of Commons shall continue for Five Years from the Day of the Return of the Writs for choosing the House (subject to be sooner dissolved by the Governor General), and no longer. **(26)**

Readjustment of representation in Commons

**51.** (1) The number of members of the House of Commons and the representation of the provinces therein shall, on the completion of each decennial census, be readjusted by such authority, in such manner, and from such time as the Parliament of Canada provides from time to time, subject and according to the following rules:

Rules

**1.** There shall be assigned to each of the provinces a number of members equal to the number obtained by dividing the population of the province by the electoral quotient and rounding up any fractional remainder to one.

**2.** If the number of members assigned to a province by the application of rule 1 and section 51A is less than the total number assigned to that province on the date of the coming into force of the *Constitution Act, 1985 (Representation)*, there shall be added to the number of members so assigned such number of members as will result in the province having the same number of members as were assigned on that date.

**3.** After the application of rules 1 and 2 and section 51A, there shall, in respect of each province that meets the condition set out in rule 4, be added, if nec-

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**(26) The term of the 12th Parliament was extended by the *British North America Act, 1916*, 6-7 Geo. V., c. 19 (U.K.), which Act was repealed by the *Statute Law Revision Act, 1927*, 17-18 Geo. V, c. 42 (U.K.). See also the *Constitution Act, 1982*, subsection 4(1), which provides that no House of Commons shall continue for longer than five years from the date fixed for the return of the writs at a general election of its members, and subsection 4(2), which provides for continuation of the House of Commons in special circumstances.**

essary, a number of members such that, on the completion of the readjustment, the number obtained by dividing the number of members assigned to that province by the total number of members assigned to all the provinces is as close as possible to, without being below, the number obtained by dividing the population of that province by the total population of all the provinces.

**4.** Rule 3 applies to a province if, on the completion of the preceding readjustment, the number obtained by dividing the number of members assigned to that province by the total number of members assigned to all the provinces was equal to or greater than the number obtained by dividing the population of that province by the total population of all the provinces, the population of each province being its population as at July 1 of the year of the decennial census that preceded that readjustment according to the estimates prepared for the purpose of that readjustment.

**5.** Unless the context indicates otherwise, in these rules, the population of a province is the estimate of its population as at July 1 of the year of the most recent decennial census.

**6.** In these rules, "electoral quotient" means

(*a*) 111,166, in relation to the readjustment following the completion of the 2011 decennial census, and

(*b*) in relation to the readjustment following the completion of any subsequent decennial census, the number obtained by multiplying the electoral quotient that was applied in the preceding readjustment by the number that is the average of the numbers obtained by dividing the population of each province by the population of the province as at July 1 of the year of the preceding decennial census according to the estimates prepared for the purpose of the preceding readjustment, and rounding up any fractional remainder of that multiplication to one.

Population estimates

(1.1) For the purpose of the rules in subsection (1), there is required to be prepared an estimate of the population of Canada and of each province as at July 1, 2001 and July 1, 2011 — and, in each year following the 2011 decennial census in which a decennial census is taken, as at July 1 of that year — by such authority, in such manner, and from such time as the Parliament of Canada provides from time to time. [(27)]

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**[(27)] As enacted by the *Fair Representation Act*, S.C. 2011, c. 26, s. 2, which came into force on royal assent on December 16, 2011.**

**The section, as originally enacted, read as follows:**

**51.** On the Completion of the Census in the Year One Thousand eight hundred and seventy-one, and of each subsequent decennial Census, the Representation of the Four Provinces shall be readjusted by such Authority, in such Manner, and from such Time, as the Parliament of Canada from Time to Time provides, subject and according to the following Rules:

(1) Quebec shall have the fixed Number of Sixty-five Members:

(2) There shall be assigned to each of the other Provinces such a Number of Members as will bear the same Proportion to the Number of its Population (ascertained at such Census) as the Number Sixty-five bears to the Number of the Population of Quebec (so ascertained):

(3) In the Computation of the Number of Members for a Province a fractional Part not exceeding One Half of the whole Number requisite for entitling the Province to a Member shall be disregarded; but a fractional Part exceeding One Half of that Number shall be equivalent to the whole Number:

(4) On any such Re-adjustment the Number of Members for a Province shall not be reduced unless the Proportion which the Number of the Population of the Province bore to the Number of the aggregate Population of Canada at the then last preceding Re-adjustment of the Number of Members for the Province is ascertained at the then latest Census to be diminished by One Twentieth Part or upwards:

(5) Such Re-adjustment shall not take effect until the Termination of the then existing Parliament.

**For further details, see endnote 2.**

Yukon Territory, Northwest Territories and Nunavut

(2) The Yukon Territory as bounded and described in the schedule to chapter Y-2 of the Revised Statutes of Canada, 1985, shall be entitled to one member, the Northwest Territories as bounded and described in section 2 of chapter N-27 of the Revised Statutes of Canada, 1985, as amended by section 77 of chapter 28 of the Statutes of Canada, 1993, shall be entitled to one member, and Nunavut as bounded and described in section 3 of chapter 28 of the Statutes of Canada, 1993, shall be entitled to one member. [28]

Constitution of House of Commons

**51A.** Notwithstanding anything in this Act a province shall always be entitled to a number of members in the House of Commons not less than the number of senators representing such province. [29]

Increase of Number of House of Commons

**52.** The Number of Members of the House of Commons may be from Time to Time increased by the Parliament of Canada, provided the proportionate Representation of the Provinces prescribed by this Act is not thereby disturbed.

## Money Votes; Royal Assent

Appropriation and Tax Bills

**53.** Bills for appropriating any Part of the Public Revenue, or for imposing any Tax or Impost, shall originate in the House of Commons.

Recommendation of Money Votes

**54.** It shall not be lawful for the House of Commons to adopt or pass any Vote, Resolution, Address, or Bill for the Appropriation of any Part of the Public Revenue, or of any Tax or Impost, to any Purpose that has not been first recommended to that House by Message of the Governor General in the Session in which such Vote, Resolution, Address, or Bill is proposed.

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**[28] As enacted by the *Constitution Act, 1999 (Nunavut)*, S.C. 1998, c. 15, Part 2. Note that the description of the territory of Yukon is now set out in Schedule 1 to the *Yukon Act*, S.C. 2002, c. 7, which replaced R.S.C. 1985, c. Y-2. Subsection 51(2) was previously amended by the *Constitution Act (No. 1), 1975*, S.C. 1974-75-76, c. 28, and read as follows:**

(2) The Yukon Territory as bounded and described in the schedule to chapter Y-2 of the Revised Statutes of Canada, 1970, shall be entitled to one member, and the Northwest Territories as bounded and described in section 2 of chapter N-22 of the Revised Statutes of Canada, 1970, shall be entitled to two members.

**[29] As enacted by the *Constitution Act, 1915*, 5-6 Geo. V, c. 45 (U.K.).**

Royal Assent to Bills, etc.

**55.** Where a Bill passed by the Houses of the Parliament is presented to the Governor General for the Queen's Assent, he shall declare, according to his Discretion, but subject to the Provisions of this Act and to Her Majesty's Instructions, either that he assents thereto in the Queen's Name, or that he withholds the Queen's Assent, or that he reserves the Bill for the Signification of the Queen's Pleasure.

Disallowance by Order in Council of Act assented to by Governor General

**56.** Where the Governor General assents to a Bill in the Queen's Name, he shall by the first convenient Opportunity send an authentic Copy of the Act to One of Her Majesty's Principal Secretaries of State, and if the Queen in Council within Two Years after Receipt thereof by the Secretary of State thinks fit to disallow the Act, such Disallowance (with a Certificate of the Secretary of State of the Day on which the Act was received by him) being signified by the Governor General, by Speech or Message to each of the Houses of the Parliament or by Proclamation, shall annul the Act from and after the Day of such Signification.

Signification of Queen's Pleasure on Bill reserved

**57.** A Bill reserved for the Signification of the Queen's Pleasure shall not have any Force unless and until, within Two Years from the Day on which it was presented to the Governor General for the Queen's Assent, the Governor General signifies, by Speech or Message to each of the Houses of the Parliament or by Proclamation, that it has received the Assent of the Queen in Council.

An Entry of every such Speech, Message, or Proclamation shall be made in the Journal of each House, and a Duplicate thereof duly attested shall be delivered to the proper Officer to be kept among the Records of Canada.

## V. PROVINCIAL CONSTITUTIONS

### Executive Power

Appointment of Lieutenant Governors of Provinces

**58.** For each Province there shall be an Officer, styled the Lieutenant Governor, appointed by the Governor General in Council by Instrument under the Great Seal of Canada.

Tenure of Office of Lieutenant Governor

**59.** A Lieutenant Governor shall hold Office during the Pleasure of the Governor General; but any Lieutenant Governor appointed after the Commencement of the First Session of the Parliament of Canada shall not be removeable within Five Years from his Appointment, except for Cause assigned, which shall be communicated to him in Writing within One Month after the Order for his Removal is made, and shall be communicated by Message to the Senate and to the House of Commons

within One Week thereafter if the Parliament is then sitting, and if not then within One Week after the Commencement of the next Session of the Parliament.

Salaries of Lieutenant Governors

**60.** The Salaries of the Lieutenant Governors shall be fixed and provided by the Parliament of Canada. [(30)]

Oaths, etc., of Lieutenant Governor

**61.** Every Lieutenant Governor shall, before assuming the Duties of his Office, make and subscribe before the Governor General or some Person authorized by him Oaths of Allegiance and Office similar to those taken by the Governor General.

Application of Provisions referring to Lieutenant Governor

**62.** The Provisions of this Act referring to the Lieutenant Governor extend and apply to the Lieutenant Governor for the Time being of each Province, or other the Chief Executive Officer or Administrator for the Time being carrying on the Government of the Province, by whatever Title he is designated.

Appointment of Executive Officers for Ontario and Quebec

**63.** The Executive Council of Ontario and of Quebec shall be composed of such Persons as the Lieutenant Governor from Time to Time thinks fit, and in the first instance of the following Officers, namely, — the Attorney General, the Secretary and Registrar of the Province, the Treasurer of the Province, the Commissioner of Crown Lands, and the Commissioner of Agriculture and Public Works, with in Quebec the Speaker of the Legislative Council and the Solicitor General. [(31)]

Executive Government of Nova Scotia and New Brunswick

**64.** The Constitution of the Executive Authority in each of the Provinces of Nova Scotia and New Brunswick shall, subject to the Provisions of this Act, continue as it exists at the Union until altered under the Authority of this Act. [(32)]

Powers to be exercised by Lieutenant Governor of Ontario or Quebec with Advice, or alone

**65.** All Powers, Authorities, and Functions which under any Act of the Parliament of Great Britain, or of the Parliament of the United Kingdom of Great Britain

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**[(30)] Provided for by the *Salaries Act*, R.S.C. 1985, c. S-3.**

**[(31)] Now provided for in Ontario by the *Executive Council Act*, R.S.O. 1990, c. E.25, and in Quebec by the *Executive Power Act*, R.S.Q., c. E-18.**

**[(32)] A similar provision was included in each of the instruments admitting British Columbia, Prince Edward Island, and Newfoundland. The Executive Authorities for Manitoba, Alberta and Saskatchewan were established by the statutes creating those provinces. See footnote (6) to section 5, above.**

and Ireland, or of the Legislature of Upper Canada, Lower Canada, or Canada, were or are before or at the Union vested in or exerciseable by the respective Governors or Lieutenant Governors of those Provinces, with the Advice or with the Advice and Consent of the respective Executive Councils thereof, or in conjunction with those Councils, or with any Number of Members thereof, or by those Governors or Lieutenant Governors individually, shall, as far as the same are capable of being exercised after the Union in relation to the Government of Ontario and Quebec respectively, be vested in and shall or may be exercised by the Lieutenant Governor of Ontario and Quebec respectively, with the Advice or with the Advice and Consent of or in conjunction with the respective Executive Councils, or any Members thereof, or by the Lieutenant Governor individually, as the Case requires, subject nevertheless (except with respect to such as exist under Acts of the Parliament of Great Britain, or of the Parliament of the United Kingdom of Great Britain and Ireland,) to be abolished or altered by the respective Legislatures of Ontario and Quebec. [(33)]

Application of Provisions referring to Lieutenant Governor in Council

**66.** The Provisions of this Act referring to the Lieutenant Governor in Council shall be construed as referring to the Lieutenant Governor of the Province acting by and with the Advice of the Executive Council thereof.

Administration in Absence, etc., of Lieutenant Governor

**67.** The Governor General in Council may from Time to Time appoint an Administrator to execute the Office and Functions of Lieutenant Governor during his Absence, Illness, or other Inability.

Seats of Provincial Governments

**68.** Unless and until the Executive Government of any Province otherwise directs with respect to that Province, the Seats of Government of the Provinces shall be as follows, namely, — of Ontario, the City of Toronto; of Quebec, the City of Quebec; of Nova Scotia, the City of Halifax; and of New Brunswick, the City of Fredericton.

## Legislative Power

### *1. Ontario*

Legislature for Ontario

**69.** There shall be a Legislature for Ontario consisting of the Lieutenant Governor and of One House, styled the Legislative Assembly of Ontario.

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[(33)] **See footnote (65) to section 129, below.**

Electoral districts

**70.** The Legislative Assembly of Ontario shall be composed of Eighty-two Members, to be elected to represent the Eighty-two Electoral Districts set forth in the First Schedule to this Act. [(34)]

### *2. Quebec*

Legislature for Quebec

**71.** There shall be a Legislature for Quebec consisting of the Lieutenant Governor and of Two Houses, styled the Legislative Council of Quebec and the Legislative Assembly of Quebec. [(35)]

Constitution of Legislative Council

**72.** The Legislative Council of Quebec shall be composed of Twenty-four Members, to be appointed by the Lieutenant Governor, in the Queen's Name, by Instrument under the Great Seal of Quebec, one being appointed to represent each of the Twenty-four Electoral Divisions of Lower Canada in this Act referred to, and each holding Office for the Term of his Life, unless the Legislature of Quebec otherwise provides under the Provisions of this Act.

Qualification of Legislative Councillors

**73.** The Qualifications of the Legislative Councillors of Quebec shall be the same as those of the Senators for Quebec.

Resignation, Disqualification, etc.

**74.** The Place of a Legislative Councillor of Quebec shall become vacant in the Cases, *mutatis mutandis*, in which the Place of Senator becomes vacant.

Vacancies

**75.** When a Vacancy happens in the Legislative Council of Quebec by Resignation, Death, or otherwise, the Lieutenant Governor, in the Queen's Name, by Instrument under the Great Seal of Quebec, shall appoint a fit and qualified Person to fill the Vacancy.

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**[(34)] Spent. Now covered by the *Representation Act, 2005*, S.O. 2005, c. 35, Schedule 1.**

**[(35)] *An Act respecting the Legislative Council of Quebec*, S.Q. 1968, c. 9, provided that the Legislature for Quebec shall consist of the Lieutenant Governor and the National Assembly of Quebec, and repealed the provisions of the *Legislature Act*, R.S.Q. 1964, c. 6, relating to the Legislative Council of Quebec. Now covered by the *National Assembly Act*, R.S.Q. c. A-23.1. Sections 72 to 79 following are therefore completely spent.**

Questions as to Vacancies, etc.

**76.** If any Question arises respecting the Qualification of a Legislative Councillor of Quebec, or a Vacancy in the Legislative Council of Quebec, the same shall be heard and determined by the Legislative Council.

Speaker of Legislative Council

**77.** The Lieutenant Governor may from Time to Time, by Instrument under the Great Seal of Quebec, appoint a Member of the Legislative Council of Quebec to be Speaker thereof, and may remove him and appoint another in his Stead.

Quorum of Legislative Council

**78.** Until the Legislature of Quebec otherwise provides, the Presence of at least Ten Members of the Legislative Council, including the Speaker, shall be necessary to constitute a Meeting for the Exercise of its Powers.

Voting in Legislative Council

**79.** Questions arising in the Legislative Council of Quebec shall be decided by a Majority of Voices, and the Speaker shall in all Cases have a Vote, and when the Voices are equal the Decision shall be deemed to be in the Negative.

Constitution of Legislative Assembly of Quebec

**80.** The Legislative Assembly of Quebec shall be composed of Sixty-five Members, to be elected to represent the Sixty-five Electoral Divisions or Districts of Lower Canada in this Act referred to, subject to Alteration thereof by the Legislature of Quebec: Provided that it shall not be lawful to present to the Lieutenant Governor of Quebec for Assent any Bill for altering the Limits of any of the Electoral Divisions or Districts mentioned in the Second Schedule to this Act, unless the Second and Third Readings of such Bill have been passed in the Legislative Assembly with the Concurrence of the Majority of the Members representing all those Electoral Divisions or Districts, and the Assent shall not be given to such Bill unless an Address has been presented by the Legislative Assembly to the Lieutenant Governor stating that it has been so passed. **(36)**

### *3. Ontario and Quebec*

**81.** Repealed. **(37)**

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**(36)** ***An Act respecting the electoral districts*, S.Q. 1970, c. 7, provides that this section no longer has effect.**

**(37)** **Repealed by the *Statute Law Revision Act, 1893*, 56-57 Vict., c. 14 (U.K.). The section read as follows:**

> **81.** The Legislatures of Ontario and Quebec respectively shall be called together not later than Six Months after the Union.

Summoning of Legislative Assemblies

**82.** The Lieutenant Governor of Ontario and of Quebec shall from Time to Time, in the Queen's Name, by Instrument under the Great Seal of the Province, summon and call together the Legislative Assembly of the Province.

Restriction on election of Holders of offices

**83.** Until the Legislature of Ontario or of Quebec otherwise provides, a Person accepting or holding in Ontario or in Quebec any Office, Commission, or Employment, permanent or temporary, at the Nomination of the Lieutenant Governor, to which an annual Salary, or any Fee, Allowance, Emolument, or Profit of any Kind or Amount whatever from the Province is attached, shall not be eligible as a Member of the Legislative Assembly of the respective Province, nor shall he sit or vote as such; but nothing in this Section shall make ineligible any Person being a Member of the Executive Council of the respective Province, or holding any of the following Offices, that is to say, the Offices of Attorney General, Secretary and Registrar of the Province, Treasurer of the Province, Commissioner of Crown Lands, and Commissioner of Agriculture and Public Works, and in Quebec Solicitor General, or shall disqualify him to sit or vote in the House for which he is elected, provided he is elected while holding such Office. [38]

Continuance of existing Election Laws

**84.** Until the legislatures of Ontario and Quebec respectively otherwise provide, all Laws which at the Union are in force in those Provinces respectively, relative to the following Matters, or any of them, namely, — the Qualifications and Disqualifications of Persons to be elected or to sit or vote as Members of the Assembly of Canada, the Qualifications or Disqualifications of Voters, the Oaths to be taken by Voters, the Returning Officers, their Powers and Duties, the Proceedings at Elections, the Periods during which such Elections may be continued, and the Trial of controverted Elections and the Proceedings incident thereto, the vacating of the Seats of Members and the issuing and execution of new Writs in case of Seats vacated otherwise than by Dissolution, — shall respectively apply to Elections of Members to serve in the respective Legislative Assemblies of Ontario and Quebec.

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[38] **Probably spent. The subject-matter of this section is now covered in Ontario by the *Legislative Assembly Act*, R.S.O. 1990, c. L.10, and in Quebec by the *National Assembly Act*, R.S.Q. c. A-23.1.**

Provided that, until the Legislature of Ontario otherwise provides, at any Election for a Member of the Legislative Assembly of Ontario for the District of Algoma, in addition to Persons qualified by the Law of the Province of Canada to vote, every Male British Subject, aged Twenty-one Years or upwards, being a Householder, shall have a Vote. [(39)]

Duration of Legislative Assemblies

**85.** Every Legislative Assembly of Ontario and every Legislative Assembly of Quebec shall continue for Four Years from the Day of the Return of the Writs for choosing the same (subject nevertheless to either the Legislative Assembly of Ontario or the Legislative Assembly of Quebec being sooner dissolved by the Lieutenant Governor of the Province), and no longer. [(40)]

Yearly Session of Legislature

**86.** There shall be a Session of the Legislature of Ontario and of that of Quebec once at least in every Year, so that Twelve Months shall not intervene between the last Sitting of the Legislature in each Province in one Session and its first Sitting in the next Session. [(41)]

Speaker, Quorum, etc.

**87.** The following Provisions of this Act respecting the House of Commons of Canada shall extend and apply to the Legislative Assemblies of Ontario and Quebec, that is to say, — the Provisions relating to the Election of a Speaker originally and on Vacancies, the Duties of the Speaker, the Absence of the Speaker, the Quorum, and the Mode of voting, as if those Provisions were here re-enacted and made applicable in Terms to each such Legislative Assembly.

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**[(39)] Probably spent. The subject-matter of this section is now covered in Ontario by the *Election Act*, R.S.O. 1990, c. E.6, and the *Legislative Assembly Act*, R.S.O. 1990, c. L.10, and in Quebec by the *Election Act*, R.S.Q. c. E-3.3 and the *National Assembly Act*, R.S.Q. c. A-23.1.**

**[(40)] The maximum duration of the Legislative Assembly of Quebec has been changed to five years. See the *National Assembly Act*, R.S.Q. c. A-23.1. See also section 4 of the *Constitution Act, 1982*, which provides a maximum duration for a legislative assembly of five years but also authorizes continuation in special circumstances.**

**[(41)] See also section 5 of the *Constitution Act, 1982*, which provides that there shall be a sitting of each legislature at least once every twelve months.**

### *4. Nova Scotia and New Brunswick*

Constitutions of Legislatures of Nova Scotia and New Brunswick

**88.** The Constitution of the Legislature of each of the Provinces of Nova Scotia and New Brunswick shall, subject to the Provisions of this Act, continue as it exists at the Union until altered under the Authority of this Act. [(42)]

### *5. Ontario, Quebec, and Nova Scotia*

**89.** Repealed. [(43)]

### *6. The Four Provinces*

Application to Legislatures of Provisions respecting Money Votes, etc.

**90.** The following Provisions of this Act respecting the Parliament of Canada, namely, — the Provisions relating to Appropriation and Tax Bills, the Recommendation of Money Votes, the Assent to Bills, the Disallowance of Acts, and the Signification of Pleasure on Bills reserved, — shall extend and apply to the Legislatures of the several Provinces as if those Provisions were here re-enacted and made applicable in Terms to the respective Provinces and the Legislatures thereof, with the Substitution of the Lieutenant Governor of the Province for the Governor General,

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**(42) Partially repealed by the *Statute Law Revision Act, 1893*, 56-57 Vict., c. 14 (U.K.), which deleted the following concluding words of the original enactment:**

> and the House of Assembly of New Brunswick existing at the passing of this Act shall, unless soooner dissolved, continue for the Period for which it was elected.

**A similar provision was included in each of the instruments admitting British Columbia, Prince Edward Island and Newfoundland. The Legislatures of Manitoba, Alberta and Saskatchewan were established by the statutes creating those provinces. See footnote (6) to section 5, above.**

**See also sections 3 to 5 of the *Constitution Act, 1982*, which prescribe democratic rights applicable to all provinces, and subitem 2(2) of the Schedule to that Act, which sets out the repeal of section 20 of the *Manitoba Act, 1870*. Section 20 of the *Manitoba Act, 1870* has been replaced by section 5 of the *Constitution Act, 1982*. Section 20 read as follows:**

> **20.** There shall be a Session of the Legislature once at least in every year, so that twelve months shall not intervene between the last sitting of the Legislature in one Session and its first sitting in the next Session.

**(43) Repealed by the *Statute Law Revision Act, 1893*, 56-57 Vict., c. 14 (U.K.). The section read as follows:**

> **89.** Each of the Lieutenant Governors of Ontario, Quebec and Nova Scotia shall cause Writs to be issued for the First Election of Members of the Legislative Assembly thereof in such Form and by such Person as he thinks fit, and at such Time and addressed to such Returning Officer as the Governor General directs, and so that the First Election of Member of Assembly for any Electoral District or any Subdivision thereof shall be held at the same Time and at the same Places as the Election for a Member to serve in the House of Commons of Canada for that Electoral District.

of the Governor General for the Queen and for a Secretary of State, of One Year for Two Years, and of the Province for Canada.

## VI. DISTRIBUTION OF LEGISLATIVE POWERS

### Powers of the Parliament

Legislative Authority of Parliament of Canada

**91.** It shall be lawful for the Queen, by and with the Advice and Consent of the Senate and House of Commons, to make Laws for the Peace, Order, and good Government of Canada, in relation to all Matters not coming within the Classes of Subjects by this Act assigned exclusively to the Legislatures of the Provinces; and for greater Certainty, but not so as to restrict the Generality of the foregoing Terms of this Section, it is hereby declared that (notwithstanding anything in this Act) the exclusive Legislative Authority of the Parliament of Canada extends to all Matters coming within the Classes of Subjects next hereinafter enumerated; that is to say,

1. Repealed. **(44)**

1A. The Public Debt and Property. **(45)**

2. The Regulation of Trade and Commerce.

2A. Unemployment insurance. **(46)**

3. The raising of Money by any Mode or System of Taxation.

4. The borrowing of Money on the Public Credit.

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**(44) A new class 1 was added by the *British North America (No. 2) Act, 1949*, 13 Geo. VI, c. 81 (U.K.). That Act and class 1 were repealed by the *Constitution Act, 1982*. The matters referred to in class 1 are provided for in subsection 4(2) and Part V of the *Constitution Act, 1982*. As enacted, class 1 read as follows:**

1. The amendment from time to time of the Constitution of Canada, except as regards matters coming within the classes of subjects by this Act assigned exclusively to the Legislatures of the provinces, or as regards rights or privileges by this or any other Constitutional Act granted or secured to the Legislature or the Government of a province, or to any class of persons with respect to schools or as regards the use of the English or the French language or as regards the requirements that there shall be a session of the Parliament of Canada at least once each year, and that no House of Commons shall continue for more than five years from the day of the return of the Writs for choosing the House: provided, however, that a House of Commons may in time of real or apprehended war, invasion or insurrection be continued by the Parliament of Canada if such continuation is not opposed by the votes of more than one-third of the members of such House.

**(45) The original class 1 was re-numbered by the *British North America (No. 2) Act, 1949*, 13 Geo. VI, c. 81 (U.K.), as class 1A.**

**(46) Added by the *Constitution Act, 1940*, 3-4 Geo. VI, c. 36 (U.K.).**

5. Postal Service.

6. The Census and Statistics.

7. Militia, Military and Naval Service, and Defence.

8. The fixing of and providing for the Salaries and Allowances of Civil and other Officers of the Government of Canada.

9. Beacons, Buoys, Lighthouses, and Sable Island.

10. Navigation and Shipping.

11. Quarantine and the Establishment and Maintenance of Marine Hospitals.

12. Sea Coast and Inland Fisheries.

13. Ferries between a Province and any British or Foreign Country or between Two Provinces.

14. Currency and Coinage.

15. Banking, Incorporation of Banks, and the Issue of Paper Money.

16. Savings Banks.

17. Weights and Measures.

18. Bills of Exchange and Promissory Notes.

19. Interest.

20. Legal Tender.

21. Bankruptcy and Insolvency.

22. Patents of Invention and Discovery.

23. Copyrights.

24. Indians, and Lands reserved for the Indians.

25. Naturalization and Aliens.

26. Marriage and Divorce.

27. The Criminal Law, except the Constitution of Courts of Criminal Jurisdiction, but including the Procedure in Criminal Matters.

28. The Establishment, Maintenance, and Management of Penitentiaries.

29. Such Classes of Subjects as are expressly excepted in the Enumeration of the Classes of Subjects by this Act assigned exclusively to the Legislatures of the Provinces.

And any Matter coming within any of the Classes of Subjects enumerated in this Section shall not be deemed to come within the Class of Matters of a local or private Nature comprised in the Enumeration of the Classes of Subjects by this Act assigned exclusively to the Legislatures of the Provinces. [(47)]

### Exclusive Powers of Provincial Legislatures

Subjects of exclusive Provincial Legislation

**92.** In each Province the Legislature may exclusively make Laws in relation to Matters coming within the Classes of Subjects next hereinafter enumerated; that is to say,

1. Repealed. [(48)]
2. Direct Taxation within the Province in order to the raising of a Revenue for Provincial Purposes.
3. The borrowing of Money on the sole Credit of the Province.
4. The Establishment and Tenure of Provincial Offices and the Appointment and Payment of Provincial Officers.
5. The Management and Sale of the Public Lands belonging to the Province and of the Timber and Wood thereon.
6. The Establishment, Maintenance, and Management of Public and Reformatory Prisons in and for the Province.

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**[(47)] Legislative authority has been conferred on Parliament by other Acts. For further details, see endnote 3.**

**[(48)] Class 1 was repealed by the *Constitution Act, 1982*. As enacted, it read as follows:**

1. The Amendment from Time to Time, notwithstanding anything in this Act, of the Constitution of the Province, except as regards the Office of Lieutenant Governor.

**Section 45 of the *Constitution Act, 1982* now authorizes legislatures to make laws amending the constitution of the province. Sections 38, 41, 42 and 43 of that Act authorize legislative assemblies to give their approval by resolution to certain other amendments to the Constitution of Canada.**

7. The Establishment, Maintenance, and Management of Hospitals, Asylums, Charities, and Eleemosynary Institutions in and for the Province, other than Marine Hospitals.

8. Municipal Institutions in the Province.

9. Shop, Saloon, Tavern, Auctioneer, and other Licences in order to the raising of a Revenue for Provincial, Local, or Municipal Purposes.

10. Local Works and Undertakings other than such as are of the following Classes:

    (*a*) Lines of Steam or other Ships, Railways, Canals, Telegraphs, and other Works and Undertakings connecting the Province with any other or others of the Provinces, or extending beyond the Limits of the Province:

    (*b*) Lines of Steam Ships between the Province and any British or Foreign Country:

    (*c*) Such Works as, although wholly situate within the Province, are before or after their Execution declared by the Parliament of Canada to be for the general Advantage of Canada or for the Advantage of Two or more of the Provinces.

11. The Incorporation of Companies with Provincial Objects.

12. The Solemnization of Marriage in the Province.

13. Property and Civil Rights in the Province.

14. The Administration of Justice in the Province, including the Constitution, Maintenance, and Organization of Provincial Courts, both of Civil and of Criminal Jurisdiction, and including Procedure in Civil Matters in those Courts.

15. The Imposition of Punishment by Fine, Penalty, or Imprisonment for enforcing any Law of the Province made in relation to any Matter coming within any of the Classes of Subjects enumerated in this Section.

16. Generally all Matters of a merely local or private Nature in the Province.

NON-RENEWABLE NATURAL RESOURCES, FORESTRY RESOURCES AND ELECTRICAL ENERGY

Laws respecting non-renewable natural resources, forestry resources and electrical energy

**92A.** (1) In each province, the legislature may exclusively make laws in relation to

(*a*) exploration for non-renewable natural resources in the province;

(*b*) development, conservation and management of non-renewable natural resources and forestry resources in the province, including laws in relation to the rate of primary production therefrom; and

(*c*) development, conservation and management of sites and facilities in the province for the generation and production of electrical energy.

Export from provinces of resources

(2) In each province, the legislature may make laws in relation to the export from the province to another part of Canada of the primary production from non-renewable natural resources and forestry resources in the province and the production from facilities in the province for the generation of electrical energy, but such laws may not authorize or provide for discrimination in prices or in supplies exported to another part of Canada.

Authority of Parliament

(3) Nothing in subsection (2) derogates from the authority of Parliament to enact laws in relation to the matters referred to in that subsection and, where such a law of Parliament and a law of a province conflict, the law of Parliament prevails to the extent of the conflict.

Taxation of resources

(4) In each province, the legislature may make laws in relation to the raising of money by any mode or system of taxation in respect of

(*a*) non-renewable natural resources and forestry resources in the province and the primary production therefrom, and

(*b*) sites and facilities in the province for the generation of electrical energy and the production therefrom,

whether or not such production is exported in whole or in part from the province, but such laws may not authorize or provide for taxation that differentiates between production exported to another part of Canada and production not exported from the province.

"Primary production"

(5) The expression "primary production" has the meaning assigned by the Sixth Schedule.

Existing powers or rights

(6) Nothing in subsections (1) to (5) derogates from any powers or rights that a legislature or government of a province had immediately before the coming into force of this section. [49]

EDUCATION

Legislation respecting Education

**93.** In and for each Province the Legislature may exclusively make Laws in relation to Education, subject and according to the following Provisions:

(1) Nothing in any such Law shall prejudicially affect any Right or Privilege with respect to Denominational Schools which any Class of Persons have by Law in the Province at the Union;

(2) All the Powers, Privileges, and Duties at the Union by Law conferred and imposed in Upper Canada on the Separate Schools and School Trustees of the Queen's Roman Catholic Subjects shall be and the same are hereby extended to the Dissentient Schools of the Queen's Protestant and Roman Catholic Subjects in Quebec;

(3) Where in any Province a System of Separate or Dissentient Schools exists by Law at the Union or is thereafter established by the Legislature of the Province, an Appeal shall lie to the Governor General in Council from any Act or Decision of any Provincial Authority affecting any Right or Privilege of the Protestant or Roman Catholic Minority of the Queen's Subjects in relation to Education;

(4) In case any such Provincial Law as from Time to Time seems to the Governor General in Council requisite for the due Execution of the Provisions of this Section is not made, or in case any Decision of the Governor General in Council on any Appeal under this Section is not duly executed by the proper Provincial Authority in that Behalf, then and in every such Case, and as far only as the Circumstances of each Case require, the Parliament of Canada may make remedial Laws for the due Execution of the Provisions of this Section and of any Decision of the Governor General in Council under this Section. [50]

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**[49] Added by section 50 of the *Constitution Act, 1982*.**

**[50] Alternative provisions have been enacted for four provinces. For further details, see endnote 4.**

Quebec

**93A.** Paragraphs (1) to (4) of section 93 do not apply to Quebec. [51]

### Uniformity of Laws in Ontario, Nova Scotia, and New Brunswick

Legislation for Uniformity of Laws in Three Provinces

**94.** Notwithstanding anything in this Act, the Parliament of Canada may make Provision for the Uniformity of all or any of the Laws relative to Property and Civil Rights in Ontario, Nova Scotia, and New Brunswick, and of the Procedure of all or any of the Courts in those Three Provinces, and from and after the passing of any Act in that Behalf the Power of the Parliament of Canada to make Laws in relation to any Matter comprised in any such Act shall, notwithstanding anything in this Act, be unrestricted; but any Act of the Parliament of Canada making Provision for such Uniformity shall not have effect in any Province unless and until it is adopted and enacted as Law by the Legislature thereof.

### Old Age Pensions

Legislation respecting old age pensions and supplementary benefits

**94A.** The Parliament of Canada may make laws in relation to old age pensions and supplementary benefits, including survivors' and disability benefits irrespective of age, but no such law shall affect the operation of any law present or future of a provincial legislature in relation to any such matter. [52]

### Agriculture and Immigration

Concurrent Powers of Legislation respecting Agriculture, etc.

**95.** In each Province the Legislature may make Laws in relation to Agriculture in the Province, and to Immigration into the Province; and it is hereby declared that the Parliament of Canada may from Time to Time make Laws in relation to Agriculture in all or any of the Provinces, and to Immigration into all or any of the Provinces; and any Law of the Legislature of a Province relative to Agriculture or to Immigration shall have effect in and for the Province as long and as far only as it is not repugnant to any Act of the Parliament of Canada.

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**[51] Added by the *Constitution Amendment, 1997 (Quebec)* (*see* SI/97-141).**

**[52] Amended by the *Constitution Act, 1964*, 12-13 Eliz. II, c. 73 (U.K.). As originally enacted by the *British North America Act, 1951*, 14-15 Geo. VI, c. 32 (U.K.), which was repealed by the *Constitution Act, 1982*, section 94A read as follows:**

**94A.** It is hereby declared that the Parliament of Canada may from time to time make laws in relation to old age pensions in Canada, but no law made by the Parliament of Canada in relation to old age pensions shall affect the operation of any law present or future of a Provincial Legislature in relation to old age pensions.

## VII. JUDICATURE

Appointment of Judges

**96.** The Governor General shall appoint the Judges of the Superior, District, and County Courts in each Province, except those of the Courts of Probate in Nova Scotia and New Brunswick.

Selection of Judges in Ontario, etc.

**97.** Until the Laws relative to Property and Civil Rights in Ontario, Nova Scotia, and New Brunswick, and the Procedure of the Courts in those Provinces, are made uniform, the Judges of the Courts of those Provinces appointed by the Governor General shall be selected from the respective Bars of those Provinces.

Selection of Judges in Quebec

**98.** The Judges of the Courts of Quebec shall be selected from the Bar of that Province.

Tenure of office of Judges

**99.** (1) Subject to subsection (2) of this section, the judges of the superior courts shall hold office during good behaviour, but shall be removable by the Governor General on address of the Senate and House of Commons.

Termination at age 75

(2) A judge of a superior court, whether appointed before or after the coming into force of this section, shall cease to hold office upon attaining the age of seventy-five years, or upon the coming into force of this section if at that time he has already attained that age. **(53)**

Salaries, etc., of Judges

**100.** The Salaries, Allowances, and Pensions of the Judges of the Superior, District, and County Courts (except the Courts of Probate in Nova Scotia and New Brunswick), and of the Admiralty Courts in Cases where the Judges thereof are for the Time being paid by Salary, shall be fixed and provided by the Parliament of Canada. **(54)**

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**(53) Amended by the *Constitution Act, 1960*, 9 Eliz. II, c. 2 (U.K.), which came into force on March 1, 1961. The original section read as follows:**

**99.** The Judges of the Superior Courts shall hold Office during good Behaviour, but shall be removable by the Governor General on Address of the Senate and House of Commons.

**(54) Now provided for in the *Judges Act*, R.S.C. 1985, c. J-1.**

General Court of Appeal, etc.

**101.** The Parliament of Canada may, notwithstanding anything in this Act, from Time to Time provide for the Constitution, Maintenance, and Organization of a General Court of Appeal for Canada, and for the Establishment of any additional Courts for the better Administration of the Laws of Canada. **(55)**

## VIII. REVENUES; DEBTS; ASSETS; TAXATION

Creation of Consolidated Revenue Fund

**102.** All Duties and Revenues over which the respective Legislatures of Canada, Nova Scotia, and New Brunswick before and at the Union had and have Power of Appropriation, except such Portions thereof as are by this Act reserved to the respective Legislatures of the Provinces, or are raised by them in accordance with the special Powers conferred on them by this Act, shall form One Consolidated Revenue Fund, to be appropriated for the Public Service of Canada in the Manner and subject to the Charges in this Act provided.

Expenses of Collection, etc.

**103.** The Consolidated Revenue Fund of Canada shall be permanently charged with the Costs, Charges, and Expenses incident to the Collection, Management, and Receipt thereof, and the same shall form the First Charge thereon, subject to be reviewed and audited in such Manner as shall be ordered by the Governor General in Council until the Parliament otherwise provides.

Interest of Provincial Public Debts

**104.** The annual Interest of the Public Debts of the several Provinces of Canada, Nova Scotia, and New Brunswick at the Union shall form the Second Charge on the Consolidated Revenue Fund of Canada.

Salary of Governor General

**105.** Unless altered by the Parliament of Canada, the Salary of the Governor General shall be Ten thousand Pounds Sterling Money of the United Kingdom of Great Britain and Ireland, payable out of the Consolidated Revenue Fund of Canada, and the same shall form the Third Charge thereon. **(56)**

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**(55) See the *Supreme Court Act*, R.S.C. 1985, c. S-26, the *Federal Courts Act*, R.S.C. 1985, c. F-7 and the *Tax Court of Canada Act*, R.S.C. 1985, c. T-2.**

**(56) Now covered by the *Governor General's Act*, R.S.C. 1985, c. G-9.**

Appropriation from Time to Time

**106.** Subject to the several Payments by this Act charged on the Consolidated Revenue Fund of Canada, the same shall be appropriated by the Parliament of Canada for the Public Service.

Transfer of Stocks, etc.

**107.** All Stocks, Cash, Banker's Balances, and Securities for Money belonging to each Province at the Time of the Union, except as in this Act mentioned, shall be the Property of Canada, and shall be taken in Reduction of the Amount of the respective Debts of the Provinces at the Union.

Transfer of Property in Schedule

**108.** The Public Works and Property of each Province, enumerated in the Third Schedule to this Act, shall be the Property of Canada.

Property in Lands, Mines, etc.

**109.** All Lands, Mines, Minerals, and Royalties belonging to the several Provinces of Canada, Nova Scotia, and New Brunswick at the Union, and all Sums then due or payable for such Lands, Mines, Minerals, or Royalties, shall belong to the several Provinces of Ontario, Quebec, Nova Scotia, and New Brunswick in which the same are situate or arise, subject to any Trusts existing in respect thereof, and to any Interest other than that of the Province in the same. [(57)]

Assets connected with Provincial Debts

**110.** All Assets connected with such Portions of the Public Debt of each Province as are assumed by that Province shall belong to that Province.

Canada to be liable for Provincial Debts

**111.** Canada shall be liable for the Debts and Liabilities of each Province existing at the Union.

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**[(57)] Manitoba, Alberta and Saskatchewan were placed in the same position as the original provinces by the *Constitution Act, 1930*, 20-21 Geo. V, c. 26 (U.K.).**

**These matters were dealt with in respect of British Columbia by the *British Columbia Terms of Union* and also in part by the *Constitution Act, 1930*.**

**Newfoundland was also placed in the same position by the *Newfoundland Act*, 12-13 Geo. V1, c. 22 (U.K.).**

**With respect to Prince Edward Island, see the Schedule to the *Prince Edward Island Terms of Union*.**

Debts of Ontario and Quebec

**112.** Ontario and Quebec conjointly shall be liable to Canada for the Amount (if any) by which the Debt of the Province of Canada exceeds at the Union Sixty-two million five hundred thousand Dollars, and shall be charged with Interest at the Rate of Five per Centum per Annum thereon.

Assets of Ontario and Quebec

**113.** The Assets enumerated in the Fourth Schedule to this Act belonging at the Union to the Province of Canada shall be the Property of Ontario and Quebec conjointly.

Debt of Nova Scotia

**114.** Nova Scotia shall be liable to Canada for the Amount (if any) by which its Public Debt exceeds at the Union Eight million Dollars, and shall be charged with Interest at the Rate of Five per Centum per Annum thereon. **(58)**

Debt of New Brunswick

**115.** New Brunswick shall be liable to Canada for the Amount (if any) by which its Public Debt exceeds at the Union Seven million Dollars, and shall be charged with Interest at the Rate of Five per Centum per Annum thereon.

Payment of interest to Nova Scotia and New Brunswick

**116.** In case the Public Debts of Nova Scotia and New Brunswick do not at the Union amount to Eight million and Seven million Dollars respectively, they shall respectively receive by half-yearly Payments in advance from the Government of Canada Interest at Five per Centum per Annum on the Difference between the actual Amounts of their respective Debts and such stipulated Amounts.

Provincial Public Property

**117.** The several Provinces shall retain all their respective Public Property not otherwise disposed of in this Act, subject to the Right of Canada to assume any Lands or Public Property required for Fortifications or for the Defence of the Country.

**118.** Repealed. **(59)**

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**(58) The obligations imposed by sections 114, 115 and 116, and similar obligations under the instruments creating or admitting other provinces, are now to be found in the *Provincial Subsidies Act*, R.S.C. 1985, c. P-26.**

**(59) Repealed by the *Statute Law Revision Act, 1950*, 14 Geo. VI, c. 6 (U.K.). For further details, see endnote 5.**

Further Grant to New Brunswick

**119.** New Brunswick shall receive by half-yearly Payments in advance from Canada for the Period of Ten Years from the Union an additional Allowance of Sixty-three thousand Dollars per Annum; but as long as the Public Debt of that Province remains under Seven million Dollars, a Deduction equal to the Interest at Five per Centum per Annum on such Deficiency shall be made from that Allowance of Sixty-three thousand Dollars. **(60)**

Form of Payments

**120.** All Payments to be made under this Act, or in discharge of Liabilities created under any Act of the Provinces of Canada, Nova Scotia, and New Brunswick respectively, and assumed by Canada, shall, until the Parliament of Canada otherwise directs, be made in such Form and Manner as may from Time to Time be ordered by the Governor General in Council.

Canadian Manufactures, etc.

**121.** All Articles of the Growth, Produce, or Manufacture of any one of the Provinces shall, from and after the Union, be admitted free into each of the other Provinces.

Continuance of Customs and Excise Laws

**122.** The Customs and Excise Laws of each Province shall, subject to the Provisions of this Act, continue in force until altered by the Parliament of Canada. **(61)**

Exportation and Importation as between Two Provinces

**123.** Where Customs Duties are, at the Union, leviable on any Goods, Wares, or Merchandises in any Two Provinces, those Goods, Wares, and Merchandises may, from and after the Union, be imported from one of those Provinces into the other of them on Proof of Payment of the Customs Duty leviable thereon in the Province of Exportation, and on Payment of such further Amount (if any) of Customs Duty as is leviable thereon in the Province of Importation. **(62)**

Lumber Dues in New Brunswick

**124.** Nothing in this Act shall affect the Right of New Brunswick to levy the Lumber Dues provided in Chapter Fifteen of Title Three of the Revised Statutes of

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**(60) Spent.**

**(61) Spent. Now covered by the *Customs Act*, R.S.C. 1985, c. 1 (2nd Supp.), the *Customs Tariff*, S.C. 1997, c. 36, the *Excise Act*, R.S.C. 1985, c. E-14, the *Excise Act, 2001*, S.C. 2002, c. 22 and the *Excise Tax Act*, R.S.C. 1985, c. E-15.**

**(62) Spent.**

New Brunswick, or in any Act amending that Act before or after the Union, and not increasing the Amount of such Dues; but the Lumber of any of the Provinces other than New Brunswick shall not be subject to such Dues. [(63)]

Exemption of Public Lands, etc.

**125.** No Lands or Property belonging to Canada or any Province shall be liable to Taxation.

Provincial Consolidated Revenue Fund

**126.** Such Portions of the Duties and Revenues over which the respective Legislatures of Canada, Nova Scotia, and New Brunswick had before the Union Power of Appropriation as are by this Act reserved to the respective Governments or Legislatures of the Provinces, and all Duties and Revenues raised by them in accordance with the special Powers conferred upon them by this Act, shall in each Province form One Consolidated Revenue Fund to be appropriated for the Public Service of the Province.

## IX. MISCELLANEOUS PROVISIONS

### General

**127.** Repealed. [(64)]

Oath of Allegiance, etc.

**128.** Every Member of the Senate or House of Commons of Canada shall before taking his Seat therein take and subscribe before the Governor General or some Person authorized by him, and every Member of a Legislative Council or Legislative Assembly of any Province shall before taking his Seat therein take and subscribe before the Lieutenant Governor of the Province or some Person authorized by him, the Oath of Allegiance contained in the Fifth Schedule to this Act; and every Member of the Senate of Canada and every Member of the Legislative Council of Quebec shall also, before taking his Seat therein, take and subscribe before the Gover-

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**[(63)] These dues were repealed in 1873 by 36 Vict., c. 16 (N.B.). Also, see *An Act respecting the Export Duties imposed on Lumber*, etc. (1873) 36 Vict., c. 41 (Canada), and section 2 of the *Provincial Subsidies Act*, R.S.C. 1985, c. P-26.**

**[(64)] Repealed by the *Statute Law Revision Act, 1893*, 56-57 Vict., c. 14 (U.K.). The section read as follows:**

> **127.** If any Person being at the passing of this Act a Member of the Legislative Council of Canada, Nova Scotia, or New Brunswick, to whom a Place in the Senate is offered, does not within Thirty Days thereafter, by Writing under his Hand addressed to the Governor General of the Province of Canada or to the Lieutenant Governor of Nova Scotia or New Brunswick (as the Case may be), accept the same, he shall be deemed to have declined the same; and any Person who, being at the passing of this Act a Member of the Legislative Council of Nova Scotia or New Brunswick, accepts a Place in the Senate shall thereby vacate his Seat in such Legislative Council.

nor General, or some Person authorized by him, the Declaration of Qualification contained in the same Schedule.

Continuance of existing Laws, Courts, Officers, etc.

**129.** Except as otherwise provided by this Act, all Laws in force in Canada, Nova Scotia, or New Brunswick at the Union, and all Courts of Civil and Criminal Jurisdiction, and all legal Commissions, Powers, and Authorities, and all Officers, Judicial, Administrative, and Ministerial, existing therein at the Union, shall continue in Ontario, Quebec, Nova Scotia, and New Brunswick respectively, as if the Union had not been made; subject nevertheless (except with respect to such as are enacted by or exist under Acts of the Parliament of Great Britain or of the Parliament of the United Kingdom of Great Britain and Ireland,) to be repealed, abolished, or altered by the Parliament of Canada, or by the Legislature of the respective Province, according to the Authority of the Parliament or of that Legislature under this Act. **(65)**

Transfer of Officers to Canada

**130.** Until the Parliament of Canada otherwise provides, all Officers of the several Provinces having Duties to discharge in relation to Matters other than those coming within the Classes of Subjects by this Act assigned exclusively to the Legislatures of the Provinces shall be Officers of Canada, and shall continue to discharge the Duties of their respective Offices under the same Liabilities, Responsibilities, and Penalties as if the Union had not been made. **(66)**

Appointment of new Officers

**131.** Until the Parliament of Canada otherwise provides, the Governor General in Council may from Time to Time appoint such Officers as the Governor General in Council deems necessary or proper for the effectual Execution of this Act.

Treaty Obligations

**132.** The Parliament and Government of Canada shall have all Powers necessary or proper for performing the Obligations of Canada or of any Province thereof, as Part of the British Empire, towards Foreign Countries, arising under Treaties between the Empire and such Foreign Countries.

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**(65) The restriction against altering or repealing laws enacted by or existing under statutes of the United Kingdom was removed by the *Statute of Westminster, 1931*, 22 Geo. V, c. 4 (U.K.), except in respect of certain constitutional documents. Comprehensive procedures for amending enactments forming part of the Constitution of Canada were provided by Part V of the *Constitution Act, 1982*.**

**(66) Spent.**

Use of English and French Languages

**133.** Either the English or the French Language may be used by any Person in the Debates of the Houses of the Parliament of Canada and of the Houses of the Legislature of Quebec; and both those Languages shall be used in the respective Records and Journals of those Houses; and either of those Languages may be used by any Person or in any Pleading or Process in or issuing from any Court of Canada established under this Act, and in or from all or any of the Courts of Quebec.

The Acts of the Parliament of Canada and of the Legislature of Quebec shall be printed and published in both those Languages. [(67)]

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**[(67)] A similar provision was enacted for Manitoba by section 23 of the *Manitoba Act, 1870*, 33 Vict., c. 3 (confirmed by the *Constitution Act, 1871*, 34-35 Vict., c. 28 (U.K.)). Section 23 reads as follows:**

> **23.** Either the English or the French language may be used by any person in the debates of the Houses of the Legislature, and both these languages shall be used in the respective Records and Journals of those Houses; and either of those languages may be used by any person, or in any Pleading or Process, in or issuing from any Court of Canada established under the British North America Act, 1867, or in or from all or any of the Courts of the Province. The Acts of the Legislature shall be printed and published in both those languages.

**Sections 17 to 19 of the *Constitution Act, 1982* restate the language rights set out in section 133 in respect of Parliament and the courts established under the *Constitution Act, 1867*, and also guarantee those rights in respect of the legislature of New Brunswick and the courts of that province.**

**Sections 16, 20, 21 and 23 of the *Constitution Act, 1982* recognize additional language rights in respect of the English and French languages. Section 22 preserves language rights and privileges of languages other than English and French.**

ONTARIO AND QUEBEC

Appointment of Executive Officers for Ontario and Quebec

**134.** Until the Legislature of Ontario or of Quebec otherwise provides, the Lieutenant Governors of Ontario and Quebec may each appoint under the Great Seal of the Province the following Officers, to hold Office during Pleasure, that is to say, — the Attorney General, the Secretary and Registrar of the Province, the Treasurer of the Province, the Commissioner of Crown Lands, and the Commissioner of Agriculture and Public Works, and in the Case of Quebec the Solicitor General, and may, by Order of the Lieutenant Governor in Council, from Time to Time prescribe the Duties of those Officers, and of the several Departments over which they shall preside or to which they shall belong, and of the Officers and Clerks thereof, and may also appoint other and additional Officers to hold Office during Pleasure, and may from Time to Time prescribe the Duties of those Officers, and of the several Departments over which they shall preside or to which they shall belong, and of the Officers and Clerks thereof. **(68)**

Powers, Duties, etc. of Executive Officers

**135.** Until the Legislature of Ontario or Quebec otherwise provides, all Rights, Powers, Duties, Functions, Responsibilities, or Authorities at the passing of this Act vested in or imposed on the Attorney General, Solicitor General, Secretary and Registrar of the Province of Canada, Minister of Finance, Commissioner of Crown Lands, Commissioner of Public Works, and Minister of Agriculture and Receiver General, by any Law, Statute, or Ordinance of Upper Canada, Lower Canada, or Canada, and not repugnant to this Act, shall be vested in or imposed on any Officer to be appointed by the Lieutenant Governor for the Discharge of the same or any of them; and the Commissioner of Agriculture and Public Works shall perform the Duties and Functions of the Office of Minister of Agriculture at the passing of this Act imposed by the Law of the Province of Canada, as well as those of the Commissioner of Public Works. **(69)**

Great Seals

**136.** Until altered by the Lieutenant Governor in Council, the Great Seals of Ontario and Quebec respectively shall be the same, or of the same Design, as those used in the Provinces of Upper Canada and Lower Canada respectively before their Union as the Province of Canada.

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**(68) Spent. Now covered in Ontario by the *Executive Council Act*, R.S.O. 1990, c. E.25 and in Quebec by the *Executive Power Act*, R.S.Q. c. E-18.**

**(69) Probably spent.**

Construction of temporary Acts

**137.** The words "and from thence to the End of the then next ensuing Session of the Legislature," or Words to the same Effect, used in any temporary Act of the Province of Canada not expired before the Union, shall be construed to extend and apply to the next Session of the Parliament of Canada if the Subject Matter of the Act is within the Powers of the same as defined by this Act, or to the next Sessions of the Legislatures of Ontario and Quebec respectively if the Subject Matter of the Act is within the Powers of the same as defined by this Act.

As to Errors in Names

**138.** From and after the Union the Use of the Words "Upper Canada" instead of "Ontario," or "Lower Canada" instead of "Quebec," in any Deed, Writ, Process, Pleading, Document, Matter, or Thing shall not invalidate the same.

As to issue of Proclamations before Union, to commence after Union

**139.** Any Proclamation under the Great Seal of the Province of Canada issued before the Union to take effect at a Time which is subsequent to the Union, whether relating to that Province, or to Upper Canada, or to Lower Canada, and the several Matters and Things therein proclaimed, shall be and continue of like Force and Effect as if the Union had not been made. **(70)**

As to issue of Proclamations after Union

**140.** Any Proclamation which is authorized by any Act of the Legislature of the Province of Canada to be issued under the Great Seal of the Province of Canada, whether relating to that Province, or to Upper Canada, or to Lower Canada, and which is not issued before the Union, may be issued by the Lieutenant Governor of Ontario or of Quebec, as its Subject Matter requires, under the Great Seal thereof; and from and after the Issue of such Proclamation the same and the several Matters and Things therein proclaimed shall be and continue of the like Force and Effect in Ontario or Quebec as if the Union had not been made. **(71)**

Penitentiary

**141.** The Penitentiary of the Province of Canada shall, until the Parliament of Canada otherwise provides, be and continue the Penitentiary of Ontario and of Quebec. **(72)**

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**(70) Probably spent.**

**(71) Probably spent.**

**(72) Spent. Penitentiaries are now provided for by the *Corrections and Conditional Release Act*, S.C. 1992, c. 20.**

Arbitration respecting Debts, etc.

**142.** The Division and Adjustment of the Debts, Credits, Liabilities, Properties, and Assets of Upper Canada and Lower Canada shall be referred to the Arbitrament of Three Arbitrators, One chosen by the Government of Ontario, One by the Government of Quebec, and One by the Government of Canada; and the Selection of the Arbitrators shall not be made until the Parliament of Canada and the Legislatures of Ontario and Quebec have met; and the Arbitrator chosen by the Government of Canada shall not be a Resident either in Ontario or in Quebec. [(73)]

Division of Records

**143.** The Governor General in Council may from Time to Time order that such and so many of the Records, Books, and Documents of the Province of Canada as he thinks fit shall be appropriated and delivered either to Ontario or to Quebec, and the same shall thenceforth be the Property of that Province; and any Copy thereof or Extract therefrom, duly certified by the Officer having charge of the Original thereof, shall be admitted as Evidence. [(74)]

Constitution of Townships in Quebec

**144.** The Lieutenant Governor of Quebec may from Time to Time, by Proclamation under the Great Seal of the Province, to take effect from a Day to be appointed therein, constitute Townships in those Parts of the Province of Quebec in which Townships are not then already constituted, and fix the Metes and Bounds thereof.

## X. INTERCOLONIAL RAILWAY

**145.** Repealed. [(75)]

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**[(73)] Spent. See pages (xi) and (xii) of the Public Accounts, 1902-1903.**

**[(74)] Probably spent. Two orders were made under this section on January 24, 1868.**

**[(75)] Repealed by the *Statute Law Revision Act, 1893*, 56-57 Vict., c. 14, (U.K.). The section read as follows:**

**145.** Inasmuch as the Provinces of Canada, Nova Scotia, and New Brunswick have joined in a Declaration that the Construction of the Intercolonial Railway is essential to the Consolidation of the Union of British North America, and to the Assent thereto of Nova Scotia and New Brunswick, and have consequently agreed that Provision should be made for its immediate Construction by the Government of Canada; Therefore, in order to give effect to that Agreement, it shall be the Duty of the Government and Parliament of Canada to provide for the Commencement, within Six Months after the Union, of a Railway connecting the River St. Lawrence with the City of Halifax in Nova Scotia, and for the Construction thereof without Intermission, and the Completion thereof with all practicable Speed.

## XI. ADMISSION OF OTHER COLONIES

Power to admit Newfoundland, etc., into the Union

**146.** It shall be lawful for the Queen, by and with the Advice of Her Majesty's Most Honourable Privy Council, on Addresses from the Houses of the Parliament of Canada, and from the Houses of the respective Legislatures of the Colonies or Provinces of Newfoundland, Prince Edward Island, and British Columbia, to admit those Colonies or Provinces, or any of them, into the Union, and on Address from the Houses of the Parliament of Canada to admit Rupert's Land and the North-western Territory, or either of them, into the Union, on such Terms and Conditions in each Case as are in the Addresses expressed and as the Queen thinks fit to approve, subject to the Provisions of this Act; and the Provisions of any Order in Council in that Behalf shall have effect as if they had been enacted by the Parliament of the United Kingdom of Great Britain and Ireland. **(76)**

As to Representation of Newfoundland and Prince Edward Island in Senate

**147.** In case of the Admission of Newfoundland and Prince Edward Island, or either of them, each shall be entitled to a Representation in the Senate of Canada of Four Members, and (notwithstanding anything in this Act) in case of the Admission of Newfoundland the normal Number of Senators shall be Seventy-six and their maximum Number shall be Eighty-two; but Prince Edward Island when admitted shall be deemed to be comprised in the third of the Three Divisions into which Canada is, in relation to the Constitution of the Senate, divided by this Act, and accordingly, after the Admission of Prince Edward Island, whether Newfoundland is admitted or not, the Representation of Nova Scotia and New Brunswick in the Senate shall, as Vacancies occur, be reduced from Twelve to Ten Members respectively, and the Representation of each of those Provinces shall not be increased at any Time beyond Ten, except under the Provisions of this Act for the Appointment of Three or Six additional Senators under the Direction of the Queen. **(77)**

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**(76) All territories mentioned in section 146 are now part of Canada. See footnote (6) to section 5, above.**

**(77) Spent. See footnotes (11), (12), (15), (16) and (17) to sections 21, 22, 26, 27 and 28, above.**

## THE FIRST SCHEDULE [(78)]

## ELECTORAL DISTRICTS OF ONTARIO

### A. Existing Electoral Divisions.

*Counties*

1. Prescott.
2. Glengarry.
3. Stormont.
4. Dundas.
5. Russell.
6. Carleton.
7. Prince Edward.
8. Halton.
9. Essex.

*Ridings of Counties*

10. North Riding of Lanark.
11. South Riding of Lanark.
12. North Riding of Leeds and North Riding of Grenville.
13. South Riding of Leeds.
14. South Riding of Grenville.
15. East Riding of Northumberland.
16. West Riding of Northumberland (excepting therefrom the Township of South Monaghan).
17. East Riding of Durham.
18. West Riding of Durham.
19. North Riding of Ontario.
20. South Riding of Ontario.
21. East Riding of York.
22. West Riding of York.
23. North Riding of York.
24. North Riding of Wentworth.
25. South Riding of Wentworth.
26. East Riding of Elgin.
27. West Riding of Elgin.
28. North Riding of Waterloo.
29. South Riding of Waterloo.
30. North Riding of Brant.
31. South Riding of Brant.

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**[(78)] Spent. See *Representation Act*, R.S.O. 1990, c. R.26.**

32. North Riding of Oxford.
33. South Riding of Oxford.
34. East Riding of Middlesex.

*Cities, Parts of Cities, and Towns*

35. West Toronto.
36. East Toronto.
37. Hamilton.
38. Ottawa.
39. Kingston.
40. London.
41. Town of Brockville, with the Township of Elizabethtown thereto attached.
42. Town of Niagara, with the Township of Niagara thereto attached.
43. Town of Cornwall, with the Township of Cornwall thereto attached.

B. New Electoral Divisions

44. The Provisional Judicial District of Algoma.

The County of Bruce, divided into Two Ridings, to be called respectively the North and South Ridings:

45. The North Riding of Bruce to consist of the Townships of Bury, Lindsay, Eastnor, Albermarle, Amable, Arran, Bruce, Elderslie, and Saugeen, and the Village of Southampton.
46. The South Riding of Bruce to consist of the Townships of Kincardine (including the Village of Kincardine), Greenock, Brant, Huron, Kinloss, Culross, and Carrick.

The County of Huron, divided into Two Ridings, to be called respectively the North and South Ridings:

47. The North Riding to consist of the Townships of Ashfield, Wawanosh, Turnberry, Howick, Morris, Grey, Colborne, Hullett, including the Village of Clinton, and McKillop.
48. The South Riding to consist of the Town of Goderich and the Townships of Goderich, Tuckersmith, Stanley, Hay, Usborne, and Stephen.

The County of Middlesex, divided into three Ridings, to be called respectively the North, West, and East Ridings:

49. The North Riding to consist of the Townships of McGillivray and Biddulph (taken from the County of Huron), and Williams East, Williams West, Adelaide, and Lobo.
50. The West Riding to consist of the Townships of Delaware, Carradoc, Metcalfe, Mosa and Ekfrid, and the Village of Strathroy.

[The East Riding to consist of the Townships now embraced therein, and be bounded as it is at present.]

51. The County of LAMBTON to consist of the Townships of Bosanquet, Warwick, Plympton, Sarnia, Moore, Enniskillen, and Brooke, and the Town of Sarnia.
52. The County of KENT to consist of the Townships of Chatham, Dover, East Tilbury, Romney, Raleigh, and Harwich, and the Town of Chatham.
53. The County of BOTHWELL to consist of the Townships of Sombra, Dawn, and Euphemia (taken from the County of Lambton), and the Townships of Zone, Camden with the Gore thereof, Orford, and Howard (taken from the County of Kent).

The County of GREY divided into Two Ridings to be called respectively the South and North Ridings:

54. The South Riding to consist of the Townships of Bentinck, Glenelg, Artemesia, Osprey, Normanby, Egremont, Proton, and Melancthon.
55. The North Riding to consist of the Townships of Collingwood, Euphrasia, Holland, Saint-Vincent, Sydenham, Sullivan, Derby, and Keppel, Sarawak and Brooke, and the Town of Owen Sound.

The County of PERTH divided into Two Ridings, to be called respectively the South and North Ridings:

56. The North Riding to consist of the Townships of Wallace, Elma, Logan, Ellice, Mornington, and North Easthope, and the Town of Stratford.
57. The South Riding to consist of the Townships of Blanchard, Downie, South Easthope, Fullarton, Hibbert, and the Villages of Mitchell and Ste. Marys.

The County of WELLINGTON divided into Three Ridings to be called respectively North, South and Centre Ridings:

58. The North Riding to consist of the Townships of Amaranth, Arthur, Luther, Minto, Maryborough, Peel, and the Village of Mount Forest.
59. The Centre Riding to consist of the Townships of Garafraxa, Erin, Eramosa, Nichol, and Pilkington, and the Villages of Fergus and Elora.
60. The South Riding to consist of the Town of Guelph, and the Townships of Guelph and Puslinch.

The County of NORFOLK, divided into Two Ridings, to be called respectively the South and North Ridings:

61. The South Riding to consist of the Townships of Charlotteville, Houghton, Walsingham, and Woodhouse, and with the Gore thereof.
62. The North Riding to consist of the Townships of Middleton, Townsend, and Windham, and the Town of Simcoe.

63. The County of HALDIMAND to consist of the Townships of Oneida, Seneca, Cayuga North, Cayuga South, Raynham, Walpole, and Dunn.
64. The County of MONCK to consist of the Townships of Canborough and Moulton, and Sherbrooke, and the Village of Dunnville (taken from the County of Haldimand), the Townships of Caister and Gainsborough (taken from the County of Lincoln), and the Townships of Pelham and Wainfleet (taken from the County of Welland).
65. The County of LINCOLN to consist of the Townships of Clinton, Grantham, Grimsby, and Louth, and the Town of St. Catherines.
66. The County of WELLAND to consist of the Townships of Bertie, Crowland, Humberstone, Stamford, Thorold, and Willoughby, and the Villages of Chippewa, Clifton, Fort Erie, Thorold, and Welland.
67. The County of PEEL to consist of the Townships of Chinguacousy, Toronto, and the Gore of Toronto, and the Villages of Brampton and Streetsville.
68. The County of CARDWELL to consist of the Townships of Albion and Caledon (taken from the County of Peel), and the Townships of Adjala and Mono (taken from the County of Simcoe).

The County of SIMCOE, divided into Two Ridings, to be called respectively the South and North Ridings:

69. The South Riding to consist of the Townships of West Gwillimbury, Tecumseth, Innisfil, Essa, Tosorontio, Mulmur, and the Village of Bradford.
70. The North Riding to consist of the Townships of Nottawasaga, Sunnidale, Vespra, Flos, Oro, Medonte, Orillia and Matchedash, Tiny and Tay, Balaklava and Robinson, and the Towns of Barrie and Collingwood.

The County of VICTORIA, divided into Two Ridings, to be called respectively the South and North Ridings:

71. The South Riding to consist of the Townships of Ops, Mariposa, Emily, Verulam, and the Town of Lindsay.
72. The North Riding to consist of the Townships of Anson, Bexley, Carden, Dalton, Digby, Eldon, Fenelon, Hindon, Laxton, Lutterworth, Macaulay and Draper, Sommerville, and Morrison, Muskoka, Monck and Watt (taken from the County of Simcoe), and any other surveyed Townships lying to the North of the said North Riding.

The County of PETERBOROUGH, divided into Two Ridings, to be called respectively the West and East Ridings:

73. The West Riding to consist of the Townships of South Monaghan (taken from the County of Northumberland), North Monaghan, Smith, and Ennismore, and the Town of Peterborough.
74. The East Riding to consist of the Townships of Asphodel, Belmont and Methuen, Douro, Dummer, Galway, Harvey, Minden, Stanhope and Dysart,

Otonabee, and Snowden, and the Village of Ashburnham, and any other surveyed Townships lying to the North of the said East Riding.

The County of HASTINGS, divided into Three Ridings, to be called respectively the West, East, and North Ridings:

75. The West Riding to consist of the Town of Belleville, the Township of Sydney, and the Village of Trenton.
76. The East Riding to consist of the Townships of Thurlow, Tyendinaga, and Hungerford.
77. The North Riding to consist of the Townships of Rawdon, Huntingdon, Madoc, Elzevir, Tudor, Marmora, and Lake, and the Village of Stirling, and any other surveyed Townships lying to the North of the said North Riding.
78. The County of LENNOX to consist of the Townships of Richmond, Adolphustown, North Fredericksburg, South Fredericksburg, Ernest Town, and Amherst Island, and the Village of Napanee.
79. The County of ADDINGTON to consist of the Townships of Camden, Portland, Sheffield, Hinchinbrooke, Kaladar, Kennebec, Olden, Oso, Anglesea, Barrie, Clarendon, Palmerston, Effingham, Abinger, Miller, Canonto, Denbigh, Loughborough, and Bedford.
80. The County of FRONTENAC to consist of the Townships of Kingston, Wolfe Island, Pittsburg and Howe Island, and Storrington.

The County of RENFREW, divided into Two Ridings, to be called respectively the South and North Ridings:

81. The South Riding to consist of the Townships of McNab, Bagot, Blithfield, Brougham, Horton, Admaston, Grattan, Matawatchan, Griffith, Lyndoch, Raglan, Radcliffe, Brudenell, Sebastopol, and the Villages of Arnprior and Renfrew.
82. The North Riding to consist of the Townships of Ross, Bromley, Westmeath, Stafford, Pembroke, Wilberforce, Alice, Petawawa, Buchanan, South Algona, North Algona, Fraser, McKay, Wylie, Rolph, Head, Maria, Clara, Haggerty, Sherwood, Burns, and Richards, and any other surveyed Townships lying North-westerly of the said North Riding.

Every Town and incorporated Village existing at the Union, not especially mentioned in this Schedule, is to be taken as Part of the County or Riding within which it is locally situate.

## THE SECOND SCHEDULE

## ELECTORAL DISTRICTS OF QUEBEC SPECIALLY FIXED

COUNTIES OF —

Pontiac.
Ottawa.
Argenteuil.
Huntingdon.
Missisquoi.
Brome.
Shefford.
Stanstead.
Compton.
Wolfe and Richmond.
Megantic.

Town of Sherbrooke.

## THE THIRD SCHEDULE

## PROVINCIAL PUBLIC WORKS AND PROPERTY TO BE THE PROPERTY OF CANADA

1. Canals, with Lands and Water Power connected therewith.
2. Public Harbours.
3. Lighthouses and Piers, and Sable Island.
4. Steamboats, Dredges, and public Vessels.
5. Rivers and Lake Improvements.
6. Railways and Railway Stocks, Mortgages, and other Debts due by Railway Companies.
7. Military Roads.
8. Custom Houses, Post Offices, and all other Public Buildings, except such as the Government of Canada appropriate for the Use of the Provincial Legislatures and Governments.
9. Property transferred by the Imperial Government, and known as Ordnance Property.
10. Armouries, Drill Sheds, Military Clothing, and Munitions of War, and Lands set apart for general Public Purposes.

## THE FOURTH SCHEDULE

## ASSETS TO BE THE PROPERTY OF ONTARIO AND QUEBEC CONJOINTLY

Upper Canada Building Fund.
Lunatic Asylums.
Normal School.
Court Houses in
Aylmer,
Montreal,
Kamouraska,
} Lower Canada.
Law Society, Upper Canada.
Montreal Turnpike Trust.
University Permanent Fund.
Royal Institution.
Consolidated Municipal Loan Fund, Upper Canada.
Consolidated Municipal Loan Fund, Lower Canada.
Agricultural Society, Upper Canada.
Lower Canada Legislative Grant.
Quebec Fire Loan.
Temiscouata Advance Account.
Quebec Turnpike Trust.
Education — East.
Building and Jury Fund, Lower Canada.
Municipalities Fund.
Lower Canada Superior Education Income Fund.

## THE FIFTH SCHEDULE

## OATH OF ALLEGIANCE

I *A.B.* do swear, That I will be faithful and bear true Allegiance to Her Majesty Queen Victoria.

*Note. — The Name of the King or Queen of the United Kingdom of Great Britain and Ireland for the Time being is to be substituted from Time to Time, with proper Terms of Reference thereto.*

## DECLARATION OF QUALIFICATION

I *A.B.* do declare and testify, That I am by Law duly qualified to be appointed a Member of the Senate of Canada [*or as the Case may be*], and that I am legally or equitably seised as of Freehold for my own Use and Benefit of Lands or Tenements held in Free and Common Socage [*or* seised or possessed for my own Use and Benefit of Lands or Tenements held in Franc-alleu or in Roture (*as the Case may be*),] in the Province of Nova Scotia [*or as the Case may be*] of the Value of Four thousand Dollars over and above all Rents, Dues, Debts, Mortgages, Charges, and In-

cumbrances due or payable out of or charged on or affecting the same, and that I have not collusively or colourably obtained a Title to or become possessed of the said Lands and Tenements or any Part thereof for the Purpose of enabling me to become a Member of the Senate of Canada [*or as the Case may be*], and that my Real and Personal Property are together worth Four thousand Dollars over and above my Debts and Liabilities.

## THE SIXTH SCHEDULE [(79)]

## PRIMARY PRODUCTION FROM NON-RENEWABLE NATURAL RESOURCES AND FORESTRY RESOURCES

1. For the purposes of section 92A of this Act,

(*a*) production from a non-renewable natural resource is primary production therefrom if

(i) it is in the form in which it exists upon its recovery or severance from its natural state, or

(ii) it is a product resulting from processing or refining the resource, and is not a manufactured product or a product resulting from refining crude oil, refining upgraded heavy crude oil, refining gases or liquids derived from coal or refining a synthetic equivalent of crude oil; and

(*b*) production from a forestry resource is primary production therefrom if it consists of sawlogs, poles, lumber, wood chips, sawdust or any other primary wood product, or wood pulp, and is not a product manufactured from wood.

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**[(79)] As enacted by section 51 of the *Constitution Act, 1982*.**

# CONSTITUTION ACT, 1982 [80]

## PART I

## CANADIAN CHARTER OF RIGHTS AND FREEDOMS

Whereas Canada is founded upon principles that recognize the supremacy of God and the rule of law:

### Guarantee of Rights and Freedoms

Rights and freedoms in Canada

**1.** The *Canadian Charter of Rights and Freedoms* guarantees the rights and freedoms set out in it subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society.

### Fundamental Freedoms

Fundamental freedoms

**2.** Everyone has the following fundamental freedoms:

(*a*) freedom of conscience and religion;

(*b*) freedom of thought, belief, opinion and expression, including freedom of the press and other media of communication;

(*c*) freedom of peaceful assembly; and

(*d*) freedom of association.

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**[80] Enacted as Schedule B to the *Canada Act 1982*, 1982, c. 11 (U.K.), which came into force on April 17, 1982. The *Canada Act 1982*, other than Schedules A and B thereto, reads as follows:**

An Act to give effect to a request by the Senate and House of Commons of Canada

Whereas Canada has requested and consented to the enactment of an Act of the Parliament of the United Kingdom to give effect to the provisions hereinafter set forth and the Senate and the House of Commons of Canada in Parliament assembled have submitted an address to Her Majesty requesting that Her Majesty may graciously be pleased to cause a Bill to be laid before the Parliament of the United Kingdom for that purpose.

Be it therefore enacted by the Queen's Most Excellent Majesty, by and with the advice and consent of the Lords Spiritual and Temporal, and Commons, in this present Parliament assembled, and by the authority of the same, as follows:

**1.** The *Constitution Act, 1982* set out in Schedule B to this Act is hereby enacted for and shall have the force of law in Canada and shall come into force as provided in that Act.

**2.** No Act of the Parliament of the United Kingdom passed after the *Constitution Act, 1982* comes into force shall extend to Canada as part of its law.

**3.** So far as it is not contained in Schedule B, the French version of this Act is set out in Schedule A to this Act and has the same authority in Canada as the English version thereof.

**4.** This Act may be cited as the *Canada Act 1982*.

## Democratic Rights

Democratic rights of citizens

**3.** Every citizen of Canada has the right to vote in an election of members of the House of Commons or of a legislative assembly and to be qualified for membership therein.

Maximum duration of legislative bodies

**4.** (1) No House of Commons and no legislative assembly shall continue for longer than five years from the date fixed for the return of the writs at a general election of its members. **(81)**

Continuation in special circumstances

(2) In time of real or apprehended war, invasion or insurrection, a House of Commons may be continued by Parliament and a legislative assembly may be continued by the legislature beyond five years if such continuation is not opposed by the votes of more than one-third of the members of the House of Commons or the legislative assembly, as the case may be. **(82)**

Annual sitting of legislative bodies

**5.** There shall be a sitting of Parliament and of each legislature at least once every twelve months. **(83)**

## Mobility Rights

Mobility of citizens

**6.** (1) Every citizen of Canada has the right to enter, remain in and leave Canada.

Rights to move and gain livelihood

(2) Every citizen of Canada and every person who has the status of a permanent resident of Canada has the right

(*a*) to move to and take up residence in any province; and

(*b*) to pursue the gaining of a livelihood in any province.

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**(81) See section 50, and footnotes (40) and (42) to sections 85 and 88, of the *Constitution Act, 1867*.**

**(82) Replaces part of Class 1 of section 91 of the *Constitution Act, 1867*, which was repealed as set out in subitem 1(3) of the schedule to the *Constitution Act, 1982*.**

**(83) See footnotes (10), (41) and (42) to sections 20, 86 and 88 of the *Constitution Act, 1867*.**

Limitation

(3) The rights specified in subsection (2) are subject to

(*a*) any laws or practices of general application in force in a province other than those that discriminate among persons primarily on the basis of province of present or previous residence; and

(*b*) any laws providing for reasonable residency requirements as a qualification for the receipt of publicly provided social services.

Affirmative action programs

(4) Subsections (2) and (3) do not preclude any law, program or activity that has as its object the amelioration in a province of conditions of individuals in that province who are socially or economically disadvantaged if the rate of employment in that province is below the rate of employment in Canada.

## Legal Rights

Life, liberty and security of person

**7.** Everyone has the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice.

Search or seizure

**8.** Everyone has the right to be secure against unreasonable search or seizure.

Detention or imprisonment

**9.** Everyone has the right not to be arbitrarily detained or imprisoned.

Arrest or detention

**10.** Everyone has the right on arrest or detention

(*a*) to be informed promptly of the reasons therefor;

(*b*) to retain and instruct counsel without delay and to be informed of that right; and

(*c*) to have the validity of the detention determined by way of *habeas corpus* and to be released if the detention is not lawful.

Proceedings in criminal and penal matters

**11.** Any person charged with an offence has the right

(*a*) to be informed without unreasonable delay of the specific offence;

(*b*) to be tried within a reasonable time;

(*c*) not to be compelled to be a witness in proceedings against that person in respect of the offence;

(*d*) to be presumed innocent until proven guilty according to law in a fair and public hearing by an independent and impartial tribunal;

(*e*) not to be denied reasonable bail without just cause;

(*f*) except in the case of an offence under military law tried before a military tribunal, to the benefit of trial by jury where the maximum punishment for the offence is imprisonment for five years or a more severe punishment;

(*g*) not to be found guilty on account of any act or omission unless, at the time of the act or omission, it constituted an offence under Canadian or international law or was criminal according to the general principles of law recognized by the community of nations;

(*h*) if finally acquitted of the offence, not to be tried for it again and, if finally found guilty and punished for the offence, not to be tried or punished for it again; and

(*i*) if found guilty of the offence and if the punishment for the offence has been varied between the time of commission and the time of sentencing, to the benefit of the lesser punishment.

Treatment or punishment

**12.** Everyone has the right not to be subjected to any cruel and unusual treatment or punishment.

Self-crimination

**13.** A witness who testifies in any proceedings has the right not to have any incriminating evidence so given used to incriminate that witness in any other proceedings, except in a prosecution for perjury or for the giving of contradictory evidence.

Interpreter

**14.** A party or witness in any proceedings who does not understand or speak the language in which the proceedings are conducted or who is deaf has the right to the assistance of an interpreter.

## Equality Rights

Equality before and under law and equal protection and benefit of law

**15.** (1) Every individual is equal before and under the law and has the right to the equal protection and equal benefit of the law without discrimination and, in particular, without discrimination based on race, national or ethnic origin, colour, religion, sex, age or mental or physical disability.

Affirmative action programs

(2) Subsection (1) does not preclude any law, program or activity that has as its object the amelioration of conditions of disadvantaged individuals or groups including those that are disadvantaged because of race, national or ethnic origin, colour, religion, sex, age or mental or physical disability. **(84)**

## Official Languages of Canada

Official languages of Canada

**16.** (1) English and French are the official languages of Canada and have equality of status and equal rights and privileges as to their use in all institutions of the Parliament and government of Canada.

Official languages of New Brunswick

(2) English and French are the official languages of New Brunswick and have equality of status and equal rights and privileges as to their use in all institutions of the legislature and government of New Brunswick.

Advancement of status and use

(3) Nothing in this Charter limits the authority of Parliament or a legislature to advance the equality of status or use of English and French.

English and French linguistic communities in New Brunswick

**16.1** (1) The English linguistic community and the French linguistic community in New Brunswick have equality of status and equal rights and privileges, including the right to distinct educational institutions and such distinct cultural institutions as are necessary for the preservation and promotion of those communities.

Role of the legislature and government of New Brunswick

(2) The role of the legislature and government of New Brunswick to preserve and promote the status, rights and privileges referred to in subsection (1) is affirmed. **(85)**

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**(84) Subsection 32(2) provides that section 15 shall not have effect until three years after section 32 comes into force. Section 32 came into force on April 17, 1982; therefore, section 15 had effect on April 17, 1985.**

**(85) Section 16.1 was added by the *Constitution Amendment, 1993 (New Brunswick)* (*see* SI/93-54).**

Proceedings of Parliament

**17.** (1) Everyone has the right to use English or French in any debates and other proceedings of Parliament. **(86)**

Proceedings of New Brunswick legislature

(2) Everyone has the right to use English or French in any debates and other proceedings of the legislature of New Brunswick. **(87)**

Parliamentary statutes and records

**18.** (1) The statutes, records and journals of Parliament shall be printed and published in English and French and both language versions are equally authoritative. **(88)**

New Brunswick statutes and records

(2) The statutes, records and journals of the legislature of New Brunswick shall be printed and published in English and French and both language versions are equally authoritative. **(89)**

Proceedings in courts established by Parliament

**19.** (1) Either English or French may be used by any person in, or in any pleading in or process issuing from, any court established by Parliament. **(90)**

Proceedings in New Brunswick courts

(2) Either English or French may be used by any person in, or in any pleading in or process issuing from, any court of New Brunswick. **(91)**

Communications by public with federal institutions

**20.** (1) Any member of the public in Canada has the right to communicate with, and to receive available services from, any head or central office of an institution of the Parliament or government of Canada in English or French, and has the same right with respect to any other office of any such institution where

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**(86)** **See section 133 of the *Constitution Act, 1867* and footnote (67).**

**(87)** ***Ibid.***

**(88)** ***Ibid.***

**(89)** ***Ibid.***

**(90)** ***Ibid.***

**(91)** ***Ibid.***

(*a*) there is a significant demand for communications with and services from that office in such language; or

(*b*) due to the nature of the office, it is reasonable that communications with and services from that office be available in both English and French.

Communications by public with New Brunswick institutions

(2) Any member of the public in New Brunswick has the right to communicate with, and to receive available services from, any office of an institution of the legislature or government of New Brunswick in English or French.

Continuation of existing constitutional provisions

**21.** Nothing in sections 16 to 20 abrogates or derogates from any right, privilege or obligation with respect to the English and French languages, or either of them, that exists or is continued by virtue of any other provision of the Constitution of Canada. **(92)**

Rights and privileges preserved

**22.** Nothing in sections 16 to 20 abrogates or derogates from any legal or customary right or privilege acquired or enjoyed either before or after the coming into force of this Charter with respect to any language that is not English or French.

## Minority Language Educational Rights

Language of instruction

**23.** (1) Citizens of Canada

(*a*) whose first language learned and still understood is that of the English or French linguistic minority population of the province in which they reside, or

(*b*) who have received their primary school instruction in Canada in English or French and reside in a province where the language in which they received that instruction is the language of the English or French linguistic minority population of the province,

have the right to have their children receive primary and secondary school instruction in that language in that province. **(93)**

Continuity of language instruction

(2) Citizens of Canada of whom any child has received or is receiving primary or secondary school instruction in English or French in Canada, have the right to have

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**(92) See, for example, section 133 of the *Constitution Act, 1867* and the reference to the *Manitoba Act, 1870* in footnote (67) to that section.**

**(93) Paragraph 23(1)(*a*) is not in force in respect of Quebec. See section 59, below.**

all their children receive primary and secondary school instruction in the same language.

Application where numbers warrant

(3) The right of citizens of Canada under subsections (1) and (2) to have their children receive primary and secondary school instruction in the language of the English or French linguistic minority population of a province

(*a*) applies wherever in the province the number of children of citizens who have such a right is sufficient to warrant the provision to them out of public funds of minority language instruction; and

(*b*) includes, where the number of those children so warrants, the right to have them receive that instruction in minority language educational facilities provided out of public funds.

ENFORCEMENT

Enforcement of guaranteed rights and freedoms

**24.** (1) Anyone whose rights or freedoms, as guaranteed by this Charter, have been infringed or denied may apply to a court of competent jurisdiction to obtain such remedy as the court considers appropriate and just in the circumstances.

Exclusion of evidence bringing administration of justice into disrepute

(2) Where, in proceedings under subsection (1), a court concludes that evidence was obtained in a manner that infringed or denied any rights or freedoms guaranteed by this Charter, the evidence shall be excluded if it is established that, having regard to all the circumstances, the admission of it in the proceedings would bring the administration of justice into disrepute.

GENERAL

Aboriginal rights and freedoms not affected by Charter

**25.** The guarantee in this Charter of certain rights and freedoms shall not be construed so as to abrogate or derogate from any aboriginal, treaty or other rights or freedoms that pertain to the aboriginal peoples of Canada including

(*a*) any rights or freedoms that have been recognized by the Royal Proclamation of October 7, 1763; and

(*b*) any rights or freedoms that now exist by way of land claims agreements or may be so acquired. **(94)**

Other rights and freedoms not affected by Charter

**26.** The guarantee in this Charter of certain rights and freedoms shall not be construed as denying the existence of any other rights or freedoms that exist in Canada.

Multicultural heritage

**27.** This Charter shall be interpreted in a manner consistent with the preservation and enhancement of the multicultural heritage of Canadians.

Rights guaranteed equally to both sexes

**28.** Notwithstanding anything in this Charter, the rights and freedoms referred to in it are guaranteed equally to male and female persons.

Rights respecting certain schools preserved

**29.** Nothing in this Charter abrogates or derogates from any rights or privileges guaranteed by or under the Constitution of Canada in respect of denominational, separate or dissentient schools. **(95)**

Application to territories and territorial authorities

**30.** A reference in this Charter to a province or to the legislative assembly or legislature of a province shall be deemed to include a reference to the Yukon Territory and the Northwest Territories, or to the appropriate legislative authority thereof, as the case may be.

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**(94) Paragraph 25(*b*) was repealed and re-enacted by the *Constitution Amendment Proclamation, 1983* (*see* SI/84-102). Paragraph 25(*b*) originally read as follows:**

(*b*) any rights or freedoms that may be acquired by the aboriginal peoples of Canada by way of land claims settlement.

**(95) See section 93 of the *Constitution Act, 1867* and footnote (50).**

Legislative powers not extended

**31.** Nothing in this Charter extends the legislative powers of any body or authority.

## Application of Charter

Application of Charter

**32.** (1) This Charter applies

(*a*) to the Parliament and government of Canada in respect of all matters within the authority of Parliament including all matters relating to the Yukon Territory and Northwest Territories; and

(*b*) to the legislature and government of each province in respect of all matters within the authority of the legislature of each province.

Exception

(2) Notwithstanding subsection (1), section 15 shall not have effect until three years after this section comes into force.

Exception where express declaration

**33.** (1) Parliament or the legislature of a province may expressly declare in an Act of Parliament or of the legislature, as the case may be, that the Act or a provision thereof shall operate notwithstanding a provision included in section 2 or sections 7 to 15 of this Charter.

Operation of exception

(2) An Act or a provision of an Act in respect of which a declaration made under this section is in effect shall have such operation as it would have but for the provision of this Charter referred to in the declaration.

Five year limitation

(3) A declaration made under subsection (1) shall cease to have effect five years after it comes into force or on such earlier date as may be specified in the declaration.

Re-enactment

(4) Parliament or the legislature of a province may re-enact a declaration made under subsection (1).

Five year limitation

(5) Subsection (3) applies in respect of a re-enactment made under subsection (4).

CITATION

Citation

**34.** This Part may be cited as the *Canadian Charter of Rights and Freedoms*.

## PART II

## RIGHTS OF THE ABORIGINAL PEOPLES OF CANADA

Recognition of existing aboriginal and treaty rights

**35.** (1) The existing aboriginal and treaty rights of the aboriginal peoples of Canada are hereby recognized and affirmed.

Definition of "aboriginal peoples of Canada"

(2) In this Act, "aboriginal peoples of Canada" includes the Indian, Inuit and Métis peoples of Canada.

Land claims agreements

(3) For greater certainty, in subsection (1) "treaty rights" includes rights that now exist by way of land claims agreements or may be so acquired.

Aboriginal and treaty rights are guaranteed equally to both sexes

(4) Notwithstanding any other provision of this Act, the aboriginal and treaty rights referred to in subsection (1) are guaranteed equally to male and female persons. **(96)**

Commitment to participation in constitutional conference

**35.1** The government of Canada and the provincial governments are committed to the principle that, before any amendment is made to Class 24 of section 91 of the "*Constitution Act, 1867*", to section 25 of this Act or to this Part,

(*a*) a constitutional conference that includes in its agenda an item relating to the proposed amendment, composed of the Prime Minister of Canada and the first ministers of the provinces, will be convened by the Prime Minister of Canada; and

(*b*) the Prime Minister of Canada will invite representatives of the aboriginal peoples of Canada to participate in the discussions on that item. **(97)**

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**(96) Subsections 35(3) and (4) were added by the *Constitution Amendment Proclamation, 1983* (*see* SI/84-102).**

**(97) Section 35.1 was added by the *Constitution Amendment Proclamation, 1983* (*see* SI/84-102).**

## PART III

## EQUALIZATION AND REGIONAL DISPARITIES

Commitment to promote equal opportunities

**36.** (1) Without altering the legislative authority of Parliament or of the provincial legislatures, or the rights of any of them with respect to the exercise of their legislative authority, Parliament and the legislatures, together with the government of Canada and the provincial governments, are committed to

(*a*) promoting equal opportunities for the well-being of Canadians;

(*b*) furthering economic development to reduce disparity in opportunities; and

(*c*) providing essential public services of reasonable quality to all Canadians.

Commitment respecting public services

(2) Parliament and the government of Canada are committed to the principle of making equalization payments to ensure that provincial governments have sufficient revenues to provide reasonably comparable levels of public services at reasonably comparable levels of taxation. **(98)**

## PART IV

## CONSTITUTIONAL CONFERENCE

**37.** Repealed. **(99)**

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**(98) See footnotes (58) and (59) to sections 114 and 118 of the *Constitution Act, 1867*.**

**(99) Section 54 of the *Constitution Act, 1982* provided for the repeal of Part IV (section 37) one year after Part VII came into force. Part VII came into force on April 17, 1982 repealing Part IV on April 17, 1983. Section 37 read as follows:**

**37.** (1) A constitutional conference composed of the Prime Minister of Canada and the first ministers of the provinces shall be convened by the Prime Minister of Canada within one year after this Part comes into force.

(2) The conference convened under subsection (1) shall have included in its agenda an item respecting constitutional matters that directly affect the aboriginal peoples of Canada, including the identification and definition of the rights of those peoples to be included in the Constitution of Canada, and the Prime Minister of Canada shall invite representatives of those peoples to participate in the discussions on that item.

(3) The Prime Minister of Canada shall invite elected representatives of the governments of the Yukon Territory and the Northwest Territories to participate in the discussions on any item on the agenda of the conference convened under subsection (1) that, in the opinion of the Prime Minister, directly affects the Yukon Territory and the Northwest Territories.

## PART IV.I

## CONSTITUTIONAL CONFERENCES

**37.1** Repealed. [100]

## PART V

## PROCEDURE FOR AMENDING CONSTITUTION OF CANADA [101]

General procedure for amending Constitution of Canada

**38.** (1) An amendment to the Constitution of Canada may be made by proclamation issued by the Governor General under the Great Seal of Canada where so authorized by

(*a*) resolutions of the Senate and House of Commons; and

(*b*) resolutions of the legislative assemblies of at least two-thirds of the provinces that have, in the aggregate, according to the then latest general census, at least fifty per cent of the population of all the provinces.

Majority of members

(2) An amendment made under subsection (1) that derogates from the legislative powers, the proprietary rights or any other rights or privileges of the legislature or government of a province shall require a resolution supported by a majority of the

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**[100] Part IV.1 (section 37.1), which was added by the *Constitution Amendment Proclamation, 1983* (*see* SI/84-102), was repealed on April 18, 1987 by section 54.1 of the *Constitution Act, 1982*. Section 37.1 read as follows:**

**37.1** (1) In addition to the conference convened in March 1983, at least two constitutional conferences composed of the Prime Minister of Canada and the first ministers of the provinces shall be convened by the Prime Minister of Canada, the first within three years after April 17, 1982 and the second within five years after that date.

(2) Each conference convened under subsection (1) shall have included in its agenda constitutional matters that directly affect the aboriginal peoples of Canada, and the Prime Minister of Canada shall invite representatives of those peoples to participate in the discussions on those matters.

(3) The Prime Minister of Canada shall invite elected representatives of the governments of the Yukon Territory and the Northwest Territories to participate in the discussions on any item on the agenda of a conference convened under subsection (1) that, in the opinion of the Prime Minister, directly affects the Yukon Territory and the Northwest Territories.

(4) Nothing in this section shall be construed so as to derogate from subsection 35(1).

**[101] Prior to the enactment of Part V, certain provisions of the Constitution of Canada and the provincial constitutions could be amended pursuant to the *Constitution Act, 1867*. See footnotes (44) and (48) to section 91, Class 1 and section 92, Class 1 of that Act, respectively. Other amendments to the Constitution could only be made by enactment of the Parliament of the United Kingdom.**

members of each of the Senate, the House of Commons and the legislative assemblies required under subsection (1).

Expression of dissent

(3) An amendment referred to in subsection (2) shall not have effect in a province the legislative assembly of which has expressed its dissent thereto by resolution supported by a majority of its members prior to the issue of the proclamation to which the amendment relates unless that legislative assembly, subsequently, by resolution supported by a majority of its members, revokes its dissent and authorizes the amendment.

Revocation of dissent

(4) A resolution of dissent made for the purposes of subsection (3) may be revoked at any time before or after the issue of the proclamation to which it relates.

Restriction on proclamation

**39.** (1) A proclamation shall not be issued under subsection 38(1) before the expiration of one year from the adoption of the resolution initiating the amendment procedure thereunder, unless the legislative assembly of each province has previously adopted a resolution of assent or dissent.

Idem

(2) A proclamation shall not be issued under subsection 38(1) after the expiration of three years from the adoption of the resolution initiating the amendment procedure thereunder.

Compensation

**40.** Where an amendment is made under subsection 38(1) that transfers provincial legislative powers relating to education or other cultural matters from provincial legislatures to Parliament, Canada shall provide reasonable compensation to any province to which the amendment does not apply.

Amendment by unanimous consent

**41.** An amendment to the Constitution of Canada in relation to the following matters may be made by proclamation issued by the Governor General under the Great Seal of Canada only where authorized by resolutions of the Senate and House of Commons and of the legislative assembly of each province:

(*a*) the office of the Queen, the Governor General and the Lieutenant Governor of a province;

(*b*) the right of a province to a number of members in the House of Commons not less than the number of Senators by which the province is entitled to be represented at the time this Part comes into force;

(*c*) subject to section 43, the use of the English or the French language;

(*d*) the composition of the Supreme Court of Canada; and

(*e*) an amendment to this Part.

Amendment by general procedure

**42.** (1) An amendment to the Constitution of Canada in relation to the following matters may be made only in accordance with subsection 38(1):

(*a*) the principle of proportionate representation of the provinces in the House of Commons prescribed by the Constitution of Canada;

(*b*) the powers of the Senate and the method of selecting Senators;

(*c*) the number of members by which a province is entitled to be represented in the Senate and the residence qualifications of Senators;

(*d*) subject to paragraph 41(*d*), the Supreme Court of Canada;

(*e*) the extension of existing provinces into the territories; and

(*f*) notwithstanding any other law or practice, the establishment of new provinces.

Exception

(2) Subsections 38(2) to (4) do not apply in respect of amendments in relation to matters referred to in subsection (1).

Amendment of provisions relating to some but not all provinces

**43.** An amendment to the Constitution of Canada in relation to any provision that applies to one or more, but not all, provinces, including

(*a*) any alteration to boundaries between provinces, and

(*b*) any amendment to any provision that relates to the use of the English or the French language within a province,

may be made by proclamation issued by the Governor General under the Great Seal of Canada only where so authorized by resolutions of the Senate and House of Commons and of the legislative assembly of each province to which the amendment applies.

Amendments by Parliament

**44.** Subject to sections 41 and 42, Parliament may exclusively make laws amending the Constitution of Canada in relation to the executive government of Canada or the Senate and House of Commons.

Amendments by provincial legislatures

**45.** Subject to section 41, the legislature of each province may exclusively make laws amending the constitution of the province.

Initiation of amendment procedures

**46.** (1) The procedures for amendment under sections 38, 41, 42 and 43 may be initiated either by the Senate or the House of Commons or by the legislative assembly of a province.

Revocation of authorization

(2) A resolution of assent made for the purposes of this Part may be revoked at any time before the issue of a proclamation authorized by it.

Amendments without Senate resolution

**47.** (1) An amendment to the Constitution of Canada made by proclamation under section 38, 41, 42 or 43 may be made without a resolution of the Senate authorizing the issue of the proclamation if, within one hundred and eighty days after the adoption by the House of Commons of a resolution authorizing its issue, the Senate has not adopted such a resolution and if, at any time after the expiration of that period, the House of Commons again adopts the resolution.

Computation of period

(2) Any period when Parliament is prorogued or dissolved shall not be counted in computing the one hundred and eighty day period referred to in subsection (1).

Advice to issue proclamation

**48.** The Queen's Privy Council for Canada shall advise the Governor General to issue a proclamation under this Part forthwith on the adoption of the resolutions required for an amendment made by proclamation under this Part.

Constitutional conference

**49.** A constitutional conference composed of the Prime Minister of Canada and the first ministers of the provinces shall be convened by the Prime Minister of Canada within fifteen years after this Part comes into force to review the provisions of this Part. **(102)**

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**(102) A First Ministers Meeting was held June 20-21, 1996.**

## PART VI

## AMENDMENT TO THE CONSTITUTION ACT, 1867

**50.** [(103)]

**51.** [(104)]

## PART VII

## GENERAL

Primacy of Constitution of Canada

**52.** (1) The Constitution of Canada is the supreme law of Canada, and any law that is inconsistent with the provisions of the Constitution is, to the extent of the inconsistency, of no force or effect.

Constitution of Canada

(2) The Constitution of Canada includes

(*a*) the *Canada Act 1982*, including this Act;

(*b*) the Acts and orders referred to in the schedule; and

(*c*) any amendment to any Act or order referred to in paragraph (*a*) or (*b*).

Amendments to Constitution of Canada

(3) Amendments to the Constitution of Canada shall be made only in accordance with the authority contained in the Constitution of Canada.

Repeals and new names

**53.** (1) The enactments referred to in Column I of the schedule are hereby repealed or amended to the extent indicated in Column II thereof and, unless repealed, shall continue as law in Canada under the names set out in Column III thereof.

Consequential amendments

(2) Every enactment, except the *Canada Act 1982*, that refers to an enactment referred to in the schedule by the name in Column I thereof is hereby amended by substituting for that name the corresponding name in Column III thereof, and any British North America Act not referred to in the schedule may be cited as the *Constitution Act* followed by the year and number, if any, of its enactment.

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**[(103)] The text of this amendment is set out in the *Constitution Act, 1867*, as section 92A.**

**[(104)] The text of this amendment is set out in the *Constitution Act, 1867*, as the Sixth Schedule.**

Repeal and consequential amendments

**54.** Part IV is repealed on the day that is one year after this Part comes into force and this section may be repealed and this Act renumbered, consequentially upon the repeal of Part IV and this section, by proclamation issued by the Governor General under the Great Seal of Canada. **(105)**

**54.1** Repealed. **(106)**

French version of Constitution of Canada

**55.** A French version of the portions of the Constitution of Canada referred to in the schedule shall be prepared by the Minister of Justice of Canada as expeditiously as possible and, when any portion thereof sufficient to warrant action being taken has been so prepared, it shall be put forward for enactment by proclamation issued by the Governor General under the Great Seal of Canada pursuant to the procedure then applicable to an amendment of the same provisions of the Constitution of Canada. **(107)**

English and French versions of certain constitutional texts

**56.** Where any portion of the Constitution of Canada has been or is enacted in English and French or where a French version of any portion of the Constitution is enacted pursuant to section 55, the English and French versions of that portion of the Constitution are equally authoritative.

English and French versions of this Act

**57.** The English and French versions of this Act are equally authoritative.

Commencement

**58.** Subject to section 59, this Act shall come into force on a day to be fixed by proclamation issued by the Queen or the Governor General under the Great Seal of Canada. **(108)**

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**(105) Part VII came into force on April 17, 1982 (*see* SI/82-97).**

**(106) Section 54.1, which was added by the *Constitution Amendment Proclamation, 1983* (*see* SI/84-102), provided for the repeal of Part IV.1 and section 54.1 on April 18, 1987. Section 54.1 read as follows:**

**54.1** Part IV.1 and this section are repealed on April 18, 1987.

**(107) The French Constitutional Drafting Committee was established in 1984 with a mandate to assist the Minister of Justice in that task. The Committee's Final Report was tabled in Parliament in December 1990.**

**(108) The Act, with the exception of paragraph 23(1)(*a*) in respect of Quebec, came into force on April 17, 1982 by proclamation issued by the Queen (*see* SI/82-97).**

Commencement of paragraph 23(1)(*a*) in respect of Quebec

**59.** (1) Paragraph 23(1)(*a*) shall come into force in respect of Quebec on a day to be fixed by proclamation issued by the Queen or the Governor General under the Great Seal of Canada.

Authorization of Quebec

(2) A proclamation under subsection (1) shall be issued only where authorized by the legislative assembly or government of Quebec. **(109)**

Repeal of this section

(3) This section may be repealed on the day paragraph 23(1)(*a*) comes into force in respect of Quebec and this Act amended and renumbered, consequentially upon the repeal of this section, by proclamation issued by the Queen or the Governor General under the Great Seal of Canada.

Short title and citations

**60.** This Act may be cited as the *Constitution Act, 1982*, and the Constitution Acts 1867 to 1975 (No. 2) and this Act may be cited together as the *Constitution Acts, 1867 to 1982*.

References

**61.** A reference to the "*Constitution Acts, 1867 to 1982*" shall be deemed to include a reference to the "*Constitution Amendment Proclamation, 1983*". **(110)**

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**(109) No proclamation has been issued under section 59.**

**(110) Section 61 was added by the *Constitution Amendment Proclamation, 1983* (*see* SI/84-102). See also section 3 of the *Constitution Act, 1985 (Representation)*, S.C. 1986, c. 8, Part I and the *Constitution Amendment, 1987 (Newfoundland Act)* (*see* SI/88-11).**

SCHEDULE TO THE CONSTITUTION ACT, 1982
*(Section 53)*

MODERNIZATION OF THE CONSTITUTION

| Item | Column I<br>Act Affected | Column II<br>Amendment | Column III<br>New Name |
|---|---|---|---|
| 1. | British North America Act, 1867, 30-31 Vict., c. 3 (U.K.) | (1) Section 1 is repealed and the following substituted therefor:<br>"1. This Act may be cited as the *Constitution Act, 1867*."<br>(2) Section 20 is repealed.<br>(3) Class 1 of section 91 is repealed.<br>(4) Class 1 of section 92 is repealed. | Constitution Act, 1867 |
| 2. | An Act to amend and continue the Act 32-33 Victoria chapter 3; and to establish and provide for the Government of the Province of Manitoba, 1870, 33 Vict., c. 3 (Can.) | (1) The long title is repealed and the following substituted therefor:<br>"*Manitoba Act, 1870*."<br>(2) Section 20 is repealed. | Manitoba Act, 1870 |
| 3. | Order of Her Majesty in Council admitting Rupert's Land and the North-Western Territory into the union, dated the 23rd day of June, 1870 | | Rupert's Land and North-Western Territory Order |
| 4. | Order of Her Majesty in Council admitting British Columbia into the Union, dated the 16th day of May, 1871. | | British Columbia Terms of Union |
| 5. | British North America Act, 1871, 34-35 Vict., c. 28 (U.K.) | Section 1 is repealed and the following substituted therefor:<br>"1. This Act may be cited as the *Constitution Act, 1871*." | Constitution Act, 1871 |
| 6. | Order of Her Majesty in Council admitting Prince Edward Island into the Union, dated the 26th day of June, 1873. | | Prince Edward Island Terms of Union |
| 7. | Parliament of Canada Act, 1875, 38-39 Vict., c. 38 (U.K.) | | Parliament of Canada Act, 1875 |

| Item | Column I<br>Act Affected | Column II<br>Amendment | Column III<br>New Name |
|---|---|---|---|
| 8. | Order of Her Majesty in Council admitting all British possessions and Territories in North America and islands adjacent thereto into the Union, dated the 31st day of July, 1880. | | Adjacent Territories Order |
| 9. | British North America Act, 1886, 49-50 Vict., c. 35 (U.K.) | Section 3 is repealed and the following substituted therefor:<br>"3. This Act may be cited as the *Constitution Act, 1886*." | Constitution Act, 1886 |
| 10. | Canada (Ontario Boundary) Act, 1889, 52-53 Vict., c. 28 (U.K.) | | Canada (Ontario Boundary) Act, 1889 |
| 11. | Canadian Speaker (Appointment of Deputy) Act, 1895, 2nd Sess., 59 Vict., c. 3 (U.K.) | The Act is repealed. | |
| 12. | The Alberta Act, 1905, 4-5 Edw. VII, c. 3 (Can.) | | Alberta Act |
| 13. | The Saskatchewan Act, 1905, 4-5 Edw. VII, c. 42 (Can.) | | Saskatchewan Act |
| 14. | British North America Act, 1907, 7 Edw. VII, c. 11 (U.K.) | Section 2 is repealed and the following substituted therefor:<br>"2. This Act may be cited as the *Constitution Act, 1907*." | Constitution Act, 1907 |
| 15. | British North America Act, 1915, 5-6 Geo. V, c. 45 (U.K.) | Section 3 is repealed and the following substituted therefor:<br>"3. This Act may be cited as the *Constitution Act, 1915*." | Constitution Act, 1915 |
| 16. | British North America Act, 1930, 20-21 Geo. V, c. 26 (U.K.) | Section 3 is repealed and the following substituted therefor:<br>"3. This Act may be cited as the *Constitution Act, 1930*." | Constitution Act, 1930 |
| 17. | Statute of Westminster, 1931, 22 Geo. V, c. 4 (U.K.) | In so far as they apply to Canada,<br>(*a*) section 4 is repealed; and<br>(*b*) subsection 7(1) is repealed. | Statute of Westminster, 1931 |
| 18. | British North America Act, 1940, 3-4 Geo. VI, c. 36 (U.K.) | Section 2 is repealed and the following substituted therefor:<br>"2. This Act may be cited as the *Constitution Act, 1940*." | Constitution Act, 1940 |

| Item | Column I<br>Act Affected | Column II<br>Amendment | Column III<br>New Name |
|---|---|---|---|
| 19. | British North America Act, 1943, 6-7 Geo. VI, c. 30 (U.K.) | The Act is repealed. | |
| 20. | British North America Act, 1946, 9-10 Geo. VI, c. 63 (U.K.) | The Act is repealed. | |
| 21. | British North America Act, 1949, 12-13 Geo. VI, c. 22 (U.K.) | Section 3 is repealed and the following substituted therefor:<br>"3. This Act may be cited as the *Newfoundland Act*." | Newfoundland Act |
| 22. | British North America (No. 2) Act, 1949, 13 Geo. VI, c. 81 (U.K.) | The Act is repealed. | |
| 23. | British North America Act, 1951, 14-15 Geo. VI, c. 32 (U.K.) | The Act is repealed. | |
| 24. | British North America Act, 1952, 1 Eliz. II, c. 15 (Can.) | The Act is repealed. | |
| 25. | British North America Act, 1960, 9 Eliz. II, c. 2 (U.K.) | Section 2 is repealed and the following substituted therefor:<br>"2. This Act may be cited as the *Constitution Act, 1960*." | Constitution Act, 1960 |
| 26. | British North America Act, 1964, 12-13 Eliz. II, c. 73 (U.K.) | Section 2 is repealed and the following substituted therefor:<br>"2. This Act may be cited as the *Constitution Act, 1964*." | Constitution Act, 1964 |
| 27. | British North America Act, 1965, 14 Eliz. II, c. 4, Part I (Can.) | Section 2 is repealed and the following substituted therefor:<br>"2. This Part may be cited as the *Constitution Act, 1965*." | Constitution Act, 1965 |
| 28. | British North America Act, 1974, 23 Eliz. II, c. 13, Part I (Can.) | Section 3, as amended by 25-26 Eliz. II, c. 28, s. 38(1) (Can.), is repealed and the following substituted therefor:<br>"3. This Part may be cited as the *Constitution Act, 1974*." | Constitution Act, 1974 |
| 29. | British North America Act, 1975, 23-24 Eliz. II, c. 28, Part I (Can.) | Section 3, as amended by 25-26 Eliz. II, c. 28, s. 31 (Can.), is repealed and the following substituted therefor:<br>"3. This Part may be cited as the *Constitution Act (No. 1), 1975*." | Constitution Act (No. 1), 1975 |

| Item | Column I<br>Act Affected | Column II<br>Amendment | Column III<br>New Name |
|---|---|---|---|
| 30. | British North America Act (No. 2), 1975, 23-24 Eliz. II, c. 53 (Can.) | Section 3 is repealed and the following substituted therefor:<br>"3. This Act may be cited as the *Constitution Act (No. 2), 1975*." | Constitution Act (No. 2), 1975 |

# ENDNOTES

## ENDNOTE 1

### FURTHER DETAILS OF CONSTITUTION ACT, 1867, SECTION 5 [FOOTNOTE (6)]

**The first territories added to the Union were Rupert's Land and the North-Western Territory (subsequently designated the Northwest Territories), which were admitted pursuant to section 146 of the *Constitution Act, 1867* and the *Rupert's Land Act, 1868*, 31-32 Vict., c. 105 (U.K.), by the *Rupert's Land and North-Western Territory Order* of June 23, 1870, effective July 15, 1870. Prior to the admission of those territories, the Parliament of Canada enacted *An Act for the temporary Government of Rupert's Land and the North-Western Territory when united with Canada* (32-33 Vict., c. 3), and the *Manitoba Act, 1870* (33 Vict., c. 3), which provided for the formation of the Province of Manitoba.**

**British Columbia was admitted into the Union pursuant to section 146 of the *Constitution Act, 1867*, by the *British Columbia Terms of Union*, being Order in Council of May 16, 1871, effective July 20, 1871.**

**Prince Edward Island was admitted pursuant to section 146 of the *Constitution Act, 1867*, by the *Prince Edward Island Terms of Union*, being Order in Council of June 26, 1873, effective July 1, 1873.**

**On June 29, 1871, the United Kingdom Parliament enacted the *Constitution Act, 1871* (34-35 Vict., c. 28) authorizing the creation of additional provinces out of territories not included in any province. Pursuant to this statute, the Parliament of Canada enacted the *Alberta Act* (July 20, 1905, 4-5 Edw. VII, c. 3) and the *Saskatchewan Act* (July 20, 1905, 4-5 Edw. VII, c. 42), providing for the creation of the provinces of Alberta and Saskatchewan, respectively. Both of these Acts came into force on September 1, 1905.**

**Meanwhile, all remaining British possessions and territories in North America and the islands adjacent thereto, except the colony of Newfoundland and its dependencies, were admitted into the Canadian Confederation by the *Adjacent Territories Order*, dated July 31, 1880.**

**The Parliament of Canada added portions of the Northwest Territories to the adjoining provinces in 1912 by *The Ontario Boundaries Extension Act*, S.C. 1912, 2 Geo. V, c. 40, *The Quebec Boundaries Extension Act, 1912*, 2 Geo. V, c. 45 and *The Manitoba Boundaries Extension Act, 1912*, 2 Geo. V, c. 32, and further additions were made to Manitoba by *The Manitoba Boundaries Extension Act, 1930*, 20-21 Geo. V, c. 28.**

**The Yukon Territory was created out of the Northwest Territories in 1898 by *The Yukon Territory Act*, 61 Vict., c. 6 (Can.).**

**Newfoundland was added on March 31, 1949, by the *Newfoundland Act*, 12-13 Geo. VI, c. 22 (U.K.), which ratified the Terms of Union of Newfoundland with Canada.**

**Nunavut was created out of the Northwest Territories in 1999 by the *Nunavut Act*, S.C. 1993, c. 28.**

## Endnote 2

### Further details of Constitution Act, 1867, section 51 [Footnote 27]

**Section 51 was amended by the *Statute Law Revision Act, 1893*, 56-57 Vict., c. 14 (U.K.) by repealing the words after "of the census" to "seventy-one and" and the word "subsequent".**

**By the *British North America Act, 1943*, 6-7 Geo. VI, c. 30 (U.K.), which Act was repealed by the *Constitution Act, 1982*, redistribution of seats following the 1941 census was postponed until the first session of Parliament after the war. The section was re-enacted by the *British North America Act, 1946*, 9-10 Geo. VI, c. 63 (U.K.), which Act was also repealed by the *Constitution Act, 1982*, to read as follows:**

**51.** (1) The number of members of the House of Commons shall be two hundred and fifty-five and the representation of the provinces therein shall forthwith upon the coming into force of this section and thereafter on the completion of each decennial census be readjusted by such authority, in such manner, and from such time as the Parliament of Canada from time to time provides, subject and according to the following rules:

(1) Subject as hereinafter provided, there shall be assigned to each of the provinces a number of members computed by dividing the total population of the provinces by two hundred and fifty-four and by dividing the population of each province by the quotient so obtained, disregarding, except as hereinafter in this section provided, the remainder, if any, after the said process of division.

(2) If the total number of members assigned to all the provinces pursuant to rule one is less than two hundred and fifty-four, additional members shall be assigned to the provinces (one to a province) having remainders in the computation under rule one commencing with the province having the largest remainder and continuing with the other provinces in the order of the magnitude of their respective remainders until the total number of members assigned is two hundred and fifty-four.

(3) Notwithstanding anything in this section, if upon completion of a computation under rules one and two, the number of members to be assigned to a province is less than the number of senators representing the said province, rules one and two shall cease to apply in respect of the said province, and there shall be assigned to the said province a number of members equal to the said number of senators.

(4) In the event that rules one and two cease to apply in respect of a province then, for the purpose of computing the number of members to be assigned to the provinces in respect of which rules one and two continue to apply, the total population of the provinces shall be reduced by the number of the population of the province in respect of which rules one and two have ceased to apply and the number two hundred and fifty-four shall be reduced by the number of members assigned to such province pursuant to rule three.

(5) Such readjustment shall not take effect until the termination of the then existing Parliament.

(2) The Yukon Territory as constituted by Chapter forty-one of the Statutes of Canada, 1901, together with any Part of Canada not comprised within a province which may from time to time be included therein by the Parliament of Canada for the purposes of representation in Parliament, shall be entitled to one member.

**The section was re-enacted as follows by the *British North America Act, 1952*, S.C. 1952, c. 15 (which Act was also repealed by the *Constitution Act, 1982*):**

**51.** (1) Subject as hereinafter provided, the number of members of the House of Commons shall be two hundred and sixty-three and the representation of the provinces therein shall forthwith upon the coming into force of this section and thereafter on the completion of each decennial census be readjusted by such authority, in such manner, and from such time as the Parliament of Canada from time to time provides, subject and according to the following rules:

1. There shall be assigned to each of the provinces a number of members computed by dividing the total population of the provinces by two hundred and sixty-one and by dividing the population of each province by the quotient so obtained, disregarding, except as hereinafter in this section provided, the remainder, if any, after the said process of division.

2. If the total number of members assigned to all the provinces pursuant to rule one is less than two hundred and sixty-one, additional members shall be assigned to the provinces (one to a province) having remainders in the computation under rule one commencing with the province having the largest remainder and continuing with

the other provinces in the order of the magnitude of their respective remainders until the total number of members assigned is two hundred and sixty-one.

3. Notwithstanding anything in this section, if upon completion of a computation under rules one and two the number of members to be assigned to a province is less than the number of senators representing the said province, rules one and two shall cease to apply in respect of the said province, and there shall be assigned to the said province a number of members equal to the said number of senators.

4. In the event that rules one and two cease to apply in respect of a province then, for the purposes of computing the number of members to be assigned to the provinces in respect of which rules one and two continue to apply, the total population of the provinces shall be reduced by the number of the population of the province in respect of which rules one and two have ceased to apply and the number two hundred and sixty-one shall be reduced by the number of members assigned to such province pursuant to rule three.

5. On any such readjustment the number of members for any province shall not be reduced by more than fifteen per cent below the representation to which such province was entitled under rules one to four of this subsection at the last preceding readjustment of the representation of that province, and there shall be no reduction in the representation of any province as a result of which that province would have a smaller number of members than any other province that according to the results of the then last decennial census did not have a larger population; but for the purposes of any subsequent readjustment of representation under this section any increase in the number of members of the House of Commons resulting from the application of this rule shall not be included in the divisor mentioned in rules one to four of this subsection.

6. Such readjustment shall not take effect until the termination of the then existing Parliament.

(2) The Yukon Territory as constituted by chapter forty-one of the statutes of Canada, 1901, shall be entitled to one member, and such other part of Canada not comprised within a province as may from time to time be defined by the Parliament of Canada shall be entitled to one member.

**Subsection 51(1) was re-enacted by the *Constitution Act, 1974*, S.C. 1974-75-76, c. 13, to read as follows:**

**51.** (1) The number of members of the House of Commons and the representation of the provinces therein shall upon the coming into force of this subsection and thereafter on the completion of each decennial census be readjusted by such authority, in such manner, and from such time as the Parliament of Canada from time to time provides, subject and according to the following Rules:

**1.** There shall be assigned to Quebec seventy-five members in the readjustment following the completion of the decennial census taken in the year 1971, and thereafter four additional members in each subsequent readjustment.

**2.** Subject to Rules 5(2) and (3), there shall be assigned to a large province a number of members equal to the number obtained by dividing the population of the large province by the electoral quotient of Quebec.

**3.** Subject to Rules 5(2) and (3), there shall be assigned to a small province a number of members equal to the number obtained by dividing

(*a*) the sum of the populations, determined according to the results of the penultimate decennial census, of the provinces (other than Quebec) having populations of less than one and a half million, determined according to the results of that census, by the sum of the numbers of members assigned to those provinces in the readjustment following the completion of that census; and

(*b*) the population of the small province by the quotient obtained under paragraph (*a*).

**4.** Subject to Rules 5(1)(*a*), (2) and (3), there shall be assigned to an intermediate province a number of members equal to the number obtained

(*a*) by dividing the sum of the populations of the provinces (other than Quebec) having populations of less than one and a half million by the sum of the number of members assigned to those provinces under any of Rules 3, 5(1)(*b*), (2) and (3);

(*b*) by dividing the population of the intermediate province by the quotient obtained under paragraph (*a*); and

(*c*) by adding to the number of members assigned to the intermediate province in the readjustment following the completion of the penultimate decennial census one-half of the difference resulting from the subtraction of that number from the quotient obtained under paragraph (*b*).

**5.** (1) On any readjustment,

(*a*) if no province (other than Quebec) has a population of less than one and a half million, Rule 4 shall not be applied and, subject to Rules 5(2) and (3), there shall be assigned to an intermediate province a number of members equal to the number obtained by dividing

(i) the sum of the populations, determined according to the results of the penultimate decennial census, of the provinces, (other than Quebec) having populations of not less than one and a half million and not more than two and a half million, determined according to the results of that census, by the sum of the numbers of members assigned to those provinces in the readjustment following the completion of that census, and

(ii) the population of the intermediate province by the quotient obtained under subparagraph (i);

(*b*) if a province (other than Quebec) having a population of

(i) less than one and a half million, or

(ii) not less than one and a half million and not more than two and a half million

does not have a population greater than its population determined according to the results of the penultimate decennial census, it shall, subject to Rules 5(2) and (3), be assigned the number of members assigned to it in the readjustment following the completion of that census.

(2) On any readjustment,

(*a*) if, under any of Rules 2 to 5(1), the number of members to be assigned to a province (in this paragraph referred to as "the first province") is smaller than the number of members to be assigned to any other province not having a population greater than that of the first province, those Rules shall not be applied to the first province and it shall be assigned a number of members equal to the largest number of members to be assigned to any other province not having a population greater than that of the first province;

(*b*) if, under any of Rules 2 to 5(1)(*a*), the number of members to be assigned to a province is smaller than the number of members assigned to it in the readjustment following the completion of the penultimate decennial census, those Rules shall not be applied to it and it shall be assigned the latter number of members;

(*c*) if both paragraphs (*a*) and (*b*) apply to a province, it shall be assigned a number of members equal to the greater of the numbers produced under those paragraphs.

(3) On any readjustment,

(*a*) if the electoral quotient of a province (in this paragraph referred to as "the first province") obtained by dividing its population by the number of members to be assigned to it under any of Rules 2 to 5(2) is greater than the electoral quotient of Quebec, those Rules shall not be applied to the first province and it shall be assigned a number of members equal to the number obtained by dividing its population by the electoral quotient of Quebec;

(*b*) if, as a result of the application of Rule 6(2)(*a*), the number of members assigned to a province under paragraph (*a*) equals the number of members to be assigned to it under any of Rules 2 to 5(2), it shall be assigned that number of members and paragraph (*a*) shall cease to apply to that province.

**6.** (1) In these Rules,

"electoral quotient" means, in respect of a province, the quotient obtained by dividing its population, determined according to the results of the then most recent decennial census, by the number of members to be assigned to it under any of Rules 1 to 5(3) in the readjustment following the completion of that census;

"intermediate province" means a province (other than Quebec) having a population greater than its population determined according to the results of the penultimate decennial census but not more than two and a half million and not less than one and a half million;

"large province" means a province (other than Quebec) having a population greater than two and a half million;

"penultimate decennial census" means the decennial census that preceded the then most recent decennial census;

"population" means, except where otherwise specified, the population determined according to the results of the then most recent decennial census;

"small province" means a province (other than Quebec) having a population greater than its population determined according to the results of the penultimate decennial census and less than one and half million.

(2) For the purposes of these Rules,

(*a*) if any fraction less than one remains upon completion of the final calculation that produces the number of members to be assigned to a province, that number of members shall equal the number so produced disregarding the fraction;

(*b*) if more than one readjustment follows the completion of a decennial census, the most recent of those readjustments shall, upon taking effect, be deemed to be the only readjustment following the completion of that census;

(*c*) a readjustment shall not take effect until the termination of the then existing Parliament.

**Subsection 51(1) was re-enacted by the *Constitution Act, 1985 (Representation)*, S.C. 1986, c. 8, Part I, as follows:**

**51.** (1) The number of members of the House of Commons and the representation of the provinces therein shall, on the coming into force of this subsection and thereafter on the completion of each decennial census, be readjusted by such authority, in such manner, and from such time as the Parliament of Canada from time to time provides, subject and according to the following rules:

Rules

**1.** There shall be assigned to each of the provinces a number of members equal to the number obtained by dividing the total population of the provinces by two hundred and seventy-nine and by dividing the population of each province by the quotient so obtained, counting any remainder in excess of 0.50 as one after the said process of division.

**2.** If the total number of members that would be assigned to a province by the application of rule 1 is less than the total number assigned to that province on the date of coming into force of this subsection, there shall be added to the number of members so assigned such number of members as will result in the province having the same number of members as were assigned on that date.

## ENDNOTE 3

## FURTHER DETAILS OF CONSTITUTION ACT, 1867, SECTION 91 [FOOTNOTE (47)]

### Acts conferring legislative authority on Parliament:

### 1. The *Constitution Act, 1871*, 34-35 Vict., c. 28 (U.K.):

**2.** The Parliament of Canada may from time to time establish new Provinces in any territories forming for the time being part of the Dominion of Canada, but not included in any Province thereof, and may, at the time of such establishment, make provision for the constitution and administration of any such Province, and for the passing of laws for the peace, order, and good government of such Province, and for its representation in the said Parliament.

**3.** The Parliament of Canada may from time to time, with the consent of the Legislature of any province of the said Dominion, increase, diminish, or otherwise alter the limits of such Province, upon such terms and conditions as may be agreed to by the said Legislature, and may, with the like consent, make provision respecting the effect and operation of any such increase or diminution or alteration of territory in relation to any Province affected thereby.

**4.** The Parliament of Canada may from time to time make provision for the administration, peace, order, and good government of any territory not for the time being included in any Province.

**5.** The following Acts passed by the said Parliament of Canada, and intituled respectively, — "An Act for the temporary government of Rupert's Land and the North Western Territory when united with Canada"; and "An Act to amend and continue the Act thirty-two and thirty-three Victoria, chapter three, and to establish and provide for the government of "the Province of Manitoba", shall be and be deemed to have been valid and effectual for all purposes whatsoever from the date at which they respectively received the assent, in the Queen's name, of the Governor General of the said Dominion of Canada.

**6.** Except as provided by the third section of this Act, it shall not be competent for the Parliament of Canada to alter the provisions of the last-mentioned Act of the said Parliament in so far as it relates to the Province of Manitoba, or of any other Act hereafter establishing new Provinces in the said Dominion, subject always to the right of the Legislature of the Province of Manitoba to alter from time to time the provisions of any law respect-

ing the qualification of electors and members of the Legislative Assembly, and to make laws respecting elections in the said Province.

**The *Rupert's Land Act, 1868*, 31-32 Vict., c. 105 (U.K.) (repealed by the *Statute Law Revision Act, 1893*, 56-57 Vict., c. 14 (U.K.)), had previously conferred similar authority in relation to Rupert's Land and the North-Western Territory upon admission of those areas.**

**2. The *Constitution Act, 1886*, 49-50 Vict., c. 35 (U.K.):**

**1.** The Parliament of Canada may from time to time make provision for the representation in the Senate and House of Commons of Canada, or in either of them, of any territories which for the time being form part of the Dominion of Canada, but are not included in any province thereof.

**3. The *Statute of Westminster, 1931*, 22 Geo. V, c. 4 (U.K.):**

**3.** It is hereby declared and enacted that the Parliament of a Dominion has full power to make laws having extra-territorial operation.

**4. Under section 44 of the *Constitution Act, 1982*, Parliament has exclusive authority to amend the Constitution of Canada in relation to the executive government of Canada or the Senate and House of Commons. Sections 38, 41, 42 and 43 of that Act authorize the Senate and House of Commons to give their approval to certain other constitutional amendments by resolution.**

## Endnote 4

## Further details of Constitution Act, 1867, section 93 [Footnote (50)]

**An alternative was provided for Manitoba by section 22 of the *Manitoba Act, 1870*, 33 Vict., c. 3 (confirmed by the *Constitution Act, 1871*, 34-35 Vict., c. 28 (U.K.)), which section reads as follows:**

**22.** In and for the Province, the said Legislature may exclusively make Laws in relation to Education, subject and according to the following provisions:

(1) Nothing in any such Law shall prejudicially affect any right or privilege with respect to Denominational Schools which any class of persons have by Law or practice in the Province at the Union:

(2) An appeal shall lie to the Governor General in Council from any Act or decision of the Legislature of the Province, or of any Provincial Authority, affecting any right or privilege, of the Protestant or Roman Catholic minority of the Queen's subjects in relation to Education:

(3) In case any such Provincial Law, as from time to time seems to the Governor General in Council requisite for the due execution of the provisions of this section, is not made, or in case any decision of the Governor General in Council on any appeal under this section is not duly executed by the proper Provincial Authority in that behalf, then, and in every such case, and as far only as the circumstances of each case require, the Parliament of Canada may make remedial Laws for the due execution of the provisions of this section, and of any decision of the Governor General in Council under this section.

**An alternative was provided for Alberta by section 17 of the *Alberta Act*, 1905, 4-5 Edw. VII, c. 3, which section reads as follows:**

**17.** Section 93 of the *Constitution Act, 1867*, shall apply to the said province, with the substitution for paragraph (1) of the said section 93 of the following paragraph:

(1) Nothing in any such law shall prejudicially affect any right or privilege with respect to separate schools which any class of persons have at the date of the passing of this Act, under the terms of chapters 29 and 30 of the Ordinances of the Northwest Territories, passed in the year 1901, or with respect to religious instruction in any public or separate school as provided for in the said ordinances.

**2.** In the appropriation by the Legislature or distribution by the Government of the province of any moneys for the support of schools organized and carried on in accordance with the said chapter 29 or any Act passed in

amendment thereof, or in substitution therefor, there shall be no discrimination against schools of any class described in the said chapter 29.

**3.** Where the expression "by law" is employed in paragraph 3 of the said section 93, it shall be held to mean the law as set out in the said chapters 29 and 30, and where the expression "at the Union" is employed, in the said paragraph 3, it shall be held to mean the date at which this Act comes into force.

**An alternative was provided for Saskatchewan by section 17 of the *Saskatchewan Act*, 1905, 4-5 Edw. VII, c. 42, which section reads as follows:**

**17.** Section 93 of the *Constitution Act, 1867*, shall apply to the said province, with the substitution for paragraph (1) of the said section 93, of the following paragraph:

(1) Nothing in any such law shall prejudicially affect any right or privilege with respect to separate schools which any class of persons have at the date of the passing of this Act, under the terms of chapters 29 and 30 of the Ordinances of the Northwest Territories, passed in the year 1901, or with respect to religious instruction in any public or separate school as provided for in the said ordinances.

**2.** In the appropriation by the Legislature or distribution by the Government of the province of any moneys for the support of schools organized and carried on in accordance with the said chapter 29, or any Act passed in amendment thereof or in substitution therefor, there shall be no discrimination against schools of any class described in the said chapter 29.

**3.** Where the expression "by law" is employed in paragraph (3) of the said section 93, it shall be held to mean the law as set out in the said chapters 29 and 30; and where the expression "at the Union" is employed in the said paragraph (3), it shall be held to mean the date at which this Act comes into force.

**An alternative was provided for Newfoundland by Term 17 of the Terms of Union of Newfoundland with Canada (confirmed by the *Newfoundland Act*, 12-13 Geo. VI, c. 22 (U.K.)). Term 17 of the Terms of Union of Newfoundland with Canada, set out in the penultimate paragraph of this note, was amended by the *Constitution Amendment, 1998 (Newfoundland Act)* (*see* SI/98-25) and the *Constitution Amendment, 2001 (Newfoundland and Labrador)* (*see* SI/2001-117), and now reads as follows:**

**17.** (1) In lieu of section ninety-three of the *Constitution Act, 1867*, this term shall apply in respect of the Province of Newfoundland and Labrador.

(2) In and for the Province of Newfoundland and Labrador, the Legislature shall have exclusive authority to make laws in relation to education, but shall provide for courses in religion that are not specific to a religious denomination.

(3) Religious observances shall be permitted in a school where requested by parents.

**Prior to the *Constitution Amendment, 1998 (Newfoundland Act)*, Term 17 of the Terms of Union of Newfoundland with Canada had been amended by the *Constitution Amendment, 1997 (Newfoundland Act)* (*see* SI/97-55) to read as follows:**

**17.** In lieu of section ninety-three of the *Constitution Act, 1867*, the following shall apply in respect of the Province of Newfoundland:

In and for the Province of Newfoundland, the Legislature shall have exclusive authority to make laws in relation to education but

(*a*) except as provided in paragraphs (*b*) and (*c*), schools established, maintained and operated with public funds shall be denominational schools, and any class of persons having rights under this Term as it read on January 1, 1995 shall continue to have the right to provide for religious education, activities and observances for the children of that class in those schools, and the group of classes that formed one integrated school system by agreement in 1969 may exercise the same rights under this Term as a single class of persons;

(*b*) subject to provincial legislation that is uniformly applicable to all schools specifying conditions for the establishment or continued operation of schools,

(i) any class of persons referred to in paragraph (*a*) shall have the right to have a publicly funded denominational school established, maintained and operated especially for that class, and

(ii) the Legislature may approve the establishment, maintenance and operation of a publicly funded school, whether denominational or non-denominational;

(*c*) where a school is established, maintained and operated pursuant to subparagraph (*b*)(i), the class of persons referred to in that subparagraph shall continue to have the right to provide for religious education, activities and observances and to direct the teaching of aspects of curriculum affecting religious beliefs, student admission policy and the assignment and dismissal of teachers in that school;

(*d*) all schools referred to in paragraphs (*a*) and (*b*) shall receive their share of public funds in accordance with scales determined on a non-discriminatory basis from time to time by the Legislature; and

(*e*) if the classes of persons having rights under this Term so desire, they shall have the right to elect in total not less than two thirds of the members of a school board, and any class so desiring shall have the right to elect the portion of that total that is proportionate to the population of that class in the area under the board's jurisdiction.

**Prior to the *Constitution Amendment, 1997 (Newfoundland Act)*, Term 17 of the Terms of Union of Newfoundland with Canada had been amended by the *Constitution Amendment, 1987 (Newfoundland Act)* (*see* SI/88-11) to read as follows:**

**17.** (1) In lieu of section ninety-three of the *Constitution Act, 1867*, the following term shall apply in respect of the Province of Newfoundland:

In and for the Province of Newfoundland the Legislature shall have exclusive authority to make laws in relation to education, but the Legislature will not have authority to make laws prejudicially affecting any right or privilege with respect to denominational schools, common (amalgamated) schools, or denominational colleges, that any class or classes of persons have by law in Newfoundland at the date of Union, and out of public funds of the Province of Newfoundland, provided for education,

(*a*) all such schools shall receive their share of such funds in accordance with scales determined on a non-discriminatory basis from time to time by the Legislature for all schools then being conducted under authority of the Legislature; and

(*b*) all such colleges shall receive their share of any grant from time to time voted for all colleges then being conducted under authority of the Legislature, such grant being distributed on a non-discriminatory basis.

(2) For the purposes of paragraph one of this Term, the Pentecostal Assemblies of Newfoundland have in Newfoundland all the same rights and privileges with respect to denominational schools and denominational colleges as any other class or classes of persons had by law in Newfoundland at the date of Union, and the words "all such schools" in paragraph (*a*) of paragraph one of this Term and the words "all such colleges" in paragraph (*b*) of paragraph one of this Term include, respectively, the schools and the colleges of the Pentecostal Assemblies of Newfoundland.

**Term 17 of the Terms of Union of Newfoundland with Canada (confirmed by the *Newfoundland Act*, 12-13 Geo. VI, c. 22 (U.K.)), which Term provided an alternative for Newfoundland, originally read as follows:**

**17.** In lieu of section ninety-three of the *Constitution Act, 1867*, the following term shall apply in respect of the Province of Newfoundland:

In and for the Province of Newfoundland the Legislature shall have exclusive authority to make laws in relation to education, but the Legislature will not have authority to make laws prejudicially affecting any right or privilege with respect to denominational schools, common (amalgamated) schools, or denominational colleges, that any class or classes of persons have by law in Newfoundland at the date of Union, and out of public funds of the Province of Newfoundland, provided for education,

(*a*) all such schools shall receive their share of such funds in accordance with scales determined on a non-discriminatory basis from time to time by the Legislature for all schools then being conducted under authority of the Legislature; and

(*b*) all such colleges shall receive their share of any grant from time to time voted for all colleges then being conducted under authority of the Legislature, such grant being distributed on a non-discriminatory basis.

**See also sections 23, 29 and 59 of the *Constitution Act, 1982*. Section 23 provides for new minority language educational rights and section 59 permits a delay in respect of the coming into force in Quebec of one aspect of those rights. Section 29 provides that**

**nothing in the *Canadian Charter of Rights and Freedoms* abrogates or derogates from any rights or privileges guaranteed by or under the Constitution of Canada in respect of denominational, separate or dissentient schools.**

## ENDNOTE 5

### FURTHER DETAILS OF CONSTITUTION ACT, 1867, SECTION 118 [FOOTNOTE (59)]

**The section originally read as follows:**

**118.** The following Sums shall be paid yearly by Canada to the several Provinces for the Support of their Governments and Legislatures:

| | Dollars. |
|---|---|
| Ontario | Eighty thousand. |
| Quebec | Seventy thousand. |
| Nova Scotia | Sixty thousand. |
| New Brunswick | Fifty thousand. |
| | Two hundred and sixty thousand; |

and an annual Grant in aid of each Province shall be made, equal to Eighty Cents per Head of the Population as ascertained by the Census of One thousand eight hundred and sixty-one, and in the Case of Nova Scotia and New Brunswick, by each subsequent Decennial Census until the Population of each of those two Provinces amounts to Four hundred thousand Souls, at which Rate such Grant shall thereafter remain. Such Grants shall be in full Settlement of all future Demands on Canada, and shall be paid half-yearly in advance to each Province; but the Government of Canada shall deduct from such Grants, as against any Province, all Sums chargeable as Interest on the Public Debt of that Province in excess of the several Amounts stipulated in this Act.

**The section was made obsolete by the *Constitution Act, 1907*, 7 Edw. VII, c. 11 (U.K.), which provided:**

**1.** (1) The following grants shall be made yearly by Canada to every province, which at the commencement of this Act is a province of the Dominion, for its local purposes and the support of its Government and Legislature:

(*a*) A fixed grant

where the population of the province is under one hundred and fifty thousand, of one hundred thousand dollars;

where the population of the province is one hundred and fifty thousand, but does not exceed two hundred thousand, of one hundred and fifty thousand dollars;

where the population of the province is two hundred thousand, but does not exceed four hundred thousand, of one hundred and eighty thousand dollars;

where the population of the province is four hundred thousand, but does not exceed eight hundred thousand, of one hundred and ninety thousand dollars;

where the population of the province is eight hundred thousand, but does not exceed one million five hundred thousand, of two hundred and twenty thousand dollars;

where the population of the province exceeds one million five hundred thousand, of two hundred and forty thousand dollars; and

(*b*) Subject to the special provisions of this Act as to the provinces of British Columbia and Prince Edward Island, a grant at the rate of eighty cents per head of the population of the province up to the number of two million five hundred thousand, and at the rate of sixty cents per head of so much of the population as exceeds that number.

(2) An additional grant of one hundred thousand dollars shall be made yearly to the province of British Columbia for a period of ten years from the commencement of this Act.

(3) The population of a province shall be ascertained from time to time in the case of the provinces of Manitoba, Saskatchewan, and Alberta respectively by the last quinquennial census or statutory estimate of population made under the Acts establishing those provinces or any other Act of the Parliament of Canada making provision for the purpose, and in the case of any other province by the last decennial census for the time being.

(4) The grants payable under this Act shall be paid half-yearly in advance to each province.

(5) The grants payable under this Act shall be substituted for the grants or subsidies (in this Act referred to as existing grants) payable for the like purposes at the commencement of this Act to the several provinces of the Dominion under the provisions of section one hundred and eighteen of the *Constitution Act, 1867*, or of any Order in Council establishing a province, or of any Act of the Parliament of Canada containing directions for the payment of any such grant or subsidy, and those provisions shall cease to have effect.

(6) The Government of Canada shall have the same power of deducting sums charged against a province on account of the interest on public debt in the case of the grant payable under this Act to the province as they have in the case of the existing grant.

(7) Nothing in this Act shall affect the obligation of the Government of Canada to pay to any province any grant which is payable to that province, other than the existing grant for which the grant under this Act is substituted.

(8) In the case of the provinces of British Columbia and Prince Edward Island, the amount paid on account of the grant payable per head of the population to the provinces under this Act shall not at any time be less than the amount of the corresponding grant payable at the commencement of this Act, and if it is found on any decennial census that the population of the province has decreased since the last decennial census, the amount paid on account of the grant shall not be decreased below the amount then payable, notwithstanding the decrease of the population.

**See the *Provincial Subsidies Act*, R.S.C. 1985, c. P-26, and the *Federal-Provincial Fiscal Arrangements Act*, R.S.C. 1985, c. F-8.**

**See also Part III of the *Constitution Act, 1982*, which sets out commitments by Parliament and the provincial legislatures respecting equal opportunities, economic development and the provision of essential public services and a commitment by Parliament and the government of Canada to the principle of making equalization payments.**

# What is Gillick competence?

Richard Griffith*



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## Abstract

This article considers the requirements for Gillick competence, it highlights the factors that must be considered when determining whether a child is competent to give consent to treatment.

**Keywords:** competence, consent, Gillick, immunization

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## Introduction

Obtaining consent for immunization becomes more complex where parental responsibility and the developmental concept of Gillick competence become intertwined as the child matures to adulthood. It is essential that health professionals are able to identify who can give consent on behalf of a child and how to determine whether a child has the competence to make a decision about receiving immunization themselves.

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## Consent

Consent is the legal expression of the moral principle of autonomy. It underpins the propriety of the treatment and furnishes a defense to the

crime of battery and civil wrong of trespass.[1] It must be obtained before an immunization can proceed.

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## Children and the Law of Consent

The United Nations Convention on Children's Rights (UNCRC; 1989) defines a child as any person under 18; however, by convention British courts refer to all persons under 18 as minors, those under 16 as children and 16 and 17 y olds as young persons.[2] The UNCRC requires that childhood is recognized as a developmental period and that our domestic laws must be developed 'in a manner consistent with the evolving capacities of the child' (United Nations 1989, Article 5).[2] As children grow and develop in maturity, their views and wishes must be given greater weight and their development toward adulthood must be respected and promoted.

This key principle is reflected in consent law applied to children. Kennedy & Grubb (1998) argue that children pass through 3 developmental stages on their journey to becoming an autonomous adult.[3]

1. The child of tender years who rely on a person with parental responsibility to consent to treatment.
2. The Gillick competent child under 16
3. Young person's 16 and 17 y old who are able to consent to treatment as if they 'were of full age'.[4]

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## The Gillick Competent Child

The right of a child under 16 to consent to medical examination and treatment, including immunization was decided by the House of Lords in *Gillick v West Norfolk and Wisbech AHA* [1986] where a mother of girls

under 16 objected to Department of Health advice that allowed doctors to give contraceptive advice and treatment to children without parental consent.[5] Their Lordships held that a child under 16 had the legal competence to consent to medical examination and treatment if they had sufficient maturity and intelligence to understand the nature and implications of that treatment.[5]

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## Gillick or Fraser an Urban Myth

Wheeler (2006) argues that something of an urban myth has emerged over the use of the term Gillick competence.[6] It suggests that Mrs Gillick wishes to disassociate her name from the assessment of children's capacity, thus carrying the implication that the objective test of a child's competence should be renamed the Fraser competence. Alteration of an established legal test would be unusual, and cause confusion and following correspondence with Victoria Gillick, Wheeler is clear that she "has never suggested to anyone, publicly or privately, that [she] disliked being associated with the term 'Gillick competent'."[6]

Gillick competence is therefore the correct term, still used by judges and health professionals, to identify children aged under 16 who have the legal competence to consent to immunization, providing they can demonstrate sufficient maturity and intelligence to understand and appraise the nature and implications of the proposed treatment, including the risks and alternative courses of actions.

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## Assessing Gillick Competence

The rule in Gillick must be applied when determining whether a child under 16 has competence to consent. The aim of Gillick competence is to reflect the transition of a child to adulthood. Legal competence to make decisions is conditional on the child gradually acquiring both:

- Maturity
- That takes account of the child's experiences and the child's ability to manage influences on their decision making such as information, peer pressure, family pressure, fear and misgivings.
- Intelligence
- That takes account of the child's understanding, ability to weigh risk and benefit, consideration of longer term factors such as effect on family life and on such things as schooling.

The degree of maturity and intelligence needed depends on the gravity of the decision. A relatively young child would have sufficient maturity and intelligence to be competent to consent to a plaster on a small cut. Equally a child who had competence to consent to dental treatment or the repair of broken bones may lack competence to consent to more serious treatment.[7] This could be because they do not understand the treatment implications or because they felt overwhelmed by the decisions they are being asked to make and so lacked the maturity to make it.

Decision making competence does not simply arrive with puberty; it depends on the maturity and intelligence of the child and the seriousness of the treatment decision to be made.

Gillick competence is a functional ability to make a decision. It is task specific so more complex procedures require greater levels of competence. When assessing Gillick competence for immunization, a health professional has to decide whether the child is or is not competent to make that particular decision. It is not just an ability to choose where the child recognizes that there is a choice to be made and is willing to make it. Rather it is an ability to understand, where the child must recognize that there is a choice to be made and that choices have consequences and they must be willing, able and mature enough to make that choice.

Health professionals must be satisfied that the child understands:

- The necessity for immunization and the reasons for it; and
- The risks, intended benefits and outcomes of the proposed immunization and alternatives to immunization, including the option of not having or delaying the immunization.

Assessment of Gillick competence requires an examination of how the child deals with the process of making a decision based on an analysis of the child's ability to understand and assess risks. It is a high test of competence that is more difficult to satisfy the more complex the treatment and its outcomes become. To date no court has found a child in need of life sustaining treatment competent to refuse that treatment.[8]

Sufficient time for the assessment must be allowed by the health professional who needs to be satisfied that a child has fully understood the nature and consequences of the proposed immunization and is mature enough to take account of broader health and social factors when making their decision.

The right to decide on competence must not be used as a license to disregard the wishes of parents whenever the health professional finds it convenient to do so. Health professionals who behave in this way would be failing to discharge their professional responsibilities and could expect to be disciplined by their professional body.[5] Where a child is considered Gillick competent then the consent is as effective as that of an adult and cannot be overruled by a parent.

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## Refusal of Treatment

If a Gillick competent child refuses medical examination or treatment then the law does allow a person with parental responsibility to consent in their place. Lord Donaldson summed up the position when he held that.[9]

*[Consent] protects the [health professional] from claims by the litigious whether they acquire it from their patient, who may be a minor over the age of 16 or a 'Gillick competent' child under that age, or from another person having parental responsibilities which include a right to consent to treatment of the minor.*

*Anyone who gives him consent may take it back, but the [health professional] only needs one and so long as they continue to have one they have the legal right to proceed.*[9]

Where a health professional accepts the consent of a Gillick competent child it cannot be overruled by the child's parent. However, where the same child refuses consent then they may obtain it from another person with parental responsibility who can consent to treatment on the child's behalf.

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## Immunization, Safeguarding or Parental Choice

Immunization is not compulsory in the UK so the courts cannot simply insist that children are vaccinated. Courts cannot treat the matter as a case of significant harm to a child that would warrant state intervention under the Children Act 1989.

However, where parents are in dispute with each other over an issue of parental responsibility, that can include disagreement over immunization, then if negotiation fails they can go to court to resolve the matter. Although a question of private law rather than state intervention into family life, the courts are still obliged to follow the provisions of the Children Act 1989 and consider the best interests of the welfare of that child.

Childhood immunization was considered by the High Court.[10] and subsequently by the Court of Appeal.[11] in a case that concerned 2 girls aged 4 and 10 y whose mothers had fundamental objections to

immunization and had refused to allow their daughters to receive any of the usual childhood vaccinations. Their fathers made an application to the court seeking the immunization of their children. The two girls lived with their respective mothers. Both fathers were in contact with their daughters and had parental responsibility through court orders. The fathers argued that the immunizations were in the children's best interests.

As the case concerned a fundamental issue of parental responsibility the High Court heard the case under the provisions of section 8 of the Children Act 1989. This provides private law remedies to settle matters of parental responsibility concerning a child. Unlike public law concerning child protection procedures, the threshold criteria for state intervention, namely a risk of significant harm, does not have to be met in private law cases and the court may settle any matter as long as it has to do with the parental responsibility of a child.

More recently the court has considered the immunization of older children. In *F v F* [2013] the High Court ordered that sisters aged 11 and 15 y must receive the MMR vaccine.[11] Mr Justice Sumner made it clear that although the case concerned a dispute between parents his only concern was for the best interests of the welfare of the children.

The judge concluded that immunization would be in the best interests of the welfare of each child. The age of the children was significant in this case. At 11 and 15 y the judge was obliged to consider whether they were Gillick competent, in that they had the maturity and intelligence to refuse the MMR vaccine. The judge concluded that neither child was competent due to the influence of the mother on their beliefs about immunization.[12]

In Re B (Child) [2003] the Court of Appeal accepted that, in general, there is wide scope for parental objection to medical intervention. Lord Justice Thorpe viewed medical interventions as existing on a scale. At one end there are the obvious cases where parental objection would have no value in child welfare terms, for example urgent lifesaving treatment

such as a blood transfusion. At the other end are cases where there is genuine scope for debate and the views of the parents are important. Immunization he held was an area where there was room for genuine debate.[11]

Immunization is voluntary and generally it is for those who have parental responsibility for a child or children who are Gillick competent to decide on immunization. It is not a question of neglect or abuse that would trigger child protection proceedings.

Although people with parental responsibility were generally free to act alone when making decisions for their children this freedom was not unfettered. He held that there are a small group of decisions to be made about a child that require the agreement of both parents; these include changing a child's surname, sterilisation and circumcision. This small group he said now included hotly disputed immunization.[11]

Go to:

## The Practicality of Enforcement

Despite the granting of an order by the High Court it is known that practical difficulties have, to date, prevented the giving of the vaccine to the children in the *F v F* [2013] case (Hickey 2013).[12,13]

A number of enforcement measures are available to the court but these are at the discretion of the judge who will again need to balance the best interests of the child against the impact of any enforcement measure. Under the Family Proceedings Rules 1991 a penal notice may be attached to a specific issues order. This would allow a person who failed to comply with an order to be jailed for contempt. Alternatively the court could direct enforcement by arranging for the removal of the child by an officer of the court for the forcible administration of the immunization. In practice both remedies are unlikely to be sanctioned as their impact on the child's welfare would be detrimental.

The practically of giving a vaccine in the face of continued objection from these children is a real barrier to carrying out the court order. Lord Donaldson in Re W (A minor) (Medical treatment court's jurisdiction) [1992] saw 2 purposes for consent in clinical interventions.[9] The first was the legal defense to an allegation of unlawful touch or trespass to the person. Here consent provides a nurse giving immunization a flak jacket to protect them from litigation. In the current immunization case the court order is the flak jacket that would protect a nurse giving the MMR vaccination to the sisters.

Lord Donaldson stressed that consent also has a second equally important clinical purpose:

*The clinical purpose (of consent) stems from the fact that in many instances the co-operation of the patient, and the patient's faith or at least confidence in the efficacy of the treatment, is a major factor contributing to the treatment's success. Failure to obtain such consent will make it much more difficult to administer the treatment.*[9]

Failure to obtain the co-operation of the children will make it very difficult to safely give the MMR. Consent is permission to touch and give the agreed treatment. It does not compel nurses to provide the treatment. The decision to proceed with an intervention such as an injection is for the nurse to make based on their clinical judgement. If the nurse's judgement is that attempting to give the immunization in the face of continued resistance from the child then it is open to the nurse to refuse to proceed at that time.

Go to:

## Conclusion

Consent is essential to the propriety of treatment and is necessary to meet the requirements of the law. Treatment cannot generally proceed without it. The United Nations Convention on the Rights of the Child requires that the evolving capacities of children are respected and this

requirement is reflected in the law of consent where a child with the necessary maturity and intelligence can give valid consent to examination or treatment.[2]

Health professionals must be confident in assessing a child's Gillick competence in order to ensure that the child's rights are respected, this requires the health professional to evaluate the child's maturity and intelligence when seeking consent to immunization. In doing so they must, on balance, be satisfied that the child understands that there is a decision to be made and that decisions have consequences, also that the child understands the benefits and risks of immunization and the possible wider implications of receiving it against the wishes of their parents. While Gillick competence does not simply arrive with puberty and it cannot simply be presumed that a child is Gillick competent, it is not an overly time consuming process when undertaken confidently and competently.

Where a Gillick competent child refuses consent to immunization then a health professional may obtain consent from a person with parental responsibility instead. Where both parents and a Gillick competent child refuse then resorting to litigation is likely to be an ineffective approach. The courts do not adopt an unquestioning recommendation of immunization but give careful consideration to each case on its facts. Immunization may not be appropriate in every case. The court views immunization as a voluntary process that both parents are entitled to be consulted on. Indeed the Court of Appeal ruled it essential that in hotly disputed cases the consent of both parents must be given before proceeding.

Yet even where, as in *F v F* [2013],[12] the courts order that children be given the immunization, the practicalities of actually doing so mean that the children remain unvaccinated. A court order is no guarantee that the vaccine will be administered.

## Disclosure of Potential Conflicts of Interest

There are no potential conflicts of interest.

Go to:

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# 62-63 ELIZABETH II

## CHAPTER 24

An Act to amend the Food and Drugs Act

[*Assented to 6th November, 2014*]

Whereas the safety of drugs and medical devices is a key concern for Canadians;

And whereas new measures are required to further protect Canadians from the risks related to drugs and medical devices, other than natural health products;

Now, therefore, Her Majesty, by and with the advice and consent of the Senate and House of Commons of Canada, enacts as follows:

ALTERNATIVE TITLE

Alternative title

**1.** This Act may be cited as the *Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)*.

R.S., c. F-27

### FOOD AND DRUGS ACT

1993, c. 34, s. 71(3)

**2. (1) The definition "device" in section 2 of the *Food and Drugs Act* is replaced by the following:**

"device"
« *instrument* »

"device" means an instrument, apparatus, contrivance or other similar article, or an *in vitro* reagent, including a component, part or accessory of any of them, that is manufactured, sold or represented for use in

(*a*) diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physical state, or any of their symptoms, in human beings or animals,

(*b*) restoring, modifying or correcting the body structure of human beings or animals or the functioning of any part of the bodies of human beings or animals,

(*c*) diagnosing pregnancy in human beings or animals,

(*d*) caring for human beings or animals during pregnancy or at or after the birth of the offspring, including caring for the offspring, or

(*e*) preventing conception in human beings or animals;

however, it does not include such an instrument, apparatus, contrivance or article, or a component, part or accessory of any of them, that does any of the actions referred to in paragraphs (*a*) to (*e*) solely by pharmacological, immunological or metabolic means or solely by chemical means in or on the body of a human being or animal;

**(2) The definition "étiquette" in section 2 of the French version of the Act is replaced by the following:**

« étiquette »
"*label*"

« étiquette » Sont assimilés aux étiquettes les inscriptions, mots ou marques accompagnant les aliments, drogues, cosmétiques, instruments ou emballages ou s'y rapportant.

**(3) Section 2 of the Act is amended by adding the following in alphabetical order:**

"confidential business information"
« *renseignements commerciaux confidentiels* »

"confidential business information", in respect of a person to whose business or affairs the information relates, means — subject to the regulations — business information

(*a*) that is not publicly available,

(*b*) in respect of which the person has taken measures that are reasonable in the circumstances to ensure that it remains not publicly available, and
(*c*) that has actual or potential economic value to the person or their competitors because it is not publicly available and its disclosure would result in a material financial loss to the person or a material financial gain to their competitors;

"therapeutic product"
« *produit thérapeutique* »
"therapeutic product" means a drug or device or any combination of drugs and devices, but does not include a natural health product within the meaning of the *Natural Health Products Regulations*;

"therapeutic product authorization"
« *autorisation relative à un produit thérapeutique* »
"therapeutic product authorization" means an authorization — including a licence and a suspended authorization or licence — that is issued under the regulations and that authorizes, as the case may be, the import, sale, advertisement, manufacture, preparation, preservation, packaging, labelling, storage or testing of a therapeutic product;

**3. The Act is amended by adding the following after section 21:**

THERAPEUTIC PRODUCTS

Power to require information — serious risk

**21.1** (1) If the Minister believes that a therapeutic product may present a serious risk of injury to human health, the Minister may order a person to provide the Minister with information that is in the person's control and that the Minister believes is necessary to determine whether the product presents such a risk.

Disclosure — serious risk

(2) The Minister may disclose confidential business information about a therapeutic product without notifying the person to whose business or affairs the information relates or obtaining their consent, if the Minister believes that the product may present a serious risk of injury to human health.

Disclosure — health or safety

(3) The Minister may disclose confidential business information about a therapeutic product without notifying the person to whose business or affairs the information relates or obtaining their consent, if the purpose of the disclosure is related to the protection or promotion of human health or the safety of the public and the disclosure is to
(*a*) a government;
(*b*) a person from whom the Minister seeks advice; or
(*c*) a person who carries out functions relating to the protection or promotion of human health or the safety of the public.

Definition of "government"

(4) In this section, "government" means any of the following or their institutions:
(*a*) the federal government;
(*b*) a corporation named in Schedule III to the *Financial Administration Act*;
(*c*) a provincial government or a public body established under an Act of the legislature of a province;
(*d*) an aboriginal government as defined in subsection 13(3) of the *Access to Information Act*;
(*e*) a government of a foreign state or of a subdivision of a foreign state; or
(*f*) an international organization of states.

Modification or replacement — labelling or packaging

**21.2** The Minister may, if he or she believes that doing so is necessary to prevent injury to health, order the holder of a therapeutic product authorization that authorizes

the import or sale of a therapeutic product to modify the product's label or to modify or replace its package.

Minister's powers — risk of injury to health

**21.3** (1) If the Minister believes that a therapeutic product presents a serious or imminent risk of injury to health, he or she may order a person who sells the product to

(*a*) recall the product; or

(*b*) send the product, or cause it to be sent, to a place specified in the order.

Recall order — corrective action

(2) For greater certainty, if the Minister makes an order under paragraph (1)(*a*) and believes that corrective action is an effective means of dealing with the risk, the order may require the person who sells the product to, instead of requesting the product's return, request the product's owner or user to allow corrective action to be taken in respect of the product and then take that corrective action, or cause it to be taken, if the request is accepted.

Prohibition — selling

(3) Subject to subsection (5), no person shall sell a therapeutic product that the Minister orders them, or another person, to recall.

Power to authorize sale

(4) The Minister may authorize a person to sell a therapeutic product, with or without conditions, even if the Minister has ordered them, or another person, to recall it.

Exception

(5) A person does not contravene subsection (3) if they sell a therapeutic product that they have been authorized under subsection (4) to sell, provided that they sell it in accordance with any conditions that the Minister establishes.

Contravention of unpublished order

(6) No person shall be convicted of an offence for the contravention of subsection (3) unless it is proved that, at the time of the alleged contravention, the person had been notified of the recall order or reasonable steps had been taken to bring the purport of the recall order to the notice of those persons likely to be affected by it.

*Statutory Instruments Act*

**21.4** (1) For greater certainty, orders made under any of sections 21.1 to 21.3 are not statutory instruments within the meaning of the *Statutory Instruments Act*.

Availability of orders

(2) The Minister shall ensure that any order made under any of sections 21.1 to 21.3 is publicly available.

Injunction

**21.5** (1) If, on the application of the Minister, it appears to a court of competent jurisdiction that a person has done, is about to do or is likely to do anything that constitutes or is directed toward the commission of an offence under this Act in respect of a therapeutic product, the court may issue an injunction ordering the person, who is to be named in the application, to

(*a*) refrain from doing anything that it appears to the court may constitute or be directed toward the commission of the offence; or

(*b*) do anything that it appears to the court may prevent the commission of the offence.

Notice

(2) No injunction is to be issued under subsection (1) unless 48 hours' notice is served on the party or parties who are named in the application or unless the urgency of the situation is such that service of notice would not be in the public interest.

False or misleading information — therapeutic products

**21.6** No person shall knowingly make a false or misleading statement to the Minister — or knowingly provide him or her with false or misleading information — in connection with any matter under this Act concerning a therapeutic product.

Terms and conditions of authorizations

**21.7** The holder of a therapeutic product authorization shall comply with the terms and conditions of the authorization that are imposed under regulations made under paragraph 30(1.2)(*b*).

Clinical trials and investigational tests

**21.71** The holder of a therapeutic product authorization referred to in paragraph 30(1.2)(*c*) shall ensure that prescribed information concerning the clinical trial or investigational test is made public within the prescribed time and in the prescribed manner.

**4. Section 21.4 of the Act is replaced by the following:**

Power to require assessment

**21.31** Subject to the regulations, the Minister may order the holder of a therapeutic product authorization to conduct an assessment of the therapeutic product to which the authorization relates and provide the Minister with the results of the assessment.

Power to require tests, studies, etc.

**21.32** Subject to the regulations, the Minister may, for the purpose of obtaining additional information about a therapeutic product's effects on health or safety, order the holder of a therapeutic product authorization to

(*a*) compile information, conduct tests or studies or monitor experience in respect of the therapeutic product; and

(*b*) provide the Minister with the information or the results of the tests, studies or monitoring.

*Statutory Instruments Act*

**21.4** (1) For greater certainty, orders made under any of sections 21.1 to 21.32 are not statutory instruments within the meaning of the *Statutory Instruments Act*.

Availability of orders

(2) The Minister shall ensure that any order made under any of sections 21.1 to 21.32 is publicly available.

**5. The Act is amended by adding the following after section 21.71:**

Health care institutions to provide information

**21.8** A prescribed health care institution shall provide the Minister, within the prescribed time and in the prescribed manner, with prescribed information that is in its control about a serious adverse drug reaction that involves a therapeutic product or a medical device incident that involves a therapeutic product.

**6. (1) Section 30 of the Act is amended by adding the following after subsection (1.1):**

Regulations — therapeutic products

(1.2) Without limiting the power conferred by any other subsection of this section, the Governor in Council may make regulations

(*a*) respecting the issuance of authorizations — including licences — that authorize, as the case may be, the import, sale, advertisement, manufacture, preparation, preservation, packaging, labelling, storage or testing of a therapeutic product, and the amendment, suspension and revocation of such authorizations;

(*b*) authorizing the Minister to impose terms and conditions on authorizations referred to in paragraph (*a*), including existing authorizations, and to amend those terms and conditions;

(*b.1*) requiring the Minister to ensure that decisions with regard to the issuance, amendment, suspension and revocation of authorizations referred to in paragraph (*a*), and to the imposition and amendment of terms and conditions referred to in paragraph (*b*), along with the reasons for those decisions, are publicly available;

(*c*) requiring holders of a therapeutic product authorization that authorizes the import or sale of a therapeutic product for a clinical trial or investigational test involving human subjects, or former holders of such an authorization, to provide the Minister, after the

trial or test is completed or discontinued, or, if the authorization is suspended or revoked, after the suspension or revocation, with safety information that the holders or former holders receive or become aware of about the therapeutic product;
(*c.1*) defining “clinical trial” and “investigational test” for the purposes of this Act;
(*d*) requiring holders of a therapeutic product authorization to provide the Minister with information, in respect of any serious risk of injury to human health, that the holders receive or become aware of and that is relevant to the safety of the therapeutic product to which the authorization relates, regarding
(i) risks that have been communicated outside Canada, and the manner of the communication,
(ii) changes that have taken place to labelling outside Canada, and
(iii) recalls, reassessments and suspensions or revocations of authorizations, including licences, in respect of a therapeutic product, that have taken place outside Canada;
(*d.1*) specifying the business information obtained under this Act in relation to an authorization under paragraph (*a*) that is not confidential business information, or the circumstances in which business information obtained under this Act in relation to such an authorization ceases to be confidential business information;
(*d.2*) authorizing the Minister to disclose, without notifying the person to whose business or affairs the information relates or obtaining their consent, business information that, under regulations made under paragraph (*d.1*),
(i) is not confidential business information, or
(ii) has ceased to be confidential business information;
(*e*) respecting modifications of labels and modifications and replacements of packages referred to in section 21.2;
(*f*) respecting the recall of a therapeutic product or the sale of a therapeutic product that is the subject of a recall; and
(*g*) prescribing anything that is to be prescribed under section 21.71.

**(2) Subsection 30(1.2) of the Act is amended by striking out “and” at the end of paragraph (*f*) and by adding the following after paragraph (*f*):**

(*f.1*) respecting assessments referred to in section 21.31, and the provision of the results of the assessments to the Minister;
(*f.2*) requiring the Minister to ensure that decisions with regard to the making of orders under section 21.31, along with the reasons for those decisions, are publicly available;
(*f.3*) respecting the compilation of information, the conducting of tests and studies and the monitoring of experience that are referred to in paragraph 21.32(*a*), and the provision to the Minister of the information or results referred to in paragraph 21.32(*b*); and

**(3) Subsection 30(1.2) of the Act is amended by striking out “and” at the end of paragraph (*f*) and by adding the following after paragraph (*g*):**

(*h*) defining “serious adverse drug reaction” and “medical device incident” for the purposes of this Act;
(*i*) respecting the provision by health care institutions referred to in section 21.8 to the Minister of information referred to in that section; and
(*j*) prescribing anything that is to be prescribed under section 21.8.

**(4) Section 30 of the Act is amended by adding the following after subsection (1.2):**

Consideration of existing information management systems

(1.3) Before recommending to the Governor in Council that a regulation be made under paragraph (1.2)(*i*) or (*j*), the Minister shall take into account existing information management systems, with a view to not recommending the making of regulations that would impose unnecessary administrative burdens.

**(5) The portion of subsection 30(2) of the Act before paragraph (*a*) is replaced by the following:**

Regulations respecting drugs manufactured outside Canada

(2) Without limiting the power conferred by any other subsection of this section, the Governor in Council may make such regulations governing, regulating or prohibiting

1994, c. 47, s. 117

**(6) Subsection 30(3) of the Act is replaced by the following:**

Regulations — North American Free Trade Agreement and WTO Agreement

(3) Without limiting the power conferred by any other subsection of this section, the Governor in Council may make any regulations that the Governor in Council considers necessary for the purpose of implementing, in relation to drugs, Article 1711 of the North American Free Trade Agreement or paragraph 3 of Article 39 of the Agreement on Trade-related Aspects of Intellectual Property Rights set out in Annex 1C to the WTO Agreement.

2004, c. 23, s. 2

**(7) Subsection 30(5) of the Act is replaced by the following:**

Regulations to implement General Council Decision

(5) Without limiting the power conferred by any other subsection of this section, the Governor in Council may make any regulations that the Governor in Council considers necessary for the purpose of implementing the General Council Decision.

2012, c. 19, s. 416

**7. Subsection 30.5(1) of the Act is replaced by the following:**

Incorporation by reference

**30.5** (1) A regulation made under this Act with respect to a food or therapeutic product and a marketing authorization may incorporate by reference any document, regardless of its source, either as it exists on a particular date or as it is amended from time to time.

1997, c. 6, s. 91

**8. The portion of section 31 of the Act before paragraph (*a*) is replaced by the following:**

Contravention of Act or regulations

**31.** Subject to sections 31.1, 31.2 and 31.4, every person who contravenes any of the provisions of this Act or of the regulations is guilty of an offence and liable

**9. The Act is amended by adding the following after section 31.1:**

Offences relating to therapeutic products

**31.2** Subject to section 31.4, every person who contravenes any provision of this Act or the regulations, as it relates to a therapeutic product, or an order made under any of sections 21.1 to 21.3 is guilty of an offence and liable

(*a*) on conviction by indictment, to a fine not exceeding $5,000,000 or to imprisonment for a term not exceeding two years or to both; and

(*b*) on summary conviction, for a first offence, to a fine not exceeding $250,000 or to imprisonment for a term not exceeding six months or to both and, for a subsequent offence, to a fine not exceeding $500,000 or to imprisonment for a term not exceeding 18 months or to both.

Due diligence

**31.3** Due diligence is a defence in a prosecution for an offence under this Act, other than an offence under section 31.4.

Offences — section 21.6 and serious risk

**31.4** A person who contravenes section 21.6, or who knowingly or recklessly causes a serious risk of injury to human health in contravening another provision of this Act or the regulations, as it relates to a therapeutic product, or an order made under any of sections 21.1 to 21.3 is guilty of an offence and liable

(*a*) on conviction on indictment, to a fine the amount of which is at the discretion of the court or to imprisonment for a term not exceeding five years or to both; and
(*b*) on summary conviction, for a first offence, to a fine not exceeding $500,000 or to imprisonment for a term not exceeding 18 months or to both and, for a subsequent offence, to a fine not exceeding $1,000,000 or to imprisonment for a term not exceeding two years or to both.

Sentencing considerations

**31.5** A court that imposes a sentence for an offence under section 31.2 or 31.4 shall take into account, in addition to any other principles that it is required to consider, the following factors:
(*a*) the harm or risk of harm caused by the commission of the offence; and
(*b*) the vulnerability of consumers of the therapeutic product.

Parties to offence

**31.6** If a person other than an individual commits an offence under section 31.2, or commits an offence under section 31.4 by reason of contravening section 21.6, then any of the person's directors, officers or agents or mandataries who directs, authorizes, assents to or acquiesces or participates in the commission of the offence is a party to the offence and is liable on conviction to the punishment provided for by this Act, even if the person is not prosecuted for the offence.

Continuing offence

**31.7** If an offence under section 31.2 or 31.4 is committed or continued on more than one day, it constitutes a separate offence for each day on which it is committed or continued.

**10. The portion of section 31.2 of the Act before paragraph (*a*) is replaced by the following:**

Offences relating to therapeutic products

**31.2** Subject to section 31.4, every person who contravenes any provision of this Act or the regulations, as it relates to a therapeutic product, or an order made under any of sections 21.1 to 21.32 is guilty of an offence and liable

**11. The portion of section 31.4 of the Act before paragraph (*a*) is replaced by the following:**

Offences — section 21.6 and serious risk

**31.4** A person who contravenes section 21.6, or who knowingly or recklessly causes a serious risk of injury to human health in contravening another provision of this Act or the regulations, as it relates to a therapeutic product, or an order made under any of sections 21.1 to 21.32 is guilty of an offence and liable

1996, c. 19, s. 78

**12. Subsection 35(1) of the Act is replaced by the following:**

Certificate of analyst

**35.** (1) Subject to this section, in any prosecution for an offence under any of sections 31 to 31.2 and 31.4, a certificate purporting to be signed by an analyst and stating that an article, sample or substance has been submitted to, and analysed or examined by, the analyst and stating the results of the analysis or examination is admissible in evidence and, in the absence of evidence to the contrary, is proof of the statements contained in the certificate without proof of the signature or official character of the person appearing to have signed it.

## TRANSITIONAL PROVISION

Therapeutic product authorizations

**13. The definition "therapeutic product authorization", as enacted by subsection 2(3), applies to authorizations — including licences and suspended authorizations or licences — that were issued before the day on which this section comes into force and that authorize, as the case may be, the import,**

**sale, advertisement, manufacture, preparation, preservation, packaging, labelling, storage or testing of a therapeutic product.**

## COORDINATING AMENDMENTS

Subsections 6(2) and (3)

**14. (1) If subsection 6(2) comes into force before subsection 6(3), then the English version of subsection 6(3) is amended by replacing "paragraph (*f*)" with "paragraph (*f.3*)".**

**(2) If subsection 6(3) comes into force before subsection 6(2), then the English version of subsection 6(2) is amended by**
**(*a*) striking out "striking out "and" at the end of paragraph (*f*) and by"; and**
**(*b*) striking out "and" at the end of the paragraph (*f.3*) of the *Food and Drugs Act* that it enacts.**

**(3) If subsections 6(2) and (3) come into force on the same day, then subsection 6(2) is deemed to have come into force before subsection 6(3) and subsection (1) applies as a consequence.**

## COMING INTO FORCE

Order in council

**15. (1) Section 4, subsection 6(2) and sections 10 and 11 come into force on a day to be fixed by order of the Governor in Council.**

Order in council

**(2) Section 5 and subsections 6(3) and (4) come into force on a day to be fixed by order of the Governor in Council.**

# J.N. v. C.G., 2022 ONSC 1198 (CanLII)




Date:
2022-02-22
File number:
987/18
Other citations:
[2022] OJ No 793 (QL) — 64 RFL (8th) 277
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**CITATION:** J.N. v. C.G., 2022 ONSC 1198
**COURT FILE**

**NO.:** 987/18

**DATE:** 2022-02-22

**ONTARIO**
**SUPERIOR COURT OF JUSTICE**

| | | |
|---|---|---|
| **BETWEEN:** | | |
| J.N. | Applicant | Self-Represented |
| – and – | | |
| C.G. | Respondent | Jesse Herman, Counsel, for the Respondent |
| | | **HEARD:** February 18, 2022 |

**JUDGMENT**

**THE HONOURABLE MR. JUSTICE A. PAZARATZ**

[1] When did it become illegal to ask questions? *Especially in the courtroom?*

[2] And when did it become unfashionable for judges to receive answers? *Especially when children's lives are at stake?*

[3] How did we lower our guard and let the words "unacceptable beliefs" get paired together? *In a democracy? On the Scales of Justice?*

[4] Should judges sit back as the concept of "Judicial Notice" gets hijacked from a *rule* of evidence to a *substitute* for evidence

[5] And is "misinformation" even a real word? Or has it become a crass, self-serving tool to pre-empt scrutiny and discredit your opponent? To de-legitimize questions and strategically avoid giving answers. Blanket denials are almost never acceptable in our adversarial system. Each party always has the onus to prove their case and yet "misinformation" has crept into the court lexicon. A childish – but sinister – way of saying *"You're so wrong, I don't even have to explain why you're wrong."*

[6] What does *any* of this have to do with family court? Sadly, these days it has *everything* to do with family court.

[7] Because when society demonizes and punishes anyone who disagrees – or even dares to ask really important questions – the resulting polarization, disrespect, and simmering anger can have devastating consequences for the mothers, fathers and children I deal with on a daily basis.

[8] It's becoming harder for family court judges to turn enemies into friends -- when governments are so recklessly turning friends into enemies.

[9] The motion before me is a typical – and frightening – example of how far we are drifting from cherished values.

[10] The father wants two children ages 12 and 10 to receive COVID vaccinations. The mother is opposed.

[11] Now, answer honestly. Did the previous paragraph give you enough information to form an opinion about how this case should turn out?

[12] We're all weary. We all wish COVID would just go away. But pandemic fatigue is no excuse for short-cuts and lowering our standards. We all have to guard against the unconscious bias of thinking *"Why won't these people just do what the government tells them to do?"*

[13] We have to decide on the basis of the best interests of each particular child in each particular fact situation.

[14] We have to rely on – and insist upon – evidence.

[15] In this case the evidence provided more questions than answers.

a. The father filed two affidavits.
b. The mother filed one.
c. They both relied extensively on unsworn "exhibits", which were basically internet downloads.
d. In addition, the father relied on numerous downloads from the mother's social media accounts.
e. They both consented to my receiving these materials, to demonstrate the sources of information which each of them is relying on in formulating their respective parenting position.

[16] The basic facts are not disputed:

a. The mother is 34 years old. The father is 35.
b. They were married on November 24, 2007 and separated on June 1, 2014.
c. They have three children, a 14 year old son C.B.G.; a 12 year old daughter L.E.G.; and a ten year old son M.D.G..
d. C.B.G. resides primarily with the father. L.E.G. and M.D.G. reside primarily with the mother.
e. Pursuant to final order based on minutes of settlement signed October 5, 2021, the father has sole decision-making authority with respect to the oldest child. The mother has sole decision-making authority with respect to the two children who are the subject of this motion. The order requires the parties to consult with each other prior to making major decisions for the children.
f. When the parties signed the minutes of settlement, they already knew that they disagreed about the issue of vaccinations. The minutes of settlement specified: *"The issue of the children L.E.G. and M.D.G. receiving a COVID-19 vaccine shall remain a live issue and shall be determined at a later date. The child C.B.G. can determine whether or not he wants to be vaccinated now."*
g. In fact, earlier in the pandemic the father went to court complaining the mother was being *too protective* of the children when it came to COVID. In August 2020 the father brought a motion trying to compel the children to attend school in person for the 2020-2021 school year. The mother argued that the risk of COVID exposure was too high; she was particularly concerned about the oldest child's medical vulnerability as a result of his history of asthma; and she proposed remote learning for the children until the pandemic risk subsided. On September 23, 2020 Justice Bale issued a lengthy endorsement dismissing the father's motion, and confirming that the mother's position was appropriate and in the best interests of the children.
h. In 2020 the father alleged the mother was being *too* protective about COVID. Now he's saying she's not protective enough. He brought a motion dated January 25, 2022 requesting that L.E.G. and M.D.G. receive the COVID vaccine and all recommended booster vaccines. He also asks that he be permitted

to arrange the vaccinations and attend with the children, because he doesn't trust that the mother will comply even if she is ordered to do so.

i. Meanwhile, soon after the parties signed Minutes in October 2021 the older child C.B.G. elected to be vaccinated. Both parents supported his decision. He's had two shots, and the parents agree he has exhibited no adverse effects.
j. The mother insists the father is misrepresenting her position. She is not opposed to vaccines. She is offended by the pejorative term "anti-vaxxer". She has always ensured that the three children received all of their regular immunizations. She says she's open minded to vaccinating both younger children if safety concerns can be better addressed. But she says her extensive research has left her with well-founded concerns that the potential benefit of the current COVID vaccines for L.E.G. and M.D.G. is outweighed by the serious potential risks. She says there are too many unknowns, and she worries that "once children are vaxed, they can't be unvaxed."
k. The mother notes that both children have already had COVID – with minimal symptoms – and they have recovered completely. She refers to medical research which says that since they have already recovered from COVID, the children now have greater protection from future infection.
l. Both parents agree L.E.G. and M.D.G. are in excellent health, with no special medical needs or vulnerabilities.
m. Neither parent provided any evidence from a medical professional about any potential positive or negative considerations with respect to *these* children receiving COVID vaccines.

[17] The mother's evidence focused entirely on the medical and scientific issues.

[18] In contrast, the father focussed extensively on labelling and discrediting the mother as a person, in a dismissive attempt to argue that her views aren't worthy of consideration.

a. This odious trend is rapidly corrupting modern social discourse: Ridicule and stigmatize your opponent as a person, rather than dealing with the ideas they want to talk about.
b. It seems to be working for politicians.
c. But is this really something we want to tolerate in a court system where parental conduct and beliefs are irrelevant except as they impact on a parent's ability to meet the needs of a child?

[19] For example, the father's affidavits included the following:

a. "I am aware that the Applicant has political affiliations with the People's Party of Canada. The Applicant is entitled to her personal beliefs and ideologies, but I am very fearful that it is having a direct, negative impact on the children, especially when it comes to this vaccine issue."
b. "I searched the Applicant's recent Facebook postings and was alarmed to see just how involved the Applicant is at perpetuating COVID-related conspiracy theories and vaccine hesitancy."

c. He attached "a collection of some of the Applicant's Facebook postings ….. which I believe are indicative of her personal views."
d. "The Applicant is a self-proclaimed 'PPC founding member'. In my opinion, she is openly promoting very dangerous beliefs. Surely, these thoughts and feelings are also being promoted in her household, which is where L.E.G. and M.D.G. primarily reside."
e. "I looked up what the PPC stance is on the COVID-19 vaccine and was not surprised to read under its website's "FACTS" section that "lockdowns, mask mandates, school closures and other authoritarian sanitary measures have not had any noticeable effect on the course of the pandemic." Unfortunately, no facts are actually provided."
f. He attaches a copy of the PPC's COVID Policy taken from its website.
g. "I am alarmed that the children are being exposed to the Applicant's unsupported views on the issue of the pandemic, and in particular the efficacy of the available and Government-recommended vaccines."
h. "The Applicant's anti-vaccination stance is much more severe than that of a regular concerned parent, who is unsure whether or not she wants the children to receive a relatively new vaccine. Rather, the Applicant is leading the charge, attending anti-vaccine rallies and refusing to follow COVID protocols."
i. He attaches a Facebook posting of the mother not wearing a mask "in a crowd of 10,000 people at a rally."
j. He makes other references to the mother's Facebook account, and attaches numerous pictures of her social media pages.
k. He attaches photographs of PPC leader Maxime Bernier addressing an audience.

[20] Where to begin.

a. How is any of this relevant?
b. Have we reached the stage where parental rights are going to be decided based on what political party you belong to?
c. Is being seen with Maxime Bernier – or anyone, for that matter – the kiss of death, as far as your court case is concerned?
d. Can you simply utter the words "conspiracy theorist" and do a mic drop?
e. If you allege that someone is "openly promoting very dangerous beliefs", shouldn't you provide a few details. A bit of proof, maybe?
f. And if you presume that a parent believes things they shouldn't believe – can you go one step further and also presume that the parent must be poisoning their children's minds with these horrible unspecified ideas? ("*Surely, these thoughts and feelings are also being promoted in her household...")*
g. The father criticizes the mother for something she didn't say. He presumes she doubts the effectiveness of school closures, and then criticizes her for providing no evidence. But on this motion she didn't raise the issue. And back in 2020 *she* was the one who wanted to keep the children out of school, and *he* fought (unsuccessfully) for them to attend. As with other allegations, the

father provides no evidence of his own, and fails to address the fact that vigorous community debate led to school closures being abandoned.

h. How far are we willing to take "guilt by association"? If you visit a website, read a book, or attend a meeting -- are you permanently tarnished by something someone else wrote or said? At what point do the "thought police" move in?

i. And really, how fine is the line between "vaccine hesitancy" and "not taking any chances with your kid"? All of the caselaw says judges have to act with the utmost caution and consider all relevant evidence in determining the best interests of the child. How can we then impose a lesser standard on a demonstrably excellent parent?

[21] It is of little consequence that an individual litigant chooses to advance such dubious and offensive arguments. Even though the father may not admit it, this is still a free country and people can say what they want. *Including him.*

[22] But there's a bigger problem here. An uglier problem.

[23] We're seeing more and more of this type of intolerance, vilification and dismissive character assassination in family court. Presumably we're seeing it inside the courtroom because it's rampant outside the courtroom. It now appears to be socially acceptable to denounce, punish and banish anyone who doesn't agree with you.

[24] A chilling example: I recently had a case where a mother tried to cut off an equal-time father's contact with his children, primarily because he was "promoting anti-government beliefs." And in Communist China, that request would likely have been granted.

[25] But this is Canada and our judicial system has an obligation to keep it Canada.

[26] I won't belabor the point, because I still have to get to my real job: determining what's in the best interests of these two children. But the word needs to get out that while the court system won't *punish* intolerance, it certainly won't reward it either.

[27] All parenting issues – including health issues – must be determined based upon the best interests of the child. Last year's amendments to the *Divorce Act* (applicable in this case) and the *Children's Law Reform Act* make it mandatory for the court to include consideration of a child's views and preferences to the extent that those views can be ascertained.

[28] As Justice Mandhane stated in *E.M.B. v. M.F.B.* 2021 ONSC 4264 (SCJ):

> 60. The requirement in s. 16(3)(e) to consider the "child's views and preferences" is new and is consistent with Article 12 of the *Child Rights Convention*. In the Legislative Background to the *Divorce Act* amendments, the Department of Justice explains that:
>
> Under Article 12 of the United Nations *Convention on the Rights of the Child,* children who are capable of forming their own views have the right to participate in a meaningful way in decisions that affect their lives, and parenting decisions made by judges and parents affect child directly. The weight to be given to children's views will generally increase with their age

> and maturity. However, in some cases, it may not be appropriate to involve the children, for example if they are too young to meaningfully participate.
>
> See also: *Official Report of Debates (Hansard)*, 42nd Parl., 1st Sess., No. 326 (26 September 2018) at p. 21866 (Hon. Jody Wilson-Raybould).
>
> 61. A human rights-based approach fundamentally recognizes children as subjects of law rather than objects of their parents. Making children more visible in legal proceedings that affect their rights is fundamentally important in Canada because children are not guaranteed legal representation in family law proceedings. Therefore, in my view, even where there is no direct evidence about the child's views and preferences, s. 16(3)(e) still requires the court should make a reasonable effort to glean and articulate the child's views and preferences wherever possible, considering the child's age and maturity and all the other evidence before it.

[29] In this case, the children's views have been *independently* ascertained -- *they both don't want to receive the COVID vaccines* – but the father is asking me to ignore how they feel and force them to be vaccinated against their will. The background:

a. In 2021, in an effort to resolve parenting issues, the parties enlisted a well-respected local social worker, Michelle Hayes, to prepare a "Voice of the Child Report". The father filed Hayes' comprehensive seven-page report dated June 22, 2021.
b. For purposes of that report the children were each interviewed twice – once in the care of each parent.
c. During the interview period the mother and father had clearly identified their respective positions on vaccination. The report specifically addressed each child's views on the topic.
d. L.E.G. advised that she had discussed vaccinations with each parent privately. She knew her father favoured getting the shot and her mother didn't. L.E.G. specifically explained to Hayes the reasons why she didn't want to receive the COVID vaccines. She explained herself in some detail.
e. Similarly, M.D.G. had discussed vaccinations with each parent privately. He also knew his father promoted vaccination and his mother didn't. M.D.G. not only told Hayes he didn't want to be vaccinated, but he said he was "fearful that his father would make him." Indeed, M.D.G. told Hayes that "he wanted the judge to know his thoughts about his parenting schedule as well as the vaccine."
f. The mother says her children are mature and intelligent, and that they have come to their own conclusions without being pressured by either parent. She feels it is important to respect their clear wishes, comfort level and anxieties. She says she adopted the same position for her older son C.B.G., and when he decided he wanted to be vaccinated she was fully supportive.
g. The father says at ages 12 and 10 the children are too young to make an informed decision about this. He admits both children have expressed fear of the COVID vaccine. He suggests the younger child's views are wavering. But he's opposed to either child being interviewed again. No matter what the children say, he doesn't think the court should listen, because he feels the mother has planted these ideas in their minds. But he offered no proof of any coaching, manipulation or inappropriate statement by the mother.

h. Hayes' June 22, 2021 report was actually a follow-up to an earlier report she prepared on March 3, 2020. She has worked with the family for a long time and got to know the children quite well. The social worker expressed no concerns or suspicions about either child being manipulated or pressured by either parent. In her summary she stated: *"As in the original report, each of the children presented confidently and thoughtfully for both interviews. As they reviewed their thoughts, they each showed consistency in their views and preferences in each interview."*

[30] While I agree with the father that these two children are not old enough to decide this complicated issue for themselves, I disagree with his suggestion that we should completely ignore how they feel about what they experience and what their bodies are subjected to. Rather than simplistically accept or reject what children say they want, the court must engage in a complex and sensitive analysis of the weight to be attributed to each child's stated views.

[31] In *Decaen v. Decaen*, 2013 ONCA 218 the Court of Appeal set out the factors to consider when assessing a child's wishes:

a. Whether both parents are able to provide adequate care;
b. How clear and unambivalent the wishes are;
c. How informed the expression is;
d. The age of the child;
e. The maturity level;
f. The strength of the wish;
g. The length of time the preference has been expressed;
h. Practicalities;
i. The influence of the parent(s) on the expressed wish or preference;
j. The overall context; and
k. The circumstances of the preferences from the child's point of view.

[32] With respect to L.E.G. and M.D.G.:

a. They have received all their regular immunizations. At ages 12 and 10 they understand the experience of getting needles. And they understand the purpose of vaccinations is to create a long-term medical consequence in their body.
b. They understand the magnitude of the COVID pandemic, and the personal and community health issues involved.
c. They understand the extended and ongoing discussion about the COVID vaccine.
d. They have both clearly and consistently stated their objection to receiving the COVID vaccine.
e. They have both outlined very specific reasons for their decision. Those reasons do not appear to be frivolous, superficial or poorly thought out.
f. Both children have sufficient age, intelligence, maturity and independence of thought to understand the issue and formulate their own views, feelings, comfort level, questions, *and fears* about what should or should not happen to their bodies.
g. They hold these views very strongly.

h. They have maintained these views for an extended period of time.
i. Despite the father's speculation, there is no evidence that the mother has inappropriately drawn the children into any sort of personal or political agenda. *Both* parents have equally engaged in appropriate and necessary discussions with the children about the many aspects of the pandemic – including vaccinations. Both parents have answered the children's questions, provided information, and stated their own beliefs. The social worker's report gives no suggestion that either parent has pressured, manipulated, or unduly influenced either child. Nor did Hayes express any concern about internal inconsistencies or ambiguities with respect to either child's strongly stated views.

[33] For the past two years *all* children have been bombarded with all sorts of information about the pandemic. It has become an inescapable, oppressive part of their daily lives. Mental health experts regularly warn us that we need to be mindful of the emotional impact of this scary new world on the young mind.

[34] In this case, the father doesn't like what the children are saying, so he submits their views aren't worthy of consideration – just as he submits the mother's views aren't worthy of consideration. *There's a bit of a pattern here.*

[35] But when a ten-year-old child says he's afraid he'll be forced to take the vaccine – *and he specifically wants the judge to know it* – I don't think that's something the court can or should ignore.

[36] Children may not have wisdom. But they have Charter rights and undeniable emotions.

[37] Any best interests analysis must take into account all relevant factors, including the impact on a child's mental health if their legitimate and powerful feelings and anxieties are ignored; and if they perceive they are being violated.

[38] A number of recent court decisions have grappled with this new "COVID vaccine" issue, and in particular with the issue of the weight to be given to children's views on the subject. In most of those cases the children were younger than L.E.G. and M.D.G., so "views and preferences" were either unascertainable or less relevant because of the child's lack of maturity.

[39] In *McDonald v. Oates* 2022 ONSC 394 (SCJ) the court disregarded a ten-year-old's views, concluding that the child was unable to make an informed choice due to the contradictory information the child was receiving from his parents.

a. But unlike the situation with 10-year-old M.D.G., in *McDonald* there was no independent information as to the nature or strength of the child's views, and the court declined to order a Voice of the Child Report, to avoid delay.
b. Here I had the benefit of a thorough and highly informative Voice of the Child Report.
c. And unlike *McDonald*, as discussed below, I find that the objecting parent's concerns cannot be dismissed as frivolous or uninformed.

d. More to the point I find that there is no evidence that either M.D.G. or L.E.G. have been unduly influenced by either their pro-vaccine or anti-vaccine parent. I am satisfied that they came to their own conclusions, for understandable reasons.

[40] In *Saint-Phard v. Saint-Phard* 2021 ONSC 6910 (SCJ) the court overruled a 13-year-old's opposition to vaccinations, as conveyed through the child's lawyer.

a. Again, the child's situation was quite different from L.E.G. and M.D.G..
b. In *Saint-Phard* the child had made inconsistent and ambiguous statements; he had been misinformed by a physician; and the court concluded he was incapable of making an informed decision.

[41] In *Rouse v. Howard* 2022 ONCJ 23 (OCJ) Justice Hilliard provided a thoughtful analysis of facts more similar to the case at bar – even though the child in question was only nine.

> 17 Although Fiona is only 9, there is evidence before me that she is, at present, opposed to receiving the COVID-19 vaccine. In A.C. v. L.L., 2021 ONSC 6530 (CanLII), [2021] O.J. No. 4992, Justice Charney considered section 4 of the Health Care Consent Act, 1996, S.O. 1996, c. 2 (HCCA), in his analysis as to whether the mother's consent was even required for the children to be vaccinated. Justice Charney noted that the HCCA does not provide any minimum age for capacity to make medical treatment decisions. That finding accords with the Supreme Court of Canada's decision in A.C. v Manitoba (Director of Child and Family Services), 2009 SCC 30, wherein Justice Abella explained the common law "mature minor" doctrine at paragraph 47:
>
> The doctrine addresses the concern that young people should not automatically be deprived of the right to make decisions affecting their medical treatment. It provides instead that the right to make those decisions varies in accordance with the young person's level of maturity, with the degree to which maturity is scrutinized intensifying in accordance with the severity of the potential consequences of the treatment or of its refusal.
>
> 18 Unlike in A.C. , where the children wanted to be vaccinated, and Saint-Phard where the child only expressed opposition to being vaccinated after the influence of the mother and her doctor, Fiona's views about vaccination appear to be long-standing and in accordance with her mother's beliefs about vaccines in general. An order granting Mr. Rouse decision-making authority would result in Mr. Rouse having the ability to override Fiona's right to withhold her consent to vaccination which may have negative emotional and/or psychological consequences.

[42] The determination of any child's best interests is a fact-specific exercise, based on the evidence presented – *and tested* – in each case. As stated, an important – but not determinative – part of the analysis consideration of each child's views and preferences.

a. In each of the recent cases where a child's stated opposition to being vaccinated was overridden, the court made unfavourable findings with respect to the objecting parent's rationale and their inappropriate influence over the child.
b. The court concluded that the pro-vaccine parent had presented more reasonable information to the child, and more compelling arguments to the court in relation to the science.
c. In each case the court was left with more confidence in the pro-vaccine parent's parental judgment and insight on the issue of vaccinations.

[43] But that's not at all what I'm dealing with in this case.

a. Despite the father's relentless campaign to dismiss the mother as some sort of lunatic, the reality is that the mother presented all her evidence and made all her oral submissions in a calm, mature, articulate, analytical, extensively researched, and entirely child-focussed manner. She is to be commended for her skillful and professional presentation as a self-represented party.
b. In contrast, the father came across as somewhat dogmatic, intolerant and paternalistic. He focussed more on discrediting the mother's ideas rather than explaining his own. And his shameless efforts to vilify the mother by ridiculing her personal beliefs bordered on hysterical.
c. I mention this to further explain why I have confidence that the mother has not inappropriately influenced the children to adopt their current views.
d. If the mother explained herself to the children the way she explained herself to me...and if the father explained himself to the children the way he explained himself to me...then I have absolutely no doubt about which of the parents communicated with the children in a more responsible manner.

[44] Finally, we have the other "evidence" filed by the parents. And here we have to think carefully about what constitutes proper or sufficient evidence – and how we should apply it.

[45] As with all the other recent COVID vaccine cases, the mother and the father attached dozens of pages of internet downloads to their affidavits. The fact that they both consented to my receiving all this unsworn material doesn't make it properly admissible. But at the very least, it informs me as to the type and quality of research each parent conducted in formulating their respective positions.

[46] Included among the father's downloads from the internet:

a. A November 23, 2021 seven page "Position Statement" from the Canadian Paediatric Society.
b. A January 2022 five page "Caring for Kids" information sheet from the Canadian Paediatric Society.
c. A December 17, 2021 nine-page "Vaccines for Children: COVID 19" information sheet from the Government of Canada.
d. A September 24, 2021 five-page "Post COVID-19 Condition" information sheet from the Government of Canada.

e. A May 18, 2021 seven-page "Vaccines for children: Deciding to Vaccinate" information sheet from the Government of Canada.
f. A May 6, 2021 three-page "The Facts About COVID-19 Vaccines" information sheet from the Government of Canada.
g. A January 20, 2022 four-page article entitled "Vaccinated kids half as likely to get Omicron but protection fades fast" from The Times of Israel.
h. A January 14, 2022 five page article entitled "COVID-19 Cases and Hospitalizations Surge Among Children" from the Canada Communicable Disease Report.

[47] Included among the mother's downloads from the internet:

a. A June 25, 2021 eight-page "Fact Sheet" issued by Pfizer, the manufacturer of one of the vaccines being proposed by the father.
b. An August 26, 2021 three-page article from the journal "Science" entitled "Having SARRS-CoV-2 once confers much greater immunity than a vaccine – but vaccination remains vital."
c. A January 31, 2012 13-page PLOS One peer-reviewed article entitled "Immunization with SARS Coronavirus Vaccines Leads to Pulmonary Immunopathology on Challenge with the SARS virus."
d. A July 10, 2021 five-page article in the medical journal "Total Health" entitled "Are people getting full facts on COVID vaccine risks?"
e. A September 26, 2018 15 page article in the medical journal "Contagion Live" entitled "High Rates of Adverse Events Linked with 2009 H1N1 Pandemic vaccine".
f. A May 28, 2021 two-page article from the Centers for Disease Control and Prevention (CDC) entitled "Clinical Considerations: Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults."
g. An August 1, 2020 29 page research paper published by eClinicalMedicine entitled "A country level analysis measuring the impact of government actions, country preparedness and socioeconomic factors on COVID -19 mortality and related health outcomes."
h. A June 9, 2021 10 page open letter from The Evidence-Based Medicine Consultancy Ltd. research organization entitled "Urgent Preliminary report of Yellow Card data up to May 26, 2021".
i. A June 22, 2021 14 page article from the World Health Organization entitled "COVID-19 advise for the public: Get vaccinated".

[48] Information obtained from the internet can be admissible if it is accompanied by indicia of reliability, including, but not limited to:

a. Whether the information comes from an official website from a well-known organization;
b. Whether the information is capable of being verified;
c. Whether the source is disclosed so that the objectivity of the person or organization posting the material can be assessed.

*ITV Technologies Inc. v. WIC Television Ltd.* 2003 FC 1056; *Sutton v. Ramos* 2017 ONSC 3181 (SCJ)

[49] Where the threshold of "admissibility" is met, it is still up to the trier of fact to weigh and assess the information to determine the relevance, if any, with respect to the issues to be decided.

[50] And since this is a motion proceeding by affidavit, we have the further limitation that even to the extent that the internet downloads are admissible, there is no opportunity for cross-examination or testing.

[51] To simplify matters, the mother does not deny the authenticity or integrity of the website information submitted by the father.

a. It's mostly statements by the Government of Canada and the Canadian Pediatric Society recommending that children should receive COVID vaccinations.
b. These are the same types of downloads which courts have considered in other recent COVID vaccine cases.
c. The mother doesn't deny that these are reputable organizations. Nor does she deny that the statements and information have been prepared by qualified persons in a responsible, professional manner.
d. She doesn't deny that the father has accurately presented *one side of the story*.
e. All she asks is that the court equally consider the other side of the story. That the court allow both sides of the story to be equally presented, tested and considered. Before making an irreversible decision for her children.

[52] *Evidence* and *both sides of the story*. We're in deep trouble if those become antiquated concepts.

[53] In almost all cases where COVID vaccinations have been ordered the court has made a finding that, on the face of it, the internet materials presented by the objecting parent have been grossly deficient, unreliable and – at times – dubious. This lack of an equally credible counter-point to government recommendations may well have been determinative in those earlier cases.

[54] But what if the objecting parent presents evidence which potentially raises some serious questions or doubts about the necessity, benefits or potential harm of COVID vaccines for children?

a. Clearly we shouldn't be too quick to embrace the naysayers.
b. But should we banish them? Without hearing from them?
c. Should we stifle and forbid a reasonable opportunity to present and test evidence, and make submissions?
d. There are obvious public policy reasons to avoid recklessly undermining confidence in public health measures.

e. But that has to be weighed against our unbridled obligation to leave no stone unturned, when it comes to protecting children.

[55] For example, the mother presented a detailed fact sheet from Pfizer. This isn't one of the fringe websites dismissed in the other cases. *It's Pfizer!* The people who make the vaccine.

[56] Under the heading "What Are The Risks of the Pfizer-BioNTech COVID-19 Vaccine", the company says:

> There is a remote chance that the Pfizer-BioNTech COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Pfizer-BioNTech COVID-19 Vaccine. For
> this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:
> • Difficulty breathing
> • Swelling of your face and throat
> • A fast heartbeat
> • A bad rash all over your body
> • Dizziness and weakness
>
> Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining
> outside the heart) have occurred in some people who have received the Pfizer-BioNTech
> COVID-19 Vaccine. In most of these people, symptoms began within a few days following
> receipt of the second dose of the Pfizer-BioNTech COVID-19 Vaccine. The chance of having
> this occur is very low. You should seek medical attention right away if you have any of the
> following symptoms after receiving the Pfizer-BioNTech COVID-19 Vaccine:
>
> • Chest pain
> • Shortness of breath
> • Feelings of having a fast-beating, fluttering, or pounding heart.
>
> Side effects that have been reported with the Pfizer-BioNTech COVID-19 Vaccine include:
>
> • severe allergic reactions
> • non-severe allergic reactions such as rash, itching, hives, or swelling of the face
> • myocarditis (inflammation of the heart muscle)

> • pericarditis (inflammation of the lining outside the heart)
> • injection site pain
> • tiredness
> • headache
> • muscle pain
> • chills
> • joint pain
> • fever
> • injection site swelling
> • injection site redness
> • nausea
> • feeling unwell
> • swollen lymph nodes (lymphadenopathy)
> • diarrhea
> • vomiting
> • arm pain
>
> These may not be all the possible side effects of the Pfizer-BioNTech COVID-19 Vaccine. Serious and unexpected side effects may occur. Pfizer-BioNTech COVID-19 Vaccine is still being studied in clinical trials.

[57] It's very hard to fault a parent for being worried about such an ominous list of potentially very serious side effects.

[58] Several of the earlier decisions requiring children to be vaccinated have noted that the evidence presented by the objecting parent was not reliable because the authors' credentials were either not-established or non-existent.

[59] But in this case, none of the materials presented by the mother are from fringe organizations or dubious authors. To the contrary, the mother quotes extensively from leaders in the medical and scientific community.

[60] For example, the article submitted by the mother "Are People Getting Full Facts on COVID Vaccine Risks?" quotes Dr. Robert W. Malone, the inventor of the mRNA vaccine. Whether he is right or wrong about the current use of COVID vaccines is a matter for discussion and determination. But with his credentials, he can hardly be dismissed as a crackpot or fringe author. The mother referred to the following excerpt from the article:

> The original inventor of the mRNA vaccine (and DNA vaccine) core platform technology currently used to create the vaccines is Dr Robert W Malone. Dr Malone has been expressing serious concerns about how therapeutic approaches that are still in the research phase are being imposed on an ill-informed public. He says that public health leadership has, "stepped over the line and is now violating the bedrock principles which form the foundation upon which the ethics of clinical research are built".

> Dr Malone asks why health leaders seem to be so afraid of sharing the adverse event data. He says, "Why is it necessary to suppress discussion and full disclosure of information concerning mRNA reactogenicity and safety risks?"
>
> He goes onto say that we should be analysing the safety data and risks vigorously. Again he asks, "Is there information or patterns that can be found, such as the recent finding of the cardiomyopathy signals, or the latent virus reactivation signals? We should be enlisting the best biostatistics and machine learning experts to examine these data, and the results should -- no must -- be made available to the public promptly".
>
> For any drug it has always been important to have systems in place for monitoring adverse events. However, for an experimental, genetic modifying approach that has not been fully tested, and where the public are effectively the guinea pigs, this information should be immediately and readily available. As previously reported...the fact that it is so difficult to access and make sense of ...reporting systems - along with low reporting simply raises further concern about what is actually happening.
>
> . . . .
>
> Dr Malone says, " .. what is being done by suppressing open disclosure and debate concerning the profile of adverse events associated with these vaccines violates fundamental bioethical principles for clinical research".
>
> With regard to the use and abuse of misinformation, the inventor of these vaccines says that the public have to be given accurate information to allow informed consent. He says, "The suppression of information, discussion, and outright censorship concerning these current COVID vaccines which are based on gene therapy technologies cast a bad light on the entire vaccine enterprise. It is my opinion that the adult public can handle information and open discussion. Furthermore, we must fully disclose any and all risks associated with these experimental research products".
>
> In short, it is simply not possible to arrive at a position of informed consent unless you have access to the full facts around your options and the associated risks and benefits.

[61] The same article outlines other serious concerns about COVID vaccines expressed by Dr. Bret Weinstein, Dr. Peter McCullough, Dr. Tess Lawrie, Professor Stanley S. Levinson (medicine, endocrinology, diabetes and metabolism) and Professor Sucharit Bhakdi (awarded the Order of Merit for medical microbiology). These are well-known leaders in their fields.

[62] Several other articles presented by the mother outline similar expressions of concern about the COVID vaccines from equally qualified and reputable sources worldwide.

[63] For clarity:

a. I am not for one moment suggesting that we should presume the mother's experts are *right*.
b. But once we determine they're not crackpots and charlatans, how can we presume that they are *wrong*? Or that they couldn't possibly be right about any of their warnings?
c. When children's lives are at stake, how can we ignore credible warnings?

[64] The following paragraphs from *Saint-Phard v. Saint-Phard* 2021 ONSC 6910 (SCJ) illustrate the approach which has been taken in a number of cases in which COVID vaccinations were approved by the court.

> 4 The decision to be made is governed by the best interests of the child: A.C. v. L.L, 2021 ONSC 6530. It is required to be based on findings of fact made from admissible evidence before the court: O.M.S. v. E.J.S, 2021 CarswellSask 547 (Q.B.); B.C.J.B. v. E.-R.R.R., 2021 CarswellOnt 13242 (S.C.J.).
>
> Judicial notice may be taken
>
> 5 Facts may be found by taking judicial notice: B.C.J.B. v. E.-R.R.R., A.P. v. L.K, 2021 ONSC 150, and A.C. v. L.L Each of these cases include findings related to the safety and efficacy of publicly funded vaccines on the basis of judicial notice. For example, in A.C. v. L.L at paragraphs 21, 23 and 25 the court made the following findings by taking judicial notice under the public documents' exception to the hearsay rule :
>
> • The COVID-19 vaccination has been approved for children aged 12-17.
>
> • All levels of government have been actively promoting vaccination against COVID-19 and expending significant resources to make it available to the public.
>
> • The safety and efficacy of the COVID-19 vaccine has been endorsed by governments and public health agencies.
>
> • The Ontario Ministry of Health website states that Pfizer-BioNTech vaccine is now licensed by Health Canada for adolescents aged 12 years and older, has been proven to be safe in clinical trials and provided excellent efficacy in adolescents, and that NACI continues to strongly recommend a complete series with an MNRA vaccine for all eligible individuals in Canada, including those 12 years of age and older, as the known and potential benefits outweigh the known and potential risks.
>
> 6 Elyon's father relied on statements made by Dr. Tam, Chief Officer of Health for Canada on the Canadian Government website recommending COVID-19 vaccinations for those between the ages of 12 and 17, stating that thorough testing has determined the vaccines to be safe and effective at preventing severe illness, hospitalization, and death from COVID-19. Dr. Kieran Moore is the Chief Medical Officer for Ontario. The father tendered his recommendation to vaccinate all youth ages 12 to 17 against COVID-19 as set out in a publication by the Ontario COVID-

> 19 Science Advisory Table. Elyon's school is administered under the Ottawa Catholic School Board. That Board released a notice advising that all students over age 12 are eligible to be vaccinated for COVID-19 and stating that the vaccine is key in protecting schools from the virus.
>
> 7 Relying on these public documents and the authority of the court in A.C. v. L.L**,** I find that the applicable government authorities have concluded that the COVID-19 vaccination is safe and effective for children ages 12-17 to prevent severe illness from COVID-19 and have encouraged eligible children to be vaccinated.

[65] And that's really what many of these cases come down to: After considering all the evidence – or often, the lack of evidence – can the court just fill in the blanks and take judicial notice of the fact that all children should get vaccinated?

a. Because if the answer is "yes", then we're wasting a lot of time and judicial resources.
b. If judges just "know" that all children should be vaccinated, then we should clearly say that that's what we're doing.
c. But equally, if that's *not* what we're supposed to be doing....then we shouldn't do it.

[66] In *R.S.P. v. H.L.C.* 2021 ONSC 8362 (SCJ) Justice Breithaupt Smith recently set out a timely warning about the danger of applying judicial notice to cases where expert opinion is unclear or in dispute. It's a warning I whole heartedly adopt:

> 56 Unfortunately, the recent case of Saint-Phard v. Saint-Phard[14] does not assist in navigating medical treatment for minors because of its fatal flaw regarding judicial notice. In that case, the Court wrote: "Facts may be found by taking judicial notice. [citations omitted] Each of these cases include findings related to the safety and efficacy of publicly funded vaccines on the basis of judicial notice." This shows a misunderstanding of the purpose of taking judicial notice, which, according to the Supreme Court's definitive decision in R. v. Find 2001 SCC 32 (CanLII) (at paragraph 48) is intended to avoid unnecessary litigation over facts that are:
>
> ...clearly uncontroversial or beyond reasonable dispute. Facts judicially noticed are not proved by evidence under oath. Nor are they tested by cross-examination. Therefore, the threshold for judicial notice is strict: a court may properly take judicial notice of facts that are either: (1) so notorious or generally accepted as not to be the subject of debate among reasonable persons; or (2) capable of immediate and accurate demonstration by resort to readily accessible sources of indisputable accuracy.
>
> 57 Judicial notice of the facts contained in government publications are "capable of immediate and accurate demonstration by resort to readily accessible sources of indisputable accuracy." Such facts could include, for example, that there are two time zones in the Province of Ontario or that there were two deaths and 39 Intensive Care

Unit admissions among Ontario children from January 15, 2020 to June 30, 2021 connected with SARS-CoV-2.

58 Judicial notice cannot be taken of expert opinion evidence. Chief Justice McLachlin for the unanimous Court in R. v. Find underscored that: "Expert evidence is by definition neither notorious nor capable of immediate and accurate demonstration. This is why it must be proved through an expert whose qualifications are accepted by the court and who is available for cross-examination" (at paragraph 49).

59 The acceptance of government-issued statements as evidence renders the facts published by the government agency (presumed to be a source of indisputable accuracy) admissible. Public Health Ontario's statement that two children died of SARS-CoV-2 between January 15, 2020 and June 30, 2021 is therefore admissible as fact. Public Health Ontario's publicly accessible document is admissible as proof of the truth of its contents. In contrast, a statement concerning the safety and efficacy of any medication in the prevention or treatment of any condition is, in and of itself, an opinion. Judicial notice cannot be taken of the opinion of any expert or government official that a medical treatment is "safe and effective." As judicial notice cannot be taken of expert opinion evidence, it is illogical to reason, as was done at paragraph 12 of Saint-Phard , that an expert's "objections raised against the vaccine were directly countered by the judicial notice taken that the vaccine is safe and effective and provides beneficial protection against the virus to those in this age group." To compound the problem, this statement draws a conclusion that is overbroad (i.e. that the vaccine provides beneficial protection to all children and ought therefore to be received by the child in question) without having considered the comparative analysis of the factors in A.C. v. Manitoba 2009 SCC 30 (CanLII). As a result, reliance upon this reasoning would be misguided.

60 In submissions, I was also referred to the case of A.C. v. L.L. 2021 ONSC 6530 (SCJ) in which both parents agreed that each of their three teenage children would be permitted to make his or her own decision with respect to the COVID-19 vaccination. Two of the three children chose to have it administered and one did not. While the Court made many very concerning and overly broad comments, all are obiter dicta. None were relevant to the result ultimately reached, namely that both parents acknowledged each child's maturity in choosing whether or not to participate in the medical procedure and agreed to allow each child to make his or her own choice. With the parents having agreed upon that point, the Court was no longer obligated to make any finding as to whether receipt of the COVID-19 vaccine was in the best interests of any of the children. As the parents had agreed to respect the decisions made by their children, one of whom declined the COVID-19 vaccine, is that child now in breach of the Court's determination, at paragraph 32, that vaccination is in that child's best interests? Of what utility is the declaration in the Order portion of the decision that "[all three] children ... shall be entitled to receive the COVID-19 vaccine"? In family litigation, unsolicited judicial opinions on parenting questions already solved by the parents serve no one. I am reminded of Justice Abella's warning that: "[the analysis of a child's maturity in making medical

decisions] does not mean ... that the standard is a license for the indiscriminate application of judicial discretion" A.C. v. Manitoba (paragraphs 90-91). Thus, while I commend the parents in A.C. v. L.L. for resolving the issue of each child's ability to make his or her own decision, the case itself does not assist this Court.

[67] Why should we be so reluctant to take judicial notice that the government is always right?

a. Did the Motherisk inquiry teach us nothing about blind deference to "experts"? Thousands of child protection cases were tainted – and lives potentially ruined – because year after year courts routinely accepted and acted upon substance abuse testing which turned out to be incompetent.
b. What about the Residential School system? For decades the government assured us that taking Indigenous children away – and being wilfully blind to their abuse – was the right thing to do. We're still finding children's bodies.
c. How about sterilizing Eskimo women? The same thing. The government knew best.
d. Japanese and Chinese internment camps during World War Two? The government told us it was an emergency and had to be done. Emergencies can be used by governments to justify a lot of things that later turn out to be wrong.
e. Few people remember Thalidomide. It was an experimental drug approved by Canada and countries throughout the world in the late 1950's. It was supposed to treat cancer and some skin conditions. Instead it caused thousands of birth defects and dead babies before it was withdrawn from the market. But for a period of time government experts said it was perfectly safe.
f. On social issues the government has fared no better. For more than a century, courts took judicial notice of the fact that it was ridiculous to think two people of the same sex could get married. At any given moment, how many active complaints are before the courts across the Country, alleging government breaches of Charter Rights? These are vitally important debates which need to be fully canvassed.
g. The list of grievous government mistakes and miscalculations is both endless and notorious. Catching and correcting those mistakes is one of the most important functions of an independent judiciary.
h. And throughout history, the people who held government to account have always been regarded as heroes – not subversives.
i. When our government serially pays out billions of dollars to apologize for unthinkable historic violations of human rights and security – how can we possibly presume that today's government "experts" are infallible?
j. Nobody is infallible.
k. And nobody who controls other people's lives – *children's lives* – should be beyond scrutiny, or impervious to review.

[68] As well, how can you take judicial notice of a moving target?

a. During the past two years of the pandemic, governments around the world – and within Canada – have constantly changed their health directives about what we should or shouldn't be doing. What works and what doesn't.
b. And the changes and uncertainty are accelerating with each passing newscast. Not a day goes by that we don't hear about COVID policies changing and restrictions being lifted.
c. Government experts sound so sure of themselves in recommending the current vaccines.
d. But they were equally sure when they told us to line up for AstraZeneca. Now they don't even mention that word.
e. Even Pfizer has changed its mind. It recently approved vaccines for kids under five. Then more recently the company changed its mind.
f. None of this is meant a criticism. Everyone is doing their best with a new and constantly evolving health crisis.
g. But how can judges take judicial notice of "facts" where there's no consensus or consistency?

[69] And then we have the issue of delegation.

a. As with almost all these vaccine motions, the father asks for an order that his children receive the current COVID vaccine "*and all recommended booster vaccines.*"
b. Which recommended booster vaccines?
c. When?
d. How many?
e. What will they contain?
f. Who will decide?
g. Will there be any opportunity for future judicial oversight, or will this simply be a forever commitment controlled by the government.
h. What are the health implications if children receive the current vaccine, but skip some or all of the boosters?
i. What future COVID variant will the boosters guard against? We already seem to be using the Delta vaccine to fight the Omicron variant. Will future boosters continue our pattern of using old medicine to fight new viruses?
j. These are all valid questions, requiring answers which are currently unavailable.
k. It is improper for the court to pre-determine future medical treatments at unknown times, in unknown circumstances, with decision making authority delegated to unknown persons.
l. If you can't take judicial notice of the *present,* you can't take judicial notice of the *future*.

[70] As well, there is a systemic issue common to most of these COVID vaccine cases.

a. The father presented his expert evidence.
b. The mother then presented her expert evidence.
c. The father responded that the mother's theories have already been "debunked" – so we shouldn't waste time talking about them.

d. Alleging that your opponent's position has already been debunked is a common tactic these days.
e. And quite effective.
f. Because unlike *stare decisis* – the doctrine of precedent which requires judges to follow specifically cited earlier court decisions – there is no such formality to the concept of debunking.
g. All you have to do is make the blanket assertion that an opposing view has already been debunked – without providing any details – and hope that nobody asks for proof.
h. In this case, I reject the father's claim that all of the mother's concerns about COVID vaccines have already been properly considered and disproven, in a process adhering to natural justice, conducted by an appropriate judicial body.
i. Quite to the contrary, I have not been able to find any indication – in the father's evidence or in the body of COVID vaccine case law – that allegedly debunked theories have ever been properly considered or tested. In any court. Anywhere.

[71] In a complex, important, and emotional case like this, it is important to remember the court's mandate:

a. I am not being asked to make a scientific determination. I am being asked to make a parenting determination.
b. I am not being asked to decide whether vaccines are good or bad.
c. I am not being asked to decide if either *parent* is good or bad.
d. My task is to determine which parent is to have decision-making authority over L.E.G. and M.D.G. with respect to the very specific and narrow issue of COVID vaccinations. Each parent has clearly identified how they would exercise such decision-making authority.

[72] Pursuant to the recent, final, consent order, the two children reside primarily with the mother.

a. She has sole decision-making authority on all issues – with the exception that the parties deferred the issue of decision-making in relation to COVID vaccinations.
b. The father suggests there should be an inference that the mother was deliberately deprived of authority over this particular issue, because she could not be trusted to make the right decision.
c. I am not prepared to make any such an inference.
d. Both parents showed commendable maturity and insight in negotiating comprehensive minutes of settlement on all but one of the issues.
e. I interpret the minutes of settlement as leaving it open for the court to consider vaccinations as a stand-alone issue, to be determined solely based on the best interests of the children, and without either parent having any presumptive advantage or disadvantage in the determination.

[73] With respect to the mother and father:

a. I find that they are both excellent parents.

b. The father has shown excellent parenting skills and familiarity with respect to the oldest child C.B.G. who is doing well in his care.
c. The mother has shown excellent parenting skills and familiarity with respect to L.E.G. and M.D.G. who are doing well in her care.

[74] With respect to the children L.E.G. and M.D.G.:

a. I find that they are both intelligent, mature, articulate and insightful with respect to their place both within the family and within the community.
b. Both children are healthy. Their medical needs have always been properly addressed.
c. I received no professional or other evidence to suggest that there are any specific medical condition or issue which either favours or disfavours vaccination.
d. I find that both children have very specific, strongly held and independently formulated views about COVID vaccinations. Those views have been verified independently by an experienced social worker who would be alive to the possibility of parental influence or interference.
e. While the mother has strongly held views on the subject, the father has equally strongly held views. It is both understandable and appropriate that each parent has discussed the issue with each child. I find that while each parent has expressed their preference and view on the topic, neither parent has pressured or manipulated the children.
f. I am confident that each child's view has been clear, consistent, thoughtful, and entirely understandable in all the circumstances.

[75] Section16(1) of the *Divorce Act* provides that the court shall take into consideration only the best interests of a child when making a parenting order or a contact order.

[76] Section 16(2) says when considering best interest factors, primary consideration is to be given to the child's physical, emotional and psychological safety, security and well-being. *Pierre v. Pierre*, 2021 ONSC 5650 (SCJ).

[77] Section 16(3) sets out a list of factors for the court to consider in considering the circumstances of a child and determining best interests:

> 16(3) Factors to be considered
>
> In determining the best interests of the child, the court shall consider all factors related to the circumstances of the child, including
>
> (a) the child's needs, given the child's age and stage of development, such as the child's need for stability;
> (b) the nature and strength of the child's relationship with each spouse, each of the child's siblings and grandparents and any other person who plays an important role in the child's life;
> (c) each spouse's willingness to support the development and maintenance of the child's relationship with the other spouse;

(d) the history of care of the child;
(e) the child's views and preferences, giving due weight to the child's age and maturity, unless they cannot be ascertained;
(f) the child's cultural, linguistic, religious and spiritual upbringing and heritage, including Indigenous upbringing and heritage;
(g) any plans for the child's care;
(h) the ability and willingness of each person in respect of whom the order would apply to care for and meet the needs of the child;
(i) the ability and willingness of each person in respect of whom the order would apply to communicate and cooperate, in particular with one another, on matters affecting the child;
(j) any family violence and its impact on, among other things,
(i) the ability and willingness of any person who engaged in the family violence to care for and meet the needs of the child, and
(ii) the appropriateness of making an order that would require persons in respect of whom the order would apply to cooperate on issues affecting the child; and
(k) any civil or criminal proceeding, order, condition, or measure that is relevant to the safety, security and well-being of the child.

[78] I find that the combination of sections 16(2) ("the child's physical, emotional and psychological safety, security and well-being") and 16(3)(e) ("the child's views and preferences...") require that significant weight should be given to each child's stated views and requests. I would be very concerned that any attempt to ignore either child's views on such a deeply personal and invasive issue would risk causing serious emotional harm and upset.

[79] With respect to the positions advanced by each parent.

a. I respect the father's decision to be guided by government and health protocols.
b. I think the father did himself a disservice by focussing so much of his case on dismissive personal attacks on the mother. Those attacks are not only misguided and mean-spirited. They raise doubts about his insight with respect to the vaccine issue – and they also raise doubts about his appreciation of the nature and quality of the important relationship between the mother (as primary resident parent) and the children.
c. I equally respect the mother's decision to make exhaustive efforts to inform herself about the vaccination issue.
d. I find that the mother took a reasonable approach in acknowledging the strengths of the pro-vaccine materials, while at the same time attempting to reconcile them with contrary viewpoints and warnings issued by equally competent and credible medical professionals.
e. I find that the mother's position is more reasonable and helpful in that she invites discussion and exploration of both sides of the story, while the father seeks to suppress it.
f. I find that the father has inaccurately and somewhat unfairly characterized both the mother's position and her evidence.

g. The father has attempted to dismiss the mother as some sort of crazy anti-vaxxer. Nothing could be further from the truth. The mother's materials and submissions actually addressed the important and complex issues in more detail and with more comprehension than conveyed by the father. She has made it very clear that she has not completely rejected COVID vaccinations for L.E.G. and M.D.G.. She is simply concerned that in her view there is overwhelming evidence of unresolved safety concerns with respect to the current vaccines being administered. She has come to the conclusion that at this time the risks associated with the vaccines outweigh the benefits.

h. As well, the mother's statement that she believes "in personal choice, knowledge, understanding and informed consent" is to be viewed in a reassuring context. She has gone to extraordinary lengths to inform herself, to maintain an open mind, and to discuss the issue with her children in a balanced, enlightened, and dispassionate manner.

i. The father has attempted to dismiss the mother's supporting materials as unreliable and less persuasive than his own materials. Once again, I find his attack to be misguided and inaccurate.

j. Pro-vaccine parents have consistently (and effectively) attempted to frame the issue as a contest between reputable government experts versus a lunatic fringe consisting of conspiracy theorists, and socially reprehensible extremists. This was absolutely the wrong case to attempt that strategy. The professional materials filed by the mother were actually more informative and more thought-provoking than the somewhat repetitive and narrow government materials filed by the father.

[80] This is not the kind of case where the court can say that either side is necessarily correct. Nor that the same determinations should apply for every child, no matter the circumstances.

[81] With the mother's materials satisfying me that a legitimate and highly complex debate exists on the efficacy and utilization of COVID vaccines, I am not prepared to apply judicial notice as a method of resolving the issue. Anyone reading even some of the articles presented by the mother would likely conclude that these are complicated and evolving issues, and there can be no simplistic presumption that one side is right and that the other side is comprised of a bunch of crackpots. That's why the court should require evidence rather than conclusory statements.

[82] The father insists the mother's views have been debunked, but he provides no example of any such determination actually having been made. It would be helpful if, once and for all, the competing positions and science could be properly explored and tested in a public trial.

[83] On balance, I am satisfied that that mother's request for a cautious approach is compelling, and reinforced by the children's views and preferences which are legitimate and must be respected. The mother has consistently made excellent decisions throughout the children's lives. Her current concerns about the vaccines are entirely understandable, given the credible warnings and commentary provided by reputable sources who are specifically acquainted with this issue.

[84] The mother has consistently made excellent, informed, and child-focussed decisions. In every respect she is an exemplary parent, fully attuned to her children's physical and emotional needs. She has demonstrated a clear understanding of the science. She has raised legitimate questions and concerns. I have confidence that she will continue to seek out answers to safeguard the physical and emotional health of her children.

[85] She is not a bad parent – *and no one is a bad citizen* – simply by virtue of asking questions of the government.

[86] At a certain point, where you have absolute confidence in a parent's insight and decision-making, you have to step back and acknowledge that they love their child; they have always done the right thing for their child...*and they will continue to do the right thing for their child*.

[87] The father's motion is dismissed.

[88] The mother shall have sole decision-making authority with respect to the issue of administering COVID vaccines for the children L.E.G. and M.D.G..

[89] If any issues other than costs need to be addressed, counsel should arrange with the Trial Co-ordinator a time for this matter to be spoken to. This should be arranged within 10 days.

[90] If only costs need to be determined, the parties should serve and file written submissions on the following timelines:

a. Mother's materials (not to exceed three pages of narrative, and not to be more than 12 pages in total including offers, with cases to be hyperlinked) by March 18, 2022.
b. Father's materials (not to exceed three pages of narrative, and not to be more than 12 pages in total including offers, with cases to be hyperlinked) by April 1, 2022.
c. Any reply by mother (not to exceed two pages) by April 11, 2022.

**POSTSCRIPT:**

[91] It's irrelevant to my decision and it's none of anyone's business.

[92] But I am fully vaccinated. My choice.

[93] I mention this because I am acutely aware of how polarized the world has become.

[94] We should all return to discussing *the issues* rather than making presumptions about one another.

Pazaratz J.

**Released:** February 22, 2022

**CITATION:** J.N. v. C.G., 2022 ONSC 1198
**COURT FILE**

**NO.:** 987/18

**DATE:** 2022-02-22

**ONTARIO**

**SUPERIOR COURT OF JUSTICE**

**B E T W E E N :**

J.N.

Applicant

**- and -**

C.G.

Respondent

**REASONS FOR JUDGMENT**

Pazaratz J.

**Released:** February 22, 2022

# Is this leaked info really Trudeau's crazy COVID plan for 2021? You decide …

*Posted by canadian report on October 14, 2020 02:17*
*Tags: COVID-19 restrictions, LPC Strategic Committee Leak*
*Categories: POLITICS RECENT POSTS*

Fw: LPC Strategic Committee LeakInboxLPC leaker

<LPC_leaker@protonmail.com>1:47 PM (7 hours ago)

Original Message -------
On Saturday, October 10, 2020 1:38 PM, REMOVED <REMOVED> wrote:

Dear REMOVED,

I want to provide you some very important information. I'm a committee member within the Liberal Party of Canada. I sit within several committee groups but the information I am providing is originating from the Strategic Planning committee (which is steered by the PMO).

I need to start off by saying that I'm not happy doing this but I have to. As a Canadian and more importantly as a parent who wants a better future not only for my children but for other children as well. The other reason I am doing this is because roughly 30% of the committee members are not pleased with the direction this will take Canada, but our opinions have been ignored and they plan on moving forward toward their goals. They have also made it very clear that nothing will stop the planned outcomes.

The road map and aim was set out by the PMO and is as follows:

– Phase in secondary lock down restrictions on a rolling basis, starting with major metropolitan areas first and expanding outward. Expected by November 2020.
– Rush the acquisition of (or construction of) isolation facilities across every province and territory. Expected by December 2020.
– Daily new cases of COVID-19 will surge beyond capacity of testing, including increases in COVID related deaths following the same growth curves. Expected by end of November 2020.
– Complete and total secondary lock down (much stricter than the first and second rolling phase restrictions). Expected by end of December 2020 – early January 2021
– Reform and expansion of the unemployment program to be transitioned into the universal basic income program. Expected by Q1 2021.
– Projected COVID-19 mutation and/or co-infection with secondary virus (referred to as COVID-21) leading to a third wave with much higher mortality rate and higher rate of infection. Expected by February 2021.
– Daily new cases of COVID-21 hospitalizations and COVID-19 and COVID-21 related deaths will exceed medical care facilities capacity. Expected Q1 – Q2 2021.
– Enhanced lock down restrictions (referred to as Third Lock Down) will be implemented. Full travel restrictions will be imposed (including inter-province and inter-city). Expected Q2 2021.

– Transitioning of individuals into the universal basic income program. Expected mid Q2 2021.
– Projected supply chain break downs, inventory shortages, large economic instability. Expected late Q2 2021.
– Deployment of military personnel into major metropolitan areas as well as all major roadways to establish travel checkpoints. Restrict travel and movement. Provide logistical support to the area. Expected by Q3 2021.

Along with that provided road map the Strategic Planning committee was asked to design an effective way of transitioning Canadians to meet a unprecedented economic endeavor. One that would change the face of Canada and forever alter the lives of Canadians. What we were told was that in order to offset what was essentially an economic collapse on a international scale, that the federal government was going to offer Canadians a total debt relief. This is how it works: the federal government will offer to eliminate all personal debts (mortgages, loans, credit cards, etc) which all funding will be provided
to Canada by the IMF under what will become known as the World Debt Reset program. In exchange for acceptance of this total debt forgiveness the individual would forfeit ownership of any and all property and assets forever. The individual would also have to agree to partake in the COVID-19 and COVID-21 vaccination schedule, which would provide the individual with unrestricted travel and unrestricted living even under a full lock down (through the use of photo identification referred to as Canada's HealthPass) .

Committee members asked who would become the owner of the forfeited property and assets in that scenario and what would happen to lenders or financial institutions, we were simply told "the World Debt Reset program will handle all of the details". Several committee members also questioned what would happen to individuals if they refused to participate in the World Debt Reset program, or the HealthPass, or the vaccination

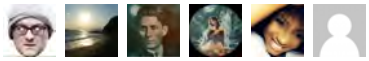
schedule, and the answer we got was very troubling. Essentially we were told it was our duty to make sure we came up with a plan to ensure that would never happen. We were told it was in the individuals best interest to participate. When several committee members pushed relentlessly to get an answer we were told that those who refused would first live under the lock down restrictions indefinitely. And that over a short period of time as more Canadians transitioned into the debt forgiveness program, the ones who refused to participate would be deemed a public safety risk and would be relocated into isolation facilities. Once in those facilities they would be given two options, participate in the debt forgiveness program and be released, or stay indefinitely in the isolation facility under the classification of a serious public health risk and have all their assets seized.

So as you can imagine after hearing all of this it turned into quite the heated discussion and escalated beyond anything I've ever witnessed before. In the end it was implied by the PMO that the whole agenda will move forward no matter who agrees with it or not. That it wont just be Canada but in fact all nations will have similar roadmaps and agendas. That we need to take advantage of the situations before us to promote change on a grander scale for the betterment of everyone. The members who were opposed and ones who brought up key issues that would arise from such a thing were completely ignored. Our opinions and concerns were ignored. We were simply told to just do it.

All I know is that I don't like it and I think its going to place Canadians into a dark future.

Vancouver, Canada·Posted Today, October 14

Like



6 bloggers like this.

Theo Caldwell: Please be honest: Are you still afraid of Covid-19? Like you, I heard the horror stories back in March, and saw the footage from China, ostensibly of dead

Corruption has found its way into our electoral process: What does this mean to the future of Canadians and the People's Party of Canada? Crystal Vargas October 28, 2019 Only days out of the election and the people of this country are feeling numb with

An Albertan's letter to voters in Ontario and Quebec. October 19, 2019 Dear Ontario and Quebec voters, On the eve of our Canadian Federal Election, I feel it is

# 146 responses to *Is this leaked info really Trudeau's crazy COVID plan for 2021? You decide …*

### Canadian politician leaks new COVID lockdown plan and 'Great Reset' dictatorship – Australia is part of it | Global TV October 20th, 2020 at 00:44

[…] Canadian whistleblower's email has been published by Canadian alt media site The Canadian Report. The deliberate leak of the information is remarkable because it is the equivalent of senior […]

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### "AS SERIOUS AS A HEART ATTACK": THE GREAT RESET & THE MAYAN ZAPATISTAS October 19th, 2020 at 23:47

[…] Is this leaked info really Trudeau's crazy COVID plan for 2021? You decide … […]

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### Covid-19 as a Pretext for The Great Reset - Lockdown Fighter October 19th, 2020 at 17:55

[…] details are starting to come into focus. In Canada, an insider from the governing Liberal Party has leaked details which […]

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### Is this leaked info really Trudeau's crazy COVID plan for 2021? You decide … – Addiction Warfare October 19th, 2020 at 16:12

[…] All I know is that I don't like it and I think its going to place Canadians into a dark future.Vancouver, Canada·Posted Today, October 14 (Click to Source) […]

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Reply

### Canadian politician leaks new COVID lockdown plan and 'Great Reset' dictatorship – Australia is part of it – Addiction Warfare October 19th, 2020 at 16:00

[…] Canadian whistleblower's email has been published by Canadian alt media site The Canadian Report. The deliberate leak of the information is remarkable because it is the equivalent of senior […]

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Reply

### artsychic2000 October 19th, 2020 at 14:35

Dr's from the Netherlands. There is no pandemic.


Loading...

Reply

**Bela** **October 19th, 2020 at 11:31**

Question:

Is the head of World Economic Forum, Klaus Schwab, Jewish?

It certainly is unnerving to hear someone with a German accent “dictating” how the world will be reshaped! :(((

Loading...

Reply

**Anonymous** **October 20th, 2020 at 12:34**

I think he’s undoubtedly Jewish, they’re the guys in charge of most sectors today.

Also the prime driver behind white replacement.

They’re really afraid that 12 percent of the global population will be the ones to say NO to them and fight back. We will…

We are….

Loading...

Reply

> **David Robertson** **October 20th, 2020 at 14:09**
>
> It is very unlikely that he is Jewish. He was born in 1938 in Germany and went through the German education system. That would be impossible if his family were Jews. The year 1938 was when Hitler consolidated his political power and became the undisputed judicial authority in Germany. The Nazis' ideological anti-Semitism argues against any Jew flourishing or even living openly in Germany at that time.
>
> Those who control nations today are members of the highest degrees in secret societies, who primarily worship Lucifer aka the Devil or Satan. They control banking, corporations, governments and academia. We are now in the final chapter of their control and a major denouement in the ongoing struggle between the forces of Evil and those of Good will take place in 2024.
>
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> Reply

## Is this leaked info really Trudeau's crazy COVID plan for 2021? – Stars Have Fallen

**October 19th, 2020 at 10:32**

[…] SOURCE […]

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Reply

## Canadian Politician Leaks new COVID Lockdown Plan and 'Great Reset' Dictatorship – Luke Catherall

**October 19th, 2020 at 04:21**

[…] Canadian whistleblower's email has been published by Canadian alt media site The Canadian Report. The deliberate leak of the information is

remarkable because it is the equivalent of senior […]

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Reply

### Co tam panie z tym planem plandemii dla Kanady | Piotr Bein's blog = blog Piotra Beina October 19th, 2020 at 02:32

[…] Publikacja w Kanadzie i forum Koment polityczny z Australii plus forum. [Podobne struktury totalitarne w rządzie brytyjskim, czekam na koment w UK Column.] […]

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Reply

### Gates-Rockefeller-World Economic Forum push for global vaccination and the Agenda 21 "new normal/new economy". - Hydroponify October 18th, 2020 at 17:53

[…] Canadian whistleblower's email has been published by Canadian alt media site The Canadian Report. The deliberate leak of the information is remarkable because it is the equivalent of senior […]

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Reply

### Is this leaked info really Trudeau's crazy COVID plan for 2021? – 2020 Research October 18th, 2020 at 08:07

[…] October 18, 2020 | No Comments Is this leaked info really Trudeau's crazy COVID plan for 2021? You decide … […]

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Reply

### Canadian politician leaks new COVID lockdown plan and 'Great Reset' dictatorship – Australia is part of it | ecoliberty October 18th, 2020 at 00:50

[…] Canadian whistleblower's email has been

published by Canadian alt media site The Canadian Report. The deliberate leak of the information is remarkable because it is the equivalent of senior […]

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Reply

### 2020 OCT 16 Canadian politician leaks new COVID lockdown plan and 'Great Reset' dictatorship – Australia is part of it – 4CMiTVworld October 17th, 2020 at 22:37

[…] SOURCE ACKNOWLEDGEMENTS Original-Source: Canadian report Original-Source-Published:  October 14, 2020 02:17 Original-Source-URL: https://thecanadianreport.ca/is-this-leaked-memo-really-trudeaus-covid-plan-for-2021-you-decide/ […]

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Reply

### mikeadamson October 17th, 2020 at 22:25

While this "release" is entertaining, I feel badly for the people believe this fiction. I'm sure it's a put up by some college kids because it's too ridiculous.

Loading...

Reply

### artsychic2000 October 17th, 2020 at 18:50

"Within the twenty years this country is going to rule the world. Kings and Emperors will soon pass away and the democracy of the United States will take their place.When the United States rules the world, the Catholic Church will rule the world.Nothing can stand against the Church. I'd like to see the politicians who would try to rule against the Church in Chicago. His reign would be short indeed" – Roman Catholic Archbishop James E.

Quigley (October 15, 1854 – July 10, 1915). Chicago Daily Tribune, May 5, 1903.

“If the liberties of the American people are ever destroyed, they will fall by the hand of the Roman Catholic cult’s clergy.” -General Lafayette under President George Washington

“The Roman Catholic motto is ourselves alone for fellow Roman Catholics. We must defeat all heretics (non Catholics) at the ballot box. The holy father states that negative tactics are fatal. The demands of the holy father (the pope) are that the public services should be 100% Roman Catholic soon. Care must be taken that no suspicion may be raised when Roman Catholics are secretly given more government jobs than Protestants, Jews and other heretics.” -Archbishop Gilroy

“There is, ere long, to be a state religion in this country, and that state religion is to be the Roman Catholic.”

1st. The Roman Catholic is to wield his vote for the purpose of securing Catholic ascendancy in this country.

2nd. All legislation must be governed by the will of God, unerringly indicated by the pope.

3rd. EDUCATION must be controlled by Catholic Authorities, and under education the opinions of the individual and the utterances of the press are included, and many opinions are to be forbidden by the secular arm, under the authority of the Church, even to war and bloodshed.” (Father Hecker, Catholic World, July 1870.)

“Undoubtedly it is the intention of the pope to possess this country. In this intention he is aided by the Jesuits, and all the Catholic prelates and priests.” (Brownson’s Review, May 1864)

Remnant of God dot org. How the vatican intends to control the world

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Reply

**Anonymous** **October 18th, 2020 at 23:56**

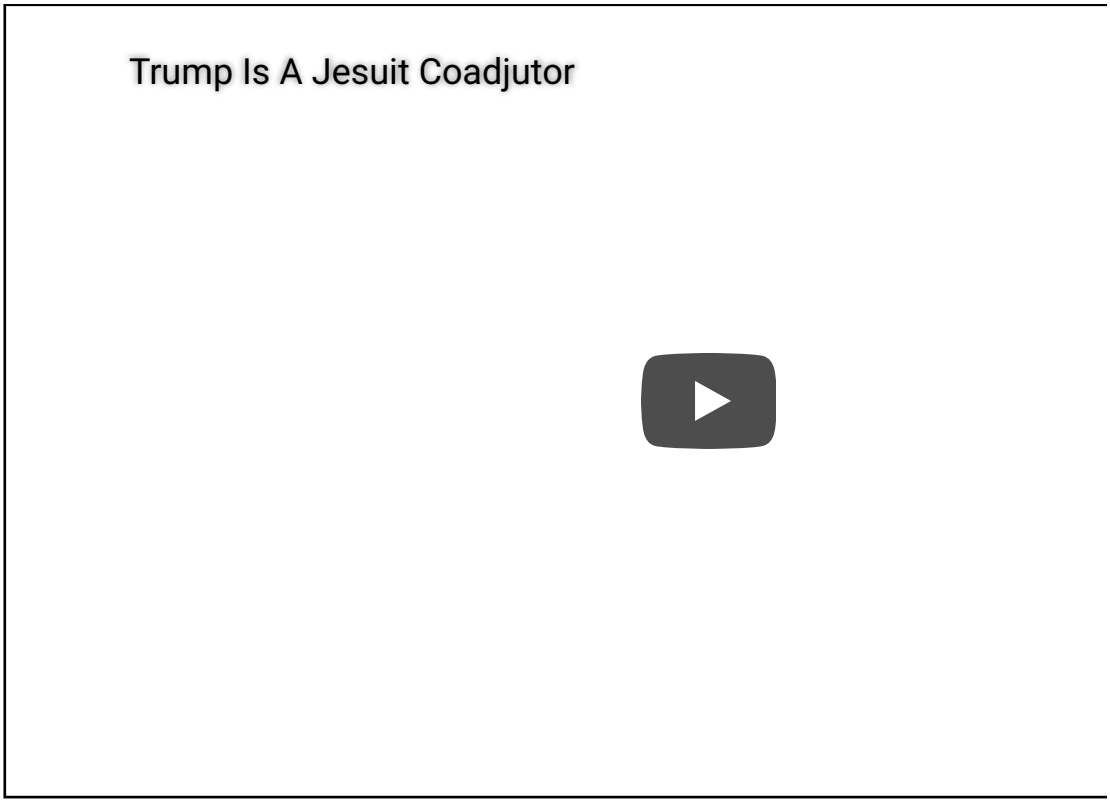
The United States is a Constitutional Republic 1st—Not a Democracy. Rule of Law not Legalese and TRUMP is returning it to it's former glory…Freedom!

Loading...

Reply

**artsychic2000** **October 19th, 2020 at 07:47**

Oh really?

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Reply

**Anonymous** **October 19th, 2020 at 13:23**

Kinda Weird almost looks as if Trump and Hillary are friends. Im' really not concerned about Catholic Jesuit take overs

though. Since this north american society is based mostly on Christian Traditions. Really doesn't seem like a problem. Bigger problem would be Joe Biden and his sicko drug addict/sex offender son

Loading...

Reply

**artsychic2000 October 19th, 2020 at 13:46**

They are…
In case you didn't notice the evangelicals are also working for the pope. Congress is almost entirely catholic. So is the supreme court. The catholic church worships lucifer on the day of the sun. It is sun god worship. Remember ezekiel!

"If the liberties of the American people are ever destroyed, they will fall by the hand of the Roman Catholic cult's clergy." -General Lafayette under President George Washington

"The Roman Catholic motto is ourselves alone for fellow Roman Catholics. We must defeat all heretics (non Catholics) at the ballot box. The holy father states that negative tactics are fatal. The demands of the holy father (the pope) are that the public services should be 100% Roman Catholic soon. Care must be taken that no suspicion may be raised when Roman Catholics are secretly given more government jobs than Protestants, Jews and other heretics." -Archbishop Gilroy

"There is, ere long, to be a state religion in this country, and that state religion is to be the Roman Catholic."

1st. The Roman Catholic is to wield his vote for

the purpose of securing Catholic ascendancy in this country.

2nd. All legislation must be governed by the will of God, unerringly indicated by the pope.

Sunday, sun god worship will be legislated.

Loading...

Reply

**artsychic2000** **October 17th, 2020 at 18:47**

https://www.remnantofgod.org/beastword.htm

Loading...

Reply

**artsychic2000** **October 17th, 2020 at 18:41**

I have a theory that they are setting us up to accept a savior. That savior may well be Donald Trump as he is behaving as though he is not part of the cabal and that he will not go along with who or the u.n. The whole world will wander after the beast. Who is like unto the beast and who is able to make war with him? The timing of the election has a great deal to do with it.
If you saw global leaders arrested would you follow after the beast?

Loading...

Reply

**Mr David McCabe** **October 18th, 2020 at 06:48**

To artsy chic, if that were true, and all things are possible, Trump would have to die and be resurrect as according to the book of Revelation. But still poss.

Loading

Reply

> **artsychic2000** **October 18th, 2020 at 07:28**
> They are behaving as though a communist dictatorship is being put into place globally.

What do we read in revelations?

Revelation 18:14 Context

11And the merchants of the earth shall weep and mourn over her; for no man buyeth their merchandise any more: 12The merchandise of gold, and silver, and precious stones, and of pearls, and fine linen, and purple, and silk, and scarlet, and all thyine wood, and all manner vessels of ivory, and all manner vessels of most precious wood, and of brass, and iron, and marble, 13And cinnamon, and odours, and ointments, and frankincense, and wine, and oil, and fine flour, and wheat, and beasts, and sheep, and horses, and chariots, and slaves, and souls of men. 14And the fruits that thy soul lusted after are departed from thee, and all things which were dainty and goodly are departed from thee, and thou shalt find them no more at all. 15The merchants of these things, which were made rich by her, shall stand afar off for the fear of her torment, weeping and wailing, 16And saying, Alas, alas, that great city, that was clothed in fine linen, and purple, and scarlet, and decked with gold, and precious stones, and pearls! 17For in one hour so great riches is come to nought. And every shipmaster, and all the company in ships, and sailors, and as many as trade by sea, stood afar off,

People assume these merchants are bankers and the rich men of the earth. I don’t believe that. I believe the rich will be ordinary people.

ebay merchants
etsy merchants
shopify merchants
face book merchants
and on and on….

They are setting up global trade routes and all the people of the earth will have access to a global market.

We should recognize the “her” referred to in this chapter is the catholic church arrayed in purple and scarlet.

When people are rich they feel no need for God or they are going to sell them on a God that wants them to prosper and bless them. Another Jesus so to speak.

Think about it.

Loading...

Reply

**Private Criminal Prosecution of Parliament, PCR Testing Document (UK), People’s Brexit Update Canadian Internment Camps? and More – Investigating The Alleged COVID-19 Pandemic October 17th, 2020 at 18:11**

[…] Is this leaked info really Trudeau’s crazy COVID plan for 2021? You decide … […]

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Reply

**artsychic2000** **October 17th, 2020 at 17:50**

This is who is behind it all
https://www.remnantofgod.org
/beastword.htm

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Reply

**artsychic2000** **October 17th, 2020 at 17:47**

I have a theory. I don't know whether it will pan out or not. We will have to wait and see. Many of you probably don't believe in scripture. I do and I judge everything by what I read in scripture. Revelations tells us what will happen in the last days preceding the coming of the Lord.
Now, scripture says "the whole world will wandered after the beast. This means that they will worship this man. Are they creating this global threat in order to get people to follow after one man who will save them from this diabolical plan? A hero?

Donald Trump will win house and senate. He himself has said that he wants America to be a light on a hill for the rest of the world. He has broken ties with who and the U.N. to a degree. If he was to put a stop to these things as some say he will, will not the world follow after him?

And they worshiped the man that gave power to the beast (vat e can) and they worshiped the beast saying "who is like unto the beast and who is able to make war with him?

https://www.remnantofgod.org
/beastword.htm#government
https://www.remnantofgod.org/beastword.htm

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Reply

**artsychic2000** **October 17th, 2020 at 17:16**

If this is true why hasn't it been taken down by the censors?

Loading...

Reply

### ШОКИРАЩО: Канада се готви за Covid-21 – много по-заразен и смъртоносен - Най-любопитните новини от България и света
**October 17th, 2020 at 14:40**

[…] Линк към публикацията […]

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Reply

### Guy Boulianne **October 17th, 2020 at 14:34**

Here is a full article in French that I published on my website (you can translate it into English with Google): https://guyboulianne.com/2020/10/16/revelations-choc-le-parti-communiste-chinois-deploie-les-troupes-de-larmee-populaire-de-liberation-apl-en-colombie-britannique.

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Reply

### Canadian politician leaks new COVID lockdown plan and 'Great Reset' dictatorship – Australia is part of it – Philosophers Stone **October 17th, 2020 at 13:00**

[…] Canadian whistleblower's email has been published by Canadian alt media site The Canadian Report. The deliberate leak of the information is remarkable because it is the equivalent of senior […]

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Reply

### Is this leaked info really Trudeau's crazy COVID plan for 2021? You decide … – The CANADIAN REPORT – Kon/Spira[!] **October 17th, 2020 at 11:15**

[…] Is this leaked info really Trudeau's crazy COVID plan for 2021? You decide … – The CANADIAN REPORT — Weiterlesen thecanadianreport.ca/is-this-leaked-memo-really-trudeaus-covid-plan-for-2021-you-decide/ […]

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Reply

**Rebel** **October 17th, 2020 at 02:49**

Has not Mr. Trudeau already bought the Canadian media for over $600-million of taxpayer funds? Has he not purchased the RCMP? Think about it. What happened in the Duffy Affair during the 2015 election? Did the $90,000 funds received by Mr. Duffy not carry through the entire election for Stephen Harper and his imminent ruin during that election? What happened to the SNC-Lavalin scandal during the following election just four years later with a Trudeau government? Did the RCMP completely remove themselves during the entire 2019 election over hundreds of millions of dollars of corrupt money involving SNC-Lavalin? Have our wonderful RCMP forces seem to totally disregard SNC-Lavalin "after" Mr. Trudeau asked the RCMP to not investigate SNC-Lavalin during the 2019 election? Now that we're in October 2020, whatever happened to the SNC-Lavalin file from 2019? And we have a Trudeau government that accused Stephen Harper of lack of transparency? Why did Mr. Trudeau prorogue parliament over his third ethics breach? Why did he pass $10.5-million "underneath" the table to Omar Khadr after he removed Khadr from the hands of the United States at Guatanamo Bay to freedom in Canada? Should that have not been enough? And the question of transparency continues with this shallow Liberal government leader that proclaimed Canada was

100-years-old and celebrating its birthday in 2017 during Mr. Trudeau's embarrassing journey to India. What is there to trust with Mr. Trudeau? What is the future of Canada with the spending habits of a buffoon?

Loading...

Reply

### HEDONISTIC ENGLISH PATRIOT
**October 16th, 2020 at 23:17**

THE QUEEN OWNS 90% OF THE LAND IN CANADA I BELIEVE? THAT GETS TAKEN BACK, PUT TO WILD AS PER UN AGENDA & ALL CANADIANS NOT LOCKED UP OR KILLED SHOVED INTO SMART CITIES. IF YOU THINK THE NEW WORLD ORDER IS A "CONSPIRACY THEORY" YOUR PART OF THE PROBLEM & FUCK ME ARE YOU HAVING A VERY RUDE AWAKENING VERY, VERY SOON. GOOD LUCK MY CANADIAN BROTHERS & SISTERS FROM UK

Loading...

Reply

### A concerned Canadian Citizen **October 17th, 2020 at 13:56**

The Queen owns nothing in Canada. The Crown gave each Province in Canada complete Sovereignty back in the 30's or 40's. The Federal Canadian Government is an illegal Government that has been lying to Canadians for decades just keep their power and and control over Canadians. The land is called Crown land but in actual fact it belongs to each Province. Listen to these two videos in this link. The videos called Critic Kill Thinker part one & part two. Spend time reviewing the website. You will come to know what I am talking about. https://www.themythiscanada.com/committees/

Reply

**Smokey** **October 16th, 2020 at 21:44**

To the Canadian government who decree unrighteous decrees:

10 Woe unto them that decree unrighteous decrees, and that write grievousness which they have prescribed;

2 To turn aside the needy from judgment, and to take away the right from the poor of my people, that widows may be their prey, and that they may rob the fatherless!

3 And what will ye do in the day of visitation, and in the desolation which shall come from far? to whom will ye flee for help? and where will ye leave your glory?

4 Without me they shall bow down under the prisoners, and they shall fall under the slain. For all this his anger is not turned away, but his hand is stretched out still.

5 O Assyrian, the rod of mine anger, and the staff in their hand is mine indignation.

6 I will send him against an hypocritical nation, and against the people of my wrath will I give him a charge, to take the spoil, and to take the prey, and to tread them down like the mire of the streets.

7 Howbeit he meaneth not so, neither doth his heart think so; but it is in his heart to destroy and cut off nations not a few.

8 For he saith, Are not my princes altogether kings?

9 Is not Calno as Carchemish? is not Hamath as Arpad? is not Samaria as Damascus?

10 As my hand hath found the kingdoms of the idols, and whose graven images did excel them of Jerusalem and of Samaria;

11 Shall I not, as I have done unto Samaria and her idols, so do to Jerusalem and her idols?

12 Wherefore it shall come to pass, that when the Lord hath performed his whole work upon mount Zion and on Jerusalem, I will punish the fruit of the stout heart of the king of Assyria, and the glory of his high looks.

13 For he saith, By the strength of my hand I have done it, and by my wisdom; for I am prudent: and I have removed the bounds of the people, and have robbed their treasures, and I have put down the inhabitants like a valiant man:

14 And my hand hath found as a nest the riches of the people: and as one gathereth eggs that are left, have I gathered all the earth; and there was none that moved the wing, or opened the mouth, or peeped.

15 Shall the axe boast itself against him that heweth therewith? or shall the saw magnify itself against him that shaketh it? as if the rod should shake itself against them that lift it up, or as if the staff should lift up itself, as if it were no wood.

16 Therefore shall the Lord, the Lord of hosts, send among his fat ones leanness; and under his glory he shall kindle a burning like the burning of a fire.

17 And the light of Israel shall be for a fire, and his Holy One for a flame: and it shall burn and devour his thorns and his briers in one day;

18 And shall consume the glory of his forest, and of his fruitful field, both soul and body: and they shall be as when a standard-bearer fainteth.

19 And the rest of the trees of his forest shall be few, that a child may write them.

20 And it shall come to pass in that day, that the remnant of Israel, and such as are escaped of the house of Jacob, shall no more again stay upon him that smote them; but shall stay upon the Lord, the Holy One of Israel, in truth.

21 The remnant shall return, even the remnant of Jacob, unto the mighty God.

22 For though thy people Israel be as the sand of the sea, yet a remnant of them shall return: the consumption decreed shall overflow with righteousness.

23 For the Lord God of hosts shall make a consumption, even determined, in the midst of all the land.

24 Therefore thus saith the Lord God of hosts, O my people that dwellest in Zion, be not afraid of the Assyrian: he shall smite thee with a rod, and shall lift up his staff against thee, after the manner of Egypt.

25 For yet a very little while, and the indignation shall cease, and mine anger in their destruction.

26 And the Lord of hosts shall stir up a scourge for him according to the slaughter of Midian at the rock of Oreb: and as his rod was upon the sea, so shall he lift it up after the manner of Egypt.

27 And it shall come to pass in that day, that his burden shall be taken away from off thy shoulder, and his yoke from off thy neck, and the yoke shall be destroyed because of the anointing.

28 He is come to Aiath, he is passed to Migron; at Michmash he hath laid up his carriages:

29 They are gone over the passage: they have

taken up their lodging at Geba; Ramah is afraid; Gibeah of Saul is fled.

30 Lift up thy voice, O daughter of Gallim: cause it to be heard unto Laish, O poor Anathoth.

31 Madmenah is removed; the inhabitants of Gebim gather themselves to flee.

32 As yet shall he remain at Nob that day: he shall shake his hand against the mount of the daughter of Zion, the hill of Jerusalem.

33 Behold, the Lord, the Lord of hosts, shall lop the bough with terror: and the high ones of stature shall be hewn down, and the haughty shall be humbled.

34 And he shall cut down the thickets of the forest with iron, and Lebanon shall fall by a mighty one.

Isaiah 10

Canadian government you were warned.

God is not mocked.

Loading...

Reply

> **creative3480** **October 17th, 2020 at 04:11**
> Have you not seen the nervousness in the room when Randy Hillier spoke, the answer he got was unsatisfactory, he was told to sit down, the speaker said “next question.” The provincial government is nervous about answering questions to do with isolation camps. What would happen if someone had the courage to say it in the House of Commons? The camps are real, I’ve seen the orders. So how is the rest not real and a fake story?
>
> Loading...
>
> Reply

**Anonymous** **October 16th, 2020 at 21:18**

If you remember earlier this year Trudeau proclaimed that he was going through with the NEW WORLD ORDER UN AGENDA as soon as HE can start

Loading...

Reply

**David Roberston** **October 16th, 2020 at 19:28**

If anyone is in any doubt about what is happening, here is an article that'll open your eyes to the effect of government and central bank actions on the economy and what to expect in the years to come.

https://www.goldmoney.com/research/goldmoney-insights/hyperinflation-is-here

Loading...

Reply

**David Goliath** **October 16th, 2020 at 12:59**

IMO Covid 19 is the beta test a dry run if you want. The show is all organised so nothing make sense Why you may ask ? They are building the opposition so they know who they will be fighting . Listen the article does not mention HOW they will fill all hospital ?? When they turn ON the weapon call 5G 60 Ghz people will litterally died and the All the opposition will be destroyed BRILLIANT THE msn WILL SAY I TOLD YOU SO ,GET THIS :5G IS A SERIES OF CAREFULLY CHOSEN WEAPONIZED MICROWAVE AND MILLIMETER WAVE FREQUENCIES THAT WILL INDUCE ILLNESS THAT WILL BE BLAMED ON A FAKE VIRUS TO FACILITATE FORCED VACCINATIONS . The financial system is toast but There is more of us we can stop this 5G is the KEY. PEACE

Loading...

Reply

**Tim Harris** **October 16th, 2020 at 12:19**

Here is the tender to open camps.

https://buyandsell.gc.ca/procurement-data/tender-notice/PW-ZL-105-38463

Loading...

Reply

**Anonymous** **October 16th, 2020 at 12:10**

https://buyandsell.gc.ca/procurement-data/tender-notice/PW-ZL-105-38463?fbclid=IwAR0w6Tdhn95yg4kWYc91gCcFzLP-IxUMbLy-B44dKafhl8Hh6M9aIMRhZBU

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Reply

**KEN GILES** **October 16th, 2020 at 11:36**

UN Agenda 21 sets this out exactly!!!

Loading...

Reply

> **George** **October 17th, 2020 at 11:38**
>
> Really do some research yourself. It's very sad your eyes must be covered by your mask to
>
> Loading...
>
> Reply
>
> > **canadian report** **October 17th, 2020 at 19:54**
> >
> > I refuse to wear a mask
> >
> > Loading...
> >
> > Reply
> >
> > > **Anonymous** **October 19th, 2020 at 15:08**

No masks for me also my friend.

Loading...

Reply

**Anonymous** **October 16th, 2020 at 11:05**

Isolation facilities? Like field hospitals maybe.

Come on Canadian Report. This is very obviously conspiracy theory nonsense. Shame on you for spreading disinformation.

Loading...

Reply

**David Robertson** **October 16th, 2020 at 19:32**

:)). It’s too late chum. The cat is well and truly out of the bag. It is no longer “theory”. It is right here, in your face. If you are an innocent abroad it is time ti wake up. If you are a professional debunker it is time to look for another job.

Loading...

Reply

**canadian report** **October 17th, 2020 at 19:57**

Feeling no shame here for the post. I’d be surprised if it was NOT true.

Loading...

Reply

**samysam1313** **October 16th, 2020 at 09:24**

The share link is just below the article on the left for those who didn’t see it. I had to look for it myself.

Loading...

Reply

**Anonymous** **October 16th, 2020 at 09:10**

There is a share button just under the article for those who didn't see it. I had to search for it.

Loading...

Reply

**Michel** **October 16th, 2020 at 06:49**

https://guyboulianne.com/2020/08/24/le-forum-economique-mondial-avoue-son-projet-criminel-de-ruiner-la-population-mondiale-par-lintermediaire-de-la-grande-reinitialisation

Loading...

Reply

**anon** **October 15th, 2020 at 23:15**

Where did you get this letter??

Loading...

Reply

**Anonymous** **October 15th, 2020 at 21:10**

It is hunting season …

Loading...

Reply

**Anonymous** **October 15th, 2020 at 19:49**

You are all so, so blind. This has been proven false on so many occasions.

Loading...

Reply

**David Robertson** **October 16th, 2020 at 14:41**

It doesn't matter. If it is true there is nothing anyone can do about it. If it isn't then there is nothing to worry about. Either way we can do nothing to change what is going to happen. Of that much at least I am certain. So just sit back and enjoy the show.

Loading...

Reply

**Anonymous** **October 16th, 2020 at 17:55**

Coward!

Loading...

Reply

**David Robertson** **October 16th, 2020 at 18:52**

Chacun à son goût. You are not a freedom lover I see. Just another Statist functionary with a very limited vocabulary, hiding behind a nameless avatar.

Loading...

Reply

**canadian report** **October 17th, 2020 at 19:58**

Proven false on so many occasions? Please explain.

Loading...

Reply

**Rob** **October 15th, 2020 at 18:39**

Trudeau has no choice, he is being threatened and blackmailed – watch "fall of the cabal" – Trudeau is guilty of serious crimes and he is following orders to save his own skin.

Loading...

Reply

**N-49** **October 15th, 2020 at 18:03**

So long as the people (sheeple) continue to believe that the ‘police/rcmp/whatever goon in a uniform flavor of the day are ‘upholding the law’ we will always be in this state of blind stupidity.
The big question is what are you doing to hold your public servants accountable?
Know for a fact ‘good people’ that the reflection you see in the mirror is the only person that can do something about your status.
The rcmp ( and most police forces) in this country are nothing more than goons and thugs.Bbbbut there are some good ones, if there are any ‘good ones’ where are they? Yeah, those ‘good ones’ were manning the provincial borders not allowing any one to pass in a ‘so-called’ free country.
We are in a [sarc] ‘state of emergency’ my friends, your rights vanished the moment that order was signed. Get used to it.
Word of advice, carry your own tube of lube for that time when you have a
‘You can’t do that- it’s against my rights’ moment, Kanada’s version of ‘brown-shirts’
like to play rough especially the steroid goons in uniform.

Loading...

Reply

**Linda** **October 15th, 2020 at 17:36**

This is ridiculous and obvious fear mongering by opposition crazies! I would bet my limited means that this is NOT from a legitimate source! Please, people, put your brain in gear before you write such nonsense.

Loading...

Reply

**Anonymous** **October 15th, 2020 at 16:48**

Fake as Trump's skin colour.

Loading...

Reply

**Cat** **October 15th, 2020 at 21:08**

You Are kidding right? It's 100% true! Wake up?

Loading...

Reply

**Kenneth G** **October 16th, 2020 at 01:26**

You need to read up on the aims of the UN's Agenda 2021 & 2030. You might get a huge wake up call.

Loading...

Reply

**GJ** **October 16th, 2020 at 09:23**

you're sure about that? There's nothing really 'fake' about what this corrupt POS has done so far !

Loading...

Reply

**Dee** **October 16th, 2020 at 12:10**

https://buyandsell.gc.ca/procurement-data/tender-notice/PW-ZL-105-38463?fbclid=IwAR0w6Tdhn95yg4kWYc91gCcFzLP-IxUMbLy-B44dKafhl8Hh6M9aIMRhZBU

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Reply

**Anonymous** **October 16th, 2020 at 12:16**

you sure about that?

https://buyandsell.gc.ca/procurement-data/tender-notice/PW-ZL-105-38463

Loading...

Reply

**Anonymous** **October 16th, 2020 at 12:16**

https://buyandsell.gc.ca/procurement-data/tender-notice/PW-ZL-105-38463

Loading...

Reply

**Tim Harris** **October 16th, 2020 at 12:18**

Are you sure about that?

https://buyandsell.gc.ca/procurement-data/tender-notice/PW-ZL-105-38463

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Reply

**Praedor** **October 16th, 2020 at 13:04**

Easy enough to check. There's a clear TIMETABLE in the leak. Give or take a few weeks, just watch for the timetable to actually be fulfilled. No need to poo-poo it completely. All you have to do is wait a few months. Hell, the first big part of the timetable is close at hand:
– Phase in secondary lock down restrictions on a rolling basis, starting with major metropolitan areas first and expanding outward. Expected by November 2020.
– Rush the acquisition of (or construction of) isolation facilities across every province and territory. Expected by December 2020.
– Daily new cases of COVID-19 will surge beyond capacity of testing, including increases in COVID

related deaths following the same growth curves. Expected by end of November 2020.

Loading...

Reply

**Anonymous** **October 16th, 2020 at 17:51**

… Phase in secondary lockdown restrictions starting with major metropolitan areas has already started.

Loading...

Reply

**David Robertson** **October 16th, 2020 at 17:56**

Exactly. All predictions are proved by their fulfilment. Prophecy 101.

Loading...

Reply

**JustMe** **October 19th, 2020 at 11:25**

The fact that it is an “Anonymous Source” makes it suspect, even though obviously a person might feel hesitant to attach his name to such a report. Still, they could have an anonymous email address or SOMETHING to help validate the material they are sharing, since they must realize how upsetting such “news” would be.

Loading...

Reply

**artsychic2000** **October 19th, 2020 at 11:39**

It’s my belief that this is being put out there to create fear. This is supposed to happen in every country internationally. The whole world will be in fear. Will this then insure a total win for Donald Trump who is supposedly

against the nwo? I predict he will win house and senate given that most people will see biden as another globalist. You may see arrests being made all over the place. The world will cheer and dance in the streets. I believe they are putting this out to ensure a win for Donald Trump. It's psychological. Reverse psychology actually. They make you think they don't want him in when in fact it's exactly what they want. I believe he is the beast. Right now, speaking like a lamb (for the people). Later, like a dragon.

Loading...

Reply

**Jan** **October 17th, 2020 at 00:11**

This is pure fiction, and not even worth watching if it were a B feature on Netflix. Badly written, no sources. Possibly commissioned by a hostile foreign government or conceived by an anarchist group intending to sow panic. Think about it people. Any credible whistleblower would provide detailed citations. Not vague dystopian fiction. Do not spread this hogwash. And learn to recognize false narratives. Do your own research and consider who gains when these unfounded, patently false stories spread. Do your part to sift for truth. False stories like this will sound true because they are alarming and apparently written by someone real. But it does not take much to unravel them. For example, how many people sit on that committee (which doesn't exist)? What's 30%? Three out of nine? One out of 3? Ten out of 30? Why not explain the committee structure and link to the gov.ca page that tells us who are the members? Why not a 'call to action' to tell us what to do to stop it, rather than dangle a bunch of

fictional ideas that have no links or citations. You're all smarter than that.

Loading...

Reply

**Anonymous** **October 17th, 2020 at 09:05**

Please prove that this isn't true! I would love to know that for sure!

Loading...

Reply

**David Robertson** **October 17th, 2020 at 16:57**

It is axiomatic that one cannot prove a negative.

Loading...

Reply

**Anonymous** **October 15th, 2020 at 16:17**

Trudeau must be stop, no matter the cost.

Loading...

Reply

**paulpaton** **October 16th, 2020 at 00:44**

I will never allow this absolutely perverted asshole to put us in to a communist regime…ever..this man needs to be arrested poste haste as a threat to our Constitution…

Loading...

Reply

**David Robertson** **October 16th, 2020 at 17:59**

How exactly do you propose to do this? Absent any workable plan it is all hot air.

Loading...

Reply

**artsychic2000** **October 17th, 2020 at 16:19**

look up Rocco Galatti on you tube

Loading...

Reply

**David Robertson** **October 17th, 2020 at 16:39**

He appears to have been singularly unsuccessful in his various attempts to challenge the law on Constitutional grounds so it seems the dice are loaded against him.

Loading...

Reply

**artsychic2000** **October 17th, 2020 at 21:14**

He’s fighting the government. Have they ever played fair?

Loading...

Reply

**David Robertson** **October 17th, 2020 at 21:26**

Not to my knowledge. Miguel De Cervantes illustrates this perfectly in his novel Don Quixote. The word that best describes the situation in my opinion is inertia. That is the innate inertia of any society with norms of thought and behaviour, i.e. orthodoxy. Anyone who seeks to challenge these norms is often described as Quixotic.

Loading...

Reply

**José Carlos** **October 19th, 2020 at 05:14**

Bright coment!.

Loading...

Reply

**Anonymous** **October 15th, 2020 at 14:42**

If this plan comes into effect you will finally feel the power of the people!!! We will not comply with this bullshit anymore!!! A revolution is brewing my friends be ready!!

Loading...

Reply

**Anonymous** **October 15th, 2020 at 14:14**

If this is true than this should be made to go viral and if the 30% of the liberals are against this then they should be crossing the floor and stopping this.

Loading...

Reply

**Anonymous** **October 15th, 2020 at 14:04**

It is time to put an end to this Lunatics “Reign”! I have never read anything, pertaining to a government “Plan” as horrible as this! This makes the Communist Manifesto look like a Human Rights Bill!!! How can the other Liberal Members NOT see the total insanity with any part of this!

Loading...

Reply

**Coleen Fahey** **October 15th, 2020 at 13:38**

What ever small amount of brain matter Trudeau had left has completely left his body. This is so EVIL and could only be carried out

by evil soul less people.

Loading...

Reply

**Jonathan Tad Ketchen** **October 15th, 2020 at 13:18**

https://thecanadianreport.ca/is-this-leaked-memo-really-trudeaus-covid-plan-for-2021-you-decide ::: 2020 has made clear that ANYTHING is possible, so pay attention and fight back! Tyrannies are far too easy to start and cataclysmic to remedy. FREEDOM! Fight for it or accept your doom. KEEP CANADA FREE! #TrudeauMustGo and #WeCanNoLongerAffordDougFord

Loading...

Reply

**LINDA** **October 15th, 2020 at 12:57**

HOLY COMMUNISM!!! THIS NEEDS TO GO VIRAL SO EVERYBODY KNOWS WHAT A COMMUNIST TRUDEAU REALLY IS AND TO STOP THIS!!!

Loading...

Reply

> **David Robertson** **October 16th, 2020 at 18:10**
>
> Probably Corporatist or Fascist would be closer to the truth. In any event the governance of whole world is now pretty much the same with varying degrees of visibility. The old differentiators are no longer applicable. That is why this latest hoax is global.
>
> We are in the midst of a shakeout when the dark underbelly of governance is being exposed and we are transitioning into their “New World Order” or so they believe. They are wrong of course and the

denouement will not be to their liking. They will not go gently however and the next few years may be a bumpy ride.

Loading...

Reply

**Jane Ford** **October 15th, 2020 at 12:12**

This is Agenda21 part of the NWO plan. This has been in development for a long long time and they are using COVID19 to make it happen.

Loading...

Reply

**David Robertson** **October 16th, 2020 at 18:02**

In other words there is no way to stop it, short of divine intervention. In that case all we can do is sit back and enjoy the show.

Loading...

Reply

**Anonymous** **October 15th, 2020 at 11:59**

It’s go to be B.S. Who finances the (so called) World Debt Program? The U.S. (certainly under Trump) would not go for such a measure and the U.S. is probably the world’s most generous country when it comes to foreign aid. Trudeau, with his minority government would like to be P.M. again and likely, the Liberals, will therefore present attractive ideas to sway the Canadian public.
Remember: If it’s too good to be true….

Loading...

Reply

**Anonymous** **October 15th, 2020 at 16:03**

The IMF are funding it,,,they want world power

Loading...

Reply

**Cat** **October 15th, 2020 at 21:49**

Consider this……what if the deep state is the dark side of evil and the DEBT RELIF is the light side of evil. This is definitely what the Bible says will happen. There is a reason Trudeau has brought in Chinese troops. This plan has been in the works for decades. There has been the deep state, the dark evil and the alliance, the light evil. Both evil, one is simply please ted in a way that seems like light.

Loading...

Reply

**David Robertson** **October 16th, 2020 at 19:40**

That's a rather depressing perspective Cat. Cheer up! God is in control.

Loading...

Reply

**David Robertson** **October 16th, 2020 at 19:19**

It has been known for quite a long time that the precondition for a world government would be a Jubilee, i.e. a cancellation of all debts, setting the stage for a takeover of all the collateral securing such indebtedness. In the present crisis the stage is being set for such an event. The New World Order means what it says. It is a complete departure from the Old World Order which presupposes a complete eradication of that Old

Order.

How this will be presented to the people remans to be seen but that it will be done in such a way as to gain their support is certain. Nevertheless everything the rulers of this present darkness are planning for their own purposes, which entail the enslavement of humanity, will be used by God to bring about the opposite result, the liberation of humanity. What they plan for evil, God plans for good.

The Jubilee will indeed take place but the collateral will not be taken by the State and those who control it. It will ultimately be given to the people so that each person will own their own home and lawfully obtained productive property to do with as they will. Any such property that has been obtained by dubious means will be taken from those who have it and distributed to those who have lived lawfully, free of opprobrium. Justice will rule the Earth. The Kingdom of God is righteousness, joy and peace in the Holy Spirit.

Loading...

Reply

**Anonymous** **October 15th, 2020 at 11:26**

We need to take this liberal govt to court for treason!

Loading...

Reply

**Kathy tickell** **October 15th, 2020 at 11:11**

It goes along with Agenda 21 and Trudeau would want it in place before the election. He is trying to kill everyone off if they don’t commit suicide before hand.

Loading...

Reply

**The Unknown** **October 15th, 2020 at 10:42**

Where did you get this information from?

Loading...

Reply

**Anonymous** **October 15th, 2020 at 06:43**

It is the plan to depopulate and enslave humanity under a communist world government. https://www.abzu2.com/ultimate-proof-covid-19-was-planned-to-usher-in-the-new-world-order-∞-edward-morgan/

Loading...

Reply

**Tanic** **October 15th, 2020 at 05:08**

I do not believe that it is true.

Loading...

Reply

**Cat** **October 15th, 2020 at 21:51**

It’s true. It’s happening in every country. This is going to be what I be.ieve is the mark of the beast the Bible talks about

Loading...

Reply

**Elma** **October 16th, 2020 at 20:56**

Rapture of the church happens first.

Loading...

Reply

**David Robertson** **October 17th, 2020 at 17:44**

That is just one interpretation of scripture

viz. the futurist doctrine of eschatology. That doctrine has been around for a little more than two hundred years, originating with a Chilean Roman Catholic priest, Manual De Lacunza. It was popularized inter alia by J.N. Darby of the Plymouth Brethren and in North America by Cyrus Scofield of no fixed denomination. It sees the return of the Jews to Palestine as the return of “Israel” to their Promised Land.

None of this is necessarily true and has been debunked by other Bible teachers as erroneous. It does however dominate the thinking of the evangelical churches at the present time. Personally I take a different view and the critical event that will prove which view is the correct one is the destiny of Jerusalem. The futurists believe that City will prevail in the coming war while I believe it will be destroyed, once and for all. Time will tell.

In either event such a belief is not relevant to salvation, which is still dependent upon faith in and commitment to the Lord Jesus Christ and the efficacy of His sacrifice, in removing the power and penalty of Sin from the human race, by taking them upon Himself and overcoming them through His Resurrection to Eternal Life from among the Dead and sharing His victory with all those who believe in Him.

Loading...

Reply

**Wills** **October 15th, 2020 at 23:38**

Believe it. Time to get yourself out of denial. Awareness is the first step.
And share this information with as many people as possible. And for god’s sake, help get rid of the

Liberal cult.

Loading...

Reply

**Anonymous** **October 16th, 2020 at 12:11**

https://buyandsell.gc.ca/procurement-data/tender-notice/PW-ZL-105-38463?fbclid=IwAR0w6Tdhn95yg4kWYc91gCcFzLP-IxUMbLy-B44dKafhl8Hh6M9aIMRhZBU

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Reply

**Vladimir Poutine** **October 15th, 2020 at 01:33**

Justin Trudope and that Rag Head have to be eliminated by ANY MEANS that is Available

Loading...

Reply

**Anonymous** **October 14th, 2020 at 23:06**

The UN is dictating this for a one world order.

Loading...

Reply

**Sue** **October 14th, 2020 at 21:30**

I sure hope all who are party to this speak up because, if true, they won't have a job in a year or two anyways

Loading...

Reply

**Anonymous** **October 15th, 2020 at 20:05**

And Canada won't be by that time!

Loading...

Reply

**Yvan** **October 14th, 2020 at 20:29**

False or Thrue?

This is the question

Who has the answer?

We need to know asap

Loading...

Reply

**Cat** **October 15th, 2020 at 21:52**

100% truth

Loading...

Reply

**Anonymous** **October 15th, 2020 at 22:26**

this is very close to what many people were saying for long time, it is more or less true unless we're all stand up! nobody can save us but ourselves….

Loading...

Reply

**Anonymous** **October 14th, 2020 at 19:56**

How does this get shared

Loading...

Reply

**lynn crowley** **October 14th, 2020 at 19:55**

how can this be shared

Loading...

Reply

**tyrranny** **October 14th, 2020 at 19:51**

The charter has been abolish period (.) no more /nada . war in our streets comming. get with the program and fast. social dislocation .

Loading...

Reply

**Mark Benkovic** **October 14th, 2020 at 19:51**

I'm not doubting thte legitimacy of this alleged "Leaked document", but there there are so many lies, frauds, deceits, propaganda and #fakenews that's it's difficult, if not impossible, to tell what is real/true/fact and what is not. Unless the source of the allegation comes out and produces the original allegation it will continue to be questioned.

Loading...

Reply

**Norm Allard** **October 14th, 2020 at 18:57**

The professional way it has been written shows it had to be done by an experienced government person. We need now a solid proof.

Loading...

Reply

**Anonymous** **October 14th, 2020 at 17:58**

Why are we allowing political prostitute make decissions for us and that destrois futuer of young generation? aren't we crasier that them?

Loading...

Reply

**Cass** **October 14th, 2020 at 17:34**

If you see "COVID-21" and think "This seems real" then I need you to lay down and take deep breaths. Your media literacy level is zero. You shouldn't be on the internet.

Loading...

Reply

**Anonymous** **October 14th, 2020 at 15:57**

He’s just doing what he wants so he can become the supreme ruler

Loading...

Reply

> **Mickey M** **October 16th, 2020 at 19:02**
>
> This is rubbish
>
> Loading...
>
> Reply
>
> > **David Robertson** **October 16th, 2020 at 19:04**
> >
> > What is rubbish?
> >
> > Loading...
> >
> > Reply

**Debbie** **October 14th, 2020 at 09:03**

If this is true than this should be made to go viral and if the 30% of the liberals are against this then they should be crossing the floor and stopping this.

Loading...

Reply

> **Sir John A. MacDonald** **October 14th, 2020 at 20:43**
>
> If anyone is capable of this level of insanity it’s Justin Trudeau.
>
> COVID-19 has been filled with corruption from the start. From the world health organization to the continued misinformation campaign in Canadian media.

The curve has been flattened for months yet we remain in global lockdown.

MP Randy Hillier spoke out this week about flawed PCR testing and false “cases” in the media.

Canada needs leadership from our doctors, politicians, military, etc. The brainwashed public needs to wake up.

Time to end this nonsense immediately.

Loading...

Reply

**candida** **October 14th, 2020 at 20:45**

The other 70% do not have any balls eh?

Loading...

Reply

**Anonymous** **October 15th, 2020 at 03:56**

This is most likely true. Trudeau is implementing the NWO Agenda for a One World Government, as is the rest of the world. The 30% are not able to cross the floor because parliament isn’t sitting and Trudeau is keeping it that way. They only MP’s able to speak publicly are within his inner circle. What we need to do is demand that opposition parties bring this to the attention of the public, in spite of the fact that our media is all controlled by Trudeau, as well as get the RCMP to start doing their job and investigate and charge Trudeau with treason.

Loading...

Reply

**N-49** **October 15th, 2020 at 17:58**

So long as the people (sheeple) continue to believe that the ‘police/rcmp/whatever

goon in a uniform flavor of the day are ‘upholding the law’ we will always be in this state of blind stupidity.
The big question is what are you doing to hold your public servants accountable?
Know for a fact ‘good people’ that the reflection you see in the mirror is the only person that can do something about your status.
The rcmp ( and most police forces) in this country are nothing more than goons and thugs.Bbbbut there are some good ones, if there are any ‘good ones’ where are they? Yeah, those ‘good ones’ were manning the provincial borders not allowing any one to pass in a ‘so-called’ free country.
We are in a [sarc] ‘state of emergency’ my friends, your rights vanished the moment that order was signed. Get used to it.
Word of advice, carry your own tube of lube for that time when you have a
‘You can’t do that- it’s against my rights’ moment, Kanada’s version of ‘brown-shirts’
like to play rough especially the steroid goons in uniform.

Loading...

Reply

**Ida Snow** **October 15th, 2020 at 09:55**

WHERE IS FACT CHECK ON THIS?

Loading...

Reply

**pierremontagne** **October 15th, 2020 at 21:35**

Is a fact checke necessary? Twitter will not allow you to load the URL for this articel.

Loading...

Reply

**willem feather** **October 15th, 2020 at 23:42**

Time to do your own fact checking. Trust yourself. Try Dr. Vernon Coleman and Amazing Polly.

Loading...

Reply

**Anonymous** **October 16th, 2020 at 13:16**

do your own fact check this had been along awaited plan

Loading...

Reply

**Elma** **October 16th, 2020 at 21:03**

Fact check is called the Bible, everything you see happening, it's all in the oldest book in the world.

Loading...

Reply

**David Robertson** **October 17th, 2020 at 18:04**

I don't think it is "the oldest book in the world". So far as I am aware, the scriptures were first committed to writing in the Pentateuch of Moses, the first five books of the Bible. I am fairly certain there are other older writings from the civilizations that preceded the Exodus, both in the West and in the East.

> The Bible does of course relate events all the way back to the beginning but how these were revealed to Moses is generally believed to be through the Holy Spirit, i.e. by God Himself. The means of such revelation may have been through Moses' own education in Egypt, inter alia, but further than that I am not able to speculate.
>
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>
> Reply

**Anonymous** **October 15th, 2020 at 12:19**

This certainly is valid because Randy Hillier, independent MPP voiced his concerns over this and Quarantine Facilities being built and was shut down and not answered in Parliament just this week. Government is doing strange things – no transparency, scandals, building facilities that can be used for detention – why? Yeah, if 30% of the Liberals aren't agreeing with this crap, the better start getting vocal because this country is going down fast.

Loading...

Reply

**joan** **October 15th, 2020 at 14:28**

if this is true the individual writing this is a coward and is more concerned for himself then the country of canada. Remember people voted in Hitler. with promises of wealth and cars ect. so i say do the right thing and come out of your closet and go public rather then cloak and dagger. there are constant lies and corruption going on even with covid most not true. your hiding is just another form of lying to canadian people.. the liberals are abusive and controlling. and why are you not crossing the floor and doing the right thing?

Loading...

Reply

**Cat** **October 15th, 2020 at 21:54**

The “leaker” does not need to come forward. If you believe what the Bible tells us, you will know this is truth. This debt relief and taking the vaccine will be presented in such a way that you will want to take it. I WILL NEVER take it. This is the mark of the beast coming in. NWO. This is not new news.

Loading...

Reply

**Anonymous** **October 15th, 2020 at 14:32**

why do we canadian not hear news about camps in canada and chinese soilder on our soil

Loading...

Reply

**Cat** **October 15th, 2020 at 21:55**

If you know the sites to look, you would know. There are. Eww sites that tell the truth

Loading...

Reply

**Anonymous** **October 15th, 2020 at 15:13**

yes stooping this. MUST READ. https://www.petitions.net/arrest_justin_trudeau_and_liberal_mps_for_treason_immediate

Loading...

Reply

# Leave a Reply

Enter your comment here...

*< TheCanadianReport home*

# We say NO to the "New Normal"

**NAME _____**

**Please take notice:**

**You are unlawfully practicing medicine by prescribing, recommending, facilitating, advertising, mandating, incentivizing, and using coercion to insist any public person under your control, including Children submit to ANY vaccine including the experimental gene therapy injections for COVID-19, commonly referred to as a "vaccine".**

**Let it be known that those named above will be held personally, civilly, and criminally liable for any injuries or deaths that may occur as a result of encouraging, facilitating, coercing, incentivizing or administering ANY vaccine including the COVID-19 experimental injections to Citizens and Children in your care and control.**

## WE ALL SAY NO

We are a strong group of parents, grandparents, concerned citizens, professionals and business owners who are committed to advocating for the Children and Citizens of Hastings, Lennox and Addington and Frontenac Counties against the "New Normal" continuing to be imposed on its Children and Citizens. Over the last 18 months, children have been made to carry the weight of the world and have been forced to endure completely unnecessary restrictions and abuse. Collectively, we say NO to masking, distancing, poisonous chemical sanitizer, isolation, testing, constant coercion and violation of bodily autonomy, and unproven injections. We say NO to ignoring our children's suffering, to putting their needs to the side and their lives in harm's way all in the name of "health and safety" and "the greater good." Our children are the most vulnerable members of society and the most valuable. We will not let their voices go unheard, we will no longer comply.

## *THEY SAID* …. "Covid19 is serious." Is that true for Children?

There have been 15 deaths in Canada between the ages of 0-19 from Covid19. There are over seven million people in Canada between ages of 0-19. That's a percentage of 0.000002 dying from Covid between these ages. How can that possibly be considered a "serious" risk for children?

https://health-infobase.canada.ca/covid-19/epidemiological-summary-covid-19-cases.html

## TO BEGIN WITH – THERE IS NO EMERGENCY

To begin with, the emergency measures are based on the claim that we are experiencing a "public health emergency". There is no evidence to substantiate this claim. In fact, the evidence indicates that we are experiencing a rate of infection consistent with a normal influenza season. 1 -The purported increase in "cases" is a direct consequence of increased testing through the inappropriate use of the PCR instrument to diagnose so-called COVID-19. It has been well established that the PCR test was never designed or intended as a diagnostic tool and is not an acceptable instrument to measure this so-called pandemic. Its inventor, Kary Mullis, has clearly indicated that the PCR testing device was never created to test for coronaviruses.
2 - Mullis warns that, "The PCR Test can be used to find almost anything, in anybody. If you can amplify one single molecule, then you can find it because that molecule is nearly in every single person".
Despite this warning, the current PCR test utilization, set at higher amplifications, is producing up to 97% false positives. 3 - Therefore, any imposed emergency measures that are based on PCR testing are unwarranted, unscientific, and quite possibly fraudulent. An international consortium of life-science scientists has also detected 10 major scientific flaws at the molecular and methodological level in a 3-peer review of the RTPCR test to detect SARS-CoV-2. 4 - In November 2020, a Portuguese court ruled that PCR tests are unreliable. 5 - On December 14, 2020, the WHO admitted the PCR Test has a 'problem' at high amplifications as it detects dead cells from old viruses, giving a false positive. 6 - Feb 16, 2021, BC Health Officer Bonnie Henry, admitted PCR tests are unreliable. 7 - On April 8, 2021, the Austrian court ruled the PCR was unsuited for COVID testing. 8 - On April 8, 2021, a German Court ruled against PCR testing stating, "the test cannot provide any information on whether a person is infected with an active pathogen or not, because the test cannot distinguish between "dead" matter and living matter."9 - On May 8, 2021, the Swedish Public Health Agency stopped PCR Testing for the same reason. 10 - On May 10th, 2021, Manitoba's Chief Microbiologist and Laboratory Specialist, Dr. Jared Bullard testified under cross-examination in a trial before the court of the Queen's Bench in Manitoba, that PCR test results do not verify infectiousness and were never intended to be used to diagnose respiratory illnesses.

**Based on this compelling and factual information, the emergency use of the COVID-19 experimental injections is not required or recommended.**

## WE SAY – NO TO MANDATES

The most staggering statistics that have come out of the past year have been the levels of childhood suicides (now the number 1 cause of death for children), depression, anxiety, eating disorders, overdoses, and abuse. These harms have been directly caused by the isolation of lockdowns and the closing of important resources. According to SickKids Hospital, more than half of children aged 8-12 reported clinically significant depressive symptoms during the 2nd wave of the pandemic. That number jumped to 70% among adolescents. There has also been an unprecedented rise in hospital admissions for eating disorders and Type 2 diabetes. These

figures alone should be enough to stop the harmful measures.

It has been well documented and proven globally that children are statistically at 0% risk of dying from Covid-19. Data from across the world, including Canada, shows that not only are children not seriously affected by this virus, they also do not spread it. In fact, children are at far more risk of serious outcomes from seasonal influenza than from Covid. Despite these facts, children have been forced to accept harmful rules and restrictions under the guise of public safety. These mandates have and continue to affect them socially, emotionally and physically. **What we know is that there is no justifiable reason to take away youth sports or to isolate them away from their family and friends or to close down parks and playgrounds or to deny access to schools and co-op placements and force them in front of a screen.** What we know is that the above causes a great deal of unnecessary distress to children and youth. We as a collective group will not accept any further locking down of these essential parts of life and liberty that each and every citizen in Canada was born with the innate right to.

## WE SAY - NO TO MASKING AND DISTANCING

The daily messaging regarding masking and distancing can be seen everywhere you turn. The propaganda in stores, on TV, on the radio, on social media and within the classroom has had a clear message to our children. The message is to fear the air they breathe and the people and objects around them. They have been told by peers, adults and teaching staff that they now have the power to kill their loved ones just by breathing air and having physical contact, or that the mask is the only way to keep themselves and others safe despite any discomfort they feel or any exemptions they may have. The damage and trauma done with this messaging can be irreversible! Masking is particularly harmful for our youngest children as they develop and learn. Children need to be able to see facial expressions and interact through play and touch in order to form healthy social connections, learn to read and speak, and feel secure in their world. Not only is masking unhealthy psychologically, it is physically hazardous. A fully peer-reviewed study published in The Journal of American Medicine (https://jamanetwork.com/journals/jamapediatrics/fullarticle/2781743) showed that after just 3 minutes of mask wearing, children were found to be inhaling over 6 to 10 times the exposure limit of carbon dioxide. This is TOXIC! With this type of exposure, children have been experiencing several symptoms of toxicity including: headaches, difficulty breathing, fatigue, loss of concentration and more. A German study of over 25,000 children also confirms these types of adverse events due to masking.

In April 2021, Health Canada set the indoor exposure limit for $CO_2$ at 1,000 ppm. With the knowledge that children are breathing in toxic levels of $CO_2$ for upwards of 8 hours per day, indoors and outdoors and during phys-ed; we can no longer allow this to occur!
In addition to the toxic air, the masks themselves, after long-term wear in this type of setting have been shown to become a breeding ground for harmful bacteria and pathogens. The warm, wet environment within the mask creates an unsafe level of risk to the wearer as he/she is continuously exposed to this as well as causes the breakdown of mask material which can be inhaled. Even with a change of mask, children are not mature enough nor should they be

required to worry about keeping themselves and a mask sterile. These are unrealistic and dangerous expectations that are leading to serious harm.

## WE SAY - NO TO DANGEROUS INJECTIONS

***The new Covid-19 injections are only authorized for Emergency Use. They are not approved by FDA or Health Canada***. There is no long term safety data at all for any age group. With the recent roll-out for children as young as 12 and the impending roll-out for children under the age of 12, we refuse to be coerced, bribed or forced to take part in these experimental injections in order to gain access to education, activities, extra-curricular and social contact. If you are told you have to take some drug in order to regain your freedoms, then you are NOT free!

As documented by Pfizer, Moderna, Astrazeneca and J&J, the experimental phase is not complete until 2023. As per the Nuremberg Code, our families have the right to refuse to participate in such an experiment. INFORMED CONSENT is non-negotiable.
These injections have not been proven safe; in fact they have shown an extremely high rate of adverse reactions and deaths as seen in government adverse event data collection systems in several countries. There have been more reported deaths and reactions caused by these injections in the last several months than for all vaccines in the last 3 decades combined!

Reports of Myocarditis, Pericarditis (especially among boys), menstrual cycle disruptions, fertility concerns, blood clots, neurological conditions and death INCLUDING child deaths are coming out all over the world. According to the CDC's own data, children aged 0-17 are at 11.3 times greater risk of injury due to Covid-19 injection in comparison to any benefit that may come from taking the shot. Schools and governments that willingly participate in medical coercion will be held liable.

Families that choose to not inject their children will not allow their child to be treated any differently via segregation, masking, plexiglas or other, in any setting. Children are not to be excluded or have their private medical information divulged. Medical Privacy Laws state that consent must not be required as a condition of service. The Health Care Consent Act Section 11 outlines consent must be voluntary and informed.

To summarize our message: Our children have the right to an education free from fear and stress and free from restrictions and suppression. Our children have the right to have their voices heard and their needs put before our own as adults. Our children have the right to a full life with normal experiences and new milestones that will shape them into healthy, happy and confident adults. The path that we are currently on is going to have serious impacts that reach far into the future. We need to end these harmful measures today as that would be following true science and true evidence that we have had over a year to look back on. It is our duty as adults to do what is right for our children. **It is OUR duty to protect them from harm, not the other way around. You do not own our Children!**

# Studies show - Low risk of Covid19 illness in Children

On May 5, 2021, Health Canada announced authorization of the experimental Pfizer vaccine for children 12-15 years of age.

Data reveals that youth are at very little risk from COVID-19; that asymptomatic transmission is negligible to non-existent; and that the known and potential risks of the vaccine are greater than any benefit from this untested, experimental injection.

Standard drug safety studies demand years of long-term safety data. The relevant Pfizer clinical trials monitored adolescents for adverse reactions for mere months. This means the long-term effects of this injection are unknown.

Of further concern is that the Pfizer trials included only 2,260 adolescents. This is a grossly small study sample for an experimental treatment intended for 1.6 million Canadian youth. Such an underpowered study means less common adverse events will not be detected.

Following the administration of 240.2 million doses of COVID-19 vaccines (as of May 21, 2021), the Vaccine Adverse Events Reporting System (VAERS) in the U.S. has recorded over 225,000 injuries — including almost 1,000 12-17-year-olds, and over **4,200** deaths following vaccination. The number of deaths following COVID-19 vaccination is already greater than the deaths following all other vaccines combined over the last 20 years!

We also know that the CDC's own commissioned study showed that less than 1% of adverse events are reported to VAERS. There is no evidence that Canada's adverse events reporting system has a better rate of reporting. Therefore, the actual numbers of injury and death are likely far higher.

A newly released study dated May 17, 2021, by Canadian Jessica Rose, PhD, summarizes the VAERS data as follows:

*"…due to both the problems of underreporting and the lag in report processing, this analysis reveals a strong signal from the VAERS data that the risk of suffering an SAE (Serious Adverse Event) following injection is significant and that the overall risk signal is high."*

Canadian doctors are speaking out privately and publicly about the risks of COVID-19 vaccines, including doctors involved with Doctors for COVID Ethics and Canada Health Alliance.

We need to listen to the thousands of health care professionals who are calling for caution in the accelerated rollout of this vaccine. We need more research before vaccinating our children to avoid recklessly endangering their futures and perhaps their lives.

There is no basis for vaccinating children from Covid-19 as indicated by Dr. Anthony Fauci - none (6 months to 11 years old). The children are at very low risk of illness, especially severe

illness from Covid, and children do not spread the illness. The most updated data by the American Academy of Pediatrics showed that "Children were 0.00%-0.19% of all COVID-19 deaths, and 10 [US] states reported zero child deaths. In states reporting, 0.00%-0.03% of all child Covid-19 cases resulted in death."

A high-quality robust study in the French Alps examined the spread of Covid-19 virus via a cluster of Covid-19. They followed one infected child who visited three different schools and interacted with other children, teachers, and various adults. They reported no instance of secondary transmission despite close interactions. These data have been available to the CDC and other health experts for over a year. Ludvigsson published a seminal paper in the *New England Journal of Medicine* on Covid-19 among children 1 to 16 years of age and their teachers in Sweden.

From the nearly 2 million children that were followed in school in Sweden, it was reported that with no mask mandates, there were zero deaths from Covid and a few instances of transmission and minimal hospitalization. A study published in *Nature* found no instances of asymptomatic spread from positive asymptomatic cases among all 1,174 close contacts of the cases, based on a base sample of 10 million persons. The World Health Organization (WHO) also made this claim that asymptomatic spread/transmission is rare. This issue of asymptomatic spread is the key issue being used to force vaccination in children. The science, however, remains contrary to this proposed policy mandate.

The recent push by the CDC, Dr. Anthony Fauci, and other television medical experts who suggest that we can only get to herd immunity by vaccinating our children is absurd and blatantly false. They are denying scientific reality. They are spreading false information to the nation. The current data suggest that we are much nearer to herd immunity than they wish it to be. They continue to inaccurately discount cross protection immunity from prior coronaviruses and common colds. They have disregarded the fact that a large swath of the population was not captured in the case load, via laboratory confirmed cases.

The estimates range that for every ONE confirmed case, there might be 6 or even 8 unidentified individuals who have had Covid. Many people have recovered from Covid and they are being disregarded in Dr. Fauci's inaccurate statements on herd immunity e.g. his absurd statement that 90% must be vaccinated. Children can become infected as they do for usual pathogens they encounter in their daily lives, 'naturally.' Like the common cold or influenza, and alike for other infections. We already know that there is no emergency in children regarding Covid-19. And so why would Moderna Inc. seek to trial this vaccine on children with a death rate in this group of 0.003% (IFR 0.00003)? Moderna must show us why it is not dangerous to put this vaccine in children, and they have not.

We argue vehemently that if children are needed from a 'numbers' point of view for driving population level 'herd' immunity, then they must be allowed to get infected naturally and harmlessly as part of day-to-day living and we do it by opening schools and allowing them to live reasonably normal lives with sensible precautions e.g. enhanced sanitation, hygiene, and

disinfectant. Children can and do get infected as they do for usual pathogens they encounter in their daily lives, 'naturally.' These pathogens include the common influenza virus and other influenza-like illnesses.

Allow child-to-child daily interaction. Not only will that drive the adaptive immunity but it will give the children a more robust defense against any mutant variants of the virus itself. This will also allow our children's immune systems to be taxed and tuned up daily; as opposed to the weakening we are subjecting it to with the year-long lockdowns and school closures. We do it while at the same time strongly protecting the elderly who are frail, the elderly in general, and those with comorbid conditions and obese individuals. We must use stringent protections of our nursing homes and other similar congregated settings (including the staff, who remain often the source of the infection). It is better science to use a more 'focused' protection and targeting that is based on age and known risk factors especially, regarding the children.

History teaches us to pause and reflect upon our previous miscues and unforced blunders that had significant consequences. It behooves us to remember the increased incidence of narcolepsy in children in Scandinavian countries following the H1N1 influenza ASO3-adjuvanted vaccine used for the 2009 pandemic (Pandemrix influenza vaccination program). Additionally, the harms caused by the dengue vaccine in children in the Philippines also come to mind that bore a burden on our society of humans. Sanofi Pasteur halted the vaccines in 2017 due to the very dangerous risk of plasma leakage akin to Ebola. "It's a complication called plasma leakage syndrome…he [Halstead] was so worried, he started writing editorials to scientific journals, even warned the Filipino government about the problem…I just say, no, you can't give a vaccine to somebody – some perfectly normal, healthy person – and now put them at risk for the rest of their lives for plasma leakage syndrome. You can't do that." The tainted polio vaccine that sickened and fatally paralyzed children in 1955 in the United States is also worthy of review in this context. The harm that can accrue from a rapid deployment of mass vaccination to the children has not proven to be safe in all the cases. Perhaps this comment is worth noting: "In 1977, for example, a triple vaccination (against diphtheria, pertussis and tetanus) from a defective batch left several children blind, deaf and disabled forever."

There are potentially real harms to these Covid vaccines and as an example; Canada has now suspended the AstraZeneca-Oxford vaccine for those under 55 based on risk. "Canada's National Advisory Committee on Immunization (NACI) is recommending provinces pause the use of the AstraZeneca-Oxford COVID-19 vaccine on those under the age of 55 because of safety concerns" (blood clotting and thrombocytopenia). There is the real concern of "disease enhancement" whereby "in the past for a few viral vaccines where those immunized suffered increased severity or death when they later encountered the virus [in the wild] or were found to have an increased frequency of infection." This is a concern for the Covid vaccines, in adults and certainly children given the past catastrophic experience with the dengue vaccine. Harms and adverse events (e.g. blood clots) are being reported in the CDC's VAERS system as well as globally and we need urgent study of the temporal relationship of reported adverse events to administration of the vaccines. Currently, there have been approximately 1,900 vaccine-related deaths reported to VAERS as of March 15th 2021. It is still

too early to tell how this will play out with these vaccines and reported harms and we remain cautiously optimistic yet cognizant that the trials have not run for the optimal duration of time to assess safety. Thus, our grave concern for our children being administered these yet proven safe vaccines.

Moreover, one has to understand that all medications and drugs including vaccines may have some adverse effects on the human body. All drugs, including all interventions carry risk. It is therefore imperative that parents of children be informed about the potential risks of any such intervention employed on a child. "But," says the CDC representative, "Individuals react differently to vaccines, and there is no way to absolutely predict the reaction of a specific individual to a particular vaccine. Anyone who takes a vaccine should be fully informed about both the benefits and the risks of vaccination." The key is to have total transparency of benefits and risks of using the vaccine in children. We agree wholeheartedly that vaccines are important and potent weapons we have in reducing disease in the population as a whole.

In comparison, we point out that with the Polio vaccine, from inception of the vaccine concept in 1931 (10 years after FDR was stricken with Polio), indications are that it took roughly 20 years before Jonas Salk used the vaccine to vaccinate his family and then the world. Over the years, vaccines have saved countless lives and will continue to do so. We believe that vaccines have a large and critically important role in protecting human lives, but these protections have been the result of a thorough and sometimes tedious ritual of testing along with long-term safety assessment over a period of years in order to be confident that any one new vaccine is both safe and effective. Unfortunately, we cannot apply these time-tested requisites to the current crop of new vaccines for Covid-19. But again, we reiterate that it's one thing to let adults decide, after informed consent, to be vaccinated but it is another thing entirely to go about vaccinating our children without evidence for long-term safety, especially when their risks of either becoming ill, or suffering severe illness from SARS-CoV-2 are infinitesimally small.

The argument for a well-tested and safe vaccine requires time under study, and this prevents unnecessary harm to the children that we aim to protect. Ensuring their safety requires a thorough review of well-established data of use of such vaccines in children. Otherwise, we as their caretakers are subjecting them to potentially real harm under the banner of doing good!

What is needed is to allow children to mingle and to acquire infection naturally and harmlessly, in their schools, home, and their everyday environments. We remain skeptical about the safety of the currently administered vaccines, since the FDA issued an emergency use authorization (EUA) and did not apply the needed full regulatory BLA approval. This continues to concern us greatly, since the safety component has not been fully assessed and essentially means that all persons taking Covid vaccines at present are in a large Phase III trial. The efficacy and safety results will be known in 2-3 years and perhaps longer for the longer-term adverse effects that become known at a later date. Exposing children to an untested Emergency Use medication implies that there is a dire risk to the children without it. There are no data to support such a potential risk. No such data, no evidence whatsoever of this exists, and for the CDC or Dr. Fauci or any medical expert to imply otherwise is duplicitous. We know the new CDC Director is

working in a highly politically charged environment with many moving parts, and we urge her to ensure that the American populations, and particularly parents, are not misled by public health experts on vaccinating children. We trust that she will ensure this.

This really is a question of risk management for parents and parents must seriously consider that Covid-19 is a far less dangerous illness for children than influenza. This is known by the medical community and parents are being deceived as to greater risk. Parents must be brave and be willing to assess this purely from a benefit versus risk position and ask themselves: 'If my child has little if any risk, near zero risk of severe sequelae or death, and thus no benefit from the vaccine, yet there could be potential harms and as yet unknown harms from the vaccine (as already reported in adults who have received the vaccines), then why would I subject my child to such a vaccine?' And in the presence of the potential risks, as well as the fact that a vaccine for Covid-19 is simply not indicated in children, why would a loving parent allow their child to be vaccinated with still-experimental vaccines? Why put a foreign substance into the body of your child when they have vanishingly low risk of spreading it or getting seriously ill if infected? Why? You must take a step back, we plead, and think this through carefully.

Furthermore, it is nonsensical to suggest that the Covid 'variants' may drive infection in children and harm them and there is no basis for such a statement. For those who are trying to frighten parents by the illogical and absurd statements that a lethal strain may emerge among the variants, then we argue that you are using terms like 'may' and 'could' and 'might.' We can find no evidence to support such claims. It is simply rampant speculation! Making such claims is not science, and decisions based on such claims are not evidence-based. We need to see the actual science and not just rampant speculation by often nonsensical media medical experts. We have heard Dr. Fauci make statements with no science or data to back his statements up. Remember the retraction of the double-mask idiocy? Remember when he said Covid is 10 times more lethal than the seasonal flu? Now they are talking about a third vaccine booster shot and it suggests that those in charge are flying by the seat of their pants and do not know what they are doing. A very prominent Professor out of Johns Hopkins, Dr. Marty Makary, gets it right now when he calls out these experts and agencies for their foolishness and fear mongering that is often inaccurate. He recently eviscerated CDC's guidelines and called out Dr. Fauci for his inaccurate claims on herd immunity.

Focusing a bit more on the variants or mutations, of concern is the emerging indication (at this time we are prognosticating and conjecturing but we are indeed concerned) that the very narrowly focused 'spike-specific' antibody immunity provoked by the existing Covid vaccines is not broad enough, or comprehensive, durable, robust, and complete as 'natural exposure immunity.' There is debate that these vaccines are not as effective as they were reported to be and are not conferring the sterilizing type immunity with strong neutralizing antibodies, rendering the emerging variants as potentially noxious, capable of blowing past the vaccine-induced immunity.

Vaccine developers may be faced with having to fix the spike protein (epitopes) immunity by swapping them out for the new variants as they emerge (else they will be ineffective), or,

providing the host immune response with a much broader vaccine with multiple protein targets on the virus and not only the spike protein. Thus, we ask, is Dr. Fauci and the CDC etc. advising parents to take a vaccine that does not and will not provide the long-term safety assessment, and will be under 'experimental' emergency use by the FDA, and that will require multiple shots given the issue we just raised about the variants and the inability for the narrow immunity to confer protection? How many shots? How regular? Why not one 'universal' vaccine administered once, and only after the long-term safety data is available and assessed? Why not allow several years of adults having the current vaccine to assess the harms before we interfere with our low-risk children? Do you understand the issues involved and how unsettling all of this is and the lack of clarity by the public health experts and decision-makers, leaving parents in the dark as to what's next? This makes no sense and is very frightening.

Our purpose is to shed light on the risky nature of the proposed vaccine policy for children. Such a policy merits detailed investigation prior to implementation. Experts have proven to be less of experts and more of the fear mongering crowd. For fear of being exposed, these experts tend to blame others, especially those that offer valid critique of their failed methodologies and enacted policies. We therefore continue to urge that parents be fully informed in the decision-making process with their physician, prior to their children receiving the vaccine. Children, especially those who have not acquired the critical thought process, must not be used to experiment upon unless there is a valid consent form bearing the parent's signature. We also reiterate that vaccines that have been tested thoroughly, such as the Mumps, Measles and Rubella vaccine, the Polio vaccine and others (to prevent vaccine preventable illnesses), are a must to avoid large-scale harm to children. But these vaccines have undergone the rigors of research and have a determinant safety record. The current Covid vaccines do not have such a detailed record of either safety or efficacy to warrant a large-scale vaccination of the children. The planned research suggests similar.

We are in a dangerous situation here by advocating vaccination of our low-risk children and we must ask these experts for the evidence to support their often ridiculous specious statements. Look at how wrong they were on lockdowns. They have failed and continue to fail in protecting the elderly while destroying families and sacrificing our kids, especially low-income families. Incredibly, they now try to blame those who criticized and questioned the lockdowns for the failure of the very lockdowns they advocated and that were implemented. It makes no sense and the hubris of these experts defies logic. So you want to trust these same people when they just tell you nonchalantly that your child is to be vaccinated? And they do it with hollowness and no scientific basis whatsoever and we are to accept that speciousness? I say no!

Our children are not for you to 'experiment' on. There is absolutely no data, no evidence, none, to support the vaccination of our children in this matter. We are against it and find this unacceptable a proposition. Our children are far too precious to experiment with.

Faust stated para that "the FDA will assess the vaccines for children and consider them safe." This is a forgone conclusion by Faust and we consider it absurd and reckless. It raises many questions for he does not know what the FDA will be assessing and what the trials will show.

We urge the mothers and fathers to demand the science, demand the evidence before embarking on this journey.

We especially urge the parents and their children to seek as much information regarding the risks of such a vaccine.

Think carefully you mothers and fathers out there, you are well capable of informed decision-making. Demand the science, demand the evidence from these talking heads, often unscientific and unsound experts who till now have devastated societies with their nonsensical, baseless, damaging, destructive lockdowns, school closures, mask mandates, and other restrictions. Minority children (and minority women often with least bargaining power) have fared the worst in all of this pandemic lockdown insanity and may well fear the worst with these experimental unnecessary vaccines. To date, no argument, no information, no statements by Dr. Fauci, the CDC, or any of the television medical experts have made any sense on why children must be vaccinated. None. If there is a credible basis, if there is evidence, then bring the evidence and let us have a look at it, but until then, please leave our children alone! If we see evidence of the necessity, we will agree, but we have seen none and all we are hearing in this is fear mongering and falsehoods and the nation's parents must not be lied to anymore! They want honesty, clarity, balanced information that could help them make informed decisions. We must not expose our children to 'unnecessary' harm. We must not expose them to a substance that has not been tested on children (or plan to be) in the way it should be and for as long as necessary. We must not expose children to a vaccine that based on their risk, is absolutely not needed. Moreover, they can become infected naturally, if their immunity is needed.

To close, we make this plea and urge those in the medical field to reiterate the need for a thorough examination of the science of efficacy, the potential risks to the children and the evidence that supports the need for such a medical intervention foisted on our children. Failing which, it would seem a violation of the Hippocratic Oath, "Above all do no harm."

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## PFIZER'S OWN CONFIDENTIAL DOCUMNET REVEALS

## THERE COVID19 VACCINE IS CAUSING DEATH AND ADVERSE REACTIONS

Thanks to the efforts of a group called Public Health and Medical Professionals for Transparency, we now have smoking gun confidential documents that show Pfizer and the FDA knew in early 2021 that **pfizer's mRNA vaccines were killing thousands of people** and causing spontaneous abortions while damaging three times more women than men.

One confidential document in particular was part of a court-ordered release of FDA files that the FDA fought by claiming the agency should have 55 years to release this information. A court judge disagreed and ordered the release of 500 documents per month, and the very first batch of documents contained this bombshell entitled, "Cumulative Analysis of Post-Authorization Adverse Event Reports."

5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021
Report Prepared by:
Worldwide Safety
Pfizer

The document reveals that within just 90 days after the EUA release of Pfizer's mRNA vaccine, the company was already aware of *voluntary* adverse reaction reports that revealed **1,223 deaths** and over **42,000 adverse reports** describing a total of **158,893 adverse reactions**. The reports originated from numerous countries, including the United States, United Kingdom, Italy, Germany, France, Portugal, Spain and other nations.

Aside from "general disorders," the No. 1 most frequently reported category of mRNA vaccine adverse reactions was **Nervous system disorders**, clocking in at **25,957** reports.

Pfizer has withheld the total number of doses released across the world, citing corporate trade secrets. This is indicated by "(b) (4)" in the document, where specific numbers and facts are redacted.

Even these numbers — already quite shocking, given the FDA's insistence that mRNA vaccines are "safe and effective" — barely scratch the surface of the damage and deaths caused by these vaccines. "Reports are submitted voluntarily, and the magnitude of underreporting is unknown," says Pfizer on page 5.

Shockingly, the document reveals that more than three times as many women were damaged by the Pfizer vaccine, compared to men. There were 29,914 adverse events recorded in women, with just 9,182 recorded in men. It is not known whether the same number of men and women

took the vaccine, but this number exposes the very real possibility of a **gender-specific vaccine damage risk** that the FDA went to great lengths to cover up.

Anecdotally, most of the neurological damage we've seen in people who have been damaged by the vaccine — convulsions, numbness, pain, etc. — has been depicted in women, not men. It looks like **the FDA knows the mRNA vaccine exhibits a disproportionate, gender-specific damage profile** that also affects women in terms of spontaneous abortions (also covered in the report).

Also to the shock of many observers who are just now digging into this smoking gun document, Pfizer told the FDA under "Safety concerns" (section 3.1.2) that its mRNA injection could cause, "Vaccine-Associated Enhanced Disease (VAED), including Vaccine-associated Enhanced Respiratory Disease (VAERD)."

This means **the FDA knew the vaccine could sicken and kill patients who were later infected with covid**.

Under the label of "missing information," Pfizer also told the FDA that it has no information about "Use in Pregnancy and lactation" nor covering "Use in Paediatric Individuals < 12 Years of Age."

"Vaccine Effectiveness" was also listead as "Missing information" by Pfizer.

In other words, **Pfizer told the FDA its vaccines could kill people and that it had no information about vaccine effectiveness**, yet the FDA fraudulently pushed the vaccine as "safe and effective" anyway. Pfizer even told the FDA that it had no safety information about use in pregnant women, yet the FDA (and Fauci, the CDC, etc.) all pushed the vaccine for pregnant women, despite the utter lack of safety information.

In the section labeled, "Use in Pregnancy and lactation," the report discusses reports of the mRNA vaccine being linked to:

*spontaneous abortion (23), outcome pending (5), premature birth with neonatal death, spontaneous abortion with intrauterine death (2 each), spontaneous abortion with neonatal death, and normal outcome (1 each).*

Notice that "spontaneous abortion" represents by far the highest number in these reports. In other words, **the FDA knew this vaccine would kill unborn babies**, but they pushed it on pregnant women anyway.

**ASK YOURSELF IF YOU WANT TO BECOME LIABLE FOR MANDATING THESE COVID19 VACCINES**

# A complete list of adverse events from the Pfizer 5.3.6 report

APPENDIX 1. LIST OF ADVERSE EVENTS OF SPECIAL INTEREST

1p36 deletion syndrome;2-Hydroxyglutaric aciduria;5'nucleotidase increased;Acoustic neuritis;Acquired C1 inhibitor deficiency;Acquired epidermolysis bullosa;Acquired epileptic aphasia;Acute cutaneous lupus erythematosus;Acute disseminated encephalomyelitis;Acute encephalitis with refractory, repetitive partial seizures;Acute febrile neutrophilic dermatosis;Acute flaccid myelitis;Acute haemorrhagic leukoencephalitis;Acute haemorrhagic oedema of infancy;**Acute kidney injury**;Acute macular outer retinopathy;**Acute motor axonal neuropathy**;Acute motor-sensory axonal neuropathy;**Acute myocardial infarction**;**Acute respiratory distress syndrome**; [note: that sounds like "Covid 19."] **Acute respiratory failure**;Addison's disease;Administration site thrombosis;Administration site vasculitis;Adrenal thrombosis;Adverse event following immunisation;Ageusia;Agranulocytosis;**Air embolism**;Alanine aminotransferase abnormal;Alanine aminotransferase increased;Alcoholic seizure;Allergic bronchopulmonary mycosis;Allergic oedema;Alloimmune hepatitis;Alopecia areata;Alpers disease;Alveolar proteinosis;Ammonia abnormal;Ammonia increased;Amniotic cavity infection;Amygdalohippocampectomy;Amyloid arthropathy;Amyloidosis;Amyloidosis senile;Anaphylactic reaction;**Anaphylactic shock**;Anaphylactic transfusion reaction;Anaphylactoid reaction;Anaphylactoid shock;Anaphylactoid syndrome of pregnancy;Angioedema;Angiopathic neuropathy;Ankylosing spondylitis;Anosmia;Antiacetylcholine receptor antibody positive;Anti-actin antibody positive;Anti-aquaporin-4 antibody positive;Anti-basal ganglia antibody positive;Anti-cyclic citrullinated peptide antibody positive;Anti-epithelial antibody positive;Anti-erythrocyte antibody positive;Anti-exosome complex antibody positive;Anti- GAD antibody negative;Anti-GAD antibody positive;Anti-ganglioside antibody positive;Antigliadin antibody positive;Anti-glomerular basement membrane antibody positive;Anti-glomerular basement membrane disease;Anti-glycyl-tRNA synthetase antibody positive;Anti-HLA antibody test positive;Anti-IA2 antibody positive;Anti-insulin antibody increased;Anti-insulin antibody positive;Anti-insulin receptor antibody increased;Anti- insulin receptor antibody positive;Anti-interferon antibody negative;Anti-interferon antibody positive;Anti-islet cell antibody positive;Antimitochondrial antibody positive;Anti-muscle specific kinase antibody positive;Anti-myelin-associated glycoprotein antibodies positive;Anti-myelin-associated glycoprotein associated polyneuropathy;Antimyocardial antibody positive;Anti-neuronal antibody positive;Antineutrophil cytoplasmic antibody increased;Antineutrophil cytoplasmic antibody positive;Anti-neutrophil cytoplasmic antibody positive vasculitis;Anti-NMDA antibody positive;Antinuclear antibody increased;Antinuclear antibody positive;Antiphospholipid antibodies positive;Antiphospholipid syndrome;Anti-platelet antibody positive;Anti-prothrombin antibody positive;Antiribosomal P antibody positive;Anti-RNA polymerase III antibody positive;Anti-saccharomyces cerevisiae antibody test positive;Anti-sperm antibody positive;Anti-SRP antibody positive;Antisynthetase syndrome;Anti-thyroid antibody positive;Anti-transglutaminase antibody increased;Anti-VGCC antibody positive;Anti- VGKC antibody positive;Anti-vimentin antibody positive;Antiviral prophylaxis;Antiviral treatment;Anti-zinc transporter 8 antibody positive;Aortic embolus;Aortic thrombosis;Aortitis;Aplasia pure red cell;Aplastic anaemia;Application site thrombosis;Application site vasculitis;Arrhythmia;Arterial bypass occlusion;Arterial bypass

thrombosis;Arterial thrombosis;Arteriovenous fistula thrombosis;Arteriovenous graft site stenosis;Arteriovenous graft thrombosis;Arteritis;Arteritis



coronary;Arthralgia;Arthritis;Arthritis enteropathic;Ascites;Aseptic cavernous sinus thrombosis;Aspartate aminotransferase abnormal;Aspartate aminotransferase increased;Aspartate-glutamate-transporter deficiency;AST to platelet ratio index increased;AST/ALT ratio abnormal;Asthma;Asymptomatic COVID-19;Ataxia;Atheroembolism;Atonic seizures;**Atrial thrombosis**;Atrophic thyroiditis;Atypical benign partial epilepsy;**Atypical pneumonia [Note: This sounds like the original definition of Covid-19 out of Wuhan]**;Aura;Autoantibody positive;Autoimmune anaemia;Autoimmune aplastic anaemia;Autoimmune arthritis;**Autoimmune blistering disease**;Autoimmune cholangitis;Autoimmune colitis;**Autoimmune demyelinating disease**;Autoimmune dermatitis;Autoimmune disorder;**Autoimmune encephalopathy**;Autoimmune endocrine disorder;Autoimmune enteropathy;Autoimmune eye disorder;Autoimmune haemolytic anaemia;Autoimmune heparin-induced thrombocytopenia;Autoimmune hepatitis;Autoimmune hyperlipidaemia;Autoimmune hypothyroidism;Autoimmune inner ear disease;Autoimmune lung disease;Autoimmune lymphoproliferative syndrome;**Autoimmune myocarditis**;Autoimmune myositis;Autoimmune nephritis;Autoimmune neuropathy;Autoimmune neutropenia;**Autoimmune pancreatitis**;Autoimmune pancytopenia;**Autoimmune pericarditis**;Autoimmune retinopathy;Autoimmune thyroid disorder;Autoimmune thyroiditis;Autoimmune uveitis;**Autoinflammation with infantile enterocolitis**;Autoinflammatory disease;Automatism epileptic;Autonomic nervous system imbalance;Autonomic seizure;Axial spondyloarthritis;Axillary vein thrombosis;Axonal and demyelinating polyneuropathy;Axonal neuropathy;Bacterascites;Baltic myoclonic epilepsy;Band sensation;Basedow's disease;Basilar artery thrombosis;Basophilopenia;B-cell aplasia;Behcet's syndrome;Benign ethnic neutropenia;Benign familial neonatal convulsions;Benign familial pemphigus;Benign rolandic epilepsy;Beta-2 glycoprotein antibody positive;Bickerstaff's encephalitis;Bile output abnormal;Bile output decreased;Biliary ascites;Bilirubin conjugated abnormal;Bilirubin conjugated increased;Bilirubin urine present;Biopsy liver abnormal;Biotinidase deficiency;Birdshot chorioretinopathy;Blood alkaline phosphatase abnormal;Blood alkaline phosphatase increased;Blood bilirubin abnormal;Blood bilirubin increased;Blood bilirubin unconjugated increased;Blood cholinesterase abnormal;Blood cholinesterase decreased;Blood pressure decreased;Blood pressure diastolic decreased;Blood pressure systolic decreased;Blue toe syndrome;Brachiocephalic vein thrombosis;**Brain stem embolism;Brain stem thrombosis**;Bromosulphthalein test abnormal;Bronchial

oedema;Bronchitis;Bronchitis mycoplasmal;Bronchitis viral;Bronchopulmonary aspergillosis allergic;Bronchospasm;Budd- Chiari syndrome;Bulbar palsy;Butterfly rash;C1q nephropathy;Caesarean section;Calcium embolism;Capillaritis;Caplan's syndrome;Cardiac amyloidosis;Cardiac arrest;Cardiac failure;Cardiac failure acute;Cardiac sarcoidosis;Cardiac ventricular thrombosis;Cardiogenic shock;Cardiolipin antibody positive;Cardiopulmonary failure;Cardio-respiratory arrest;Cardio-respiratory distress;Cardiovascular insufficiency;Carotid arterial embolus;Carotid artery thrombosis;Cataplexy;Catheter site thrombosis;Catheter site vasculitis;Cavernous sinus thrombosis;CDKL5 deficiency disorder;CEC syndrome;Cement embolism;Central nervous system lupus;Central nervous system vasculitis;Cerebellar artery thrombosis;Cerebellar embolism;Cerebral amyloid angiopathy;Cerebral arteritis;**Cerebral artery embolism;Cerebral artery thrombosis**;Cerebral gas embolism;**Cerebral microembolism**;Cerebral septic infarct;Cerebral thrombosis;Cerebral venous sinus thrombosis;Cerebral venous thrombosis;Cerebrospinal thrombotic



tamponade;Cerebrovascular accident;Change in seizure presentation;Chest discomfort;Child-Pugh-Turcotte score abnormal;Child-Pugh-Turcotte score increased;Chillblains;Choking;**Choking sensation**;Cholangitis sclerosing;Chronic autoimmune glomerulonephritis;Chronic cutaneous lupus erythematosus;Chronic fatigue syndrome;Chronic gastritis;Chronic inflammatory demyelinating polyradiculoneuropathy;Chronic lymphocytic inflammation with pontine perivascular enhancement responsive to steroids;Chronic recurrent multifocal osteomyelitis;Chronic respiratory failure;Chronic spontaneous urticaria;Circulatory collapse;Circumoral oedema;Circumoral swelling;Clinically isolated syndrome;Clonic convulsion;Coeliac disease;Cogan's syndrome;Cold agglutinins positive;Cold type haemolytic anaemia;Colitis;Colitis erosive;Colitis herpes;Colitis microscopic;Colitis ulcerative;Collagen disorder;Collagen-vascular disease;Complement factor abnormal;Complement factor C1 decreased;Complement factor C2 decreased;Complement factor C3 decreased;Complement factor C4 decreased;Complement factor decreased;Computerised tomogram liver abnormal;Concentric sclerosis;Congenital anomaly;Congenital bilateral perisylvian syndrome;Congenital herpes simplex infection;Congenital myasthenic syndrome;Congenital varicella infection;Congestive hepatopathy;**Convulsion in childhood**;Convulsions local;Convulsive threshold lowered;Coombs positive haemolytic anaemia;Coronary artery disease;**Coronary artery embolism**;**Coronary artery thrombosis**;Coronary bypass thrombosis;Coronavirus infection;Coronavirus test;**Coronavirus test negative**;Coronavirus test positive;Corpus callosotomy;Cough;Cough variant asthma;COVID-19;COVID-19 immunisation;**COVID-19 pneumonia**;COVID-19 prophylaxis;COVID-19 treatment;Cranial

nerve disorder;**Cranial nerve palsies multiple;Cranial nerve paralysis**;CREST syndrome;Crohn's disease;Cryofibrinogenaemia;Cryoglobulinaemia;CSF oligoclonal band present;CSWS syndrome;Cutaneous amyloidosis;Cutaneous lupus erythematosus;Cutaneous sarcoidosis;Cutaneous vasculitis;Cyanosis;Cyclic neutropenia;Cystitis interstitial;Cytokine release syndrome;Cytokine storm;De novo purine synthesis inhibitors associated acute inflammatory syndrome;**Death neonatal;Deep vein thrombosis**;Deep vein thrombosis postoperative;Deficiency of bile secretion;Deja vu;Demyelinating polyneuropathy;Demyelination;Dermatitis;Dermatitis bullous;Dermatitis herpetiformis;Dermatomyositis;Device embolisation;Device related thrombosis;Diabetes mellitus;Diabetic ketoacidosis;Diabetic mastopathy;Dialysis amyloidosis;Dialysis membrane reaction;Diastolic hypotension;Diffuse vasculitis;Digital pitting scar;Disseminated intravascular coagulation;Disseminated intravascular coagulation in newborn;Disseminated neonatal herpes simplex;Disseminated varicella;Disseminated varicella zoster vaccine virus infection;Disseminated varicella zoster virus infection;DNA antibody positive;Double cortex syndrome;Double stranded DNA antibody positive;Dreamy state;Dressler's syndrome;Drop attacks;Drug withdrawal convulsions;Dyspnoea;Early infantile epileptic encephalopathy with burst-suppression;Eclampsia;Eczema herpeticum;Embolia cutis medicamentosa;Embolic cerebellar infarction;Embolic cerebral infarction;Embolic pneumonia;Embolic stroke;Embolism;Embolism arterial;Embolism venous;Encephalitis;Encephalitis allergic;Encephalitis autoimmune;**Encephalitis brain stem;Encephalitis haemorrhagic**;Encephalitis periaxialis diffusa;**Encephalitis post immunisation**;Encephalomyelitis;Encephalopathy;Endocrine disorder;Endocrine ophthalmopathy;Endotracheal intubation;Enteritis;Enteritis leukopenic;Enterobacter pneumonia;Enterocolitis;Enteropathic spondylitis;Eosinopenia;Eosinophilic



fasciitis;Eosinophilic granulomatosis with polyangiitis;Eosinophilic oesophagitis;Epidermolysis;Epilepsy;Epilepsy surgery;Epilepsy with myoclonic-atonic seizures;Epileptic aura;Epileptic psychosis;Erythema;Erythema induratum;Erythema multiforme;Erythema nodosum;Evans syndrome;Exanthema subitum;Expanded disability status scale score decreased;Expanded disability status scale score increased;Exposure to communicable disease;Exposure to SARS-CoV-2;Eye oedema;Eye pruritus;Eye swelling;Eyelid oedema;Face oedema;Facial paralysis;Facial paresis;Faciobrachial dystonic seizure;Fat embolism;Febrile convulsion;Febrile infection-related epilepsy syndrome;Febrile neutropenia;Felty's syndrome;Femoral artery embolism;Fibrillary glomerulonephritis;Fibromyalgia;Flushing;Foaming at mouth;Focal cortical resection;Focal

dyscognitive seizures;**Foetal distress syndrome;Foetal placental thrombosis;Foetor hepaticus;Foreign body embolism;Frontal lobe epilepsy**;Fulminant type 1 diabetes mellitus;Galactose elimination capacity test abnormal;Galactose elimination capacity test decreased;Gamma-glutamyltransferase abnormal;Gamma-glutamyltransferase increased;Gastritis herpes;Gastrointestinal amyloidosis;Gelastic seizure;Generalised onset non-motor seizure;Generalised tonic-clonic seizure;Genital herpes;Genital herpes simplex;Genital herpes zoster;Giant cell arteritis;Glomerulonephritis;Glomerulonephritis membranoproliferative;Glomerulonephritis membranous;Glomerulonephritis rapidly progressive;Glossopharyngeal nerve paralysis;Glucose transporter type 1 deficiency syndrome;Glutamate dehydrogenase increased;Glycocholic acid increased;GM2 gangliosidosis;Goodpasture's syndrome;Graft thrombosis;Granulocytopenia;Granulocytopenia neonatal;Granulomatosis with polyangiitis;Granulomatous dermatitis;Grey matter heterotopia;Guanase increased;Guillain- Barre syndrome;Haemolytic anaemia;Haemophagocytic lymphohistiocytosis;Haemorrhage;Haemorrhagic ascites;Haemorrhagic disorder;Haemorrhagic pneumonia;Haemorrhagic varicella syndrome;Haemorrhagic vasculitis;Hantavirus pulmonary infection;Hashimoto's encephalopathy;Hashitoxicosis;Hemimegalencephaly;Henoch-Schonlein purpura;Henoch- Schonlein purpura nephritis;Hepaplastin abnormal;Hepaplastin decreased;Heparin-induced thrombocytopenia;Hepatic amyloidosis;Hepatic artery embolism;Hepatic artery flow decreased;**Hepatic artery thrombosis**;Hepatic enzyme abnormal;Hepatic enzyme decreased;Hepatic enzyme increased;Hepatic fibrosis marker abnormal;Hepatic fibrosis marker increased;Hepatic function abnormal;Hepatic hydrothorax;Hepatic hypertrophy;Hepatic hypoperfusion;Hepatic lymphocytic infiltration;Hepatic mass;Hepatic pain;Hepatic sequestration;Hepatic vascular resistance increased;Hepatic vascular thrombosis;Hepatic vein embolism;Hepatic vein thrombosis;Hepatic venous pressure gradient abnormal;Hepatic venous pressure gradient increased;Hepatitis;Hepatobiliary scan abnormal;Hepatomegaly;Hepatosplenomegaly;Hereditary angioedema with C1 esterase inhibitor deficiency;Herpes dermatitis;Herpes gestationis;Herpes oesophagitis;Herpes ophthalmic;Herpes pharyngitis;Herpes sepsis;Herpes simplex;Herpes simplex cervicitis;Herpes simplex colitis;Herpes simplex encephalitis;Herpes simplex gastritis;Herpes simplex hepatitis;Herpes simplex meningitis;Herpes simplex meningoencephalitis;Herpes simplex meningomyelitis;Herpes simplex necrotising retinopathy;Herpes simplex oesophagitis;Herpes simplex otitis externa;Herpes simplex pharyngitis;Herpes simplex pneumonia;Herpes simplex reactivation;Herpes simplex sepsis;Herpes simplex viraemia;Herpes simplex virus conjunctivitis neonatal;Herpes simplex visceral;Herpes virus

infection;Herpes zoster;Herpes zoster cutaneous disseminated;Herpes zoster infection neurological;Herpes zoster meningitis;Herpes zoster meningoencephalitis;Herpes zoster meningomyelitis;Herpes zoster meningoradiculitis;Herpes zoster necrotising retinopathy;Herpes zoster oticus;Herpes zoster pharyngitis;Herpes zoster reactivation;Herpetic radiculopathy;Histone antibody positive;Hoigne's syndrome;Human herpesvirus 6 encephalitis;Human herpesvirus 6 infection;Human herpesvirus 6 infection reactivation;Human herpesvirus 7 infection;Human herpesvirus 8 infection;Hyperammonaemia;Hyperbilirubinaemia;Hypercholia;Hypergammaglobulinaemia benign monoclonal;Hyperglycaemic seizure;Hypersensitivity;Hypersensitivity vasculitis;Hyperthyroidism;Hypertransaminasaemia;Hyperventilation;Hypoalbuminaemia;Hypocalcaemic seizure;Hypogammaglobulinaemia;Hypoglossal nerve paralysis;Hypoglossal nerve paresis;Hypoglycaemic seizure;Hyponatraemic seizure;Hypotension;Hypotensive crisis;Hypothenar hammer syndrome;Hypothyroidism;Hypoxia;**Idiopathic CD4 lymphocytopenia**; **[Note: sounds like "AIDS" except Fauci re-defined AIDS in 1993, after the "Amsterdam Surprise" as only occurring when HIV was "present" so all thousands the non HIV, "idiopathic CD4 lympho-cytopenia cases were excluded, creating a tautological definition that came to be "HIV/AIDS." ]** Idiopathic generalised epilepsy;Idiopathic interstitial pneumonia;Idiopathic neutropenia;Idiopathic pulmonary fibrosis;IgA nephropathy;IgM nephropathy;IIIrd nerve paralysis;IIIrd nerve paresis;Iliac artery embolism;Immune thrombocytopenia;Immune- mediated adverse reaction;Immune-mediated cholangitis;Immune-mediated cholestasis;Immune-mediated cytopenia;Immune-mediated encephalitis;Immune-mediated encephalopathy;Immune-mediated endocrinopathy;Immune-mediated enterocolitis;Immune- mediated gastritis;Immune-mediated hepatic disorder;Immune-mediated hepatitis;Immune- mediated hyperthyroidism;Immune-mediated hypothyroidism;Immune-mediated myocarditis;Immune-mediated myositis;Immune-mediated nephritis;Immune-mediated neuropathy;Immune-mediated pancreatitis;Immune-mediated pneumonitis;Immune-mediated renal disorder;Immune-mediated thyroiditis;Immune-mediated uveitis;Immunoglobulin G4 related disease;Immunoglobulins abnormal;Implant site thrombosis;Inclusion body myositis;Infantile genetic agranulocytosis;Infantile spasms;Infected vasculitis;Infective thrombosis;Inflammation;Inflammatory bowel disease;Infusion site thrombosis;Infusion site vasculitis;Injection site thrombosis;Injection site urticaria;Injection site vasculitis;Instillation site thrombosis;Insulin autoimmune syndrome;Interstitial granulomatous dermatitis;Interstitial lung disease;Intracardiac mass;Intracardiac thrombus;Intracranial pressure increased;Intrapericardial thrombosis;Intrinsic factor antibody abnormal;Intrinsic factor antibody positive;IPEX syndrome;Irregular breathing;IRVAN syndrome;IVth nerve paralysis;IVth nerve paresis;JC polyomavirus test positive;JC virus CSF test positive;Jeavons syndrome;Jugular vein embolism;Jugular vein thrombosis;Juvenile idiopathic arthritis;Juvenile myoclonic epilepsy;Juvenile polymyositis;Juvenile psoriatic arthritis;Juvenile spondyloarthritis;Kaposi sarcoma inflammatory cytokine syndrome;Kawasaki's disease;Kayser-Fleischer ring;Keratoderma blenorrhagica;Ketosis- prone diabetes mellitus;Kounis syndrome;Lafora's myoclonic epilepsy;Lambl's excrescences;Laryngeal dyspnoea;Laryngeal oedema;Laryngeal rheumatoid arthritis;Laryngospasm;Laryngotracheal oedema;Latent autoimmune diabetes in adults;LE cells present;Lemierre syndrome;Lennox-Gastaut syndrome;Leucine aminopeptidase increased;Leukoencephalomyelitis;Leukoencephalopathy;Leukopenia;Leukopenia neonatal;Lewis-Sumner syndrome;Lhermitte's sign;Lichen planopilaris;Lichen planus;Lichen sclerosus;Limbic encephalitis;Linear IgA disease;Lip oedema;Lip swelling;Liver function test

increased;Liver opacity;Liver palpable;Liver sarcoidosis;Liver scan abnormal;Liver tenderness;Low birth weight baby;Lower respiratory tract herpes infection;Lower respiratory tract infection;Lower respiratory tract infection viral;Lung abscess;Lupoid hepatic cirrhosis;Lupus cystitis;Lupus encephalitis;Lupus endocarditis;Lupus enteritis;Lupus hepatitis;Lupus myocarditis;Lupus myositis;Lupus nephritis;Lupus pancreatitis;Lupus pleurisy;Lupus pneumonitis;Lupus vasculitis;Lupus-like syndrome;Lymphocytic hypophysitis;Lymphocytopenia neonatal;Lymphopenia;MAGIC syndrome;Magnetic resonance imaging liver abnormal;Magnetic resonance proton density fat fraction measurement;Mahler sign;Manufacturing laboratory analytical testing issue;Manufacturing materials issue;Manufacturing production issue;Marburg's variant multiple sclerosis;Marchiafava-Bignami disease;Marine Lenhart syndrome;Mastocytic enterocolitis;Maternal exposure during pregnancy;Medical device site thrombosis;Medical device site vasculitis;MELAS syndrome;Meningitis;Meningitis aseptic;Meningitis herpes;Meningoencephalitis herpes simplex neonatal;Meningoencephalitis herpetic;Meningomyelitis herpes;MERS-CoV test;MERS-CoV test negative;MERS-CoV test positive;Mesangioproliferative glomerulonephritis;Mesenteric artery embolism;Mesenteric artery thrombosis;Mesenteric vein thrombosis;Metapneumovirus infection;Metastatic cutaneous Crohn's disease;Metastatic pulmonary embolism;Microangiopathy;Microembolism;Microscopic polyangiitis;Middle East respiratory syndrome;Migraine-triggered seizure;Miliary pneumonia;Miller Fisher syndrome;Mitochondrial aspartate aminotransferase increased;Mixed connective tissue disease;Model for end stage liver disease score abnormal;Model for end stage liver disease score increased;Molar ratio of total branched-chain amino acid to tyrosine;Molybdenum cofactor deficiency;Monocytopenia;Mononeuritis;Mononeuropathy multiplex;Morphoea;Morvan syndrome;Mouth swelling;Moyamoya disease;Multifocal motor neuropathy;**Multiple organ dysfunction syndrome**;Multiple sclerosis;Multiple sclerosis relapse;Multiple sclerosis relapse prophylaxis;Multiple subpial transection;Multisystem inflammatory syndrome in children;Muscular sarcoidosis;Myasthenia gravis;Myasthenia gravis crisis;Myasthenia gravis neonatal;Myasthenic syndrome;Myelitis;**Myelitis transverse**;Myocardial infarction;Myocarditis;Myocarditis post infection;Myoclonic epilepsy;Myoclonic epilepsy and ragged-red fibres;Myokymia;Myositis;Narcolepsy;Nasal herpes;Nasal obstruction;Necrotising herpetic retinopathy;Neonatal Crohn's disease;Neonatal epileptic seizure;Neonatal lupus erythematosus;Neonatal mucocutaneous herpes simplex;**Neonatal pneumonia**;Neonatal

seizure;Nephritis;Nephrogenic systemic fibrosis;Neuralgic amyotrophy;Neuritis;Neuritis cranial;Neuromyelitis optica pseudo relapse;Neuromyelitis optica spectrum disorder;Neuromyotonia;Neuronal neuropathy;Neuropathy peripheral;Neuropathy, ataxia, retinitis pigmentosa syndrome;Neuropsychiatric lupus;Neurosarcoidosis;Neutropenia;Neutropenia neonatal;Neutropenic colitis;Neutropenic infection;Neutropenic sepsis;Nodular rash;Nodular vasculitis;Noninfectious myelitis;Noninfective encephalitis;Noninfective encephalomyelitis;Noninfective oophoritis;Obstetrical pulmonary embolism;Occupational exposure to communicable disease;Occupational exposure to SARS-CoV-2;Ocular hyperaemia;Ocular myasthenia;Ocular pemphigoid;Ocular sarcoidosis;Ocular vasculitis;Oculofacial paralysis;Oedema;Oedema blister;Oedema due to hepatic disease;Oedema mouth;Oesophageal achalasia;Ophthalmic artery thrombosis;Ophthalmic herpes simplex;Ophthalmic herpes zoster;Ophthalmic vein thrombosis;Optic neuritis;Optic



neuropathy;Optic perineuritis;Oral herpes;Oral lichen planus;Oropharyngeal oedema;Oropharyngeal spasm;Oropharyngeal swelling;Osmotic demyelination syndrome;Ovarian vein thrombosis;Overlap syndrome;Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection;Paget-Schroetter syndrome;Palindromic rheumatism;Palisaded neutrophilic granulomatous dermatitis;Palmoplantar keratoderma;Palpable purpura;Pancreatitis;Panencephalitis;Papillophlebitis;Paracancerous pneumonia;Paradoxical embolism;Parainfluenzae viral laryngotracheobronchitis;Paraneoplastic dermatomyositis;Paraneoplastic pemphigus;Paraneoplastic thrombosis;Paresis cranial nerve;Parietal cell antibody positive;Paroxysmal nocturnal haemoglobinuria;Partial seizures;Partial seizures with secondary generalisation;Patient isolation;Pelvic venous thrombosis;Pemphigoid;Pemphigus;Penile vein thrombosis;Pericarditis;Pericarditis lupus;Perihepatic discomfort;Periorbital oedema;Periorbital swelling;Peripheral artery thrombosis;Peripheral embolism;Peripheral ischaemia;Peripheral vein thrombus extension;Periportal oedema;Peritoneal fluid protein abnormal;Peritoneal fluid protein decreased;Peritoneal fluid protein increased;Peritonitis lupus;Pernicious anaemia;Petit mal epilepsy;Pharyngeal oedema;Pharyngeal swelling;Pityriasis lichenoides et varioliformis acuta;Placenta praevia;Pleuroparenchymal fibroelastosis;Pneumobilia;Pneumonia;Pneumonia adenoviral;Pneumonia cytomegaloviral;Pneumonia herpes viral;Pneumonia influenzal;Pneumonia measles;Pneumonia mycoplasmal;Pneumonia necrotising;Pneumonia parainfluenzae viral;Pneumonia respiratory syncytial viral;Pneumonia viral;POEMS syndrome;Polyarteritis nodosa;Polyarthritis;Polychondritis;Polyglandular autoimmune syndrome

type I;Polyglandular autoimmune syndrome type II;Polyglandular autoimmune syndrome type III;Polyglandular disorder;Polymicrogyria;Polymyalgia rheumatica;Polymyositis;Polyneuropathy;Polyneuropathy idiopathic progressive;Portal pyaemia;Portal vein embolism;Portal vein flow decreased;Portal vein pressure increased;Portal vein thrombosis;Portosplenomesenteric venous thrombosis;Post procedural hypotension;Post procedural pneumonia;Post procedural pulmonary embolism;Post stroke epilepsy;Post stroke seizure;Post thrombotic retinopathy;Post thrombotic syndrome;Post viral fatigue syndrome;Postictal headache;Postictal paralysis;Postictal psychosis;Postictal state;Postoperative respiratory distress;Postoperative respiratory failure;Postoperative thrombosis;Postpartum thrombosis;Postpartum venous thrombosis;Postpericardiotomy syndrome;Post-traumatic epilepsy;Postural orthostatic tachycardia syndrome;Precerebral artery thrombosis;Pre-eclampsia;Preictal state;Premature labour;Premature menopause;Primary amyloidosis;Primary biliary cholangitis;Primary progressive multiple sclerosis;Procedural shock;Proctitis herpes;Proctitis ulcerative;Product availability issue;Product distribution issue;Product supply issue;Progressive facial hemiatrophy;Progressive multifocal leukoencephalopathy;Progressive multiple sclerosis;Progressive relapsing multiple sclerosis;Prosthetic cardiac valve thrombosis;Pruritus;Pruritus allergic;Pseudovasculitis;Psoriasis;Psoriatic arthropathy;Pulmonary amyloidosis;Pulmonary artery thrombosis;**Pulmonary embolism**;Pulmonary fibrosis;Pulmonary haemorrhage;Pulmonary microemboli;Pulmonary oil microembolism;Pulmonary renal syndrome;Pulmonary sarcoidosis;Pulmonary sepsis;Pulmonary thrombosis;Pulmonary tumour thrombotic microangiopathy;Pulmonary vasculitis;Pulmonary veno-occlusive disease;Pulmonary venous thrombosis;Pyoderma gangrenosum;Pyostomatitis vegetans;Pyrexia;Quarantine;Radiation leukopenia;Radiculitis



brachial;Radiologically isolated syndrome;Rash;Rash erythematous;Rash pruritic;Rasmussen encephalitis;Raynaud's phenomenon;Reactive capillary endothelial proliferation;Relapsing multiple sclerosis;Relapsing-remitting multiple sclerosis;Renal amyloidosis;Renal arteritis;Renal artery thrombosis;Renal embolism;Renal failure;Renal vascular thrombosis;Renal vasculitis;Renal vein embolism;Renal vein thrombosis;Respiratory arrest;Respiratory disorder;Respiratory distress;Respiratory failure;Respiratory paralysis;Respiratory syncytial virus bronchiolitis;Respiratory syncytial virus bronchitis;Retinal artery embolism;Retinal artery occlusion;Retinal artery thrombosis;Retinal vascular thrombosis;Retinal vasculitis;Retinal vein occlusion;Retinal vein thrombosis;Retinol binding protein decreased;Retinopathy;Retrograde portal vein flow;Retroperitoneal fibrosis;Reversible airways obstruction;Reynold's syndrome;Rheumatic brain disease;Rheumatic disorder;Rheumatoid arthritis;Rheumatoid factor

increased;Rheumatoid factor positive;Rheumatoid factor quantitative increased;Rheumatoid lung;Rheumatoid neutrophilic dermatosis;Rheumatoid nodule;Rheumatoid nodule removal;Rheumatoid scleritis;Rheumatoid vasculitis;Saccadic eye movement;SAPHO syndrome;Sarcoidosis;SARS-CoV-1 test;SARS-CoV-1 test negative;SARS-CoV-1 test positive;SARS-CoV-2 antibody test;SARS-CoV-2 antibody test negative;SARS-CoV-2 antibody test positive;SARS-CoV-2 carrier;SARS-CoV-2 sepsis;SARS-CoV-2 test;SARS- CoV-2 test false negative;SARS-CoV-2 test false positive;SARS-CoV-2 test negative;SARS- CoV-2 test positive;SARS-CoV-2 viraemia;Satoyoshi syndrome;Schizencephaly;Scleritis;Sclerodactylia;Scleroderma;Scleroderma associated digital ulcer;Scleroderma renal crisis;Scleroderma-like reaction;Secondary amyloidosis;Secondary cerebellar degeneration;Secondary progressive multiple sclerosis;Segmented hyalinising vasculitis;Seizure;Seizure anoxic;Seizure cluster;Seizure like phenomena;Seizure prophylaxis;Sensation of foreign body;Septic embolus;Septic pulmonary embolism;Severe acute respiratory syndrome;Severe myoclonic epilepsy of infancy;Shock;**Shock symptom;Shrinking lung syndrome**;Shunt thrombosis;Silent thyroiditis;Simple partial seizures;Sjogren's syndrome;Skin swelling;SLE arthritis;Smooth muscle antibody positive;Sneezing;**Spinal artery embolism**;Spinal artery thrombosis;Splenic artery thrombosis;Splenic embolism;Splenic thrombosis;Splenic vein thrombosis;Spondylitis;Spondyloarthropathy;Spontaneous heparin-induced thrombocytopenia syndrome;Status epilepticus;**Stevens-Johnson syndrome**; **[Note: This, SJS, can result in the skin coming off the body altogether, from the body's attempt to rid itself of poison.]** Stiff leg syndrome;Stiff person syndrome;Stillbirth;Still's disease;Stoma site thrombosis;Stoma site vasculitis;Stress cardiomyopathy;Stridor;Subacute cutaneous lupus erythematosus;Subacute endocarditis;Subacute inflammatory demyelinating polyneuropathy;Subclavian artery embolism;Subclavian artery thrombosis;Subclavian vein thrombosis;Sudden unexplained death in epilepsy;Superior sagittal sinus thrombosis;Susac's syndrome;Suspected COVID- 19;Swelling;Swelling face;Swelling of eyelid;Swollen tongue;Sympathetic ophthalmia;Systemic lupus erythematosus;Systemic lupus erythematosus disease activity index abnormal;Systemic lupus erythematosus disease activity index decreased;Systemic lupus erythematosus disease activity index increased;Systemic lupus erythematosus rash;Systemic scleroderma;Systemic sclerosis pulmonary;Tachycardia;Tachypnoea;Takayasu's arteritis;Temporal lobe epilepsy;Terminal ileitis;Testicular autoimmunity;Throat tightness;Thromboangiitis obliterans;Thrombocytopenia;Thrombocytopenic purpura;Thrombophlebitis;Thrombophlebitis migrans;Thrombophlebitis

neonatal;Thrombophlebitis septic;Thrombophlebitis superficial;Thromboplastin antibody positive;Thrombosis;Thrombosis corpora cavernosa;Thrombosis in device;Thrombosis mesenteric vessel;Thrombotic cerebral infarction;Thrombotic microangiopathy;Thrombotic stroke;Thrombotic thrombocytopenic purpura;Thyroid disorder;Thyroid stimulating immunoglobulin increased;Thyroiditis;Tongue amyloidosis;Tongue biting;Tongue oedema;Tonic clonic movements;Tonic convulsion;Tonic posturing;Topectomy;Total bile acids increased;Toxic epidermal necrolysis;Toxic leukoencephalopathy;Toxic oil syndrome;Tracheal obstruction;Tracheal oedema;Tracheobronchitis;Tracheobronchitis mycoplasmal;Tracheobronchitis viral;Transaminases abnormal;Transaminases increased;Transfusion-related alloimmune neutropenia;Transient epileptic amnesia;Transverse sinus thrombosis;Trigeminal nerve paresis;Trigeminal neuralgia;Trigeminal palsy;Truncus coeliacus thrombosis;Tuberous sclerosis complex;Tubulointerstitial nephritis and uveitis syndrome;Tumefactive multiple sclerosis;Tumour embolism;Tumour thrombosis;Type 1 diabetes mellitus;Type I hypersensitivity;Type III immune complex mediated reaction;Uhthoff's phenomenon;Ulcerative keratitis;Ultrasound liver abnormal;Umbilical cord thrombosis;Uncinate fits;Undifferentiated connective tissue disease;Upper airway obstruction;Urine bilirubin increased;Urobilinogen urine decreased;Urobilinogen urine increased;Urticaria;Urticaria papular;Urticarial vasculitis;Uterine rupture;Uveitis;Vaccination site thrombosis;Vaccination site vasculitis;Vagus nerve paralysis;Varicella;Varicella keratitis;Varicella post vaccine;Varicella zoster gastritis;Varicella zoster oesophagitis;Varicella zoster pneumonia;Varicella zoster sepsis;Varicella zoster virus infection;Vasa praevia;Vascular graft thrombosis;Vascular pseudoaneurysm thrombosis;Vascular purpura;Vascular stent thrombosis;Vasculitic rash;Vasculitic ulcer;Vasculitis;Vasculitis gastrointestinal;Vasculitis necrotising;Vena cava embolism;Vena cava thrombosis;Venous intravasation;Venous recanalisation;**Venous thrombosis**;Venous thrombosis in pregnancy;Venous thrombosis limb;Venous thrombosis neonatal;Vertebral artery thrombosis;Vessel puncture site thrombosis;Visceral venous thrombosis;VIth nerve paralysis;VIth nerve paresis;Vitiligo;Vocal cord paralysis;Vocal cord paresis;Vogt-Koyanagi-Harada disease;Warm type haemolytic anaemia;Wheezing;White nipple sign;XIth nerve paralysis;X-ray hepatobiliary abnormal;Young's syndrome;Zika virus associated Guillain Barre syndrome.

**- Overwhelming Evidence that this Pfizer Covid19 vaccine is not safe.**

**- Are these Covid19 vaccines what you are mandating Citizens and Children take?**

**- Should you not have asked questions and become aware before mandating these vaccines?**

**- Mandating vaccination - is clearly coercion which violates all legislation, acts and statues that refer to consent and voluntary consent especially the Ontario Health Care Consent Act. And is also clearly extortion because it states, do this (take a vaccine).**

**- The Nuremberg trials are evidence that "I was just following orders" was not an acceptable defense and will not exonerate anyone from responsibility. You will be held accountable.**

## These are the Laws and Acts which you will become liable under by prescribing, recommending, facilitating, advertising, mandating, incentivizing, and using coercion to insist any public person under your control, including children submit to ANY vaccine including the experimental gene therapy injections for COVID-19, commonly referred to as a "vaccine". You should judge yourself accordingly.

**1 - Canadian Charter of Rights and Freedoms**
**2 - Canadian Bill Of Rights**
**3 – Canadian and Ontario Human Rights Codes**
**4 – Ontario Freedom of Information and Protection of Privacy Act**
**5 – Ontario Personal Health Information Protection Act**
**6 – Ontario Health Care Consent Act**
**7 – Ontario Occupational Health and Safety Act**
**8 – Ontario Regulated Health Professional Act**
**9 – Immunization in Canada Act**
**10 – Canadian Criminal Code**
**11 – The Nuremberg Code**
**12 – Helsinki Declaration**
**13 – Universal Declaration on Bioethics and Human Rights**
**14 – Siracusa Principles**
**15 – Canadian Genetic Non-Discrimination Act**

## 1- Canadian Charter of Rights and Freedoms

52. (1) The Constitution of Canada is the supreme law of Canada, and any law that is inconsistent with the provisions of the Constitution is, to the extent of the inconsistency, of no force or effect.

## 2- Canadian Bill of Rights, SC 1960, c. 44

An Act for the Recognition and Protection of Human Rights and Fundamental Freedoms

**Preamble**
The Parliament of Canada, affirming that the Canadian Nation is founded upon principles that acknowledge the supremacy of God, the dignity and worth of the human person and the position of the family in a society of free men and free institutions;

Affirming also that men and institutions remain free only when freedom is founded upon respect for moral and spiritual values and the rule of law;

And being desirous of enshrining these principles and the human rights and fundamental freedoms derived from them, in a Bill of Rights which shall reflect the respect of Parliament for its constitutional authority and which shall ensure the protection of these rights and freedoms in Canada;

Therefore Her Majesty, by and with the advice and consent of the Senate and House of Commons of Canada, enacts as follows:

**PART I**

**Bill of Rights**

**Recognition and declaration of rights and freedoms**

**1** It is hereby recognized and declared that in Canada there have existed and shall continue to exist without discrimination by reason of race, national origin, colour, religion or sex, the following human rights and fundamental freedoms, namely,

(1) the right of the individual to life, liberty, and security of the person and enjoyment of property, and the right not to be deprived thereof except by due process of law;

**Construction of law**

**2** Every law of Canada shall, unless it is expressly declared by an Act of Parliament of Canada that it shall operate notwithstanding the *Canadian Bill of Rights*, be so construed and applied as not to abrogate, abridge or infringe or to authorize the abrogation, abridgement or infringement of any of the rights or freedoms herein recognized and declared, and in particular, no law of Canada shall be construed or applied so as to

(a) authorize or effect the arbitrary detention, imprisonment or exile of any person;

(b) impose or authorize the imposition of cruel and unusual treatment or punishment;

(c) deprive a person who has been arrested or detained

(i) of the right to be informed promptly of the reason for his arrest or detention,

(ii) of the right to retain and instruct counsel without delay, or

(iii) of the remedy by way of habeas corpus for the detention of the validity of his detention and for his release if the detention is not lawful;

(d) authorize a court, tribunal, commission, board or other authority to compel a person to give evidence if he is denied counsel, protection against self crimination or other constitutional safeguards;

(e) deprive a person of the right to a fair hearing in accordance with the principles of fundamental justice for the determination of his rights and obligations;

## 3- Ontario Human Rights Code, R.S.O. 1990, C h. 19

And Whereas it is public policy in Ontario to recognize the dignity and worth of every person and to provide for equal rights and opportunities without discrimination that is contrary to law, and having as its aim the creation of a climate of understanding and mutual respect for the dignity and worth of each person so that each person feels a part of the community and able to contribute fully to the development and well-being of the community and the Province.

**Contracts**
3 Every person having legal capacity has a right to contract on equal terms without discrimination because of race, ancestry, place of origin, colour, ethnic origin, citizenship, **creed**, sex, sexual orientation, gender identity, gender expression, age, marital status, family status or disability. R.S.O. 1990, c. H.19, s. 3; 1999, c. 6, s. 28 (4); 2001, c. 32, s. 27 (1); 2005, c. 5, s. 32 (4); 2012, c. 7, s. 3.

**Employment**
5 (1)Every person has a right to equal treatment with respect to employment without discrimination because of race, ancestry, place of origin, colour, ethnic origin, citizenship, **creed**, sex, sexual orientation, gender identity, gender expression, age, record of offences, marital status, family status or disability. R.S.O. 1990, c. H.19, s. 5 (1); 1999, c. 6, s. 28 (5); 2001, c. 32, s. 27 (1); 2005, c. 5, s. 32 (5); 2012, c. 7, s. 4 (1).

**Harassment in employment**
(2) Every person who is an employee has a right to freedom from harassment in the workplace by the employer or agent of the employer or by another employee because of race, ancestry, place of origin, colour, ethnic origin, citizenship, creed, sexual orientation, gender identity, gender expression, age, record of offences, marital status, family status or disability. R.S.O. 1990, c. H.19, s. 5 (2); 1999, c. 6, s. 28 (6); 2001, c. 32, s. 27 (1); 2005, c. 5, s. 32 (6); 2012, c. 7, s. 4 (2).

**Announced intention to discriminate**
13 (1) A right under Part I is infringed by a person who publishes or displays before the public or cause the publication or display before the public of any notice, sign, symbol, emblem, or other similar representation that indicates the intention of the person to infringe a right under Part I or that is intended by the person to incite the infringement of a right under Part I. R.S.O. 1990, c. H.19, s. 13 (1).

## 4 – Ontario Freedom of Information and Protection of Privacy Act

**Definitions**
2 (1) In this Act, “personal information” means recorded information about an identifiable individual, including, c) any identifying number, symbol or other particular assigned to the individual, (e) the personal opinions or views of the individual except where they relate to another individual, h) the individual’s name where it appears with other personal information relating to the individual or where the disclosure of the name would reveal other personal information about the individual.

**Collection of personal information**
(2) No person shall collect personal information on behalf of an institution unless the collection is expressly authorized by statute, used for the purposes of law enforcement or necessary to the proper administration of a lawfully authorized activity. R.S.O. 1990, c. F.31, s. 38 (2).

**Offences**
61 (1) No person shall,
(a) willfully disclose personal information in contravention to this Act;

## 5 – Ontario Personal Health Information Protection Act

**Personal health information**
4 (1) In this Act, “personal health information”, subject to subsections (3) and (4), means identifying information about an individual in oral or recorded form.

**Identifying information**
(2) In this section, “identifying information” means information that identifies an individual or for which it is reasonably foreseeable in the circumstances that it could be utilized, either alone or with other information, to identify an individual. 2004, c. 3, Sched. A, s. 4 (2).

**Elements of consent**
18 (1) If this Act or any other Act requires the consent of an individual for the collection , use or disclosure of personal health information by a health information custodian, the consent, d) must not be obtained through deception or coercion. 2004, c. 3, Sched. A, s. 18 (1)

## 6 – Ontario Health Care Consent Act

**Elements of consent**
11 (1) The following are the elements required for consent to treatment: 1. The consent must relate to the treatment.2. The consent must be informed. 3. The consent must be given voluntarily.
4. The consent must not be obtained through misrepresentation or fraud. 1996, c. 2, Sched. A, s. 11 (1

**Informed consent**
(2) A consent to treatment is informed if, before giving it, (a) the person received the information about the matters set out in subsection (3) that a reasonable person in the same circumstances would require in order to make a decision about the treatment; and (b) the person received responses to his or her requests for additional information about those matters. 1996, c. 2, Sched. A, s. 11 (2).
**Same**
(3) The matters referred to in subsection (2) are: 1. The nature of the treatment.2. The expected benefits of the treatment.3. The material risks of the treatment.4. The material side effects of the treatment.
5. Alternative courses of action.6. The likely consequences of not having the treatment. 1996, c. 2, Sched. A, s. 11 (3).

**Withdrawal of consent**
14 A consent that has been given by or on behalf of the person for whom the treatment was proposed may be withdrawn at any time.

## 7 – Ontario Occupational Health and Safety Act

Employer access to health records 63 (2) No employer shall seek to gain access, except by an order of the court or other tribunal or in order to comply with another statute, to a health record concerning a worker without the worker’s written consent. R.S.O. 1990, c. O.1, s. 63 (2).

## 8 – Immunization in Canada Act

***Unlike some countries, immunization is not mandatory in Canada; it cannot be made mandatory because of the Canadian Constitution.*** Only three provinces have legislation or regulations under their health-protection acts to require proof of immunization for school entrance. Ontario and New Brunswick require proof for diphtheria, tetanus, polio, measles, mumps, and rubella immunization. In Manitoba, only measles vaccination is covered. ***It must be emphasized that, in these three provinces, exceptions are permitted for medical or religious grounds and reasons of conscience; legislation and regulations must not be interpreted to imply compulsory immunization.***

## 9 - Regulated Health Professions Act

Prohibitions
Controlled acts restricted
27 (1) No person shall perform a controlled act set out in subsection (2) in the course of providing health care services to an individual unless,

(a) the person is a member authorized by a health profession Act to perform the controlled act; or

(b) the performance of the controlled act has been delegated to the person by a member described in clause (a). 1991, c. 18, s. 27 (1); 1998, c. 18, Sched. G, s. 6.

## 10 – Canadian Criminal Code, RSC 1985, c. C-46

**Parties to offence**
21 (1) Every one is a party to an offence who (a) actually commits it; (b) does or omits to do anything for the purpose of aiding any person to commit it; or (c) abets any person in committing it.
**Common intention**
(2) Where two or more persons form an intention in common to carry out an unlawful purpose and to assist each other therein and any one of them, in carrying out the common purpose, commits an offence, each of them who knew or ought to have known that the commission of the offence would be a probable consequence of carrying out the common purpose is a party to that offence.
**Person counselling offence**
22 (1) Where a person counsels another person to be a party to an offence and that other person is afterwards a party to that offence, the person who counselled is a party to that offence.

**Assault**
265 (1) A person commits an assault when
(a) without the consent of another person, he applies force intentionally to that other person, directly or indirectly;

**Assault**
266 Every one who commits an assault is guilty of
(a) an indictable offence and is liable to imprisonment for a term not exceeding five years; or
(b) an offence punishable on summary conviction.

**Unlawfully causing bodily harm**

269 Everyone who unlawfully causes bodily harm to any person is guilty of
(a) an indictable offence and liable to imprisonment for a term not exceeding ten years; or
(b) an offence punishable on summary conviction.

**Torture**
269.1 (1) Every official, or every person acting at the instigation of or with the consent or acquiescence of an official, who inflicts torture on any other person is guilty of an indictable offence and liable to imprisonment for a term not exceeding fourteen years.

**Definitions**
(2) For the purposes of this section, official means (a) a peace officer, (b) a public officer, (c) a member of the Canadian Forces, or (d) any person who may exercise powers, pursuant to a law in force in a foreign state, that would, in Canada, be exercised by a person referred to in paragraph (a), (b), or (c), whether the person exercises powers in Canada or outside Canada. Torture means any act or omission by which severe pain or suffering, whether physical or mental, is intentionally inflicted on a person (a) for a purpose including (i) obtaining from the person or from a third person information or a statement, (ii) punishing the person for an act that the person or a third person has committed or is suspected of having committed, and (iii) intimidating or coercing the person or a third person, or (b) for any reason based on discrimination of any kind.

**No defense**
(***3) It is no defense to a charge under this section that the accused was ordered by a superior or a public authority to perform the act or omission that forms the subject-matter of the charge or that the act or omission is alleged to have been justified by exceptional circumstances, including a state of war, a threat of war, internal political instability or any other public emergency.***

**Intimidation**
423 (1) Everyone is guilty of an indictable offence and liable to imprisonment for a term of not more than five years or is guilty of an offence punishable on summary conviction who, wrongfully and without lawful authority, for the purpose of compelling another person to abstain from doing anything that he or she has a lawful right to do, or to do anything that he or she has a lawful right to abstain from doing,

## 11 - The Nuremberg Code (1947)

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

## 12 – Helsinki Declaration (1964; Rev. 2013)

**Informed Consent**

25. Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees.

26. In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information.

After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed. All medical research subjects should be given the option of being informed about the general outcome and results of the study.

## 13 – Universal Declaration on Bioethics and Human Rights (2005)

Article 3 – Human dignity and human rights
1. Human dignity, human rights and fundamental freedoms are to be fully respected.

2. The interests and welfare of the individual should have priority over the sole interest of science or society.

Article 4 – Benefit and harm
In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized.

Article 5 – Autonomy and individual responsibility
The autonomy of persons to make decisions, while taking responsibility for those decisions and respecting the autonomy of others, is to be respected. For persons who are not capable of exercising autonomy, special measures are to be taken to protect their rights and interests.

Article 6 – Consent

1. Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.

2. Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards adopted by States, consistent with the principles and provisions set out in this Declaration, in particular in Article 27, and international human law.
3. In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual's informed consent.

## 14 -Siracusa Principles under the heading of Non-Derogable Rights provides:

**No state party shall, even in time of emergency threatening the life of the nation, derogate from the Covenant's guarantees** of the right to life; freedom from torture, cruel, inhuman or degrading treatment or punishment, **and from medical or scientific experimentation without free consent**; freedom from slavery or involuntary servitude; the right not be imprisoned for contractual debt; the right not to be convicted or sentenced to a heavier penalty by virtue of retroactive criminal legislation; the right to recognition as a person before the law; and freedom of thought, conscience and religion. **These rights are not derivable under any conditions even for the asserted purpose of preserving the life of the nation**. This is consistent with Article 4 of the *International Covenant on Civil and Political Rights.*

# 15 - Genetic Non-Discrimination Act, SC 2017, c. 3

## Interpretation

**Definitions 2** The following definitions apply in this Act.disclose includes to authorize disclosure. (communiquer)genetic test means a test that analyzes DNA, RNA or chromosomes for purposes such as the prediction of disease or vertical transmission risks, or monitoring, diagnosis or prognosis. (test génétique)health care practitioner means a person lawfully entitled under the law of a province to provide health services in the place in which the services are provided by that person. (professionnel de la santé)

## Prohibitions

Genetic test3 (1) It is prohibited for any person to require an individual to undergo a genetic test as a condition of(a) providing goods or services to that individual;(b) entering into or continuing a contract or agreement with that individual; or(c) offering or continuing specific terms or conditions in a contract or agreement with that individual.

**Refusal to undergo genetic test**

(2) It is prohibited for any person to refuse to engage in an activity described in any of paragraphs (1)(a) to (c) in respect of an individual on the grounds that the individual has refused to undergo a genetic test.

**Disclosure of results**

**4** (1) It is prohibited for any person to require an individual to disclose the results of a genetic test as a condition of engaging in an activity described in any of the paragraphs 3(1)(a) to (c).

**Refusal to disclose results**

(2) It is prohibited for any person to refuse to engage in an activity described in any of paragraphs 3(1)(a) to (c) in respect of an individual on the grounds that the individual has refused to disclose the results of a genetic test.

**Written consent**

**5** It is prohibited for any person who is engaged in an activity described in any of paragraphs 3(1)(a) to (c) in respect of any individual to collect, use or disclose the results of a genetic test of the individual without the individual's written consent.

## Offences and Punishment

Contravention of sections 3 to 5

**7** Every person who contravenes any of sections 3 to 5 is guilty of an offence and is liable

(a) on conviction on indictment, to a fine not exceeding $1,000,000 or to imprisonment for a term not exceeding five years, or to both; or

(b) on summary of conviction, to a fine not exceeding $300,000 or to imprisonment for a term not exceeding twelve months, or to both.

# YOU SHOULD READ THIS VERY CLEARLY

1- Unlike many other vaccinations such as those used to stop the spread of tetanus, yellow fever and smallpox, COVID vaccinations are not designed to stop COVID. They are designed to reduce the symptoms of the virus; however a fully vaccinated person can contract and transmit COVID. c. The World Health Organization has stated that most people diagnosed with COVID will recover without the need for any medical treatment. e. There are side effects to the COVID vaccines that are now known. That side effects exist is not a conspiracy theory. f. The long-term effects of the COVID vaccines are unknown.

2- There is nothing controversial in stating that vaccines do not *eliminate* the risk of COVID, given that those who are vaccinated can catch and transmit COVID. By way of one example, a report issued by the Centers for Disease Control and Prevention (CDC) in the United States on 6 August 2021 25 looked at an outbreak of COVID in Massachusetts during July 2021. Of the 469 COVID cases identified, 74% were fully vaccinated. Of this group, 79% were symptomatic. In total, 5 people required hospitalization and of these, 4 were fully vaccinated. This is not an anomaly – the data from many countries and other parts of the United States provides a similar picture, although obtaining similar data from the United States will now be problematic given the decision by the CDC on 1 May 2021 to cease monitoring and recording breakthrough case information unless the person is hospitalized or dies. What is clear, however, is that the vaccine is not an effective control measure to deal with transmission of COVID by itself.

**3 -** Consent is required for all participation in a clinical trial. Consent is necessary because people have a fundamental right to bodily integrity, that being autonomy and self-determination over their own body without unconsented physical intrusion. Voluntary consent for any medical treatment has been a fundamental part of the laws of Canada and internationally for decades.
It is legally, ethically and morally wrong to coerce a person to participate in a clinical trial.

**4 -** Coercion is not consent. Coercion is the practice of persuading someone to do something using force or threats. Some have suggested that there is no coercion in threatening a person with dismissal and withdrawing their ability to participate in society if that person does not have the COVID vaccine. However, nothing could be further from the truth.

**5 -** Blanket rules, such as mandating vaccinations for everyone across a whole community or country regardless of the actual risk, fail the tests of proportionality, necessity and reasonableness. It is more than the absolute minimum necessary to combat the crisis and cannot be justified on health grounds. It is a lazy and fundamentally flawed approach to risk management and should be soundly rejected by courts when challenged.

**6 -** The requirement for consent in this context is not new and should never be controversial. The Nuremburg Code (the Code), formulated in 1947 in response to Nazi doctors performing

medical experiments on people during WWII, is one of the most important documents in the history of the ethics of medical research. The first principle of the Code is that "The voluntary consent of the human subject is absolutely essential". The Code goes on to say that "This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. "Informed and freely given consent is at the heart of the Code and is rightly viewed as a protection of a person's human rights.

7 - In short, there is no justifiable basis for health officials or governments to mandate COVID vaccinations to meet their health and safety obligations when other options are available to appropriately manage the risk.

8 - Ministry of Health
Proof of Vaccination Guidance under the
Reopening Ontario (A Flexible Response to
COVID-19) Act, 2020
Version 4– November 16, 2021

***Exemptions***
***Unless otherwise specified by a local medical officer of health or a specific organization, the proof of identification and proof of vaccination against COVID-19 requirements under provincial O. Reg. 364/20 do not apply to:***
***a) Workers, contractors, repair workers, delivery workers, students, volunteers, inspectors or others who are entering the business or organization for work purposes and not as patrons.***

This guidance document does not preclude businesses, organizations, facilities and locations that are subject to section 2.1 from establishing their own additional policies or requirements pertaining to their patrons. ***These settings may wish to consult a lawyer should they consider creating their own additional policies or requirements.***

***It is very clear that Exemptions cover everyone in Ontario except health care settings. Therefore if you are mandating policy outside of these exemptions then as it states, "YOU MAY WISH TO CONSULT A LAWYER." You will become liable in doing so.***

9 - Freely given consent to any medical treatment, particularly in the context of a clinical trial, is not optional. Coercion is completely incompatible with consent, and denying a person the ability to work and participate in society if the person does not have a COVID vaccine will unquestionably breach this fundamental and internationally recognized human right.

10 - This vaccine, and others, is often called "experimental." Calling off this failed experiment is long overdue. Continuing or even mandating the use of this poisonous vaccine, and the apparently imminent issuance of full approval for it - ***are crimes against humanity.***

## Vaccine Acquired Immune Deficiency Syndrome (VAIDS): 'We should anticipate seeing this immune erosion more widely.' Vaccination is causing the Covid19 virus to spread study shows.

A *Lancet* **study comparing vaccinated and unvaccinated** people in Sweden was conducted among **1.6 million individuals over nine months**. It **showed** that protection against symptomatic COVID-19 declined with time, such that by six months, some of the more **vulnerable vaccinated groups were at greater risk than their unvaccinated peers.**

Doctors are calling this phenomena in the repeatedly vaccinated **"immune erosion"** or **"acquired immune deficiency"**, accounting for elevated incidence of myocarditis and other post-vaccine illnesses that either affect them more rapidly, resulting in death, or more slowly, resulting in chronic illness.

COVID vaccines are not traditional vaccines. Rather, they cause cells to reproduce one portion of the SARS-CoV-2 virus, the spike protein. The vaccines thus induce the body to create spike proteins. A person only creates antibodies against this one limited portion (the spike protein) of the virus. This has several downstream deleterious effects.

## There is no science to this experimental treatment – it just don't work

**First, these vaccines "mis-train" the immune system to recognize only a small part of the virus (the spike protein). Variants that differ, even slightly, in this protein are able to escape the narrow spectrum of antibodies created by the vaccines.**

**Second, the vaccines create "vaccine addicts," meaning persons become dependent upon regular booster shots, because they have been "vaccinated" only against a tiny portion of a mutating virus. Australian Health Minister Dr. Kerry Chant has stated that** COVID will be with us forever **and people will "have to get used to" taking endless vaccines. "This will be a regular cycle of vaccination and revaccination."**

**Third, the vaccines do not prevent infection in the nose and upper airways, and vaccinated individuals have been shown to have much higher viral loads in these regions. This leads to the vaccinated becoming "super-spreaders" as they carry extremely high viral loads.**

**In addition, the vaccinated become more clinically ill than the unvaccinated. Scotland** reported **that the infection fatality rate in the vaccinated is 3.3 times the unvaccinated, and the risk of death if hospitalized is 2.15 times the unvaccinated.**

A June **report** on Israel's *Channel 12 News* revealed that in the months since the vaccines were rolled out, 6,765 people who received both shots had contracted coronavirus, while epidemiological tracing revealed an additional 3,133 people **contracted COVID-19 from those vaccinated** individuals.

Meanwhile, ***New England Journal of Medicine*** researchers have found that autoimmune response to the coronavirus spike protein may last indefinitely: "Ab2 antibodies binding to the original receptor on normal cells therefore have the potential to mediate profound effects on the cell that could result in pathologic changes, particularly in the long term — long after the original antigen itself has disappeared." These antibodies produced against the coronavirus spike protein could be responsible for the current unprecedented wave of myocarditis and neurological illnesses, and even more problems in the future.

Indefinite uncontrolled autoimmune response to the coronavirus spike protein may produce a wave of antibodies called anti-idiotype antibodies or Ab2s that continue to damage human bodies long after clearing either Sars-Cov-2 itself or those spike proteins that the shots cause the body's cells to produce.

Spike protein antibodies may themselves produce a second wave of antibodies, called anti-idiotype antibodies or Ab2s. Those Ab2s may modulate the immune system's initial response by binding with and destroying the first wave of antibodies.

"Our immune systems produce these antibodies in response to both vaccination and natural infection with COVID," wrote Berenson. "However - though the researchers do not say so explicitly, possibly because doing so would be politically untenable - spike protein antibody levels are MUCH higher following vaccination than infection. Thus the downstream response to vaccination may be more severe."

Now there is the widespread use of so-called 'booster' shots. It has to be said: No one has any safety data about such a plan. If immune erosion occurs after two doses and just a few months, how can we exclude the possibility that effects of an untested 'booster' will not erode more rapidly and to a greater extent? And what then would be the response?

A - Fourth injection - fifth, sixth, seventh and eighth. **It is just Madness.**

**You decide if you want to become liable.**

**WE URGE YOU TO SEEK THE LAWFUL PRINCILPES OF CANADA**

Our Country has fundamental freedoms that have long secured the right to life, liberty, and security of a person. Those rights are ingrained in our Canadian Charter of Rights and Freedoms and other notable laws. These fundamental laws of justice and principals guide the fabric of being for each of us as we endeavor to have enjoyment of our health, property and faiths.

The Covid19 dilemma has resulted in a complete erosion of our freedoms. Whatever you think of the principles of Lockdowns, Mandatory Vaccines or Vaccine Passport, undoubtedly, you can attest that these freedoms as a Canadian Citizen are being disrespected by too much governmental oversight.

You have received this package of fact in the hope that you would become aware of both sides of the story. As anyone you should desire to find the basis of truth to continue the wellbeing of your surrounding community. We urge you in the strongest possible terms to seek the lawful principles and recognize the rights of all Canadians including our local community citizens.

As you have become aware upon viewing this letter you have seen that there are many measures and laws that you in an authority capacity may become liable if you insist that anyone in your control submit to an mandatory vaccine mandate and/or a vaccine passport to come onto school property or participate in school or community activities and work. Judge yourself according that if you recommend a student/person to be vaccinated or take action to mandate vaccination or proof of vaccination you may become liable for these actions.

This information was set forth to educate yourself on Laws that apply for humans to give consent such as the Nuremburg Code. Under *(1) the voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be* ***able to exercise free power of choice, without*** **the intervention of any element of force**. The Nuremberg Code outlines the conduct of how we as humans should honor the health and wellbeing of humanity. Ask yourself if the Covid19 dilemma was carried out by the governments or anyone asking for mandatory vaccination or any Covid19 vaccinations under the Nuremberg Code.

**Finally, it should be clearly understood that anyone who mandates vaccinations will be liable for any adverse reactions anyone may experience, given this is a foreseeable outcome for many people as you can see by evidence supplied by this letter. Please note - a Humans Right Complaint shall be filed against you if you do not rescind your decisions.**

*YOURS TRULY*

*CONCERNED CITIZENS OF*

# Avoiding the Great Reset

# Preface

By Edward Embury

The ultimate goal of full centralization is to erase the very idea of free markets and to allow a handful of people to micromanage every aspect of trade and business. It's not just about influence; it's about their economic empire. But in order to achieve a global central bank they must first implement a one world currency plan and digital ID.

**A One World Digital Currency System**

The IMF has been talking about using their Special Drawing Rights basket as the foundation for a global currency for years (since at least the year 2000). Around a decade ago China started taking on trillions of dollars in debt just to qualify as a member of the SDR system, and the IMF has hinted that when all is said and done that system will go digital. All that is needed is the right kind of crisis to shock the public into compliance. Enter the 2022 food crisis.

This was evident at the height of the Covid19 pandemic lockdowns and the threat of economic disaster when globalist institutions began to suggest that the IMF's SDR could be used as a safety net for nations, with strings attached, of course. But beyond the stresses of the pandemic there is a much bigger crisis; namely the stagflationary crisis now on our doorstep. With multiple national currencies in decline and the dollar's world reserve status increasingly in question, I have no doubt that the globalists will take the opportunity to offer the public their digital currency as a solution.

The new system would be more like a phantom currency for a time. The SDR would be the glue or the backing while national currencies remain in circulation until the digital framework becomes pervasive. The IMF and the people behind it would become the defacto world central bank, with the power to steer the course of all national economies through a single currency mechanism. This would be done through the channels of the World Parliament Association.

On the micro-economic side, each and every individual would now be dependent on a digital currency or cryptocurrency which removes all privacy in trade. All transactions would be tracked, and by the very nature of block chain technology and the digital ledger this would be required. The money elites wouldn't have to explain the tracking, all they would have to say is "That's how the technology functions; without the ledger it doesn't work."

**A Global Social Credit System**

The evil inherent in globalism was readily apparent during the recent lockdowns and the violent push for medical tyranny. Despite the fact that Covid19 only had a median Infection Fatality Rate of only 0.27% according to dozens of official studies, the WEF contingent of politicians

and world leaders were frothing at the mouth, proclaiming that the existence of Covid19 gave them the right to take total control of people's lives.

Klaus Schwab and the WEF happily announced that the pandemic was the beginning of the "Great Reset" and the 4th Industrial Revolution, stating that the Covid19 crisis presented a perfect "opportunity" for change.

The vaccine passports were thankfully defeated by numerous conservative red states in the US, leading to the complete reversal of such policies across most of the western world. We were free for years while many blue states and other countries were facing authoritarianism and this caused a lot of problems for the globalists. It's hard to institute a global medical dystopia when people around the world can look at the conservatives in the US and see that they were living just fine without the controls.

**You Will Own Nothing and Be Happy**

The "Sharing Economy" (also sometimes referenced in parallel with "Stakeholder Capitalism") is a concept that has been making the rounds in the WEF for a few years now. The media has attempted at every turn to spread lies and disinformation claiming that the plan does not exist; but again, it is openly admitted.

The sharing economy is essentially a communistic economy, but distilled down to a bizarre minimalism even people who lived in the Soviet Union did not have to experience. The structure is described as a kind of commune based society in which people live in Section 8-style housing, with shared kitchens, shared bathrooms, and barely any privacy. All property is rented, or borrowed. All cars are borrowed and shared, most transit is mass transit, basic personal items such as computers, phones, and even cooking utensils might be shared or borrowed items. All business will become part of the state. And what food you eat will be controlled. As the WEF says, you will own nothing.

Being happy about it is another matter.

Their argument for this kind of society is of course that "climate change" and the frailties of consumer economics demand that we reduce our living standards to near zero and abandon the sacred ideal of property ownership for the sake of the planet.

Set aside the fact that carbon based global warming is a farce. The world's temperatures have only risen by 1 DEGREE CELSIUS in the span of a century, according to the NOAA. This was data that climate scientists had attempted to hide or gloss over for years, but now it is out there for everyone to see. There is no proof of man-made global warming. None period.

The globalists have been scheming to use environmentalism as an excuse for centralization since at least 1972, when the Club of Rome published a treatise titled 'The Limits to Growth'. Twenty years later they would publish a book titled 'The First Global Revolution.' In that document they specifically recommend using global warming as a vehicle:

**"In searching for a common enemy against whom we can unite, we came up with the idea that pollution, the threat of global warming, water shortages, famine and the like, would fit the bill. In their totality and their interactions these phenomena do constitute a common threat which must be confronted by everyone together. But in designating these dangers as the enemy, we fall into the trap, which we have already warned readers about, namely mistaking symptoms for causes. All these dangers are caused by human intervention in natural processes, and it is only through changed attitudes and behavior that they can be overcome. The real enemy then is humanity itself."**

The statement comes from Chapter 5 – The Vacuum, which covers their position on the need for global government. The quote is relatively clear; a common enemy must be conjured in order to trick humanity into uniting under a single banner, and the elites see environmental catastrophe, caused by mankind itself, as the best possible motivator.

They present the solution of the shared economy concept as if it is a new and bold idea. What the globalists ultimately want for their Great Reset, however, is a tidal wave reversal from freedom and individual prosperity back to a very old manner of doing things, similar to ancient feudalism. You become a peasant working on land owned by the elites, or by the state, and you will never be allowed to own that land.

The only difference would be that in a feudal empire of the past peasants could not own land because of the class system. This time around, you won't be allowed to own anything, including land, because wanting to own anything is "selfish" and destructive to the planet.

**Total Information Control**

The truth is a rare commodity these days, but nowhere near as rare as it will be if these elitists get what they want. The globalists are far more open about their agenda today than they have ever been before, and I suspect this is because they believe they will be able to rewrite the history of today's events with impunity after the Reset unfolds. They think they will own the world of information and will be able to edit our cultural memory as they go.

The mainstream media calls all of this "conspiracy theory." I call it conspiracy reality. It's hard to deny openly spoken admissions by the globalists themselves, all they can do is try to spin the information as much as possible to keep the public on the fence in terms of what needs to be done, which is a purge of the globalists from our country and perhaps the entire world.

If we do not do this, there will come a time when nothing I say here is remembered and no evidence of the Reset plan will exist. The establishment will have eliminated all notions of it from written history, leaving only a fantasy tale of how the world collapsed and a small organization of "visionary" globalists saved it from oblivion through a new religion of centralization.

# Avoiding the Great Reset

**1 – Get out of debt-** The new world system being introduced will encourage everyone to be a part of it. The system will involve a digital ID and a digital currency across the entire world. It may start off in one country but will spread to each country in a short timeframe. The new world system will confiscate all debts owed – thus the term – "You will own nothing and be happy." Being out of debt will increase you odds of not being part of the forced system and therefore is a #1 top priority. Whatever you can do to eliminate - decrease or restructure your debt needs to happen without delay.

**2 – Live on less –** Stop buying things you do not need. Focus on bringing your household up to higher standard. Live with the furniture you have. Live with the vehicle you have. Put off major purchase if you have to use credit. Sell things you don't need to help the efforts of getting ready.

**3 – Grow your own Food –** This makes you free and independent. Without your own food supply you will be depended on the system. A Community Food Hub would be incentive to have so foods can be sourced from all sectors local. Start to make a plan for yourself and others in your community to become independent. Food will be your #1 asset. Think long term.

**4 – Learn life Skills –** The ability to grow food and preserve it , grow animals and feed them, repairs things that are broke, treat wounds and medical knowledge, hunt and fish, cut wood to burn, these are just a few of the many skills you will need to get through the reset. If you have to rely on someone else chances are you will not be able to with stand the system. So make it a priority to learn skills. It may be as simple as printing these skills off from the internet to be used later. Require the skill set now well you can.

**5 – Create a Family Plan –** I highly recommend that you discuss with your family what your goals should be. If you find it hard to pull this together after the initial discussion, it may be a sensible idea to involve someone that can explain the fundamentals of what we face, and what's at stake. Your plan needs to be structured to your needs in your financial terms. Take your time and work this plan out as it may change as everyone's knowledge increases.

**6 – Life Healthy –** Moving yourself and family to a healthier lifestyle will again mean not being part of the system. The first things to cut would be cigarettes, alcohol, drugs. Not only will these be in short supply due to the reset, you don't want your body craving them when you need to be fully engaged in survival mode and thinking. Start growing or purchasing microgreens, eating real food like milk, meat, vegetables not manufactured junk. Take your

health seriously. Learn things (foods, supplements) that can curb – high blood pressure, diabetes and other health issues naturally. Get started with books and internet help to get informed, talk with others. You should reach out to your doctor or get help from a nutritionist before you begin your journey. The more ideas you have to point your health in a better direction for change will be to your benefit.

**7 – Independent Employment –** One of the things the Covid19 taught us was that if you were self-employed you had a less likelihood to become vaccinated. If you can work independently you can very well likely operate outside the system being imposed. Start something small – work your way into it. Do something on the side – so you can fall back on that when you need to. Again it may be a new skill you inquire. Think outside the box.

**8 – Built a Local Community –** A Community of likeminded people will be of prime importance to avoid the system and the reset. The community should have no bigger than a 10 km radius. (Outreaching to others outside that radius if possible.) The community must be capable of providing water, food, health, finance and security to all. I don't believe in the lone-wolf idealism, very few people are able to operate with that skill set. You will require lots of skill sets to avoid the reset hardships. Involving yourself in discussions with others and starting a group immediately will be of high importance. Make a list of all the bases that need to be covered and the people and business that can provide the help.

**9 – Built your Knowledge –** My favorite Bible verse is Hosea Chapter 4 vs 6 – *My people are destroy for the lack of knowledge: because thou hast rejected knowledge, I will also reject thee.* Knowledge will be the key to your goal of all issues. Everything you do will require a knowledge set different than what you are being told from those involved in the reset. Take time to consult with others and ask questions, become familiar with laws. Take time to research the facts; too many people don't know the facts of the story or issues. Presenting factual knowledge to those surrounding you will be important to resolving issues that come up. Knowledge will be your savior when the going gets tough.

**10 – Preserving your Wealth -** We are heading into uncharted territory so it's important to have plenty of philosophies to preserve your wealth. A mixture of things is likely the best idea, not all your apples in one basket per say. I like to use the **$100** scenario – goes like this. **$20** in Cash - **$30** in Silver - **$25** in Gold - **$25** in barter items. (*Note this example does not take into account your bank account*). I do not like cryptocurrencies for two reasons; 1- I can't hold them in my hand. 2- The internet which they need to operate within will need a digital ID from you. You need to get your wealth preservation under way – time is not on your side.

On November 2, 2021 in the province of New Brunswick, CUPE Local 2745 brought forth a Labour Board Challenge on Designated Employees being forced into unpaid leave for protecting their rights not to disclose their medical status to their employers, not complying with forced vaccinations and refusal to submit to diagnostic testing for the COVID-19 virus. According to New Brunswick's Public Sector Labour Relations Act, which is similar to Ontario's Employment Standards Act, this Act protects workers from forced unpaid leave by employers. Less than 6 hours after The Labour Board heard the case, The Labour Board Chair issued a cease and desist order to the Government. All employees, that were deemed essential were ordered back to work for the following work day. Any Employer that refused the entrance of these employees would be penalized for not following the Order upon receiving reports by the employee trespassed against. This is a big win for not only New Brunswick but potentially, all Canadians.

Ontario has The Employment Standards Act which was Amended to cor-respond with the enacted Emergency Measures and Civil Protection Act (EMCPA) to protect Employers during the Lockdowns. The Amendment allowed employers to place employees on unpaid leave of absences due to lack of work, lack of income or supplies due to the lockdowns and/or due to the organization having to shut their doors because of their un-essential status. Typically, only employees can put themselves on leave without pay. The Employee must supply reasons and/or resources in order for an employer to accept the leave of absence. Under Section 50 of the Act, once the EMCPA is revoked the Employer leave of absence expires within 6 weeks of the revocation. The EMCPA was revoked on June 9, 2021 and therefore, the Employer forced leave of absence expired on July 28, 2021. Any, and All employer forced leave of absences violate the Employment Standards Act and cannot be enforced after July 28, 2021. All employers are bound by the Employment Standards Act, including Unionized Employers. All Employers that negotiate with Unions must still abide by the law as a minimum in all contracts but are afforded the luxury of adding in bonuses for employees.

The decision of The Labour Board in New Brunswick will have rippling effects all across Canada. The decision will have set a precedent that can be used in all other provinces to protect ALL employees from unfair treatment and discrimination based on their lawful right to refuse consent to not only an experimental medical treatment and testing for diagnostic purposes, but also the right to keep their medical health status private from their employer. All employees that have been placed on unpaid leave must report back to their place of employment immediately. They must record themselves logging in if involved in an at home work environment or attempting to enter their work place. If the employee is refused access, the employee must immediately report in writing to HR or their union representative that they are not in agreement with the unpaid leave of absence. They must get it on record that they attempted to go back to work but were refused in order to take action against the Employer.


Pursuant to the ***Canadian Bill of Rights*** **section 1**, 2 (a) and the ***Criminal Code of Canada*** **section 34** this notice is to all peace officers and other officials including:

## Police officers,
## Municipal bylaw officers,
## Public health officers

**TAKE NOTICE THAT YOU,**

ARE PROHIBITED FROM trespassing against persons and property upon on the property known as:

ADDRESS:_____
_____

At any time for any reason whatsoever except with a criminal warrant to enter the premises.

**AND FURTHER TAKE NOTICE** that should you enter upon the said lands and premises contrary to this Notice, you may be charged or in the case of forced entry without a criminal warrant the property will be defended from this unlawful entry.

**AND FURTHER TAKE NOTICE** that failure to comply is an offence pursuant to the Canadian Bill of Rights section 1 and the Criminal code of Canada you may be convicted when arrested, on conviction, be fined or jailed or the occupiers may use force against you pursuant to section 34 of the Criminal Code of Canada.

**AND FURTHER TAKE NOTICE** that this Notice takes effect on _____. Should you fail to comply, a prosecution will be commenced against you without further notice.

Date:_____
Land owner or occupier name printed:_____
Land owner or occupier's signature:_____

www.ontario.ca/page/ontarios-digital-id-where-it-could-be-used

Follow the **COVID-19 restrictions and public health measures** and **book your appointment to get vaccinated**.



# Ontario's Digital ID: Where it could be used

Find out some of the ways people and businesses might one day use digital ID.

## On this pageSkip this page navigation

- Operating a business
- Government services for businesses

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**Related information on digital ID**

**Digital ID in Ontario**
**Technology and standards**
**Getting involved**

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Ontario's Digital ID will open up enormous opportunities for individuals and businesses across all business segments.

**This is not a complete list of where digital ID could one day be used.** We've chosen these examples to help you understand some of digital ID's many potential applications.

## Financial services

### Banking

- Open a bank account or investment account
- Apply for a personal or mortgage loan
- Apply for a business account or loan

### Insurance

- Apply for insurance products
- Make an insurance claim

### Other

- Purchase or sell real estate
- Purchase, rent or sell a vehicle

## Health care

### Traditional

- Make a medical appointment
- Visit a doctor or health care provider in person
- Pick up a prescription
- Access and use vaccination records

### Digital

- Access medical records online
- Attend a virtual care appointment

## Government services for individuals

- Get, renew or replace a driver's licence
- Apply for, renew or replace a health card
- Renew or replace a licence plate sticker
- Get or renew an outdoors card
- Get a hunting or fishing licence
- Apply for OSAP
- Apply for provincial benefits or tax credits
- Apply for child support or spousal support or division of property
- File an application with the Landlord and Tenant Board

## Bringing on new customers or business

- Verify another business's credentials/history
- Verify other businesses that offer products and services online
- Verify a customer's identity without a password or their physical presence

## Operating a business

### Operations

- Rent properties or vehicles for a business
- Conduct employee background checks
- Request customers' proof of age
- Get import/export licensing and/or documentation
- Verify another business's credentials/history

### Ownership

- Prove ownership to another business

### Digital

- Execute digital contracts
- Request and send digital signatures
- Receive online payments

## Government services for businesses

### Licensing

- Get business registration, permits and/or licences
- Get import/export licensing and/or documentation

### Benefits

- Apply for government grants and/or benefits
- Get trade finance for international trade

### Reporting

- File taxes or other statutory/regulatory reporting

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The ways in which digital ID will change how we access services and preform transactions are truly endless and we welcome your thoughts and ideas. Visit our Digital ID: Getting involved page to learn about upcoming opportunities to share your feedback.

Updated: November 18, 2021
Published: November 18, 2021

Image

# Government of Ontario

The Government of Ontario includes ministries, agencies and Crown corporations.

- about Ontario
- accessibility
- news
- privacy
- terms of use



- **Contact us**

### Topics

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- Arts and culture
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- Rural and north
- Taxes and benefits
- Travel and recreation

# A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS

| | |
|---|---|
| **Study Sponsor:** | BioNTech |
| **Study Conducted By:** | Pfizer |
| **Study Intervention Number:** | PF-07302048 |
| **Study Intervention Name:** | RNA-Based COVID-19 Vaccines |
| **US IND Number:** | 19736 |
| **EudraCT Number:** | 2020-002641-42 |
| **Protocol Number:** | C4591001 |
| **Phase:** | 1/2/3 |

**Short Title:** A Phase 1/2/3 Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals

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# 1. PROTOCOL SUMMARY

## 1.1. Synopsis

**Short Title:** A Phase 1/2/3 Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals

### Rationale

A pneumonia of unknown cause detected in Wuhan, China, was first reported in December 2019. On 08 January 2020, the pathogen causing this outbreak was identified as a novel coronavirus 2019. The outbreak was declared a Public Health Emergency of International Concern on 30 January 2020. On 12 February 2020, the virus was officially named as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), and the WHO officially named the disease caused by SARS-CoV-2 as coronavirus disease 2019 (COVID-19). On 11 March 2020, the WHO upgraded the status of the COVID-19 outbreak from epidemic to pandemic, which is now spreading globally at high speed.

There are currently no licensed vaccines to prevent infection with SARS-CoV-2 or COVID-19. Given the rapid transmission of COVID-19 and incidence of disease in the United States and elsewhere, the rapid development of an effective vaccine is of utmost importance.

BioNTech has developed RNA-based vaccine candidates using a platform approach that enables the rapid development of vaccines against emerging viral diseases, including SARS-CoV-2. Each vaccine candidate is based on a platform of nucleoside-modified messenger RNA (modRNA, BNT162b). Each vaccine candidate expresses 1 of 2 antigens: the SARS-CoV-2 full-length, P2 mutant, prefusion spike glycoprotein (P2 S) (version 9) or a trimerized SARS-CoV-2 spike glycoprotein receptor-binding domain (RBD) (version 5). The 2 SARS-CoV-2 vaccine candidates that will be tested in this study are therefore:

BNT162b1 (variant RBP020.3): a modRNA encoding the RBD;

BNT162b2 (variant RBP020.2): a modRNA encoding P2 S.

All candidates are formulated in the same lipid nanoparticle (LNP) composition. This study is intended to investigate the safety, immunogenicity, and efficacy of these prophylactic BNT162 vaccines against COVID-19.

## Objectives, Estimands, and Endpoints

## For Phase 1

| Objectives | Estimands | Endpoints |
|---|---|---|
| **Primary:** | **Primary:** | **Primary:** |
| To describe the safety and tolerability profiles of prophylactic BNT162 vaccines in healthy adults after 1 or 2 doses | In participants receiving at least 1 dose of study intervention, the percentage of participants reporting:<br>• Local reactions for up to 7 days following each dose<br>• Systemic events for up to 7 days following each dose<br>• Adverse events (AEs) from Dose 1 to 1 month after the last dose<br>• Serious AEs (SAEs) from Dose 1 to 6 months after the last dose | • Local reactions (pain at the injection site, redness, and swelling)<br>• Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain)<br>• AEs<br>• SAEs |
| | In addition, the percentage of participants with:<br>• Abnormal hematology and chemistry laboratory values 1 and 7 days after Dose 1; and 7 days after Dose 2<br>• Grading shifts in hematology and chemistry laboratory assessments between baseline and 1 and 7 days after Dose 1; and before Dose 2 and 7 days after Dose 2 | Hematology and chemistry laboratory parameters detailed in Section 10.2 |
| **Secondary:** | **Secondary:** | **Secondary:** |
| To describe the immune responses elicited by prophylactic BNT162 vaccines in healthy adults after 1 or 2 doses | In participants complying with the key protocol criteria (evaluable participants) at the following time points after receipt of study intervention:<br><br>7 and 21 days after Dose 1; 7 and 14 days and 1, 6, 12, and 24 months after Dose 2 | |
| | • Geometric mean titers (GMTs) at each time point<br>• Geometric mean fold rise (GMFR) from before vaccination to each subsequent time point after vaccination<br>• Proportion of participants achieving ≥4-fold rise from before vaccination to each subsequent time point after vaccination | SARS-CoV-2 neutralizing titers |

| Objectives | Estimands | Endpoints |
|---|---|---|
| | • Geometric mean concentrations (GMCs) at each time point<br>• GMFR from before vaccination to each subsequent time point after vaccination<br>• Proportion of participants achieving ≥4-fold rise from before vaccination to each subsequent time point after vaccination | S1-binding IgG levels and RBD-binding IgG levels |
| | • Geometric mean ratio (GMR), estimated by the ratio of the geometric mean of SARS-CoV-2 neutralizing titers to the geometric mean of binding IgG levels at each time point | • SARS-CoV-2 neutralizing titers<br>• S1-binding IgG levels<br>• RBD-binding IgG levels |

## For Phase 2/3

| Objectives[a] | Estimands | Endpoints |
|---|---|---|
| **Primary Efficacy** | | |
| To evaluate the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 7 days after the second dose in participants without evidence of infection before vaccination | In participants complying with the key protocol criteria (evaluable participants) at least 7 days after receipt of the second dose of study intervention:<br>100 × (1 – IRR) [ratio of active vaccine to placebo] | COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT in participants with no serological or virological evidence (up to 7 days after receipt of the second dose) of past SARS-CoV-2 infection |
| To evaluate the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 7 days after the second dose in participants with and without evidence of infection before vaccination | In participants complying with the key protocol criteria (evaluable participants) at least 7 days after receipt of the second dose of study intervention:<br>100 × (1 – IRR) [ratio of active vaccine to placebo] | COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT |
| **Primary Safety** | | |
| To define the safety profile of prophylactic BNT162b2 in the first 360 participants randomized (Phase 2) | In participants receiving at least 1 dose of study intervention, the percentage of participants reporting:<br>• Local reactions for up to 7 days following each dose<br>• Systemic events for up to 7 days following each dose<br>• AEs from Dose 1 to 7 days after the second dose<br>• SAEs from Dose 1 to 7 days after the second dose | • Local reactions (pain at the injection site, redness, and swelling)<br>• Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain)<br>• AEs<br>• SAEs |

| Objectives[a] | Estimands | Endpoints |
|---|---|---|
| To define the safety profile of prophylactic BNT162b2 in all participants randomized in Phase 2/3 | In participants receiving at least 1 dose of study intervention, the percentage of participants reporting:<br>• Local reactions for up to 7 days following each dose<br>• Systemic events for up to 7 days following each dose<br>• AEs from Dose 1 to 1 month after the second dose<br>• SAEs from Dose 1 to 6 months after the second dose | • AEs<br>• SAEs<br>• In a subset of at least 6000 participants:<br>o Local reactions (pain at the injection site, redness, and swelling)<br>o Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain) |
| To define the safety profile of prophylactic BNT162b2 in participants 12 to 15 years of age in Phase 3 | In participants receiving at least 1 dose of study intervention, the percentage of participants reporting:<br>• Local reactions for up to 7 days following each dose<br>• Systemic events for up to 7 days following each dose<br>• AEs from Dose 1 to 1 month after the second dose<br>• SAEs from Dose 1 to 6 months after the second dose | • Local reactions (pain at the injection site, redness, and swelling)<br>• Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain)<br>• AEs<br>• SAEs |
| **Secondary Efficacy** | | |
| To evaluate the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 14 days after the second dose in participants without evidence of infection before vaccination | In participants complying with the key protocol criteria (evaluable participants) at least 14 days after receipt of the second dose of study intervention:<br>100 × (1 – IRR) [ratio of active vaccine to placebo] | COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT in participants with no serological or virological evidence (up to 14 days after receipt of the second dose) of past SARS-CoV-2 infection |
| To evaluate the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 14 days after the second dose in participants with and without evidence of infection before vaccination | In participants complying with the key protocol criteria (evaluable participants) at least 14 days after receipt of the second dose of study intervention:<br>100 × (1 – IRR) [ratio of active vaccine to placebo] | COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT |
| To evaluate the efficacy of prophylactic BNT162b2 against confirmed severe COVID-19 occurring from 7 days and from 14 days after the second dose in participants without evidence of infection before vaccination | In participants complying with the key protocol criteria (evaluable participants)<br>• at least 7 days<br>and<br>• at least 14 days<br>after receipt of the second dose of study intervention:<br>100 × (1 – IRR) [ratio of active vaccine to placebo] | Confirmed severe COVID-19 incidence per 1000 person-years of follow-up in participants with no serological or virological evidence (up to 7 days and up to 14 days after receipt of the second dose) of past SARS-CoV-2 infection |

| Objectives[a] | Estimands | Endpoints |
|---|---|---|
| To evaluate the efficacy of prophylactic BNT162b2 against confirmed severe COVID-19 occurring from 7 days and from 14 days after the second dose in participants with and without evidence of infection before vaccination | In participants complying with the key protocol criteria (evaluable participants)<br>• at least 7 days<br>and<br>• at least 14 days<br>after receipt of the second dose of study intervention:<br>100 × (1 – IRR) [ratio of active vaccine to placebo] | Confirmed severe COVID-19 incidence per 1000 person-years of follow-up |
| To describe the efficacy of prophylactic BNT162b2 against confirmed COVID-19 (according to the CDC-defined symptoms) occurring from 7 days and from 14 days after the second dose in participants without evidence of infection before vaccination | In participants complying with the key protocol criteria (evaluable participants)<br>• at least 7 days<br>and<br>• at least 14 days<br>after receipt of the second dose of study intervention:<br>100 × (1 – IRR) [ratio of active vaccine to placebo] | COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT in participants with no serological or virological evidence (up to 7 days and up to 14 days after receipt of the second dose) of past SARS-CoV-2 infection |
| To describe the efficacy of prophylactic BNT162b2 against confirmed COVID-19 (according to the CDC-defined symptoms) occurring from 7 days and from 14 days after the second dose in participants with and without evidence of infection before vaccination | In participants complying with the key protocol criteria (evaluable participants)<br>• at least 7 days<br>and<br>• at least 14 days<br>after receipt of the second dose of study intervention:<br>100 × (1 – IRR) [ratio of active vaccine to placebo] | COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT |
| **Secondary Immunogenicity** | | |
| To demonstrate the noninferiority of the immune response to prophylactic BNT162b2 in participants 12 to 15 years of age compared to participants 16 to 25 years of age | GMR, estimated by the ratio of the geometric mean of SARS-CoV-2 neutralizing titers in the 2 age groups (12-15 years of age to 16-25 years of age) 1 month after completion of vaccination | SARS-CoV-2 neutralizing titers in participants with no serological or virological evidence (up to 1 month after receipt of the second dose) of past SARS-CoV-2 infection |
| **Exploratory** | | |
| To evaluate the immune response over time to prophylactic BNT162b2 and persistence of immune response in participants with and without serological or virological evidence of SARS-CoV-2 infection before vaccination | GMC/GMT, GMFR, and percentage of participants with titers greater than defined threshold(s), at baseline and 1, 6, 12, and 24 months after completion of vaccination | • S1-binding IgG levels and/or RBD-binding IgG levels<br>• SARS-CoV-2 neutralizing titers |
| To evaluate the immune response (non-S) to SARS-CoV-2 in participants with and without confirmed COVID-19 during the study | | • N-binding antibody |
| To describe the serological responses to the BNT vaccine candidate in cases of:<br>• Confirmed COVID-19<br>• Confirmed severe COVID-19<br>• SARS-CoV-2 infection without confirmed COVID-19 | | • S1-binding IgG levels and/or RBD-binding IgG levels<br>• SARS-CoV-2 neutralizing titers |

| Objectives[a] | Estimands | Endpoints |
|---|---|---|
| To describe the safety, immunogenicity, and efficacy of prophylactic BNT162b2 in individuals with confirmed stable HIV disease | | • All safety, immunogenicity, and efficacy endpoints described above |
| To describe the safety and immunogenicity of prophylactic BNT162b2 in individuals 16 to 55 years of age vaccinated with study intervention produced by manufacturing "Process 1" or "Process 2"[b] | | • All safety endpoints described above<br>• SARS-CoV-2 neutralizing titers |

a. HIV-positive participants in Phase 3 will not be included in analyses of the objectives, with the exception of the specific exploratory objective.
b. See Section 6.1.1 for a description of the manufacturing process.

## Overall Design

This is a Phase 1/2/3, multicenter, multinational, randomized, placebo-controlled, observer-blind, dose-finding, vaccine candidate–selection, and efficacy study in healthy individuals.

The study consists of 2 parts: Phase 1: to identify preferred vaccine candidate(s) and dose level(s); Phase 2/3: an expanded cohort and efficacy part. These parts, and the progression between them, are detailed in the schema (Section 1.2).

The study will evaluate the safety, tolerability, and immunogenicity of 2 different SARS-CoV-2 RNA vaccine candidates against COVID-19 and the efficacy of 1 candidate:

- As a 2-dose (separated by 21 days) schedule;
- At various different dose levels in Phase 1;
- In 3 age groups (Phase 1: 18 to 55 years of age, 65 to 85 years of age; Phase 2/3: ≥12 years of age [stratified as 12-15, 16-55, or >55 years of age]).

Dependent upon safety and/or immunogenicity data generated during the course of this study, or the BioNTech study conducted in Germany (BNT162-01), it is possible that groups in Phase 1 may be started at the next highest dose, groups may not be started, groups may be terminated early, and/or groups may be added with dose levels below the lowest stated dose or intermediate between the lowest and highest stated doses.

The vaccine candidate selected for Phase 2/3 evaluation is BNT162b2 at a dose of 30 µg.

**Number of Participants**

Each group in Phase 1 will comprise 15 participants (12 receiving active vaccine and 3 receiving placebo). In this phase, 13 groups will be studied, corresponding to a total of 195 participants.

The vaccine candidate selected for Phase 2/3, BNT162b2 at a dose of 30 µg, will comprise 21,999 vaccine recipients. The 12- to 15-year stratum will comprise up to approximately 2000 participants (1000 vaccine recipients) enrolled at selected investigational sites. It is intended that a minimum of 40% of participants will be in the >55-year stratum. An equal number of participants will receive placebo, ie, randomized in a 1:1 ratio.

**Intervention Groups and Duration**

The study will evaluate a 2-dose (separated by 21 days) schedule of various different dose levels of 2 investigational RNA vaccine candidates for active immunization against COVID-19 in 3 age groups (Phase 1: 18 to 55 years of age, 65 to 85 years of age; Phase 2/3: ≥12 years of age [stratified as 12-15, 16-55, or >55 years of age]):

- BNT162b1 (BNT162 RNA-LNP vaccine utilizing modRNA and encoding the RBD): 10 µg, 20 µg, 30 µg, 100 µg
- BNT162b2 (BNT162 RNA-LNP vaccine utilizing modRNA and encoding the P2 S): 10 µg, 20 µg, 30 µg

The vaccine candidate selected for Phase 2/3 evaluation is BNT162b2 at a dose of 30 µg.

Participants are expected to participate for up to a maximum of approximately 26 months. The duration of study follow-up may be shorter among participants enrolled in Phase 1 dosing arms that are not evaluated in Phase 2/3.

**Data Monitoring Committee or Other Independent Oversight Committee**

The study will utilize an IRC, an internal Pfizer committee that will review data to allow dose escalation or changes to continuation of specific groups.

An external data monitoring committee (DMC) will be formed and will review cumulative unblinded data throughout the study.

**Statistical Methods**

The sample size for Phase 1 of the study is not based on any statistical hypothesis testing.

For Phase 2/3, the VE evaluation will be the primary objective. The VE is defined as VE = 100 × (1 – IRR), where IRR is calculated as the ratio of the first confirmed COVID-19 illness rate in the vaccine group to the corresponding illness rate in the placebo group. With assumptions of a true VE of 60% and 4 IAs planned, 164 COVID-19 cases will provide 90%

power to conclude true VE >30%. This would be achieved with a total 43,998 participants (21,999 vaccine recipients), based on the assumption of a 1.3% per year incidence in the placebo group, accrual of 164 primary-endpoint cases within 6 months, and 20% of the participants being nonevaluable. If the attack rate is much higher, case accrual would be expected to be more rapid, enabling the study's primary endpoint to be evaluated much sooner. The total number of participants enrolled in Phase 2/3 may vary depending on the incidence of COVID-19 at the time of the enrollment, the true underlying VE, and a potential early stop for efficacy or futility.

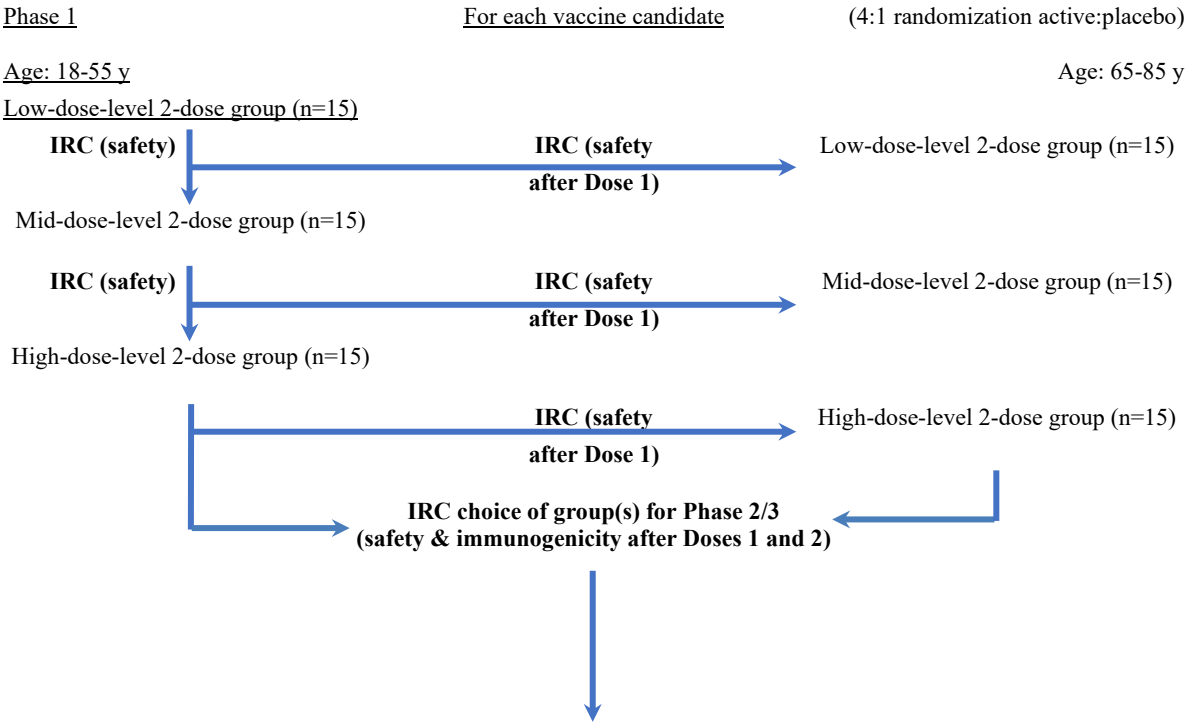
VE will be evaluated using a beta-binomial model and the posterior probability of VE being >30% will be assessed.

In Phase 3, up to approximately 2000 participants are anticipated to be 12 to 15 years of age. Noninferiority of immune response to prophylactic BNT162b2 in participants 12 to 15 years of age to response in participants 16 to 25 years of age will be assessed based on the GMR of SARS-CoV-2 neutralizing titers using a 1.5-fold margin. A sample size of 200 evaluable participants (or 250 vaccine recipients) per age group will provide a power of 90.8% to declare the noninferiority in terms of GMR (lower limit of 95% CI for GMR >0.67).

The primary safety objective will be evaluated by descriptive summary statistics for local reactions, systemic events, AEs/SAEs, and abnormal hematology and chemistry laboratory parameters (Phase 1 only), for each vaccine group. A 3-tier approach will be used to summarize AEs in Phase 2/3.

Except for the objective to assess the noninferiority of immune response in participants 12 to 15 years of age compared to participants 16 to 25 years of age, the other immunogenicity objectives will be evaluated descriptively by GMT, GMC, GMFR, percentage of participants with ≥4-fold rise, percentage of participants with ≥ specified threshold, and GMC ratio, and the associated 95% confidence intervals (CIs), for SARS-CoV-2 neutralizing titers, S1-binding IgG levels, and/or RBD-binding IgG levels at the various time points.

## 1.2. Schema




Abbreviation: IRC = internal review committee.

## 1.3. Schedule of Activities

The SoA table provides an overview of the protocol visits and procedures. Refer to the STUDY ASSESSMENTS AND PROCEDURES section of the protocol for detailed information on each procedure and assessment required for compliance with the protocol.

The investigator may schedule visits (unplanned visits) in addition to those listed in the SoA table, in order to conduct evaluations or assessments required to protect the well-being of the participant.

### 1.3.1. Phase 1

An unplanned potential COVID-19 illness visit and unplanned potential COVID-19 convalescent visit are required at any time between Visit 1 (Vaccination 1) and Visit 10 (24-month follow-up visit) that COVID-19 is suspected.

| Visit Number | Screening | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Unplanned | Unplanned |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Visit Description** | **Screening** | **Vax 1** | **Next-Day Follow-up Visit (Vax 1)** | **1-Week Follow-up Visit (Vax 1)** | **Vax 2** | **1-Week Follow-up Visit (Vax 2)** | **2-Week Follow-up Visit (Vax 2)** | **1-Month Follow-up Visit** | **6-Month Follow-up Visit** | **12-Month Follow-up Visit** | **24-Month Follow-up Visit** | **Potential COVID-19 Illness Visit[a]** | **Potential COVID-19 Convalescent Visit** |
| **Visit Window (Days)** | **0 to 28 Days Before Visit 1** | **Day 1** | **1 to 3 Days After Visit 1** | **6 to 8 Days After Visit 1** | **19 to 23 Days After Visit 1** | **6 to 8 Days After Visit 4** | **12 to 16 Days After Visit 4** | **28 to 35 Days After Visit 4** | **175 to 189 Days After Visit 4** | **350 to 378 Days After Visit 4** | **714 to 742 Days After Visit 4** | **Optimally Within 3 Days After Potential COVID-19 Illness Onset** | **28 to 35 Days After Potential COVID-19 Illness Visit** |
| Obtain informed consent | X | | | | | | | | | | | | |
| Assign participant number | X | | | | | | | | | | | | |
| Obtain demography and medical history data | X | | | | | | | | | | | | |
| Obtain details of medications currently taken | X | | | | | | | | | | | | |
| Perform physical examination | X | X | X | X | X | X | X | | | | | | |

| Visit Number | Screening | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Unplanned | Unplanned |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Visit Description** | **Screening** | **Vax 1** | **Next-Day Follow-up Visit (Vax 1)** | **1-Week Follow-up Visit (Vax 1)** | **Vax 2** | **1-Week Follow-up Visit (Vax 2)** | **2-Week Follow-up Visit (Vax 2)** | **1-Month Follow-up Visit** | **6-Month Follow-up Visit** | **12-Month Follow-up Visit** | **24-Month Follow-up Visit** | **Potential COVID-19 Illness Visit[a]** | **Potential COVID-19 Convalescent Visit** |
| **Visit Window (Days)** | **0 to 28 Days Before Visit 1** | **Day 1** | **1 to 3 Days After Visit 1** | **6 to 8 Days After Visit 1** | **19 to 23 Days After Visit 1** | **6 to 8 Days After Visit 4** | **12 to 16 Days After Visit 4** | **28 to 35 Days After Visit 4** | **175 to 189 Days After Visit 4** | **350 to 378 Days After Visit 4** | **714 to 742 Days After Visit 4** | **Optimally Within 3 Days After Potential COVID-19 Illness Onset** | **28 to 35 Days After Potential COVID-19 Illness Visit** |
| Measure vital signs (including body temperature) | X | X | X | X | X | X | X | | | | | | |
| Collect blood sample for hematology and chemistry laboratory tests[b] | ~10 mL | | ~10 mL | ~10 mL | ~10 mL | ~10 mL | | | | | | | |
| Collect screening blood sample for HIV, HBsAg, HBc Ab, and HCV Ab tests | ~10 mL | | | | | | | | | | | | |
| Serological test for prior COVID-19 infection | ~20 mL | | | | | | | | | | | | |
| Perform urine pregnancy test (if appropriate) | X | X | | | X | | | | | | | | |
| Obtain nasal (midturbinate) swab(s)[c] | | X | | | X | | | | | | | X | |
| Collect nonstudy vaccine information | X | X | X | X | X | X | X | X | X | | | | |
| Confirm eligibility | X | X | | | X | | | | | | | | |
| Collect prohibited medication use | | | X | X | X | X | X | X | X | X | X | X | X |
| Review hematology and chemistry results | | X | | X | X | X | X | | | | | | |
| Review temporary delay criteria | | X | | | X | | | | | | | | |
| Confirm use of contraceptives (if appropriate) | X | X | X | X | X | X | X | X | | | | | |

| Visit Number | Screening | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Unplanned | Unplanned |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Visit Description** | **Screening** | **Vax 1** | **Next-Day Follow-up Visit (Vax 1)** | **1-Week Follow-up Visit (Vax 1)** | **Vax 2** | **1-Week Follow-up Visit (Vax 2)** | **2-Week Follow-up Visit (Vax 2)** | **1-Month Follow-up Visit** | **6-Month Follow-up Visit** | **12-Month Follow-up Visit** | **24-Month Follow-up Visit** | **Potential COVID-19 Illness Visit[a]** | **Potential COVID-19 Convalescent Visit** |
| **Visit Window (Days)** | **0 to 28 Days Before Visit 1** | **Day 1** | **1 to 3 Days After Visit 1** | **6 to 8 Days After Visit 1** | **19 to 23 Days After Visit 1** | **6 to 8 Days After Visit 4** | **12 to 16 Days After Visit 4** | **28 to 35 Days After Visit 4** | **175 to 189 Days After Visit 4** | **350 to 378 Days After Visit 4** | **714 to 742 Days After Visit 4** | **Optimally Within 3 Days After Potential COVID-19 Illness Onset** | **28 to 35 Days After Potential COVID-19 Illness Visit** |
| Obtain randomization number and study intervention allocation | | X | | | | | | | | | | | |
| Collect blood sample for immunogenicity assessment | | ~50 mL | | ~50 mL | ~50 mL | ~50 mL + optional[e] ~170 mL | ~50 mL + optional[e] ~170 mL | ~50 mL + optional[e] ~170 mL | ~20 mL | ~20 mL | ~20 mL | | ~20 mL |
| Administer study intervention | | X | | | X | | | | | | | | |
| Assess acute reactions for at least 30 minutes after study intervention administration[d] | | X | | | X | | | | | | | | |
| Explain participant communication methods (including for e-diary completion), assist the participant with downloading the app, or issue provisioned device, if required | | X | | | | | | | | | | | |
| Provide thermometer and measuring device | | X | | | X | | | | | | | | |
| Review reactogenicity e-diary data (daily review is optimal during the active diary period) | | ◄ | ——— | ► | ◄ | ► | | | | | | | |
| Review ongoing reactogenicity e-diary | | | | | X | | X | | | | | | |

| Visit Number | Screening | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Unplanned | Unplanned |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Visit Description** | **Screening** | **Vax 1** | **Next-Day Follow-up Visit (Vax 1)** | **1-Week Follow-up Visit (Vax 1)** | **Vax 2** | **1-Week Follow-up Visit (Vax 2)** | **2-Week Follow-up Visit (Vax 2)** | **1-Month Follow-up Visit** | **6-Month Follow-up Visit** | **12-Month Follow-up Visit** | **24-Month Follow-up Visit** | **Potential COVID-19 Illness Visit[a]** | **Potential COVID-19 Convalescent Visit** |
| **Visit Window (Days)** | **0 to 28 Days Before Visit 1** | **Day 1** | **1 to 3 Days After Visit 1** | **6 to 8 Days After Visit 1** | **19 to 23 Days After Visit 1** | **6 to 8 Days After Visit 4** | **12 to 16 Days After Visit 4** | **28 to 35 Days After Visit 4** | **175 to 189 Days After Visit 4** | **350 to 378 Days After Visit 4** | **714 to 742 Days After Visit 4** | **Optimally Within 3 Days After Potential COVID-19 Illness Onset** | **28 to 35 Days After Potential COVID-19 Illness Visit** |
| symptoms and obtain stop dates | | | | | | | | | | | | | |
| Collect AEs and SAEs as appropriate | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Collect e-diary or assist the participant to delete application | | | | | | | | | | | X | | |

| Visit Number | Screening | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Unplanned | Unplanned |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Visit Description** | **Screening** | **Vax 1** | **Next-Day Follow-up Visit (Vax 1)** | **1-Week Follow-up Visit (Vax 1)** | **Vax 2** | **1-Week Follow-up Visit (Vax 2)** | **2-Week Follow-up Visit (Vax 2)** | **1-Month Follow-up Visit** | **6-Month Follow-up Visit** | **12-Month Follow-up Visit** | **24-Month Follow-up Visit** | **Potential COVID-19 Illness Visit[a]** | **Potential COVID-19 Convalescent Visit** |
| **Visit Window (Days)** | **0 to 28 Days Before Visit 1** | **Day 1** | **1 to 3 Days After Visit 1** | **6 to 8 Days After Visit 1** | **19 to 23 Days After Visit 1** | **6 to 8 Days After Visit 4** | **12 to 16 Days After Visit 4** | **28 to 35 Days After Visit 4** | **175 to 189 Days After Visit 4** | **350 to 378 Days After Visit 4** | **714 to 742 Days After Visit 4** | **Optimally Within 3 Days After Potential COVID-19 Illness Onset** | **28 to 35 Days After Potential COVID-19 Illness Visit** |
| Collection of COVID-19–related clinical and laboratory information (including local diagnosis) | | | | | | | | | | | | X | X |

Abbreviations: e-diary = electronic diary; HBc Ab = hepatitis B core antibody; HBsAg = hepatitis B surface antigen; HCV Ab = hepatitis C virus antibody; HIV = human immunodeficiency virus; NAAT = nucleic acid amplification test; vax = vaccination.

a. The COVID-19 illness visit may be conducted as an in-person or telehealth visit.
b. Hematology: hemoglobin, complete blood count with differential, and platelets. Blood chemistry: alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase, total bilirubin, blood urea nitrogen (BUN), and creatinine.
c. Two swabs will be taken at Visits 1 and 4. One will be tested (if possible at the site, otherwise at the central laboratory) within 24 hours and vaccination will only proceed if it is NAAT-negative for SARS-CoV-2 genomes. The second will be sent to the central laboratory for potential later testing.
d. The first 5 participants in in each group will be observed at the site for at least 4 hours after study intervention administration. Further vaccination will commence no sooner than 24 hours after the fifth participant received his or her vaccination.
e. An optional blood draw of ~170 mL will be taken at 1 of the visits (from selected participants who consent) for exploratory COVID-19 research.

### 1.3.2. Phase 2/3

An unplanned potential COVID-19 illness visit and unplanned potential COVID-19 convalescent visit are required at any time between Visit 1 (Vaccination 1) and Visit 6 (24-month follow-up visit) that potential COVID-19 symptoms are reported, including MIS-C.

| Visit Number | 1 | 2 | 3 | 4 | 5 | 6 | Unplanned | Unplanned |
|---|---|---|---|---|---|---|---|---|
| **Visit Description** | **Vaccination 1** | **Vaccination 2** | **1-Month Follow-up Visit** | **6-Month Follow-up Visit** | **12-Month Follow-up Visit** | **24-Month Follow-up Visit** | **Potential COVID-19 Illness Visit[a]** | **Potential COVID-19 Convalescent Visit** |
| **Visit Window (Days)** | **Day 1[b]** | **19 to 23 Days After Visit 1** | **28 to 35 Days After Visit 2** | **175 to 189 Days After Visit 2** | **350 to 378 Days After Visit 2** | **714 to 742 Days After Visit 2** | **Optimally Within 3 Days After Potential COVID-19 Illness Onset** | **28 to 35 Days After Potential COVID-19 Illness Visit** |
| Obtain informed consent | X | | | | | | | |
| Assign participant number | X | | | | | | | |
| Obtain demography and medical history data | X | | | | | | | |
| Perform clinical assessment[c] | X | | | | | | | |
| For participants who are HIV-positive, record latest CD4 count and HIV viral load | X | | X | X | X | X | | |
| Measure height and weight | X | | | | | | | |
| Measure temperature (body) | X | X | | | | | | |
| Perform urine pregnancy test (if appropriate) | X | X | | | | | | |
| Confirm use of contraceptives (if appropriate) | X | X | X | | | | | |
| Collect nonstudy vaccine information | X | X | X | X | | | | |
| Collect prohibited medication use | | X | X | X | X | X | X | X |
| Confirm eligibility | X | X | | | | | | |
| Review temporary delay criteria | X | X | | | | | | |
| Collect blood sample for immunogenicity assessment[d] | ~20 mL/ ~10 mL | | ~20 mL/ ~10 mL | ~20 mL/ ~10 mL | ~20 mL/ ~10 mL | ~20 mL/ ~10 mL | | ~20 mL/ ~10 mL |
| Obtain nasal (midturbinate) swab | X | X | | | | | X | |

| Visit Number | 1 | 2 | 3 | 4 | 5 | 6 | Unplanned | Unplanned |
|---|---|---|---|---|---|---|---|---|
| **Visit Description** | **Vaccination 1** | **Vaccination 2** | **1-Month Follow-up Visit** | **6-Month Follow-up Visit** | **12-Month Follow-up Visit** | **24-Month Follow-up Visit** | **Potential COVID-19 Illness Visit[a]** | **Potential COVID-19 Convalescent Visit** |
| **Visit Window (Days)** | **Day 1[b]** | **19 to 23 Days After Visit 1** | **28 to 35 Days After Visit 2** | **175 to 189 Days After Visit 2** | **350 to 378 Days After Visit 2** | **714 to 742 Days After Visit 2** | **Optimally Within 3 Days After Potential COVID-19 Illness Onset** | **28 to 35 Days After Potential COVID-19 Illness Visit** |
| Obtain randomization number and study intervention allocation | X | | | | | | | |
| Administer study intervention | X | X | | | | | | |
| Assess acute reactions for at least 30 minutes after study intervention administration | X | X | | | | | | |
| Explain participant communication methods (including for e-diary completion), assist the participant with downloading the app, or issue provisioned device, if required | X | | | | | | | |
| Provide/ensure the participant has a thermometer (all participants) and measuring device (reactogenicity subset participants only) | X | X | | | | | | |
| Review reactogenicity e-diary data (daily review is optimal during the active diary period)[e] | ◄—► | ◄—► | | | | | | |
| Review ongoing reactogenicity e-diary symptoms and obtain stop dates[e] | | X | X | | | | | |
| Collect AEs and SAEs as appropriate | X | X | X | X[f] | X[f] | X[f] | X | X[f] |
| Collect e-diary or assist the participant to delete application | | | | | | X | | |

| Visit Number | 1 | 2 | 3 | 4 | 5 | 6 | Unplanned | Unplanned |
|---|---|---|---|---|---|---|---|---|
| **Visit Description** | **Vaccination 1** | **Vaccination 2** | **1-Month Follow-up Visit** | **6-Month Follow-up Visit** | **12-Month Follow-up Visit** | **24-Month Follow-up Visit** | **Potential COVID-19 Illness Visit[a]** | **Potential COVID-19 Convalescent Visit** |
| **Visit Window (Days)** | **Day 1[b]** | **19 to 23 Days After Visit 1** | **28 to 35 Days After Visit 2** | **175 to 189 Days After Visit 2** | **350 to 378 Days After Visit 2** | **714 to 742 Days After Visit 2** | **Optimally Within 3 Days After Potential COVID-19 Illness Onset** | **28 to 35 Days After Potential COVID-19 Illness Visit** |
| Collection of COVID-19–related clinical and laboratory information (including local diagnosis) | | | | | | | X | X |

Abbreviations: HIV = human immunodeficiency virus; e-diary = electronic diary.

a. The COVID-19 illness visit may be conducted as an in-person or telehealth visit.
b. The visit may be conducted across 2 consecutive days; if so, all steps from assessing the inclusion and exclusion criteria onwards must be conducted on the same day.
c. Including, if indicated, a physical examination.
d. 20 mL is to be collected from participants ≥16 years of age; 10 mL is to be collected from participants 12 to 15 years of age.
e. Reactogenicity subset participants only.
f. Any AEs occurring up to 48 hours after the blood draw must be recorded (see Section 8.3.1).

# 2. INTRODUCTION

The BNT162 RNA-based COVID-19 vaccines are currently being investigated for prevention of COVID-19 in healthy individuals.

## 2.1. Study Rationale

The purpose of the study is to rapidly describe the safety, tolerability, and immunogenicity of 2 BNT162 RNA-based COVID-19 vaccine candidates against COVID-19, and the efficacy of 1 candidate, in healthy individuals. There are currently no licensed vaccines to prevent infection with SARS-CoV-2 or COVID-19. Given the global crisis of COVID-19 and fast expansion of the disease in the United States and elsewhere, the rapid development of an effective vaccine is of utmost importance.

## 2.2. Background

In December 2019, a pneumonia outbreak of unknown cause occurred in Wuhan, China. In January 2020, it became clear that a novel coronavirus (2019-nCoV) was the underlying cause. Later in January, the genetic sequence of the 2019-nCoV became available to the World Health Organization (WHO) and public (MN908947.3), and the virus was categorized in the *Betacoronavirus* subfamily. By sequence analysis, the phylogenetic tree revealed a closer relationship to severe acute respiratory syndrome (SARS) virus isolates than to another coronavirus infecting humans, the Middle East respiratory syndrome (MERS) virus.

SARS-CoV-2 infections and the resulting disease, COVID-19, have spread globally, affecting a growing number of countries.

On 11 March 2020, the WHO characterized the COVID-19 outbreak as a pandemic.[1] The WHO Situation Update Report dated 30 March 2020 noted 693,224 confirmed cases with 33,106 deaths globally, including 142,081 confirmed cases with 2457 deaths in the Americas.[2] The United States currently has the most reported cases globally. At the time of this communication, the number of confirmed cases continues to rise globally. There are currently no vaccines or effective antiviral drugs to treat SARS-CoV-2 infections or the disease it causes, COVID-19.[3]

A prophylactic, RNA-based SARS-CoV-2 vaccine provides one of the most flexible and fastest approaches available to immunize against the emerging virus.[4,5]

The development of an RNA-based vaccine encoding a viral antigen, which is then expressed by the vaccine recipient as a protein capable of eliciting protective immune responses, provides significant advantages over more traditional vaccine approaches. Unlike live attenuated vaccines, RNA vaccines do not carry the risks associated with infection and may be given to people who cannot be administered live virus (eg, pregnant women and immunocompromised persons). RNA-based vaccines are manufactured via a cell-free in vitro transcription process, which allows an easy and rapid production and the prospect of producing high numbers of vaccination doses within a shorter time period than achieved with traditional vaccine approaches. This capability is pivotal to enable the most effective response in outbreak scenarios.

Two SARS-CoV-2–RNA lipid nanoparticle (RNA-LNP) vaccines based on a platform of nucleoside-modified messenger RNA (modRNA, BNT162b) will be evaluated in this study. Each vaccine candidate expresses 1 of 2 antigens: the SARS-CoV-2 full-length, P2 mutant, prefusion spike glycoprotein (P2 S) (version 9) or a trimerized SARS-CoV-2 spike glycoprotein-receptor binding domain (RBD) (version 5). The 2 SARS-CoV-2 vaccine candidates that will be tested in this study are therefore:

- **BNT162b1** (variant RBP020.3): nucleoside-modified messenger RNA (modRNA) with blunted innate immune sensor–activating capacity and augmented expression encoding the RBD.

- **BNT162b2** (variant RBP020.2): nucleoside-modified messenger RNA (modRNA) as above, but encoding P2 S.

The vaccine candidate selected for Phase 2/3 evaluation is BNT162b2.

### 2.2.1. Clinical Overview

Prior to this study, given clinical data from other similarly formulated uRNA liposomal vaccines from BioNTech in oncology trials[6] and recent published results from clinical trials using modRNA influenza vaccines by Moderna,[7] the BNT162 vaccines were expected to have a favorable safety profile with mild, localized, and transient effects. BNT162 vaccines based on modRNA have now been administered to humans for the first time in this study and the BNT162-01 study conducted in Germany by BioNTech, at doses between 1 µg and 100 µg. The currently available safety and immunogenicity data are presented in the BNT162 IB.

## 2.3. Benefit/Risk Assessment

There is an ongoing global pandemic of COVID-19 with no preventative or therapeutic options available. While there were no data available from clinical trials on the use of BNT162 vaccines in humans at the outset of this study, available nonclinical data with these vaccines, and data from nonclinical studies and clinical trials with the same or related RNA components, or antigens, supported a favorable risk/benefit profile. Anticipated AEs after vaccination were expected to be manageable using routine symptom-driven standard of care as determined by the investigators and, as a result, the profile of these vaccine candidates supported initiation of this Phase 1/2/3 clinical study.

Updates as part of protocol amendment 6:

- In order for the overall Phase 3 study population to be as representative and diverse as possible, the inclusion of participants with known chronic stable HIV, HCV, or HBV infection is permitted. Individuals with chronic viral diseases are at increased risk for COVID-19 complications and severe disease. In addition, with the currently available therapies for their treatment, many individuals with chronic stable HIV, HCV, and HBV infections are unlikely to be at higher safety risk as a

participant in this vaccine study than individuals with other chronic stable medical conditions.

- All participants with chronic stable HIV disease will be included in the reactogenicity subset (see Section 8.2.2).

Updates as part of protocol amendment 7:

- The minimum age for inclusion in Phase 3 is lowered to 12 years, therefore allowing the inclusion of participants 12 to 15 years of age.

- For individuals 12 to 15 years of age, the immune responses in this age group may be higher and reactogenicity is expected to be similar to younger adults 18 to 25 years of age. Inclusion of individuals 12 to 15 years of age was based upon a satisfactory blinded safety profile in participants 18 to 25 years of age.

- All participants 12 to 15 years of age will be included in the reactogenicity subset (see Section 8.2.2).

More detailed information about the known and expected benefits and risks and reasonably expected AEs of BNT162 RNA-based COVID-19 vaccines may be found in the IB, which is the SRSD for this study.

### 2.3.1. Risk Assessment

| Potential Risk of Clinical Significance | Summary of Data/Rationale for Risk | Mitigation Strategy |
|---|---|---|
| **Study Intervention: BNT162 RNA-Based COVID-19 Vaccine** | | |
| Potential for local reactions (injection site redness, injection site swelling, and injection site pain) and systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, muscle pain, and joint pain) following vaccination. | These are common adverse reactions seen with other vaccines, as noted in the FDA Center for Biologics Evaluation and Research (CBER) guidelines on toxicity grading scales for healthy adult volunteers enrolled in preventive vaccine clinical trials.[8] | The Phase 1 study design includes the use of controlled vaccination and dose escalation to closely monitor and limit the rate of enrollment to ensure participant safety. The study employs the use of a reactogenicity e-diary to monitor local reactions and systemic events in real time. Stopping rules are also in place. The first 5 participants in each group in Phase 1 will be observed for 4 hours after vaccination to assess any immediate AEs. All other participants will be observed for at least 30 minutes after vaccination. |
| Unknown AEs and laboratory abnormalities with a novel vaccine. | This study is one of the first 2 parallel-running clinical studies with the BNT162 vaccine candidates and as such there are no clinical data available for this vaccine. | The Phase 1 study design includes the use of controlled vaccination and dose escalation to closely monitor and limit the rate of enrollment to ensure participant safety. An IRC (in Phase 1) and DMC (throughout the study) will also review safety data. Stopping rules are also in place. The first 5 participants in each group in Phase 1 will be observed for 4 hours after vaccination to assess any immediate AEs. All other participants will be observed for at least 30 minutes after vaccination. |
| Potential for COVID-19 enhancement. | Disease enhancement has been seen following vaccination with respiratory syncytial virus (RSV), feline coronavirus, and Dengue virus vaccines. | Phase 1 excludes participants with likely previous or current COVID-19. In Phase 2/3, temporary delay criteria defer vaccination of participants with symptoms of potential COVID-19. All participants are followed for any potential COVID-19 illness, including markers of severity, and have blood samples taken for potential measurement of SARS-CoV-2 antigen-specific antibody and SARS-CoV-2 neutralizing titers. |

| Potential Risk of Clinical Significance | Summary of Data/Rationale for Risk | Mitigation Strategy |
|---|---|---|
| **Study Procedures** | | |
| Participants will be required to attend healthcare facilities during the global SARS-CoV-2 pandemic. | Without appropriate social distancing and PPE, there is a potential for increased exposure to SARS-CoV-2. | Pfizer will work with sites to ensure an appropriate COVID-19 prevention strategy. Potential COVID-19 illness visits can be conducted via telehealth, without the need for an in-person visit, if required, with the participant performing a self-swab. |
| Venipuncture will be performed during the study. | There is the risk of bleeding, bruising, hematoma formation, and infection at the venipuncture site. | Only appropriately qualified personnel would obtain the blood draw. |

### 2.3.2. Benefit Assessment

Benefits to individual participants may include:

- Receipt of a potentially efficacious COVID-19 vaccine during a global pandemic
- Access to COVID-19 diagnostic testing
- Contributing to research to help others in a time of global pandemic

### 2.3.3. Overall Benefit/Risk Conclusion

Taking into account the measures taken to minimize risk to participants participating in this study, the potential risks identified in association with BNT162 RNA-based COVID-19 vaccine are justified by the anticipated benefits that may be afforded to healthy participants.

## 3. OBJECTIVES, ESTIMANDS, AND ENDPOINTS

### 3.1. For Phase 1

| Objectives | Estimands | Endpoints |
|---|---|---|
| **Primary:** | **Primary:** | **Primary:** |
| To describe the safety and tolerability profiles of prophylactic BNT162 vaccines in healthy adults after 1 or 2 doses | In participants receiving at least 1 dose of study intervention, the percentage of participants reporting:<br>• Local reactions for up to 7 days following each dose<br>• Systemic events for up to 7 days following each dose<br>• Adverse events (AEs) from Dose 1 to 1 month after the last dose<br>• Serious AEs (SAEs) from Dose 1 to 6 months after the last dose<br><br>In addition, the percentage of participants with:<br>• Abnormal hematology and chemistry laboratory values 1 and 7 days after Dose 1; and 7 days after Dose 2<br>• Grading shifts in hematology and chemistry laboratory assessments between baseline and 1 and 7 days after Dose 1; and before Dose 2 and 7 days after Dose 2 | • Local reactions (pain at the injection site, redness, and swelling)<br>• Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain)<br>• AEs<br>• SAEs<br><br>Hematology and chemistry laboratory parameters detailed in Section 10.2 |

| Objectives | Estimands | Endpoints |
|---|---|---|
| **Secondary:** | **Secondary:** | **Secondary:** |
| To describe the immune responses elicited by prophylactic BNT162 vaccines in healthy adults after 1 or 2 doses | In participants complying with the key protocol criteria (evaluable participants) at the following time points after receipt of study intervention: 7 and 21 days after Dose 1; 7 and 14 days and 1, 6, 12, and 24 months after Dose 2 | |
| | • Geometric mean titers (GMTs) at each time point<br>• Geometric mean fold rise (GMFR) from before vaccination to each subsequent time point after vaccination<br>• Proportion of participants achieving ≥4-fold rise from before vaccination to each subsequent time point after vaccination | SARS-CoV-2 neutralizing titers |
| | • Geometric mean concentrations (GMCs) at each time point<br>• GMFR from prior to first dose of study intervention to each subsequent time point<br>• Proportion of participants achieving ≥4-fold rise from before vaccination to each subsequent time point after vaccination | S1-binding IgG levels and RBD-binding IgG levels |
| | • Geometric mean ratio (GMR), estimated by the ratio of the geometric mean of SARS-CoV-2 neutralizing titers to the geometric mean of binding IgG levels at each time point | • SARS-CoV-2 neutralizing titers<br>• S1-binding IgG levels<br>• RBD-binding IgG levels |

## 3.2. For Phase 2/3

| Objectives[a] | Estimands | Endpoints |
|---|---|---|
| **Primary Efficacy** | | |
| To evaluate the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 7 days after the second dose in participants without evidence of infection before vaccination | In participants complying with the key protocol criteria (evaluable participants) at least 7 days after receipt of the second dose of study intervention:<br>100 × (1 – IRR) [ratio of active vaccine to placebo] | COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT in participants with no serological or virological evidence (up to 7 days after receipt of the second dose) of past SARS-CoV-2 infection |
| To evaluate the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 7 days after the second dose in participants with and without evidence of infection before vaccination | In participants complying with the key protocol criteria (evaluable participants) at least 7 days after receipt of the second dose of study intervention:<br>100 × (1 – IRR) [ratio of active vaccine to placebo] | COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT |
| **Primary Safety** | | |
| To define the safety profile of prophylactic BNT162b2 in the first 360 participants randomized (Phase 2) | In participants receiving at least 1 dose of study intervention, the percentage of participants reporting:<br>• Local reactions for up to 7 days following each dose<br>• Systemic events for up to 7 days following each dose<br>• AEs from Dose 1 to 7 days after the second dose<br>• SAEs from Dose 1 to 7 days after the second dose | • Local reactions (pain at the injection site, redness, and swelling)<br>• Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain)<br>• AEs<br>• SAEs |
| To define the safety profile of prophylactic BNT162b2 in all participants randomized in Phase 2/3 | In participants receiving at least 1 dose of study intervention, the percentage of participants reporting:<br>• Local reactions for up to 7 days following each dose<br>• Systemic events for up to 7 days following each dose<br>• AEs from Dose 1 to 1 month after the second dose<br>• SAEs from Dose 1 to 6 months after the second dose | • AEs<br>• SAEs<br>• In a subset of at least 6000 participants:<br>o Local reactions (pain at the injection site, redness, and swelling)<br>o Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain) |
| To define the safety profile of prophylactic BNT162b2 in participants 12 to 15 years of age in Phase 3 | In participants receiving at least 1 dose of study intervention, the percentage of participants reporting:<br>• Local reactions for up to 7 days following each dose<br>• Systemic events for up to 7 days following each dose<br>• AEs from Dose 1 to 1 month after the second dose<br>• SAEs from Dose 1 to 6 months after the second dose | • Local reactions (pain at the injection site, redness, and swelling)<br>• Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain)<br>• AEs<br>• SAEs |

| Objectives[a] | Estimands | Endpoints |
|---|---|---|
| **Secondary Efficacy** | | |
| To evaluate the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 14 days after the second dose in participants without evidence of infection before vaccination | In participants complying with the key protocol criteria (evaluable participants) at least 14 days after receipt of the second dose of study intervention:<br>100 × (1 – IRR) [ratio of active vaccine to placebo] | COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT in participants with no serological or virological evidence (up to 14 days after receipt of the second dose) of past SARS-CoV-2 infection |
| To evaluate the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 14 days after the second dose in participants with and without evidence of infection before vaccination | In participants complying with the key protocol criteria (evaluable participants) at least 14 days after receipt of the second dose of study intervention:<br>100 × (1 – IRR) [ratio of active vaccine to placebo] | COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT |
| To evaluate the efficacy of prophylactic BNT162b2 against confirmed severe COVID-19 occurring from 7 days and from 14 days after the second dose in participants without evidence of infection before vaccination | In participants complying with the key protocol criteria (evaluable participants)<br>• at least 7 days<br>and<br>• at least 14 days<br>after receipt of the second dose of study intervention:<br>100 × (1 – IRR) [ratio of active vaccine to placebo] | Confirmed severe COVID-19 incidence per 1000 person-years of follow-up in participants with no serological or virological evidence (up to 7 days and up to 14 days after receipt of the second dose) of past SARS-CoV-2 infection |
| To evaluate the efficacy of prophylactic BNT162b2 against confirmed severe COVID-19 occurring from 7 days and from 14 days after the second dose in participants with and without evidence of infection before vaccination | In participants complying with the key protocol criteria (evaluable participants)<br>• at least 7 days<br>and<br>• at least 14 days<br>after receipt of the second dose of study intervention:<br>100 × (1 – IRR) [ratio of active vaccine to placebo] | Confirmed severe COVID-19 incidence per 1000 person-years of follow-up |
| To describe the efficacy of prophylactic BNT162b2 against confirmed COVID-19 (according to the CDC-defined symptoms) occurring from 7 days and from 14 days after the second dose in participants without evidence of infection before vaccination | In participants complying with the key protocol criteria (evaluable participants)<br>• at least 7 days<br>and<br>• at least 14 days<br>after receipt of the second dose of study intervention:<br>100 × (1 – IRR) [ratio of active vaccine to placebo] | COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT in participants with no serological or virological evidence (up to 7 days and up to 14 days after receipt of the second dose) of past SARS-CoV-2 infection |
| To describe the efficacy of prophylactic BNT162b2 against confirmed COVID-19 (according to the CDC-defined symptoms) occurring from 7 days and from 14 days after the second dose in participants with and without evidence of infection before vaccination | In participants complying with the key protocol criteria (evaluable participants)<br>• at least 7 days<br>and<br>• at least 14 days<br>after receipt of the second dose of study intervention:<br>100 × (1 – IRR) [ratio of active vaccine to placebo] | COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT |

| Objectives[a] | Estimands | Endpoints |
|---|---|---|
| **Secondary Immunogenicity** | | |
| To demonstrate the noninferiority of the immune response to prophylactic BNT162b2 in participants 12 to 15 years of age compared to participants 16 to 25 years of age | GMR, estimated by the ratio of the geometric mean of SARS-CoV-2 neutralizing titers in the 2 age groups (12-15 years of age to 16-25 years of age) 1 month after completion of vaccination | SARS-CoV-2 neutralizing titers in participants with no serological or virological evidence (up to 1 month after receipt of the second dose) of past SARS-CoV-2 infection |
| **Exploratory** | | |
| To evaluate the immune response over time to prophylactic BNT162b2 and persistence of immune response in participants with and without serological or virological evidence of SARS-CoV-2 infection before vaccination | GMC/GMT, GMFR, and percentage of participants with titers greater than defined threshold(s), at baseline and 1, 6, 12, and 24 months after completion of vaccination | • S1-binding IgG levels and/or RBD-binding IgG levels<br>• SARS-CoV-2 neutralizing titers |
| To evaluate the immune response (non-S) to SARS-CoV-2 in participants with and without confirmed COVID-19 during the study | | • N-binding antibody |
| To describe the serological responses to the BNT vaccine candidate in cases of:<br>• Confirmed COVID-19<br>• Confirmed severe COVID-19<br>• SARS-CoV-2 infection without confirmed COVID-19 | | • S1-binding IgG levels and/or RBD-binding IgG levels<br>• SARS-CoV-2 neutralizing titers |
| To describe the safety, immunogenicity, and efficacy of prophylactic BNT162b2 in individuals with confirmed stable HIV disease | | • All safety, immunogenicity, and efficacy endpoints described above |
| To describe the safety and immunogenicity of prophylactic BNT162b2 in individuals 16 to 55 years of age vaccinated with study intervention produced by manufacturing "Process 1" or "Process 2"[b] | | • All safety endpoints described above<br>• SARS-CoV-2 neutralizing titers |

a. HIV-positive participants in Phase 3 will not be included in analyses of the objectives, with the exception of the specific exploratory objective.
b. See Section 6.1.1 for description of the manufacturing process.

This protocol will use a group of internal case reviewers to determine whether certain investigator-reported events meet the definition of disease-related efficacy endpoints, using predefined endpoint criteria.

For those AEs that are handled as disease-related efficacy endpoints (which may include death), a DMC will conduct unblinded reviews on a regular basis throughout the trial (see Section 9.6).

Any AE that is determined by the internal case reviewers NOT to meet endpoint criteria is reported back to the investigator site of incidence. Refer to Section 8.3.1.1 for instructions on how to report any such AE that meets the criteria for seriousness to Pfizer Safety.

# 4. STUDY DESIGN

## 4.1. Overall Design

This is a multicenter, multinational, Phase 1/2/3, randomized, placebo-controlled, observer-blind, dose-finding, vaccine candidate–selection, and efficacy study in healthy individuals.

The study consists of 2 parts. Phase 1: to identify preferred vaccine candidate(s) and dose level(s); Phase 2/3: an expanded cohort and efficacy part. These parts, and the progression between them, are detailed in the schema (Section 1.2).

The study will evaluate the safety, tolerability, and immunogenicity of 2 different SARS-CoV-2 RNA vaccine candidates against COVID-19 and the efficacy of 1 candidate:

- As a 2-dose (separated by 21 days) schedule;
- At various different dose levels in Phase 1;
- In 3 age groups (Phase 1: 18 to 55 years of age, 65 to 85 years of age; Phase 2/3: ≥12 years of age [stratified as 12-15, 16-55, or >55 years of age]).

Dependent upon safety and/or immunogenicity data generated during the course of this study, or the BioNTech study conducted in Germany (BNT162-01), it is possible that groups in Phase 1 may be started at the next highest dose, groups may not be started, groups may be terminated early, and/or groups may be added with dose levels below the lowest stated dose or intermediate between the lowest and highest stated doses.

The study is observer-blinded, as the physical appearance of the investigational vaccine candidates and the placebo may differ. The participant, investigator, study coordinator, and other site staff will be blinded. At the study site, only the dispenser(s)/administrator(s) are unblinded.

To facilitate rapid review of data in real time, sponsor staff will be unblinded to vaccine allocation for the participants in Phase 1.

### 4.1.1. Phase 1

Each group (vaccine candidate/dose level/age group) will comprise 15 participants; 12 participants will be randomized to receive active vaccine and 3 to receive placebo.

For each vaccine candidate/dose level/age group, the following apply:

- Additional safety assessments (see Section 8.2)

- Controlled enrollment (required only for the first candidate and/or dose level studied):
    - No more than 5 participants (4 active, 1 placebo) can be vaccinated on the first day
    - The first 5 participants must be observed by blinded site staff for at least 4 hours after vaccination for any acute reactions
    - Vaccination of the remaining participants will commence no sooner than 24 hours after the fifth participant received his or her vaccination
- Application of stopping rules
- IRC review of safety data to determine escalation to the next dose level in the 18- to 55-year age cohort:
    - Escalation between dose levels will be based on IRC review of at least 7-day post–Dose 1 safety data in this study and/or the BioNTech study conducted in Germany (BNT162-01)
    - Note that, since both candidates are based upon the same RNA platform, dose escalation for the second candidate studied may be based upon the safety profile of the first candidate studied being deemed acceptable at the same, or a higher, dose level by the IRC

Groups of participants 65 to 85 years of age will not be started until safety data for the RNA platform have been deemed acceptable at the same, or a higher, dose level in the 18- to 55-year age cohort by the IRC.

In this phase, 13 groups will be studied, corresponding to a total of 195 participants.

The IRC will select 1 vaccine candidate that, in Phase 1, has an established dose level per age group based on induction of a post–Dose 2 immune response, including neutralizing antibodies, which is expected to be associated with protection against COVID-19, for progression into Phase 2/3.

### 4.1.2. Phase 2/3

On the basis of safety and/or immunogenicity data generated during the course of this study, and/or the BioNTech study conducted in Germany (BNT162-01), 1 vaccine candidate was selected to proceed into Phase 2/3. Participants in this phase will be ≥12 years of age, stratified as follows: 12 to 15 years, 16 to 55 years, or >55 years. The 12- to 15-year stratum will comprise up to approximately 2000 participants enrolled at selected investigational sites. It is intended that a minimum of 40% of participants will be in the >55-year stratum. Commencement of each age stratum will be based upon satisfactory post–Dose 2 safety and immunogenicity data from the 18- to 55-year and 65- to 85-year age groups in Phase 1,

respectively. The vaccine candidate selected for Phase 2/3 evaluation is BNT162b2 at a dose of 30 μg.

Phase 2/3 is event-driven. Under the assumption of a true VE rate of ≥60%, after the second dose of investigational product, a target of 164 primary-endpoint cases of confirmed COVID-19 due to SARS-CoV-2 occurring at least 7 days following the second dose of the primary series of the candidate vaccine will be sufficient to provide 90% power to conclude true VE >30% with high probability. The total number of participants enrolled in Phase 2/3 may vary depending on the incidence of COVID-19 at the time of the enrollment, the true underlying VE, and a potential early stop for efficacy or futility.

Assuming a COVID-19 attack rate of 1.3% per year in the placebo group, accrual of 164 first primary-endpoint cases within 6 months, an estimated 20% nonevaluable rate, and 1:1 randomization, the BNT162b2 vaccine candidate selected for Phase 2/3 is expected to comprise approximately 21,999 vaccine recipients. This is the number of participants initially targeted for Phase 2/3 and may be adjusted based on advice from DMC analyses of case accumulation and the percentage of participants who are seropositive at baseline. Dependent upon the evolution of the pandemic, it is possible that the COVID-19 attack rate may be much higher, in which case accrual would be expected to be more rapid, enabling the study's primary endpoint to be evaluated much sooner.

The first 360 participants enrolled (180 to active vaccine and 180 to placebo, stratified equally between 18 to 55 years and >55 to 85 years) will comprise the "Phase 2" portion. Safety data through 7 days after Dose 2 and immunogenicity data through 1 month after Dose 2 from these 360 participants will be analyzed by the unblinded statistical team, reviewed by the DMC, and submitted to appropriate regulatory authorities for review. Enrollment may continue during this period and these participants would be included in the efficacy evaluation in the "Phase 3" portion of the study.

In Phase 3, up to approximately 2000 participants, enrolled at selected sites, are anticipated to be 12 to 15 years of age. Noninferiority of immune response to prophylactic BNT162b2 in participants 12 to 15 years of age to response in participants 16 to 25 years of age will be assessed based on the GMR of SARS-CoV-2 neutralizing titers using a 1.5-fold margin. A sample size of 200 evaluable participants (or 250 vaccine recipients) per age group will provide a power of 90.8% to declare the noninferiority in terms of GMR (lower limit of 95% CI for GMR >0.67). A random sample of 250 participants from each of the 2 age groups (12 to 15 years and 16 to 25 years) will be selected as an immunogenicity subset for the noninferiority assessment.

The initial BNT162b2 was manufactured using "Process 1"; however, "Process 2" was developed to support an increased scale of manufacture. In the study, each lot of "Process 2"-manufactured BNT162b2 will be administered to approximately 250 participants 16 to 55 years of age. The safety and immunogenicity of prophylactic BNT162b2 in individuals 16 to 55 years of age vaccinated with "Process 1" and each lot of "Process 2" study intervention will be described. A random sample of 250 participants from those

vaccinated with study intervention produced by manufacturing "Process 1" will be selected for this descriptive analysis.

Participants are expected to participate for up to a maximum of approximately 26 months. The duration of study follow-up may be shorter among participants enrolled in Phase 1 dosing arms that are not evaluated in Phase 2/3.

### 4.2. Scientific Rationale for Study Design

Additional surveillance for COVID-19 will be conducted as part of the study, given the potential risk of disease enhancement. If a participant experiences symptoms, as detailed in Section 8.13, a COVID-19 illness and subsequent convalescent visit will occur. As part of these visits, samples (nasal [midturbinate] swab and blood) will be taken for antigen and antibody assessment as well as recording of COVID-19–related clinical and laboratory information (including local diagnosis).

Human reproductive safety data are not available for BNT162 RNA-based COVID-19 vaccines, but there is no suspicion of human teratogenicity based on the intended mechanism of action of the compound. Therefore, the use of a highly effective method of contraception is required (see Appendix 4).

### 4.3. Justification for Dose

Because of the requirement for a rapid response to the newly emerged COVID-19 pandemic, sufficient data were not available to experimentally validate the dose selection and initial starting dose. Therefore, the original planned starting dose of 10 µg (for both BNT162b1 and BNT162b2) in this study was based on nonclinical experience with the same RNAs encoding other viral antigens (such as influenza and HIV antigens). The general safety and effectiveness of uRNA and modRNA platforms have been demonstrated in oncological clinical trials with different administration routes (NCT02410733, NCT03871348). Doses of up to 400 µg total uRNA have been administered IV as RNA lipoplex (RNA-LPX) and doses of up to 1000 µg total naked modRNA have been administered intratumorally, both without signs of unpredictable overstimulation of the immune system.

Based on nonclinical data of the RNA components, with other liposomes or in conjunction with the lipid nanoparticles as will be tested clinically in this study, it was expected that doses in the 1- to 5-µg range would be immunogenic and induce neutralizing antibodies; however, it was anticipated that 3- to 10-fold higher doses would likely be required to elicit a stronger antibody response. Based on previous clinical and nonclinical experience, it was expected that doses of up to 100 µg would be well tolerated.

Update as part of protocol amendment 2: preliminary experience in this study and the BioNTech study conducted in Germany (BNT162-01) suggests that, for vaccine candidates based on the modRNA platform, a dose level between 30 µg and 100 µg warrants consideration. Therefore, a 50-µg dose level is formally included for BNT162b1 and BNT162b2.

Update as part of protocol amendment 3: as data have become available from this study and the BNT162-01 study in Germany, it was decided:

- To not study the BNT162a1 and BNT162c2 vaccine candidates at this time, so these candidates have been removed from the protocol; and
- That lower dose levels of BNT162b1 and BNT162b2 warrant consideration. Therefore, a 20-µg dose level is formally included for both candidates.

Update as part of protocol amendment 4: the 50-µg dose level for BNT162b1 and BNT162b2 is removed and the 100-µg dose level for BNT162b2 is removed; similar dose levels of BNT162b3 may be studied as for BNT162b1 and BNT162b2.

Update as part of protocol amendment 5: the vaccine candidate selected for Phase 2/3 evaluation is BNT162b2 at a dose of 30 µg. BNT162b3 will not be studied.

### 4.4. End of Study Definition

A participant is considered to have completed the study if he/she has completed all phases of the study, including the last visit. Note that participants enrolled in Phase 1 in groups that do not proceed to Phase 2/3 may be followed for fewer than 24 months (but no less than 6 months after the last vaccination).

The end of the study is defined as the date of last visit of the last participant in the study.

## 5. STUDY POPULATION

This study can fulfill its objectives only if appropriate participants are enrolled. The following eligibility criteria are designed to select participants for whom participation in the study is considered appropriate. All relevant medical and nonmedical conditions should be taken into consideration when deciding whether a particular participant is suitable for this protocol.

Prospective approval of protocol deviations to recruitment and enrollment criteria, also known as protocol waivers or exemptions, is not permitted.

### 5.1. Inclusion Criteria

Participants are eligible to be included in the study only if all of the following criteria apply:

**Age and Sex:**

1. Male or female participants between the ages of 18 and 55 years, inclusive, and 65 and 85 years, inclusive (Phase 1), or ≥12 years (Phase 2/3), at randomization. Note that participants <18 years of age cannot be enrolled in the EU.
    - Refer to Appendix 4 for reproductive criteria for male (Section 10.4.1) and female (Section 10.4.2) participants.

**Type of Participant and Disease Characteristics:**

2. Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures.

3. Healthy participants who are determined by medical history, physical examination (if required), and clinical judgment of the investigator to be eligible for inclusion in the study.

   **Note**: Healthy participants with preexisting stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment, can be included. Specific criteria for Phase 3 participants with known stable infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) can be found in Section 10.8.

4. **Phase 2/3 only:** Participants who, in the judgment of the investigator, are at higher risk for acquiring COVID-19 (including, but not limited to, use of mass transportation, relevant demographics, and frontline essential workers).

**Informed Consent:**

5. Capable of giving personal signed informed consent/have parent(s)/legal guardian capable of giving signed informed consent as described in Appendix 1, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol.

### 5.2. Exclusion Criteria

Participants are excluded from the study if any of the following criteria apply:

**Medical Conditions:**

1. Other medical or psychiatric condition including recent (within the past year) or active suicidal ideation/behavior or laboratory abnormality that may increase the risk of study participation or, in the investigator's judgment, make the participant inappropriate for the study.

2. **Phases 1 and 2 only:** Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV).

3. History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s).

4. Receipt of medications intended to prevent COVID-19.

5. Previous clinical (based on COVID-19 symptoms/signs alone, if a SARS-CoV-2 NAAT result was not available) or microbiological (based on COVID-19 symptoms/signs and a positive SARS-CoV-2 NAAT result) diagnosis of COVID-19.

6. **Phase 1 only:** Individuals at high risk for severe COVID-19, including those with any of the following risk factors:

    - Hypertension
    - Diabetes mellitus
    - Chronic pulmonary disease
    - Asthma
    - Current vaping or smoking
    - History of chronic smoking within the prior year
    - Chronic liver disease
    - Stage 3 or worse chronic kidney disease (glomerular filtration rate <60 mL/min/1.73 $m^2$)
    - Resident in a long-term facility
    - BMI >30 $kg/m^2$
    - Anticipating the need for immunosuppressive treatment within the next 6 months

7. **Phase 1 only:** Individuals currently working in occupations with high risk of exposure to SARS-CoV-2 (eg, healthcare worker, emergency response personnel).

8. Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination.

9. **Phase 1 only:** Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention, including but not limited to: systemic or cutaneous lupus erythematosus, autoimmune arthritis/rheumatoid arthritis, Guillain-Barré syndrome, multiple sclerosis, Sjögren's syndrome, idiopathic thrombocytopenia purpura, glomerulonephritis, autoimmune thyroiditis, giant cell arteritis (temporal arteritis), psoriasis, and insulin-dependent diabetes mellitus (type 1).

10. Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection.

11. Women who are pregnant or breastfeeding.

**Prior/Concomitant Therapy:**

12. Previous vaccination with any coronavirus vaccine.

13. Individuals who receive treatment with immunosuppressive therapy, including cytotoxic agents or systemic corticosteroids, eg, for cancer or an autoimmune disease, or planned receipt throughout the study. If systemic corticosteroids have been administered short term (<14 days) for treatment of an acute illness, participants should not be enrolled into

the study until corticosteroid therapy has been discontinued for at least 28 days before study intervention administration. Inhaled/nebulized (except for participants in Phase 1 – see exclusion criterion 14), intra-articular, intrabursal, or topical (skin or eyes) corticosteroids are permitted.

14. **Phase 1 only:** Regular receipt of inhaled/nebulized corticosteroids.

15. Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study.

**Prior/Concurrent Clinical Study Experience:**

16. Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation.

17. Previous participation in other studies involving study intervention containing lipid nanoparticles.

**Diagnostic Assessments:**

18. **Phase 1 only:** Positive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit.

19. **Phase 1 only:** Any screening hematology and/or blood chemistry laboratory value that meets the definition of a ≥ Grade 1 abnormality.

    **Note:** With the exception of bilirubin, participants with any stable Grade 1 abnormalities (according to the toxicity grading scale) may be considered eligible at the discretion of the investigator. (Note: A "stable" Grade 1 laboratory abnormality is defined as a report of Grade 1 on an initial blood sample that remains ≤ Grade 1 upon repeat testing on a second sample from the same participant.)

20. **Phase 1 only:** Positive test for HIV, hepatitis B surface antigen (HBsAg), hepatitis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV Abs) at the screening visit.

21. **Phase 1 only:** SARS-CoV-2 NAAT-positive nasal swab within 24 hours before receipt of study intervention.

**Other Exclusions:**

22. Investigator site staff or Pfizer/BioNTech employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members.

## 5.3. Lifestyle Considerations

### 5.3.1. Contraception

The investigator or his or her designee, in consultation with the participant, will confirm that the participant has selected an appropriate method of contraception for the individual participant and his or her partner(s) from the permitted list of contraception methods (see Appendix 4, Section 10.4.4) and will confirm that the participant has been instructed in its consistent and correct use. At time points indicated in the SoA, the investigator or designee will inform the participant of the need to use highly effective contraception consistently and correctly and document the conversation and the participant's affirmation in the participant's chart (participants need to affirm their consistent and correct use of at least 1 of the selected methods of contraception). In addition, the investigator or designee will instruct the participant to call immediately if the selected contraception method is discontinued or if pregnancy is known or suspected in the participant or partner.

## 5.4. Screen Failures

Screen failures are defined as participants who consent to participate in the clinical study but are not subsequently randomly assigned to study intervention. A minimal set of screen failure information is required to ensure transparent reporting of screen failure participants to meet the CONSORT publishing requirements and to respond to queries from regulatory authorities. Minimal information includes demography, screen failure details, eligibility criteria, and any SAE.

Individuals who do not meet the criteria for participation in this study (screen failure) may be rescreened under a different participant number.

## 5.5. Criteria for Temporarily Delaying Enrollment/Randomization/Study Intervention Administration

The following conditions are temporary or self-limiting and a participant may be vaccinated once the condition(s) has/have resolved and no other exclusion criteria are met.

1. Current febrile illness (body temperature ≥100.4°F [≥38°C]) or other acute illness within 48 hours before study intervention administration. This includes current symptoms that could represent a potential COVID-19 illness:

    - New or increased cough;
    - New or increased shortness of breath;
    - Chills;
    - New or increased muscle pain;
    - New loss of taste/smell;
    - Sore throat;

- Diarrhea;
- Vomiting.

2. Receipt of any seasonal or pandemic influenza vaccine within 14 days, or any other nonstudy vaccine within 28 days, before study intervention administration.

3. Anticipated receipt of any seasonal or pandemic influenza vaccine within 14 days, or any other nonstudy vaccine within 28 days, after study intervention administration.

4. Receipt of short-term (<14 days) systemic corticosteroids. Study intervention administration should be delayed until systemic corticosteroid use has been discontinued for at least 28 days. Inhaled/nebulized, intra-articular, intrabursal, or topical (skin or eyes) corticosteroids are permitted.

## 6. STUDY INTERVENTION

Study intervention is defined as any investigational intervention(s), marketed product(s), placebo, medical device(s), or study procedure(s) intended to be administered to a study participant according to the study protocol.

The study will evaluate a 2-dose (separated by 21 days) schedule of various different dose levels of 2 investigational RNA vaccine candidates for active immunization against COVID-19 in 3 age groups (18 to 55 years of age, 65 to 85 years of age, and ≥12 years of age [stratified as 12-15, 16-55, or >55 years of age]).

These 2 investigational RNA vaccine candidates, with the addition of saline placebo, are the 3 potential study interventions that may be administered to a study participant:

- BNT162b1 (BNT162 RNA-LNP vaccine utilizing modRNA and encoding the RBD): 10 µg, 20 µg, 30 µg, 100 µg
- BNT162b2 (BNT162 RNA-LNP vaccine utilizing modRNA and encoding the P2 S): 10 µg, 20 µg, 30 µg
- Normal saline (0.9% sodium chloride solution for injection)

The vaccine candidate selected for Phase 2/3 evaluation is BNT162b2 at a dose of 30 µg.

## 6.1. Study Intervention(s) Administered

| Intervention Name | BNT162b1 (BNT162 RNA-LNP vaccine utilizing modRNA) | BNT162b2 (BNT162 RNA-LNP vaccine utilizing modRNA) | Saline Placebo |
|---|---|---|---|
| **Type** | Vaccine | Vaccine | Placebo |
| **Dose Formulation** | modRNA | modRNA | Normal saline (0.9% sodium chloride solution for injection) |
| **Unit Dose Strength(s)** | 250 µg/0.5 mL | 250 µg/0.5 mL | N/A |
| **Dosage Level(s)**[a] | 10-, 20-, 30-, 100-µg | 10-, 20-, 30-µg | N/A |
| **Route of Administration** | Intramuscular injection | Intramuscular injection | Intramuscular injection |
| **Use** | Experimental | Experimental | Placebo |
| **IMP or NIMP** | IMP | IMP | IMP |
| **Sourcing** | Provided centrally by the sponsor | Provided centrally by the sponsor | Provided centrally by the sponsor |
| **Packaging and Labeling** | Study intervention will be provided in a glass vial as open-label supply. Each vial will be labeled as required per country requirement | Study intervention will be provided in a glass vial as open-label supply. Each vial will be labeled as required per country requirement | Study intervention will be provided in a glass or plastic vial as open-label supply. Each vial will be labeled as required per country requirement |

a. Dependent upon safety and/or immunogenicity data generated during the course of this study, or the BioNTech study conducted in Germany (BNT162-01), it is possible that groups may be started at the next highest dose, groups may not be started, groups may be terminated early, and/or groups may be added with dose levels below the lowest stated dose or intermediate between the lowest and highest stated doses.

The vaccine candidate selected for Phase 2/3 evaluation is BNT162b2 at a dose of 30 µg.

### 6.1.1. Manufacturing Process

The scale of the BNT162b2 manufacturing has been increased to support future supply. BNT162b2 generated using the manufacturing process supporting an increased supply ("Process 2") will be administered to approximately 250 participants 16 to 55 years of age, per lot, in the study. The safety and immunogenicity of prophylactic BNT162b2 in individuals 16 to 55 years of age vaccinated with material generated using the existing manufacturing process "Process 1," and with material from lots generated using the manufacturing process supporting increased supply, "Process 2," will be described.

In brief, the process changes relate to the method of production for the DNA template that RNA drug substance is transcribed from, and the RNA drug substance purification method. The BNT162b2 drug product is then produced using a scaled-up LNP manufacturing process.

### 6.1.2. Administration

Participants will receive 1 dose of study intervention as randomized at each vaccination visit (Visits 1 and 4 for Phase 1 participants, Visits 1 and 2 for Phase 2/3 participants) in accordance with the study's SoA. The volume to be administered may vary by vaccine candidate and dose level; full details are described in the IP manual.

Study intervention should be administered intramuscularly into the deltoid muscle, preferably of the nondominant arm, by an **unblinded** administrator.

Standard vaccination practices must be observed and vaccine must not be injected into blood vessels. Appropriate medication and other supportive measures for management of an acute hypersensitivity reaction should be available in accordance with local guidelines for standard immunization practices.

Administration of study interventions should be performed by an appropriately qualified, GCP-trained, and vaccine-experienced member of the study staff (eg, physician, nurse, physician's assistant, nurse practitioner, pharmacist, or medical assistant) as allowed by local, state, and institutional guidance.

Study intervention administration details will be recorded on the CRF.

### 6.2. Preparation/Handling/Storage/Accountability

1. The investigator or designee must confirm appropriate temperature conditions have been maintained during transit for all study interventions received and any discrepancies are reported and resolved before use of the study intervention.

2. Only participants enrolled in the study may receive study intervention and only authorized site staff may supply or administer study intervention. All study interventions must be stored in a secure, environmentally controlled, and monitored (manual or automated recording) area in accordance with the labeled storage conditions with access limited to the investigator and authorized site staff. At a minimum, daily minimum and maximum temperatures for all site storage locations must be documented and available upon request. Data for nonworking days must indicate the minimum and maximum temperatures since previously documented for all site storage locations upon return to business.

3. Any excursions from the study intervention label storage conditions should be reported to Pfizer upon discovery along with any actions taken. The site should actively pursue options for returning the study intervention to the storage conditions described in the labeling, as soon as possible. Once an excursion is identified, the study intervention must be quarantined and not used until Pfizer provides permission to use the study intervention. Specific details regarding the definition of an excursion and information the site should report for each excursion will be provided to the site in the IP manual.

4. Any storage conditions stated in the SRSD will be superseded by the storage conditions stated on the label.

5. Study interventions should be stored in their original containers.

6. See the IP manual for storage conditions of the study intervention.

7. The investigator, institution, or the head of the medical institution (where applicable) is responsible for study intervention accountability, reconciliation, and record maintenance (ie, receipt, reconciliation, and final disposition records), such as the IPAL or sponsor-approved equivalent. All study interventions will be accounted for using a study intervention accountability form/record.

8. Further guidance and information for the final disposition of unused study interventions are provided in the IP manual. All destruction must be adequately documented. If destruction is authorized to take place at the investigator site, the investigator must ensure that the materials are destroyed in compliance with applicable environmental regulations, institutional policy, and any special instructions provided by Pfizer.

Upon identification of a product complaint, notify the sponsor within 1 business day of discovery as described in the IP manual.

### 6.2.1. Preparation and Dispensing

See the IP manual for instructions on how to prepare the study intervention for administration. Study intervention should be prepared and dispensed by an appropriately qualified and experienced member of the study staff (eg, physician, nurse, physician's assistant, nurse practitioner, pharmacy assistant/technician, or pharmacist) as allowed by local, state, and institutional guidance. A second staff member will verify the dispensing.

Study intervention and placebo will be prepared by qualified unblinded site personnel according to the IP manual. The study intervention will be administered in such a way to ensure the participants remain blinded.

## 6.3. Measures to Minimize Bias: Randomization and Blinding

### 6.3.1. Allocation to Study Intervention

Allocation (randomization) of participants to vaccine groups will proceed through the use of an IRT system (IWR). The site personnel (study coordinator or specified designee) will be required to enter or select information including but not limited to the user's ID and password, the protocol number, and the participant number. The site personnel will then be provided with a vaccine assignment and randomization number. The IRT system will provide a confirmation report containing the participant number, randomization number, and study intervention allocation assigned. The confirmation report must be stored in the site's files.

The study-specific IRT reference manual and IP manual will provide the contact information and further details on the use of the IRT system.

### 6.3.2. Blinding of Site Personnel

In this observer blinded study, the study staff receiving, storing, dispensing, preparing, and administering the study interventions will be unblinded. All other study and site personnel, including the investigator, investigator staff, and participants, will be blinded to study

intervention assignments. In particular, the individuals who evaluate participant safety will be blinded. Because the BNT162 RNA-based COVID-19 vaccine candidates and placebo are different in physical appearance, the study intervention syringes will be administered in a manner that prevents the study participants from identifying the study intervention type based on its appearance.

The responsibility of the unblinded dispenser and administrator must be assigned to an individual or individuals who will not participate in the evaluation of any study participants. Contact between the unblinded dispenser and study participants and unblinded administrator and study participants should be kept to a minimum. The remaining site personnel must not know study intervention assignments.

### 6.3.3. Blinding of the Sponsor

To facilitate rapid review of data in real time, sponsor staff will be unblinded to study intervention allocation for the participants in Phase 1. The majority of sponsor staff will be blinded to study intervention allocation in Phase 2/3. All laboratory testing personnel performing serology assays will remain blinded to study intervention assigned/received throughout the study. The following sponsor staff, who will have no part in the blinded conduct of the study, will be unblinded in Phase 2/3 (further details will be provided in a data blinding plan):

- Those study team members who are involved in ensuring that protocol requirements for study intervention preparation, handling, allocation, and administration are fulfilled at the site will be unblinded for the duration of the study (eg, unblinded study manager, unblinded clinical research associate).

- Unblinded clinician(s), who are not direct members of the study team and will not participate in any other study-related activities, will review unblinded protocol deviations.

- An unblinded team supporting interactions with, and analyses for, the DMC (see Section 9.6). This will comprise a statistician, programmer(s), a clinical scientist, and a medical monitor who will review cases of severe COVID-19 as they are received, and will review AEs at least weekly for additional potential cases of severe COVID-19 (see Section 8.2.3).

- An unblinded submissions team will be responsible for preparing unblinded analyses and documents to support regulatory activities that may be required while the study is ongoing. This team will only be unblinded at the group level and not have access to individual participant assignments. The programs that produce the summary tables will be developed and validated by the blinded study team, and these programs will be run by the unblinded DMC team. The submissions team will not have access to unblinded COVID-19 cases unless efficacy is achieved in either an interim analysis or the final analysis, as determined by the DMC.

### 6.3.4. Breaking the Blind

The IRT will be programmed with blind-breaking instructions. In case of an emergency, the investigator has the sole responsibility for determining if unblinding of a participant's study intervention assignment is warranted. Participant safety must always be the first consideration in making such a determination. If the investigator decides that unblinding is warranted, the investigator should make every effort to contact the sponsor prior to unblinding a participant's vaccine assignment unless this could delay further management of the participant. If a participant's vaccine assignment is unblinded, the sponsor must be notified within 24 hours after breaking the blind. The date and reason that the blind was broken must be recorded in the source documentation and CRF.

The study-specific IRT reference manual and IP manual will provide the contact information and further details on the use of the IRT system.

## 6.4. Study Intervention Compliance

When participants are dosed at the site, they will receive study intervention directly from the investigator or designee, under medical supervision. The date and time of each dose administered in the clinic will be recorded in the source documents and recorded in the CRF. The dose of study intervention and study participant identification will be confirmed at the time of dosing by a member of the study site staff other than the person administering the study intervention.

## 6.5. Concomitant Therapy

The following concomitant medications and vaccinations will be recorded in the CRF:

- All vaccinations received from 28 days prior to study enrollment until the 6-month follow-up visit (Visit 8 for Phase 1 participants, and Visit 4 for Phase 2/3 participants).
- Prohibited medications listed in Section 6.5.1 will be recorded, to include start and stop dates, name of the medication, dose, unit, route, and frequency.
- In addition, for participants enrolled in Phase 1, all current medication at baseline will be recorded, to include start date, name of the medication, dose, unit, route, and frequency.

### 6.5.1. Prohibited During the Study

Receipt of the following vaccines and medications during the time periods listed below may exclude a participant from the per-protocol analysis from that point onwards, and may require vaccinations to be discontinued in that participant; however, it is anticipated that the participant would not be withdrawn from the study (see Section 7). Medications should not be withheld if required for a participant's medical care.

Unless considered medically necessary, no vaccines other than study intervention should be administered within 28 days before and 28 days after each study vaccination. One exception

to this is that seasonal and pandemic influenza vaccine can be given at least 14 days after, or at least 14 days prior to, the administration of study intervention.

Receipt of chronic systemic treatment with known immunosuppressant medications, or radiotherapy, within 60 days before enrollment through conclusion of the study.

Receipt of systemic corticosteroids (≥20 mg/day of prednisone or equivalent) for ≥14 days is prohibited from 28 days prior to enrollment to Visit 7 for Phase 1 participants, and Visit 3 for Phase 2/3 participants).

Receipt of inhaled/nebulized corticosteroids from 28 days prior to enrollment to Visit 7 (1-month follow-up visit) for Phase 1 participants.

Receipt of blood/plasma products or immunoglobulins within 60 days before enrollment through conclusion of the study.

Receipt of any other (nonstudy) coronavirus vaccine at any time prior to or during study participation is prohibited.

Prophylactic antipyretics and other pain medication to prevent symptoms associated with study intervention administration are not permitted. However, if a participant is taking a medication for another condition, even if it may have antipyretic or pain-relieving properties, it should not be withheld prior to study vaccination.

### 6.5.2. Permitted During the Study

The use of antipyretics and other pain medication to treat symptoms associated with study intervention administration or ongoing conditions is permitted.

Medication other than that described as prohibited in Section 6.5.1 required for treatment of preexisting stable conditions is permitted.

Inhaled (except in Phase 1 participants – see Section 6.5.1), topical, or localized injections of corticosteroids (eg, intra-articular or intrabursal administration) are permitted.

## 6.6. Dose Modification

This protocol allows some alteration of vaccine dose for individual participants and/or dose groups from the currently outlined dosing schedule. For reasons of reactogenicity, tolerability, or safety, the IRC may recommend to reduce the second dose of study intervention and/or increase the interval between doses.

If, due to a medication error, a participant receives 1 dose of BNT162b2 at Visit 1 and 1 dose of placebo at Visit 2 (or vice versa), the participant should be offered the possibility to receive a second dose of BNT162b2 at an unscheduled visit. In this situation:

- Obtain informed consent for administration of the additional dose.

- Measure the participant's body temperature.
- Perform urine pregnancy test on WOCBP as described in Section 8.2.6.
- Discuss contraceptive use as described in Section 10.4.
- Ensure that the participant meets none of the temporary delay criteria as described in Section 5.5.
- Unblinded site staff member(s) will dispense/administer 1 dose of study intervention into the deltoid muscle of the preferably nondominant arm. Please refer to the IP manual for further instruction on this process.
- Blinded site staff must observe the participant for at least 30 minutes after study intervention administration for any acute reactions. Record any acute reactions (including time of onset) in the participant's source documents and on the AE page of the CRF, and on an SAE form as applicable.
- The participant should continue to adhere to the normal visit schedule but must be followed for nonserious AEs for 1 month and SAEs for 6 months after the second dose of BNT162b2. This will require AEs to be elicited either by unscheduled telephone contact(s) and/or in-person visit(s).

### 6.7. Intervention After the End of the Study

No intervention will be provided to study participants at the end of the study.

## 7. DISCONTINUATION OF STUDY INTERVENTION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

### 7.1. Discontinuation of Study Intervention

In rare instances, it may be necessary for a participant to permanently discontinue study intervention (definitive discontinuation). Reasons for definitive discontinuation of study intervention may include the following: AEs; participant request; investigator request; pregnancy; protocol deviation (including no longer meeting all the inclusion criteria, or meeting 1 or more exclusion criteria). In general, unless the investigator considers it unsafe to administer the second dose, or the participant does not wish to receive it, it is preferred that the second dose be administered. Note that a positive SARS-CoV-2 NAAT result without symptoms does not meet exclusion criterion 5 and should not result in discontinuation of study intervention, whereas a COVID-19 diagnosis does meet exclusion criterion 5 and should result in discontinuation of study intervention (see Section 8.15).

Note that discontinuation of study intervention does not represent withdrawal from the study. Per the study estimands, if study intervention is definitively discontinued, the participant will remain in the study to be evaluated for safety, immunogenicity, and efficacy. See the SoA for data to be collected at the time of discontinuation of study intervention and follow-up for any further evaluations that need to be completed.

In the event of discontinuation of study intervention, it must be documented on the appropriate CRF/in the medical records whether the participant is discontinuing further receipt of study intervention or also from study procedures, posttreatment study follow-up, and/or future collection of additional information.

## 7.2. Participant Discontinuation/Withdrawal From the Study

A participant may withdraw from the study at any time at his/her own request. Reasons for discontinuation from the study may include the following:

- Refused further follow-up;
- Lost to follow-up;
- Death;
- Study terminated by sponsor;
- AEs;
- Participant request;
- Investigator request;
- Protocol deviation.

If a participant does not return for a scheduled visit, every effort should be made to contact the participant. All attempts to contact the participant and information received during contact attempts must be documented in the participant's source document. In any circumstance, every effort should be made to document participant outcome, if possible.

The investigator or his or her designee should capture the reason for withdrawal in the CRF for all participants.

If a participant withdraws from the study, he/she may request destruction of any remaining samples taken and not tested, and the investigator must document any such requests in the site study records and notify the sponsor accordingly.

If the participant withdraws from the study and also withdraws consent (see Section 7.2.1) for disclosure of future information, no further evaluations should be performed and no additional data should be collected. The sponsor may retain and continue to use any data collected before such withdrawal of consent.

Lack of completion of all or any of the withdrawal/early termination procedures will not be viewed as protocol deviations so long as the participant's safety was preserved.

### 7.2.1. Withdrawal of Consent

Participants who request to discontinue receipt of study intervention will remain in the study and must continue to be followed for protocol-specified follow-up procedures. The only exception to this is when a participant specifically withdraws consent for any further contact

with him or her or persons previously authorized by the participant to provide this information. Participants should notify the investigator in writing of the decision to withdraw consent from future follow-up, whenever possible. The withdrawal of consent should be explained in detail in the medical records by the investigator, as to whether the withdrawal is only from further receipt of study intervention or also from study procedures and/or posttreatment study follow-up, and entered on the appropriate CRF page. In the event that vital status (whether the participant is alive or dead) is being measured, publicly available information should be used to determine vital status only as appropriately directed in accordance with local law.

### 7.3. Lost to Follow-up

A participant will be considered lost to follow-up if he or she repeatedly fails to return for scheduled visits and is unable to be contacted by the study site.

The following actions must be taken if a participant fails to attend a required study visit:

- The site must attempt to contact the participant and reschedule the missed visit as soon as possible and counsel the participant on the importance of maintaining the assigned visit schedule and ascertain whether or not the participant wishes to and/or should continue in the study;

- Before a participant is deemed lost to follow-up, the investigator or designee must make every effort to regain contact with the participant (where possible, 3 telephone calls and, if necessary, a certified letter to the participant's last known mailing address or local equivalent methods). These contact attempts should be documented in the participant's medical record;

- Should the participant continue to be unreachable, he/she will be considered to have withdrawn from the study.

## 8. STUDY ASSESSMENTS AND PROCEDURES

The investigator (or an appropriate delegate at the investigator site) must obtain a signed and dated ICD before performing any study-specific procedures.

The full date of birth will be collected to critically evaluate the immune response and safety profile by age.

Study procedures and their timing are summarized in the SoA. Protocol waivers or exemptions are not allowed.

Safety issues should be discussed with the sponsor immediately upon occurrence or awareness to determine whether the participant should continue or discontinue study intervention.

Adherence to the study design requirements, including those specified in the SoA, is essential and required for study conduct.

All screening evaluations must be completed and reviewed to confirm that potential participants meet all eligibility criteria. The investigator will maintain a screening log to record details of all participants screened and to confirm eligibility or record reasons for screening failure, as applicable.

Every effort should be made to ensure that protocol-required tests and procedures are completed as described. However, it is anticipated that from time to time there may be circumstances outside the control of the investigator that may make it unfeasible to perform the test. In these cases, the investigator must take all steps necessary to ensure the safety and well-being of the participant. When a protocol-required test cannot be performed, the investigator will document the reason for the missed test and any corrective and preventive actions that he or she has taken to ensure that required processes are adhered to as soon as possible. The study team must be informed of these incidents in a timely manner.

For samples being collected and shipped, detailed collection, processing, storage, and shipment instructions and contact information will be provided to the investigator site prior to initiation of the study.

The total blood sampling volume for individual participants in this study is approximately up to: 515 mL for participants in Phase 1, 110 mL for Phase 2/3 participants ≥16 years of age, and 50 mL for participants in the 12- to 15-year age stratum. Additionally, 20 mL of blood for participants ≥16 years of age and 10 mL for participants in the 12- to 15-year age stratum will be taken at an unplanned convalescent visit at any time a participant develops respiratory symptoms indicating a potential COVID-19 infection. Select participants in Phase 1 will also be asked to provide an additional blood sample of approximately 170 mL at either Visit 5, 6, or 7. These participants would therefore have a total blood sampling volume of 700 mL during the 24-month study period. Other additional blood samples may be taken for safety assessments at times specified by Pfizer, provided the total volume taken during the study does not exceed 550 mL during any period of 60 consecutive days.

### 8.1. Efficacy and/or Immunogenicity Assessments

Efficacy will be assessed throughout a participant's involvement in the study through surveillance for potential cases of COVID-19. If, at any time, a participant develops acute respiratory illness (see Section 8.13), for the purposes of the study he or she will be considered to potentially have COVID-19 illness.[9] In this circumstance, the participant should contact the site, an in-person or telehealth visit should occur, and assessments should be conducted as specified in the SoA. The assessments will include a nasal (midturbinate) swab, which will be tested at a central laboratory using a reverse transcription–polymerase chain reaction (RT-PCR) test (Cepheid; FDA approved under EUA), or other equivalent nucleic acid amplification–based test (ie, NAAT), to detect SARS-CoV-2. In addition, clinical information and results from local standard-of-care tests (as detailed in Section 8.13) will be assessed. The central laboratory NAAT result will be used for the case definition, unless no result is available from the central laboratory, in which case a local NAAT result may be used if it was obtained using 1 of the following assays:

- Cepheid Xpert Xpress SARS-CoV-2

- Roche cobas SARS-CoV-2 real-time RT-PCR test (EUA200009/A001)
- Abbott Molecular/RealTime SARS-CoV-2 assay (EUA200023/A001)

Two definitions of SARS-CoV-2–related cases, and SARS-CoV-2–related severe cases, will be considered (for both, the onset date of the case will be the date that symptoms were first experienced by the participant; if new symptoms are reported within 4 days after resolution of all previous symptoms, they will be considered as part of a single illness):

- Confirmed COVID-19: presence of at least 1 of the following symptoms and SARS-CoV-2 NAAT-positive during, or within 4 days before or after, the symptomatic period, either at the central laboratory or at a local testing facility (using an acceptable test):
    - Fever;
    - New or increased cough;
    - New or increased shortness of breath;
    - Chills;
    - New or increased muscle pain;
    - New loss of taste or smell;
    - Sore throat;
    - Diarrhea;
    - Vomiting.

  The second definition, which may be updated as more is learned about COVID-19, will include the following additional symptoms defined by the CDC (listed at https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html):

    - Fatigue;
    - Headache;
    - Nasal congestion or runny nose;
    - Nausea.
- Confirmed severe COVID-19: confirmed COVID-19 and presence of at least 1 of the following:

- Clinical signs at rest indicative of severe systemic illness (RR ≥30 breaths per minute, HR ≥125 beats per minute, $SpO_2$ ≤93% on room air at sea level, or $PaO_2/FiO_2$ <300 mm Hg);
- Respiratory failure (defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation, or ECMO);
- Evidence of shock (SBP <90 mm Hg, DBP <60 mm Hg, or requiring vasopressors);
- Significant acute renal, hepatic, or neurologic dysfunction*;
- Admission to an ICU;
- Death.

The DMC may recommend modification of the definition of severe disease according to emerging information.

* Three blinded case reviewers (medically qualified Pfizer staff members) will review all potential COVID-19 illness events. If a NAAT-confirmed case in Phase 2/3 may be considered severe, or not, solely on the basis of this criterion, the blinded data will be reviewed by the case reviewers to assess whether the criterion is met; the majority opinion will prevail.

In addition, a serological definition will be used for participants without clinical presentation of COVID-19:

- Confirmed seroconversion to SARS-CoV-2 without confirmed COVID-19: positive N-binding antibody result in a participant with a prior negative N-binding antibody result

Serum samples will be obtained for immunogenicity testing at the visits specified in the SoA. The following assays will be performed:

- SARS-CoV-2 neutralization assay
- S1-binding IgG level assay
- RBD-binding IgG level assay
- N-binding antibody assay

Note that all immunogenicity analyses will be based upon samples analyzed at the central laboratory; the rapid test will only be performed at screening by all sites recruiting participants in Phase 1 (see Section 8.11.1.1) to determine eligibility.

Serum obtained from the additional ~170-mL blood sample from select participants in Phase 1 at either Visit 5, 6, or 7 will be used for exploratory COVID-19 research, intended to establish a surrogate endpoint that is reasonably likely to predict clinical benefit.

### 8.1.1. Biological Samples

Blood and nasal swab samples will be used only for scientific research. Each sample will be labeled with a code so that the laboratory personnel testing the samples will not know the participant's identity. Samples that remain after performing assays outlined in the protocol may be stored by Pfizer. Unless a time limitation is required by local regulations or ethical requirements, the samples will be stored for up to 15 years after the end of the study and then destroyed. If allowed by the ICD, stored samples may be used for additional testing to better understand the immune responses to the vaccine(s) under study in this protocol, to inform the development of other products, and/or for vaccine-related assay work supporting vaccine programs. No testing of the participant's DNA will be performed.

The participant may request that his or her samples, if still identifiable, be destroyed at any time; however, any data already collected from those samples will still be used for this research. The biological samples may be shared with other researchers as long as confidentiality is maintained and no testing of the participant's DNA is performed.

## 8.2. Safety Assessments

Planned time points for all safety assessments are provided in the SoA. Unscheduled clinical laboratory measurements may be obtained at any time during the study to assess any perceived safety issues.

A clinical assessment, including medical history, will be performed on all participants at his/her first visit to establish a baseline. Significant medical history and observations from any physical examination, if performed, will be documented in the CRF.

AEs and SAEs are collected, recorded, and reported as defined in Section 8.3.

Acute reactions within the first 4 hours after administration of the study intervention (for the first 5 participants vaccinated in each Phase 1 group), and within the first 30 minutes (for the remainder of participants), will be assessed and documented in the AE CRF.

The safety parameters also include reactogenicity e-diary reports of local reactions and systemic events (including fever), and use of antipyretic medication that occur in the 7 days after administration of the study intervention in a subset of participants. These prospectively self-collected occurrences of local reactions and systemic events are graded as described in Section 8.2.2. For participants who are not in the reactogenicity subset, these local reactions and systemic events should be detected and reported as AEs, in accordance with Section 8.3.2.

### 8.2.1. Clinical Safety Laboratory Assessments (Phase 1 Participants Only)

See Appendix 2 for the list of clinical safety laboratory tests to be performed and the SoA for the timing and frequency. All protocol-required laboratory assessments, as defined in Appendix 2, must be conducted in accordance with the laboratory manual and the SoA. Unscheduled clinical laboratory measurements may be obtained at any time during the study to assess any perceived safety issues.

The investigator must review the laboratory report, document this review, and record any clinically relevant changes occurring during the study in the AE section of the CRF. See Appendix 2 for the grading scale for assessment of clinically significant abnormal laboratory findings. Clinically significant abnormal laboratory findings are those which are not associated with the underlying disease, unless judged by the investigator to be more severe than expected for the participant's condition.

All laboratory tests with values considered clinically significantly abnormal during participation in the study or within 28 days after the last dose of study intervention should be repeated until the values return to normal or baseline or are no longer considered clinically significant by the investigator or medical monitor.

If such values do not return to normal/baseline within a period of time judged reasonable by the investigator, the etiology should be identified and the sponsor notified.

See Appendix 5 for suggested actions and follow-up assessments in the event of potential drug-induced liver injury (DILI).

### 8.2.2. Electronic Diary

Participants will be required to complete a reactogenicity e-diary through an application (see Section 8.14) installed on a provisioned device or on the participant's own personal device. All participants in Phase 1, and a subset of at least the first 6000 randomized in Phase 2/3, will be asked to monitor and record local reactions, systemic events, and antipyretic medication usage for 7 days following administration of the study intervention. All participants in Phase 3 who are HIV-positive or 12 to 15 years of age will be included in this subset. In addition, participants 16 through 17 years of age enrolled under protocol amendment 9 and onwards will be included in the reactogenicity subset. The reactogenicity e-diary allows recording of these assessments only within a fixed time window, thus providing the accurate representation of the participant's experience at that time. Data on local reactions and systemic events reported in the reactogenicity e-diary will be transferred electronically to a third-party vendor, where they will be available for review by investigators and the Pfizer clinicians at all times via an internet-based portal.

At intervals agreed to by the vendor and Pfizer, these data will be transferred electronically into Pfizer's database for analysis and reporting. These data do not need to be reported by the investigator in the CRF as AEs.

Investigators (or designee) will be required to review the reactogenicity e-diary data online at frequent intervals as part of the ongoing safety review.

The investigator or designee must obtain stop dates from the participant for any ongoing local reactions, systemic events, or use of antipyretic medication on the last day that the reactogenicity e-diary was completed. The stop dates should be documented in the source documents and the information entered in the CRF.

#### 8.2.2.1. Grading Scales

The grading scales used in this study to assess local reactions and systemic events as described below are derived from the FDA Center for Biologics Evaluation and Research (CBER) guidelines on toxicity grading scales for healthy adult volunteers enrolled in preventive vaccine clinical trials.[8]

#### 8.2.2.2. Local Reactions

During the reactogenicity e-diary reporting period, participants will be asked to assess redness, swelling, and pain at the injection site and to record the symptoms in the reactogenicity e-diary. If a local reaction persists beyond the end of the reactogenicity e-diary period following vaccination, the participant will be requested to report that information. The investigator will enter this additional information in the CRF.

Redness and swelling will be measured and recorded in measuring device units (range: 1 to 21) and then categorized during analysis as absent, mild, moderate, or severe based on the grading scale in Table 1. Measuring device units can be converted to centimeters according to the following formula: 1 measuring device unit = 0.5 cm. Pain at the injection site will be assessed by the participant as absent, mild, moderate, or severe according the grading scale in Table 1.

If a Grade 3 local reaction is reported in the reactogenicity e-diary, a telephone contact should occur to ascertain further details and determine whether a site visit is clinically indicated. Only an investigator or medically qualified person is able to classify a participant's local reaction as Grade 4. If a participant experiences a confirmed Grade 4 local reaction, the investigator must immediately notify the sponsor and, if it is determined to be related to the administration of the study intervention, further vaccinations will be discontinued in that participant.

**Table 1. Local Reaction Grading Scale**

| | Mild (Grade 1) | Moderate (Grade 2) | Severe (Grade 3) | Potentially Life Threatening (Grade 4) |
|---|---|---|---|---|
| **Pain at the injection site** | Does not interfere with activity | Interferes with activity | Prevents daily activity | Emergency room visit or hospitalization for severe pain |
| **Redness** | >2.0 cm to 5.0 cm (5 to 10 measuring device units) | >5.0 cm to 10.0 cm (11 to 20 measuring device units) | >10 cm (≥21 measuring device units) | Necrosis or exfoliative dermatitis |
| **Swelling** | >2.0 cm to 5.0 cm (5 to 10 measuring device units) | >5.0 cm to 10.0 cm (11 to 20 measuring device units) | >10 cm (≥21 measuring device units) | Necrosis |

### 8.2.2.3. Systemic Events

During the reactogenicity e-diary reporting period, participants will be asked to assess vomiting, diarrhea, headache, fatigue, chills, new or worsened muscle pain, and new or worsened joint pain and to record the symptoms in the reactogenicity e-diary. The symptoms will be assessed by the participant as absent, mild, moderate, or severe according to the grading scale in Table 2.

If a Grade 3 systemic event is reported in the reactogenicity e-diary, a telephone contact should occur to ascertain further details and determine whether a site visit is clinically indicated. Only an investigator or medically qualified person is able to classify a participant's systemic event as Grade 4. If a participant experiences a confirmed Grade 4 systemic event, the investigator must immediately notify the sponsor and, if it is determined to be related to the administration of the study intervention, further vaccinations will be discontinued in that participant.

**Table 2. Systemic Event Grading Scale**

| | Mild (Grade 1) | Moderate (Grade 2) | Severe (Grade 3) | Potentially Life Threatening (Grade 4) |
|---|---|---|---|---|
| **Vomiting** | 1-2 times in 24 hours | >2 times in 24 hours | Requires IV hydration | Emergency room visit or hospitalization for hypotensive shock |
| **Diarrhea** | 2 to 3 loose stools in 24 hours | 4 to 5 loose stools in 24 hours | 6 or more loose stools in 24 hours | Emergency room visit or hospitalization for severe diarrhea |
| **Headache** | Does not interfere with activity | Some interference with activity | Prevents daily routine activity | Emergency room visit or hospitalization for severe headache |
| **Fatigue/ tiredness** | Does not interfere with activity | Some interference with activity | Prevents daily routine activity | Emergency room visit or hospitalization for severe fatigue |
| **Chills** | Does not interfere with activity | Some interference with activity | Prevents daily routine activity | Emergency room visit or hospitalization for severe chills |
| **New or worsened muscle pain** | Does not interfere with activity | Some interference with activity | Prevents daily routine activity | Emergency room visit or hospitalization for severe new or worsened muscle pain |
| **New or worsened joint pain** | Does not interfere with activity | Some interference with activity | Prevents daily routine activity | Emergency room visit or hospitalization for severe new or worsened joint pain |

Abbreviation: IV = intravenous.

#### 8.2.2.4. Fever

In order to record information on fever, a thermometer will be given to participants with instructions on how to measure oral temperature at home. Temperature will be collected in the reactogenicity e-diary in the evening daily during the reactogenicity e-diary reporting period. It will also be collected at any time during the reactogenicity e-diary data collection periods when fever is suspected. Fever is defined as an oral temperature of ≥38.0°C (100.4°F). The highest temperature for each day will be recorded in the reactogenicity e-diary. Temperature will be measured and recorded to 1 decimal place and then categorized during analysis according to the scale shown in Table 3.

If a fever of ≥39.0°C (102.1°F) is reported in the reactogenicity e-diary, a telephone contact should occur to ascertain further details and determine whether a site visit is clinically indicated. Only an investigator or medically qualified person is able to confirm a participant's fever as >40.0°C (>104.0°F). If a participant experiences a confirmed fever >40.0°C (>104.0°F), the investigator must immediately notify the sponsor and, if it is determined to be related to the administration of the study intervention, further vaccinations will be discontinued in that participant.

**Table 3. Scale for Fever**

| |
|---|
| ≥38.0-38.4°C (100.4-101.1°F) |
| >38.4-38.9°C (101.2-102.0°F) |
| >38.9-40.0°C (102.1-104.0°F) |
| >40.0°C (>104.0°F) |

#### 8.2.2.5. Antipyretic Medication

The use of antipyretic medication to treat symptoms associated with study intervention administration will be recorded in the reactogenicity e-diary daily during the reporting period (Day 1 to Day 7).

### 8.2.3. Phase 1 Stopping Rules

The following stopping rules are in place for all Phase 1 participants, based on review of AE data and e-diary reactogenicity data, until the start of Phase 2/3 or 30 days after the last dose of study intervention in Phase 1, whichever is later. These data will be monitored on an ongoing basis by the investigator (or medically qualified designee) and sponsor in order to promptly identify and flag any event that potentially contributes to a stopping rule.

The sponsor study team will be unblinded during Phase 1, so will be able to assess whether or not a stopping rule has been met on the basis of a participant's individual study intervention allocation.

In the event that sponsor personnel confirm that a stopping rule is met, the following actions will commence:

- The IRC will review all appropriate data.
- The stopping rule will PAUSE randomization and study intervention administration for the impacted vaccine candidate all dose levels and age groups.
- The DMC will review all appropriate data.
- For all participants vaccinated, all other routine study conduct activities, including ongoing data entry, reporting of AEs, participant reactogenicity e-diary completion, blood sample collection, and participant follow-up, will continue during the pause.

A stopping rule is met if any of the following rules occur after administration of investigational BNT162 vaccine; data from placebo recipients will not contribute to the stopping rules. Reactogenicity e-diary data confirmed by the investigator as being entered by the participant in error will not contribute toward a stopping rule.

The BNT162b RNA platform will be evaluated for contribution to stopping rules overall; vaccine candidate dose levels within the platform and age groups will contribute to stopping rules together. However, it is possible that the recommendations may include halting or continuing randomization with any of the BNT162 vaccine candidates.

**Stopping Rule Criteria for Each BNT162 Vaccine Candidate:**

1. If any participant vaccinated with the BNT162 candidate (at any dose level) develops an SAE that is assessed by the investigator as possibly related, or for which there is no alternative, plausible, attributable cause.

2. If any participant vaccinated with the BNT162 candidate (at any dose level) develops a Grade 4 local reaction or systemic event after vaccination (see Section 8.2.2) that is assessed as possibly related by the investigator, or for which there is no alternative, plausible, attributable cause.

3. If any participant vaccinated with the BNT162 candidate (at any dose level) develops a fever >40.0°C (>104.0°F) for at least 1 daily measurement after vaccination (see Section 8.2.2.4) that is assessed as possibly related by the investigator, or for which there is no alternative, plausible, attributable cause.

4. If any 2 participants vaccinated with the BNT162 candidate (at any dose level) report the same or similar severe (Grade 3) AE (including laboratory abnormalities) after vaccination, assessed as possibly related by the investigator, or for which there is no alternative, plausible, attributable cause.

5. If any participant dies or requires ICU admission due to SARS-CoV-2 infection; if this stopping rule is met, all available clinical and preclinical safety and immunogenicity data should be reviewed to evaluate for enhanced COVID-19.

### 8.2.4. Surveillance of Events That Could Represent Enhanced COVID-19 and Phase 2/3 Stopping Rule

Participants in all phases of the study will be surveilled for potential COVID-19 illness from Visit 1 onwards (see Section 8.13).

As this is a sponsor open-label study during Phase 1, the sponsor will conduct unblinded reviews of the data during the course of the study, including for the purpose of safety assessment. All NAAT-confirmed cases in Phase 1 will be reviewed contemporaneously by the IRC and the DMC (see Section 9.6).

In Phase 2/3, the unblinded team supporting the DMC, including an unblinded medical monitor, will review cases of severe COVID-19 as they are received and will review AEs at least weekly for additional potential cases of severe COVID-19. At any point, the unblinded team may discuss with the DMC chair whether the DMC should review cases for an adverse imbalance of cases of COVID-19 and/or severe COVID-19 between the vaccine and placebo groups.

The purpose of these reviews will be to identify whether any features of each case appear unusual, in particular greater in severity, compared to available information at the time of review. Indicators of severity may include accelerated deterioration, need for hospitalization, need for ventilation, or death. Observed rates of these indicators will be compared with what could be expected in a similar population to the study participants based upon available information at the time of review.

Stopping and alert rules will be applied as follows. The stopping rule will be triggered when the 1-sided probability of observing the same or a more extreme case split is 5% or less when the true incidence of severe disease is the same for vaccine and placebo participants, and alert criteria are triggered when this probability is less than 11%. In addition, when the total number of severe cases is low (15 or less), the unblinded team supporting the DMC will implement the alert rule when a reverse case split of 2:1 or worse is observed. For example, at 3 cases 2:1, at 4 cases 3:1, etc. Below 15 cases, this rule is more rigorous than requiring the probability of an observed adverse split or worse be <11%. Further details can be found in Section 10.7.

### 8.2.5. Randomization and Vaccination After a Stopping Rule Is Met

Once the IRC (if in Phase 1) and DMC (all phases) have reviewed the safety data and provided guidance, a notification will be sent from the sponsor to the sites with guidance on how to proceed.

### 8.2.6. Pregnancy Testing

Pregnancy tests may be urine or serum tests, but must have a sensitivity of at least 25 mIU/mL. Pregnancy tests will be performed in WOCBP at the times listed in the SoA, immediately before the administration of each vaccine dose. A negative pregnancy test result will be required prior to the participant's receiving the study intervention. Pregnancy tests may also be repeated if requested by IRBs/ECs or if required by local regulations. In the case of a positive confirmed pregnancy, the participant will be withdrawn from administration of study intervention but may remain in the study.

## 8.3. Adverse Events and Serious Adverse Events

The definitions of an AE and an SAE can be found in Appendix 3.

AEs will be reported by the participant (or, when appropriate, by a caregiver, surrogate, or the participant's parent(s)/legal guardian).

The investigator and any qualified designees are responsible for detecting, documenting, and recording events that meet the definition of an AE or SAE and remain responsible to pursue and obtain adequate information both to determine the outcome and to assess whether the event meets the criteria for classification as an SAE or caused the participant to discontinue the study intervention (see Section 7.1).

Each participant/parent(s)/legal guardian will be questioned about the occurrence of AEs in a nonleading manner.

In addition, the investigator may be requested by Pfizer Safety to obtain specific follow-up information in an expedited fashion.

### 8.3.1. Time Period and Frequency for Collecting AE and SAE Information

The time period for actively eliciting and collecting AEs and SAEs ("active collection period") for each participant begins from the time the participant/parent(s)/legal guardian provides informed consent, which is obtained before the participant's participation in the study (ie, before undergoing any study-related procedure and/or receiving study intervention), through and including Visit 7 for Phase 1 participants, and Visit 3 for Phase 2/3 participants. In addition, any AEs occurring up to 48 hours after each subsequent blood draw must be recorded on the CRF.

SAEs will be collected from the time the participant/parent(s)/legal guardian provides informed consent to approximately 6 months after the last dose of study intervention (Visit 8 for Phase 1 participants, and Visit 4 for Phase 2/3 participants).

Follow-up by the investigator continues throughout and after the active collection period and until the AE or SAE or its sequelae resolve or stabilize at a level acceptable to the investigator and Pfizer concurs with that assessment.

For participants who are screen failures, the active collection period ends when screen failure status is determined.

If the participant withdraws from the study and also withdraws consent for the collection of future information, the active collection period ends when consent is withdrawn.

If a participant definitively discontinues or temporarily discontinues study intervention because of an AE or SAE, the AE or SAE must be recorded on the CRF and the SAE reported using the Vaccine SAE Report Form.

Investigators are not obligated to actively seek AEs or SAEs after the participant has concluded study participation. However, if the investigator learns of any SAE, including a death, at any time after a participant has completed the study, and he/she considers the event to be reasonably related to the study intervention, the investigator must promptly report the SAE to Pfizer using the Vaccine SAE Report Form.

#### 8.3.1.1. Reporting SAEs to Pfizer Safety

All SAEs occurring in a participant during the active collection period as described in Section 8.3.1 are reported to Pfizer Safety on the Vaccine SAE Report Form immediately upon awareness and under no circumstance should this exceed 24 hours, as indicated in Appendix 3. The investigator will submit any updated SAE data to the sponsor within 24 hours of it being available.

#### 8.3.1.2. Recording Nonserious AEs and SAEs on the CRF

All nonserious AEs and SAEs occurring in a participant during the active collection period, which begins after obtaining informed consent as described in Section 8.3.1, will be recorded on the AE section of the CRF.

The investigator is to record on the CRF all directly observed and all spontaneously reported AEs and SAEs reported by the participant.

### 8.3.2. Method of Detecting AEs and SAEs

The method of recording, evaluating, and assessing causality of AEs and SAEs and the procedures for completing and transmitting SAE reports are provided in Appendix 3.

Care will be taken not to introduce bias when detecting AEs and/or SAEs. Open-ended and nonleading verbal questioning of the participant is the preferred method to inquire about AE occurrences.

### 8.3.3. Follow-up of AEs and SAEs

After the initial AE/SAE report, the investigator is required to proactively follow each participant at subsequent visits/contacts. For each event, the investigator must pursue and obtain adequate information until resolution, stabilization, the event is otherwise explained, or the participant is lost to follow-up (as defined in Section 7.3).

In general, follow-up information will include a description of the event in sufficient detail to allow for a complete medical assessment of the case and independent determination of possible causality. Any information relevant to the event, such as concomitant medications and illnesses, must be provided. In the case of a participant death, a summary of available autopsy findings must be submitted as soon as possible to Pfizer Safety.

Further information on follow-up procedures is given in Appendix 3.

### 8.3.4. Regulatory Reporting Requirements for SAEs

Prompt notification by the investigator to the sponsor of an SAE is essential so that legal obligations and ethical responsibilities towards the safety of participants and the safety of a study intervention under clinical investigation are met.

The sponsor has a legal responsibility to notify both the local regulatory authority and other regulatory agencies about the safety of a study intervention under clinical investigation. The sponsor will comply with country-specific regulatory requirements relating to safety reporting to the regulatory authority, IRBs/ECs, and investigators.

Investigator safety reports must be prepared for SUSARs according to local regulatory requirements and sponsor policy and forwarded to investigators as necessary.

An investigator who receives SUSARs or other specific safety information (eg, summary or listing of SAEs) from the sponsor will review and then file it along with the SRSD(s) for the study and will notify the IRB/EC, if appropriate according to local requirements.

### 8.3.5. Exposure During Pregnancy or Breastfeeding, and Occupational Exposure

Exposure to the study intervention under study during pregnancy or breastfeeding and occupational exposure are reportable to Pfizer Safety within 24 hours of investigator awareness.

#### 8.3.5.1. Exposure During Pregnancy

An EDP occurs if:

- A female participant is found to be pregnant while receiving or after discontinuing study intervention.
- A male participant who is receiving or has discontinued study intervention exposes a female partner prior to or around the time of conception.
- A female is found to be pregnant while being exposed or having been exposed to study intervention due to environmental exposure. Below are examples of environmental exposure during pregnancy:
    - A female family member or healthcare provider reports that she is pregnant after having been exposed to the study intervention by inhalation or skin contact.

- A male family member or healthcare provider who has been exposed to the study intervention by inhalation or skin contact then exposes his female partner prior to or around the time of conception.

The investigator must report EDP to Pfizer Safety within 24 hours of the investigator's awareness, irrespective of whether an SAE has occurred. The initial information submitted should include the anticipated date of delivery (see below for information related to termination of pregnancy).

- If EDP occurs in a participant or a participant's partner, the investigator must report this information to Pfizer Safety on the Vaccine SAE Report Form and an EDP Supplemental Form, regardless of whether an SAE has occurred. Details of the pregnancy will be collected after the start of study intervention and until 6 months after the last dose of study intervention.

- If EDP occurs in the setting of environmental exposure, the investigator must report information to Pfizer Safety using the Vaccine SAE Report Form and EDP Supplemental Form. Since the exposure information does not pertain to the participant enrolled in the study, the information is not recorded on a CRF; however, a copy of the completed Vaccine SAE Report Form is maintained in the investigator site file.

Follow-up is conducted to obtain general information on the pregnancy and its outcome for all EDP reports with an unknown outcome. The investigator will follow the pregnancy until completion (or until pregnancy termination) and notify Pfizer Safety of the outcome as a follow-up to the initial EDP Supplemental Form. In the case of a live birth, the structural integrity of the neonate can be assessed at the time of birth. In the event of a termination, the reason(s) for termination should be specified and, if clinically possible, the structural integrity of the terminated fetus should be assessed by gross visual inspection (unless preprocedure test findings are conclusive for a congenital anomaly and the findings are reported).

Abnormal pregnancy outcomes are considered SAEs. If the outcome of the pregnancy meets the criteria for an SAE (ie, ectopic pregnancy, spontaneous abortion, intrauterine fetal demise, neonatal death, or congenital anomaly), the investigator should follow the procedures for reporting SAEs. Additional information about pregnancy outcomes that are reported to Pfizer Safety as SAEs follows:

- Spontaneous abortion including miscarriage and missed abortion;

- Neonatal deaths that occur within 1 month of birth should be reported, without regard to causality, as SAEs. In addition, infant deaths after 1 month should be reported as SAEs when the investigator assesses the infant death as related or possibly related to exposure to the study intervention.

Additional information regarding the EDP may be requested by the sponsor. Further follow-up of birth outcomes will be handled on a case-by-case basis (eg, follow-up on preterm infants to identify developmental delays). In the case of paternal exposure, the investigator will provide the participant with the Pregnant Partner Release of Information Form to deliver to his partner. The investigator must document in the source documents that the participant was given the Pregnant Partner Release of Information Form to provide to his partner.

#### 8.3.5.2. Exposure During Breastfeeding

An exposure during breastfeeding occurs if:

- A female participant is found to be breastfeeding while receiving or after discontinuing study intervention.
- A female is found to be breastfeeding while being exposed or having been exposed to study intervention (ie, environmental exposure). An example of environmental exposure during breastfeeding is a female family member or healthcare provider who reports that she is breastfeeding after having been exposed to the study intervention by inhalation or skin contact.

The investigator must report exposure during breastfeeding to Pfizer Safety within 24 hours of the investigator's awareness, irrespective of whether an SAE has occurred. The information must be reported using the Vaccine SAE Report Form. When exposure during breastfeeding occurs in the setting of environmental exposure, the exposure information does not pertain to the participant enrolled in the study**,** so the information is not recorded on a CRF. However, a copy of the completed Vaccine SAE Report Form is maintained in the investigator site file.

An exposure during breastfeeding report is not created when a Pfizer drug specifically approved for use in breastfeeding women (eg, vitamins) is administered in accord with authorized use. However, if the infant experiences an SAE associated with such a drug, the SAE is reported together with the exposure during breastfeeding.

#### 8.3.5.3. Occupational Exposure

An occupational exposure occurs when a person receives unplanned direct contact with the study intervention, which may or may not lead to the occurrence of an AE. Such persons may include healthcare providers, family members, and other roles that are involved in the trial participant's care.

The investigator must report occupational exposure to Pfizer Safety within 24 hours of the investigator's awareness, regardless of whether there is an associated SAE. The information must be reported using the Vaccine SAE Report Form. Since the information does not pertain to a participant enrolled in the study, the information is not recorded on a CRF; however, a copy of the completed Vaccine SAE Report Form is maintained in the investigator site file.

### 8.3.6. Cardiovascular and Death Events

Not applicable.

### 8.3.7. Disease-Related Events and/or Disease-Related Outcomes Not Qualifying as AEs or SAEs

Potential COVID-19 illnesses and their sequelae that are consistent with the clinical endpoint definition should not be recorded as AEs. These data will be captured as efficacy assessment data only on the relevant pages of the CRF, as these are expected endpoints.

Potential COVID-19 illnesses and their sequelae will not be reported according to the standard process for expedited reporting of SAEs, even though the event may meet the definition of an SAE. These events will be recorded on the COVID-19 illness pages in the participant's CRF within 1 day.

NOTE: However, if either of the following conditions applies, then the event must be recorded and reported as an SAE (instead of a disease-related event):

The event is, in the investigator's opinion, of greater intensity, frequency, or duration than expected for the individual participant.

OR

The investigator considers that there is a reasonable possibility that the event was related to study intervention.

Potential COVID-19 illness events and their sequelae will be reviewed by a group of internal blinded case reviewers. Any SAE that is determined by the internal case reviewers NOT to meet endpoint criteria is reported back to the investigator site of incidence. The investigator must report the SAE to Pfizer Safety within 24 hours of being made aware that the SAE did not meet endpoint criteria. The investigator's SAE awareness date is the date on which the investigator site of incidence receives the SAE back from the internal case reviewers.

### 8.3.8. Adverse Events of Special Interest

Not applicable.

#### 8.3.8.1. Lack of Efficacy

Lack of efficacy is reportable to Pfizer Safety only if associated with an SAE.

### 8.3.9. Medical Device Deficiencies

Not applicable.

### 8.3.10. Medication Errors

Medication errors may result from the administration or consumption of the study intervention by the wrong participant, or at the wrong time, or at the wrong dosage strength.

Exposures to the study intervention under study may occur in clinical trial settings, such as medication errors.

| Safety Event | Recorded on the CRF | Reported on the Vaccine SAE Report Form to Pfizer Safety Within 24 Hours of Awareness |
|---|---|---|
| Medication errors | All (regardless of whether associated with an AE) | Only if associated with an SAE |

Medication errors include:

- Medication errors involving participant exposure to the study intervention;
- Potential medication errors or uses outside of what is foreseen in the protocol that do or do not involve the study participant;
- The administration of expired study intervention;
- The administration of an incorrect study intervention;
- The administration of an incorrect dosage;
- The administration of study intervention that has undergone temperature excursion from the specified storage range, unless it is determined by the sponsor that the study intervention under question is acceptable for use.

Such medication errors occurring to a study participant are to be captured on the medication error page of the CRF, which is a specific version of the AE page.

In the event of a medication dosing error, the sponsor should be notified within 24 hours.

Whether or not the medication error is accompanied by an AE, as determined by the investigator, the medication error is recorded on the medication error page of the CRF and, if applicable, any associated AE(s), serious and nonserious, are recorded on the AE page of the CRF.

Medication errors should be reported to Pfizer Safety within 24 hours on a Vaccine SAE Report Form **only when associated with an SAE.**

### 8.4. Treatment of Overdose

For this study, any dose of study intervention greater than 1 dose of study intervention within a 24-hour time period will be considered an overdose.

Pfizer does not recommend specific treatment for an overdose.

In the event of an overdose, the investigator should:

1. Contact the medical monitor within 24 hours.
2. Closely monitor the participant for any AEs/SAEs.
3. Document the quantity of the excess dose as well as the duration of the overdose in the CRF.
4. Overdose is reportable to Safety **only when associated with an SAE.**

Decisions regarding dose interruptions or modifications will be made by the investigator in consultation with the medical monitor based on the clinical evaluation of the participant.

### 8.5. Pharmacokinetics

Pharmacokinetic parameters are not evaluated in this study.

### 8.6. Pharmacodynamics

Pharmacodynamic parameters are not evaluated in this study.

### 8.7. Genetics

Genetics (specified analyses) are not evaluated in this study.

### 8.8. Biomarkers

Biomarkers are not evaluated in this study.

### 8.9. Immunogenicity Assessments

Immunogenicity assessments are described in Section 8.1.

### 8.10. Health Economics

Health economics/medical resource utilization and health economics parameters are not evaluated in this study.

### 8.11. Study Procedures

#### 8.11.1. Phase 1

##### 8.11.1.1. Screening: (0 to 28 Days Before Visit 1)

Before enrollment and before any study-related procedures are performed, voluntary, written study-specific informed consent will be obtained from the participant. Each signature on the ICD must be personally dated by the signatory. The investigator or his or her designee will also sign the ICD. A copy of the signed and dated ICD must be given to the participant. The source data must reflect that the informed consent was obtained before participation in the study.

It is anticipated that the procedures below will be conducted in a stepwise manner; however, the visit can occur over more than 1 day.

- Assign a single participant number using the IRT system.
- Obtain the participant's demography (including date of birth, sex, race, and ethnicity). The full date of birth will be collected to critically evaluate the immune response and safety profile by age.
- Obtain any medical history of clinical significance.
- Obtain details of any medications currently taken.
- Perform physical examination including vital signs (weight, height, body temperature, pulse rate, and seated blood pressure), evaluating any clinically significant abnormalities within the following body systems: general appearance; skin; head, eyes, ears, nose, and throat; heart; lungs; abdomen; musculoskeletal; extremities; neurological; and lymph nodes.
- Collect a blood sample (approximately 20 mL) for potential future serological assessment and to perform a rapid test for prior COVID-19 infection.
- Collect a blood sample (approximately 10 mL) for hematology and chemistry laboratory tests as described in Section 10.2.
- Collect a blood sample (approximately 10 mL) for HIV, HBsAg, HBc Ab, and HCV Ab tests.
- Perform urine pregnancy test on WOCBP as described in Section 8.2.6.
- Discuss contraceptive use as described in Section 10.4.
- Record nonstudy vaccinations as described in Section 6.5.
- Ensure and document that all of the inclusion criteria and none of the exclusion criteria are met.
- Record AEs as described in Section 8.3. AEs that occur prior to dosing should be noted on the Medical History CRF.
- Ask the participant to contact the site staff or investigator immediately if any significant illness or hospitalization occurs.
- Ask the participant to contact the site staff or investigator immediately if he or she experiences any respiratory symptoms as detailed in Section 8.13.
- Schedule an appointment for the participant to return for the next study visit.

- Complete the source documents.
- Complete the CRF.

#### 8.11.1.2. Visit 1 – Vaccination 1: (Day 1)

It is anticipated that the procedures below will be conducted in a stepwise manner; ensure that procedures listed prior to administration of the vaccine are conducted prior to vaccination.

- Record AEs as described in Section 8.3.
- Measure vital signs (body temperature, pulse rate, and seated blood pressure), and, if indicated by any change in the participant's health since the previous visit, perform a physical examination, evaluating any clinically significant abnormalities within the following body systems: general appearance; skin; head, eyes, ears, nose, and throat; heart; lungs; abdomen; musculoskeletal; extremities; neurological; and lymph nodes.
- Perform urine pregnancy test on WOCBP as described in Section 8.2.6.
- Discuss contraceptive use as described in Section 10.4.
- Record nonstudy vaccinations as described in Section 6.5.
- Review screening laboratory results (hematology and chemistry, and HIV, HBsAg, HBc Ab, and HCV Ab tests).
- Obtain 2 nasal (midturbinate) swabs (collected by site staff). One will be tested (if possible at the site, otherwise at the central laboratory) within 24 hours and vaccination will proceed only if it is NAAT-negative for SARS-CoV-2 genomes. The second will be sent to the central laboratory for potential later testing.
- Ensure and document that all of the inclusion criteria and none of the exclusion criteria are met.
- Ensure that the participant meets none of the temporary delay criteria as described in Section 5.5.
- Obtain the participant's randomization number and study intervention allocation using the IRT system. Only an unblinded site staff member may obtain this information.
- Collect a blood sample (approximately 50 mL) for immunogenicity testing.
- Unblinded site staff member(s) will dispense/administer 1 dose of study intervention into the deltoid muscle of the preferably nondominant arm. Please refer to the IP manual for further instruction on this process.

- The first 5 participants vaccinated in each group must be observed by blinded site staff for any acute reactions for at least 4 hours after vaccination. For participants enrolled thereafter, blinded site staff must observe the participant for at least 30 minutes after study intervention administration for any acute reactions. Record any acute reactions (including time of onset) in the participant's source documents and on the AE page of the CRF, and on an SAE form as applicable.

- Issue a measuring device to measure local reactions at the injection site and a thermometer for recording daily temperatures and provide instructions on their use.

- Explain the e-diary technologies available for this study (see Section 8.14), and assist the participant in downloading the study application onto the participant's own device or issue a provisioned device if required. Provide instructions on e-diary completion and ask the participant to complete the reactogenicity e-diary from Day 1 to Day 7, with Day 1 being the day of vaccination and, if utilized, the COVID-19 illness e-diary (to be completed if the participant is diagnosed with COVID-19 or has possible new or increased symptoms, and when he/she receives a reminder, at least weekly).

- Ask the participant to contact the site staff or investigator immediately if he or she experiences any of the following from Day 1 to Day 7 after vaccination (where Day 1 is the day of vaccination) to determine if an unscheduled reactogenicity visit is required:
  - Fever ≥39.0°C (≥102.1°F).
  - Redness or swelling at the injection site measuring greater than 10 cm (>20 measuring device units).
  - Severe pain at the injection site.
  - Any severe systemic event.
- Ask the participant to contact the site staff or investigator if a medically attended event (eg, doctor's visit, emergency room visit) or hospitalization occurs.
- Ask the participant to contact the site staff or investigator (this could be via the COVID-19 illness e-diary) immediately if he or she experiences any respiratory symptoms as detailed in Section 8.13.
- Schedule an appointment for the participant to return for the next study visit.
- Remind the participant to bring the e-diary to the next visit.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs and an unblinded dispenser/administrator updates the study intervention accountability records.
- The investigator or appropriately qualified designee reviews the reactogenicity e-diary data online following vaccination to evaluate participant compliance and as part of the ongoing safety review. Daily review is optimal during the active diary period.

#### 8.11.1.3. Visit 2 – Next-Day Follow-up Visit (Vaccination 1): (1 to 3 Days After Visit 1)

- Record AEs as described in Section 8.3.
- Measure vital signs (body temperature, pulse rate, and seated blood pressure), and, if indicated by any change in the participant's health since the previous visit, perform a physical examination, evaluating any clinically significant abnormalities within the following body systems: general appearance; skin; head, eyes, ears, nose, and throat; heart; lungs; abdomen; musculoskeletal; extremities; neurological; and lymph nodes.
- Collect a blood sample (approximately 10 mL) for hematology and chemistry laboratory tests as described in Section 10.2.

- Record nonstudy vaccinations as described in Section 6.5.
- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for his or her clinical care.
- Discuss contraceptive use as described in Section 10.4.
- Ask the participant to contact the site staff or investigator immediately if he or she experiences any of the following from Day 1 to Day 7 after vaccination (where Day 1 is the day of vaccination) to determine if an unscheduled reactogenicity visit is required:
  - Fever ≥39.0°C (≥102.1°F).
  - Redness or swelling at the injection site measuring greater than 10 cm (>20 measuring device units).
  - Severe pain at the injection site.
  - Any severe systemic event.
- Ask the participant to contact the site staff or investigator if a medically attended event (eg, doctor's visit, emergency room visit) or hospitalization occurs.
- Ask the participant to contact the site staff or investigator (this could be via the COVID-19 illness e-diary) immediately if he or she experiences any respiratory symptoms as detailed in Section 8.13.
- Schedule an appointment for the participant to return for the next study visit.
- Remind the participant to bring the e-diary to the next visit.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs.
- The investigator or appropriately qualified designee reviews the reactogenicity e-diary data online following vaccination to evaluate participant compliance and as part of the ongoing safety review. Daily review is optimal during the active diary period.

#### 8.11.1.4. Visit 3 – 1-Week Follow-up Visit (Vaccination 1): (6 to 8 Days After Visit 1)

- Record AEs as described in Section 8.3.
- Review hematology and chemistry laboratory results and record any AEs in accordance with Appendix 2.
- Measure vital signs (body temperature, pulse rate, and seated blood pressure), and, if indicated by any change in the participant's health since the previous visit, perform a physical examination, evaluating any clinically significant abnormalities within the following body systems: general appearance; skin; head, eyes, ears, nose, and throat; heart; lungs; abdomen; musculoskeletal; extremities; neurological; and lymph nodes.
- Collect a blood sample (approximately 10 mL) for hematology and chemistry laboratory tests as described in Section 10.2.
- Record nonstudy vaccinations as described in Section 6.5.
- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for his or her clinical care.
- Discuss contraceptive use as described in Section 10.4.
- Collect a blood sample (approximately 50 mL) for immunogenicity testing.
- Ask the participant to contact the site staff or investigator immediately if he or she experiences any of the following from Day 1 to Day 7 after vaccination (where Day 1 is the day of vaccination) to determine if an unscheduled reactogenicity visit is required:
  - Fever ≥39.0°C (≥102.1°F).
  - Redness or swelling at the injection site measuring greater than 10 cm (>20 measuring device units).
  - Severe pain at the injection site.
  - Any severe systemic event.
- Ask the participant to contact the site staff or investigator if a medically attended event (eg, doctor's visit, emergency room visit) or hospitalization occurs.
- Ask the participant to contact the site staff or investigator (this could be via the COVID-19 illness e-diary) immediately if he or she experiences any respiratory symptoms as detailed in Section 8.13.
- Schedule an appointment for the participant to return for the next study visit.

- Remind the participant to bring the e-diary to the next visit.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs.
- The investigator or appropriately qualified designee reviews the reactogenicity e-diary data online following vaccination to evaluate participant compliance and as part of the ongoing safety review. Daily review is optimal during the active diary period.

#### 8.11.1.5. Visit 4 – Vaccination 2: (19 to 23 Days After Visit 1)

It is anticipated that the procedures below will be conducted in a stepwise manner; ensure that procedures listed prior to administration of the vaccine are conducted prior to vaccination.

- Record AEs as described in Section 8.3.
- Review the participant's reactogenicity e-diary data. Collect stop dates of any reactogenicity e-diary events ongoing on the last day that the reactogenicity e-diary was completed and record stop dates in the CRF if required.
- Review hematology and chemistry laboratory results and record any AEs in accordance with Appendix 2.
- Measure vital signs (body temperature, pulse rate, and seated blood pressure), and, if indicated by any change in the participant's health since the previous visit, perform a physical examination, evaluating any clinically significant abnormalities within the following body systems: general appearance; skin; head, eyes, ears, nose, and throat; heart; lungs; abdomen; musculoskeletal; extremities; neurological; and lymph nodes.
- Perform urine pregnancy test on WOCBP as described in Section 8.2.6.
- Discuss contraceptive use as described in Section 10.4.
- Record nonstudy vaccinations as described in Section 6.5.
- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for his or her clinical care.
- Obtain 2 nasal (midturbinate) swabs (collected by site staff). One will be tested (if possible at the site, otherwise at the central laboratory) within 24 hours and vaccination will only proceed if it is NAAT-negative for SARS-CoV-2 genomes. The second will be sent to the central laboratory for potential later testing.
- Ensure and document that all of the inclusion criteria and none of the exclusion criteria are met. If not, the participant should not receive further study intervention

but will remain in the study to be evaluated for safety, immunogenicity, and efficacy (see Section 7.1).

- Ensure that the participant meets none of the temporary delay criteria as described in Section 5.5.
- Collect a blood sample (approximately 10 mL) for hematology and chemistry laboratory tests as described in Section 10.2.
- Collect a blood sample (approximately 50 mL) for immunogenicity testing.
- Unblinded site staff member(s) will dispense/administer 1 dose of study intervention into the deltoid muscle of the preferably nondominant arm. Please refer to the IP manual for further instruction on this process.
- Blinded site staff must observe the participant for at least 30 minutes after study intervention administration for any acute reactions. Record any acute reactions (including time of onset) in the participant's source documents and on the AE page of the CRF, and on an SAE form as applicable.
- Ensure the participant has a measuring device to measure local reactions at the injection site and a thermometer for recording daily temperatures.
- Ensure the participant remains comfortable with his or her chosen e-diary platform, confirm instructions on e-diary completion, and ask the participant to complete the reactogenicity e-diary from Day 1 to Day 7, with Day 1 being the day of vaccination.
- Ask the participant to contact the site staff or investigator immediately if he or she experiences any of the following from Day 1 to Day 7 after vaccination (where Day 1 is the day of vaccination) to determine if an unscheduled reactogenicity visit is required:
  - Fever ≥39.0°C (≥102.1°F).
  - Redness or swelling at the injection site measuring greater than 10 cm (>20 measuring device units).
  - Severe pain at the injection site.
  - Any severe systemic event.
- Ask the participant to contact the site staff or investigator if a medically attended event (eg, doctor's visit, emergency room visit) or hospitalization occurs.
- Ask the participant to contact the site staff or investigator (this could be via the COVID-19 illness e-diary) immediately if he or she experiences any respiratory symptoms as detailed in Section 8.13.

- Schedule an appointment for the participant to return for the next study visit.
- Remind the participant to bring the e-diary to the next visit.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs and an unblinded dispenser/administrator updates the study intervention accountability records.
- The investigator or appropriately qualified designee reviews the reactogenicity e-diary data online following vaccination to evaluate participant compliance and as part of the ongoing safety review. Daily review is optimal during the active diary period.

#### 8.11.1.6. Visit 5 – 1-Week Follow-up Visit (Vaccination 2): (6 to 8 Days After Visit 4)

- Record AEs as described in Section 8.3.
- Review hematology and chemistry laboratory results and record any AEs in accordance with Appendix 2.
- Measure vital signs (body temperature, pulse rate, and seated blood pressure), and, if indicated by any change in the participant's health since the previous visit, perform a physical examination, evaluating any clinically significant abnormalities within the following body systems: general appearance; skin; head, eyes, ears, nose, and throat; heart; lungs; abdomen; musculoskeletal; extremities; neurological; and lymph nodes.
- Collect a blood sample (approximately 10 mL) for hematology and chemistry laboratory tests as described in Section 10.2.
- Record nonstudy vaccinations as described in Section 6.5.
- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for his or her clinical care.
- Discuss contraceptive use as described in Section 10.4.
- Collect a blood sample (approximately 50 mL) for immunogenicity testing.
- If the participant (select participants only, details will be provided by the sponsor) consents, collect an additional 170 mL blood sample for exploratory COVID-19 research.
- Ask the participant to contact the site staff or investigator immediately if he or she experiences any of the following from Day 1 to Day 7 after vaccination (where Day 1 is the day of vaccination) to determine if an unscheduled reactogenicity visit is required:

- Fever ≥39.0°C (≥102.1°F).
- Redness or swelling at the injection site measuring greater than 10 cm (>20 measuring device units).
- Severe pain at the injection site.
- Any severe systemic event.

- Ask the participant to contact the site staff or investigator if a medically attended event (eg, doctor's visit, emergency room visit) or hospitalization occurs.
- Ask the participant to contact the site staff or investigator immediately if he or she experiences any respiratory symptoms as detailed in Section 8.13.
- Schedule an appointment for the participant to return for the next study visit.
- Remind the participant to bring the e-diary to the next visit.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs.
- The investigator or appropriately qualified designee reviews the reactogenicity e-diary data online following vaccination to evaluate participant compliance and as part of the ongoing safety review. Daily review is optimal during the active diary period.

#### 8.11.1.7. Visit 6 – 2-Week Follow-up Visit (Vaccination 2): (12 to 16 Days After Visit 4)

- Record AEs as described in Section 8.3.
- Review the participant's reactogenicity e-diary data. Collect stop dates of any reactogenicity e-diary events ongoing on the last day that the reactogenicity e-diary was completed and record stop dates in the CRF if required.
- Review hematology and chemistry laboratory results and record any AEs in accordance with Appendix 2.
- Measure vital signs (body temperature, pulse rate, and seated blood pressure), and, if indicated by any change in the participant's health since the previous visit, perform a physical examination, evaluating any clinically significant abnormalities within the following body systems: general appearance; skin; head, eyes, ears, nose, and throat; heart; lungs; abdomen; musculoskeletal; extremities; neurological; and lymph nodes.
- Record nonstudy vaccinations as described in Section 6.5.

- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for his or her clinical care.
- Discuss contraceptive use as described in Section 10.4.
- Collect a blood sample (approximately 50 mL) for immunogenicity testing.
- If not collected at Visit 5, and the participant (select participants only, details will be provided by the sponsor) consents, collect an additional 170-mL blood sample for exploratory COVID-19 research.
- Ask the participant to contact the site staff or investigator if a medically attended event (eg, doctor's visit, emergency room visit) or hospitalization occurs.
- Ask the participant to contact the site staff or investigator immediately (this could be via the COVID-19 illness e-diary) if he or she experiences any respiratory symptoms as detailed in Section 8.13.
- Schedule an appointment for the participant to return for the next study visit.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs.

#### 8.11.1.8. Visit 7 – 1-Month Follow-up Visit: (28 to 35 Days After Visit 4)

- Record AEs as described in Section 8.3.
- Record nonstudy vaccinations as described in Section 6.5.
- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for his or her clinical care.
- Discuss contraceptive use as described in Section 10.4.
- Collect a blood sample (approximately 50 mL) for immunogenicity testing.
- If not collected at Visit 5 or 6, and the participant (select participants only, details will be provided by the sponsor) consents, collect an additional 170-mL blood sample for exploratory COVID-19 research.
- Ask the participant to contact the site staff or investigator if a medically attended event (eg, doctor's visit, emergency room visit) or hospitalization occurs.
- Ask the participant to contact the site staff or investigator (this could be via the COVID-19 illness e-diary) immediately if he or she experiences any respiratory symptoms as detailed in Section 8.13.

- Schedule an appointment for the participant to return for the next study visit.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs.

#### 8.11.1.9. Visit 8 – 6-Month Follow-up Visit: (175 to 189 Days After Visit 4)

- Record SAEs as described in Section 8.3.
- Record nonstudy vaccinations as described in Section 6.5.
- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for his or her clinical care.
- Collect a blood sample (approximately 20 mL) for immunogenicity testing.
- Ask the participant to contact the site staff or investigator if a medically attended event (eg, doctor's visit, emergency room visit) or hospitalization occurs.
- Ask the participant to contact the site staff or investigator (this could be via the COVID-19 illness e-diary) immediately if he or she experiences any respiratory symptoms as detailed in Section 8.13.
- Schedule an appointment for the participant to return for the next study visit.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs.
- Record any AEs that occur within the 48 hours after the blood draw as described in Section 8.3.

#### 8.11.1.10. Visit 9 – 12-Month Follow-up Visit: (350 to 378 Days After Visit 4)

- Collect a blood sample (approximately 20 mL) for immunogenicity testing.
- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for his or her clinical care.
- Ask the participant to contact the site staff or investigator (this could be via the COVID-19 illness e-diary) immediately if he or she experiences any respiratory symptoms as detailed in Section 8.13.
- Schedule an appointment for the participant to return for the next study visit.
- Complete the source documents.

- The investigator or an authorized designee completes the CRFs.
- Record any AEs that occur within the 48 hours after the blood draw as described in Section 8.3.

#### 8.11.1.11. Visit 10 – 24-Month Follow-up Visit: (714 to 742 Days After Visit 4)

- Collect a blood sample (approximately 20 mL) for immunogenicity testing.
- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for his or her clinical care.
- Collect the participant's e-diary or assist the participant to remove the study application from his or her own personal device.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs.
- Record any AEs that occur within the 48 hours after the blood draw as described in Section 8.3.

### 8.11.2. Phase 2/3

#### 8.11.2.1. Visit 1 – Vaccination 1: (Day 1)

Before enrollment and before any study-related procedures are performed, voluntary, written, study-specific informed consent will be obtained from the participant or his/her parent(s)/legal guardian, as appropriate. Each signature on the ICD must be personally dated by the signatory. The investigator or his or her designee will also sign the ICD. A copy of the signed and dated ICD must be given to the participant/participant's parent(s)/legal guardian. The source data must reflect that the informed consent was obtained before participation in the study.

It is anticipated that the procedures below will be conducted in a stepwise manner. The visit may be conducted across 2 consecutive days; if so, all steps from assessing the inclusion and exclusion criteria onwards must be conducted on the same day.

- Assign a single participant number using the IRT system.
- Obtain the participant's demography (including date of birth, sex, race, and ethnicity). The full date of birth will be collected to critically evaluate the immune response and safety profile by age.
- Obtain any medical history of clinical significance. For participants who are HIV-positive, record HIV viral load and CD4 count results from the most recent test performed in the previous 6 months.

- Perform a clinical assessment. If the clinical assessment indicates that a physical examination is necessary to comprehensively evaluate the participant, perform a physical examination and record any findings in the source documents and, if clinically significant, record on the medical history CRF.
- Measure the participant's height and weight.
- Measure the participant's body temperature.
- Perform urine pregnancy test on WOCBP as described in Section 8.2.6.
- Discuss contraceptive use as described in Section 10.4.
- Record nonstudy vaccinations as described in Section 6.5.
- Ensure and document that all of the inclusion criteria and none of the exclusion criteria are met.
- Ensure that the participant meets none of the temporary delay criteria as described in Section 5.5.
- Record AEs as described in Section 8.3.
- Collect a blood sample (approximately 20 mL for participants ≥16 years of age and approximately 10 mL for participants in the 12- to 15-year age stratum) for immunogenicity testing.
- Obtain a nasal (midturbinate) swab (collected by site staff).
- Obtain the participant's randomization number and study intervention allocation number using the IRT system. Only an unblinded site staff member may obtain this information.
- Unblinded site staff member(s) will dispense/administer 1 dose of study intervention into the deltoid muscle of the preferably nondominant arm. Please refer to the IP manual for further instruction on this process.
- Blinded site staff must observe the participant for at least 30 minutes after study intervention administration for any acute reactions. Record any acute reactions (including time of onset) in the participant's source documents and on the AE page of the CRF, and on an SAE form as applicable.
- For participants in the reactogenicity subset, issue a measuring device to measure local reactions at the injection site and a thermometer for recording daily temperatures and provide instructions on their use.

- For participants not in the reactogenicity subset, issue a thermometer to monitor for fever (for COVID-19 surveillance) and provide instructions on its use.

- Explain the e-diary technologies available for this study (see Section 8.14), and assist the participant or his/her parent(s)/legal guardian, as appropriate, in downloading the study application onto the participant's own device or issue a provisioned device if required.

    - For participants in the reactogenicity subset, provide instructions on reactogenicity e-diary completion and ask the participant or his/her parent(s)/legal guardian, as appropriate, to complete the reactogenicity e-diary from Day 1 to Day 7, with Day 1 being the day of vaccination.

    - For all participants, provide instructions on COVID-19 illness e-diary completion and ask the participant or his/her parent(s)/legal guardian, as appropriate, to complete the COVID-19 illness e-diary if the participant is diagnosed with COVID-19 or has possible new or increased symptoms, and when he/she receives a reminder, at least weekly. See Section 8.14 for further details.

- If the participant is part of the reactogenicity subset, ask the participant or his/her parent(s)/legal guardian, as appropriate, to contact the site staff or investigator immediately if the participant experiences any of the following from Day 1 to Day 7 after vaccination (where Day 1 is the day of vaccination) to determine if an unscheduled reactogenicity visit is required:

    - Fever ≥39.0°C (≥102.1°F).

    - Redness or swelling at the injection site measuring greater than 10 cm (>20 measuring device units).

    - Severe pain at the injection site.

    - Any severe systemic event.

- Ask the participant or his/her parent(s)/legal guardian, as appropriate, to contact the site staff or investigator if a medically attended event (eg, doctor's visit, emergency room visit) or hospitalization occurs.

- Ask the participant or his/her parent(s)/legal guardian, as appropriate, to contact the site staff or investigator (this could be via the COVID-19 illness e-diary) immediately if he or she experiences any respiratory symptoms as detailed in Section 8.13.

- Schedule an appointment for the participant to return for the next study visit.

- Remind the participant or his/her parent(s)/legal guardian, as appropriate, to bring the e-diary to the next visit.

- Complete the source documents.
- The investigator or an authorized designee completes the CRFs and an unblinded dispenser/administrator updates the study intervention accountability records.

If the participant is part of the reactogenicity subset, the investigator or appropriately qualified designee reviews the reactogenicity e-diary data online following vaccination to evaluate participant compliance and as part of the ongoing safety review. Daily review is optimal during the active diary period.

#### 8.11.2.2. Visit 2 – Vaccination 2: (19 to 23 Days After Visit 1)

It is anticipated that the procedures below will be conducted in a stepwise manner; ensure that procedures listed prior to administration of the vaccine are conducted prior to vaccination.

- Record AEs as described in Section 8.3.
- If the participant is part of the reactogenicity subset, review the participant's reactogenicity e-diary data. Collect stop dates of any reactogenicity e-diary events ongoing on the last day that the reactogenicity e-diary was completed and record stop dates in the CRF if required.
- Perform urine pregnancy test on WOCBP as described in Section 8.2.6.
- Discuss contraceptive use as described in Section 10.4.
- Record nonstudy vaccinations as described in Section 6.5.
- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for his or her clinical care.
- Ensure and document that all of the inclusion criteria and none of the exclusion criteria are met. If not, the participant may not receive further study intervention but will remain in the study to be evaluated for safety, immunogenicity, and efficacy (see Section 7.1).
- Measure the participant's body temperature.
- Ensure that the participant meets none of the temporary delay criteria as described in Section 5.5.
- Obtain a nasal (midturbinate) swab (collected by site staff).
- Unblinded site staff member(s) will dispense/administer 1 dose of study intervention into the deltoid muscle of the preferably nondominant arm. Please refer to the IP manual for further instruction on this process.

- Blinded site staff must observe the participant for at least 30 minutes after study intervention administration for any acute reactions. Record any acute reactions (including time of onset) in the participant's source documents and on the AE page of the CRF, and on an SAE form as applicable.

- Ensure the participant or his/her parent(s)/legal guardian, as appropriate, has a measuring device to measure local reactions at the injection site and a thermometer for recording daily temperatures.

- Ensure the participant or his/her parent(s)/legal guardian, as appropriate, remains comfortable with the chosen e-diary platform, confirm instructions on e-diary completion, and, if the participant is part of the reactogenicity subset, ask the participant or his/her parent(s)/legal guardian, as appropriate, to complete the reactogenicity e-diary from Day 1 to Day 7, with Day 1 being the day of vaccination.

- If the participant is part of the reactogenicity subset, ask the participant or his/her parent(s)/legal guardian, as appropriate, to contact the site staff or investigator immediately if the participant experiences any of the following from Day 1 to Day 7 after vaccination (where Day 1 is the day of vaccination) to determine if an unscheduled reactogenicity visit is required:

  - Fever ≥39.0°C (≥102.1°F).

  - Redness or swelling at the injection site measuring greater than 10 cm (>20 measuring device units).

  - Severe pain at the injection site.

  - Any severe systemic event.

- Ask the participant or his/her parent(s)/legal guardian, as appropriate, to contact the site staff or investigator if a medically attended event (eg, doctor's visit, emergency room visit) or hospitalization occurs.

- Ask the participant or his/her parent(s)/legal guardian, as appropriate, to contact the site staff or investigator (this could be via the COVID-19 illness e-diary) immediately if the participant experiences any respiratory symptoms as detailed in Section 8.13.

- Schedule an appointment for the participant to return for the next study visit.

- Remind the participant or his/her parent(s)/legal guardian, as appropriate, to bring the e-diary to the next visit.

- Complete the source documents.

- The investigator or an authorized designee completes the CRFs and an unblinded dispenser/administrator updates the study intervention accountability records.

If the participant is part of the reactogenicity subset, the investigator or appropriately qualified designee reviews the reactogenicity e-diary data online following vaccination to evaluate participant compliance and as part of the ongoing safety review. Daily review is optimal during the active diary period.

#### 8.11.2.3. Visit 3 – 1-Month Follow-up Visit (After Vaccination 2): (28 to 35 Days After Visit 2)

- Record AEs as described in Section 8.3.
- Review the participant's reactogenicity e-diary data. If the participant is part of the reactogenicity subset, review the participant's reactogenicity e-diary data. Collect stop dates of any reactogenicity e-diary events ongoing on the last day that the reactogenicity e-diary was completed and record stop dates in the CRF if required.
- Record nonstudy vaccinations as described in Section 6.5.
- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for his or her clinical care.
- For participants who are HIV-positive, record HIV viral load and CD4 count results from the most recent test performed since Visit 1 (if any).
- Discuss contraceptive use as described in Section 10.4.
- Collect a blood sample (approximately 20 mL for participants ≥16 years of age, and approximately 10 mL for participants in the 12- to 15-year age stratum) for immunogenicity testing.
- Ask the participant or his/her parent(s)/legal guardian, as appropriate, to contact the site staff or investigator if a medically attended event (eg, doctor's visit, emergency room visit) or hospitalization occurs.
- Ask the participant or his/her parent(s)/legal guardian, as appropriate, to contact the site staff or investigator (this could be via the COVID-19 illness e-diary) immediately if the participant experiences any respiratory symptoms as detailed in Section 8.13.
- Schedule an appointment for the participant to return for the next study visit.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs.

#### 8.11.2.4. Visit 4 – 6-Month Follow-up Visit: (175 to 189 Days After Visit 2)

- Record SAEs as described in Section 8.3.
- Record nonstudy vaccinations as described in Section 6.5.
- For participants who are HIV-positive, record HIV viral load and CD4 count results from the most recent test performed since Visit 3 (if any).
- Collect a blood sample (approximately 20 mL for participants ≥16 years of age and approximately 10 mL for participants in the 12- to 15-year age stratum) for immunogenicity testing.
- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for his or her clinical care.
- Ask the participant or his/her parent(s)/legal guardian, as appropriate, to contact the site staff or investigator (this could be via the COVID-19 illness e-diary) immediately if the participant experiences any respiratory symptoms as detailed in Section 8.3.
- Schedule an appointment for the participant to return for the next study visit.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs.
- Record any AEs that occur within the 48 hours after the blood draw as described in Section 8.3.

#### 8.11.2.5. Visit 5 – 12-Month Follow-up Visit: (350 to 378 Days After Visit 2)

- Collect a blood sample (approximately 20 mL for participants ≥16 years of age and approximately 10 mL for participants in the 12- to 15-year age stratum) for immunogenicity testing.
- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for his or her clinical care.
- For participants who are HIV-positive, record HIV viral load and CD4 count results from the most recent test performed since Visit 4 (if any).
- Ask the participant or his/her parent(s)/legal guardian, as appropriate, to contact the site staff or investigator (this could be via the COVID-19 illness e-diary) immediately if the participant experiences any respiratory symptoms as detailed in Section 8.13.
- Schedule an appointment for the participant to return for the next study visit.
- Complete the source documents.

- The investigator or an authorized designee completes the CRFs.
- Record any AEs that occur within the 48 hours after the blood draw as described in Section 8.3.

#### 8.11.2.6. Visit 6 – 24-Month Follow-up Visit: (714 to 742 Days After Visit 2)

- Collect a blood sample (approximately 20 mL for participants ≥16 years of age and approximately 10 mL for participants in the 12- to 15-year age stratum) for immunogenicity testing.
- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for his or her clinical care.
- For participants who are HIV-positive, record HIV viral load and CD4 count results from the most recent test performed since Visit 5 (if any).
- Collect the participant's e-diary or assist the participant to remove the study application from his or her own personal device.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs.
- Record any AEs that occur within the 48 hours after the blood draw as described in Section 8.3.

### 8.12. Unscheduled Visit for a Grade 3 or Suspected Grade 4 Reaction

If a Grade 3 local reaction (Section 8.2.2.2), systemic event (Section 8.2.2.3), or fever (Section 8.2.2.4) is reported in the reactogenicity e-diary, a telephone contact should occur to ascertain further details and determine whether a site visit is clinically indicated. If suspected Grade 4 local reaction (Section 8.2.2.2), systemic event (Section 8.2.2.3), or fever (Section 8.2.2.4) is reported in the reactogenicity e-diary, a telephone contact or site visit should occur to confirm whether the event meets the criteria for Grade 4.

A site visit must be scheduled as soon as possible to assess the participant unless any of the following is true:

- The participant is unable to attend the unscheduled visit.
- The local reaction/systemic event is no longer present at the time of the telephone contact.
- The participant or his/her parent(s)/legal guardian, as appropriate, recorded an incorrect value in the reactogenicity e-diary (confirmation of a reactogenicity e-diary data entry error).

- The PI or authorized designee determined it was not needed.

This telephone contact will be recorded in the participant's source documentation and the CRF.

If the participant is unable to attend the unscheduled visit, or the PI or authorized designee determined it was not needed, any ongoing local reactions/systemic events must be assessed at the next study visit.

During the unscheduled visit, the reactions should be assessed by the investigator or a medically qualified member of the study staff such as a study physician or a study nurse, as applicable to the investigator's local practice, who will:

- Measure body temperature (°F/°C).
- Measure minimum and maximum diameters of redness (if present).
- Measure minimum and maximum diameters of swelling (if present).
- Assess injection site pain (if present) in accordance with the grades provided in Section 8.2.2.2.
- Assess systemic events (if present) in accordance with the grades provided in Section 8.2.2.3.
- Assess for other findings associated with the reaction and record on the AE page of the CRF, if appropriate.

The investigator or an authorized designee will complete the unscheduled visit assessment page of the CRF.

### 8.13. COVID-19 Surveillance (All Participants)

If a participant experiences any of the following (irrespective of perceived etiology or clinical significance), he or she is instructed to contact the site immediately and, if confirmed, participate in an in-person or telehealth visit as soon as possible, optimally within 3 days of symptom onset (and at the latest 4 days after symptom resolution). Note that:

- If new symptoms are reported within 4 days after resolution of all previous symptoms, they will be considered as part of a single illness and a second illness visit is not required;
- Surveillance of potential COVID-19 symptoms should continue even if a participant has a positive SARS-CoV-2 test earlier in the study.

During the 7 days following each vaccination, potential COVID-19 symptoms that overlap with specific systemic events (ie, fever, chills, new or increased muscle pain, diarrhea, vomiting) should not trigger a potential COVID-19 illness visit unless, in the investigator's

opinion, the clinical picture is more indicative of a possible COVID-19 illness than vaccine reactogenicity. If, in the investigator's opinion, the symptoms are considered more likely to be vaccine reactogenicity, but a participant is required to demonstrate that they are SARS-CoV-2–negative, a local SARS-CoV-2 test may be performed: if positive, the symptoms should be recorded as a potential COVID-19 illness; if not, the symptoms should be recorded as AEs (unless already captured in the reactogenicity e-diary).

Participants may utilize a COVID-19 illness e-diary through an application (see Section 8.14) installed on a provisioned device or on the participant's own personal device to prompt him/her to report any symptoms. Note that this does not substitute for a participant's routine medical care. Therefore, participants should be encouraged to seek care, if appropriate, from their usual provider.

- A diagnosis of COVID-19;
- Fever;
- New or increased cough;
- New or increased shortness of breath;
- Chills;
- New or increased muscle pain;
- New loss of taste/smell;
- Sore throat;
- Diarrhea;
- Vomiting.

### 8.13.1. Potential COVID-19 Illness Visit: (Optimally Within 3 Days After Potential COVID-19 Illness Onset)

This visit may be conducted as an in-person or telehealth visit; a telehealth visit involves the sharing of healthcare information and services via telecommunication technologies (eg, audio, video, video-conferencing software) remotely, thus allowing the participant and investigator to communicate on aspects of clinical care.

As a participant's COVID-19 illness may evolve over time, several contacts may be required to obtain the following information:

- Record AEs, as appropriate as described in Section 8.3. Note: Potential COVID-19 illnesses that are consistent with the clinical endpoint definition should not be recorded as AEs. These data will be captured as efficacy assessment data only on the relevant pages of the CRF, as these are expected endpoints.

- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for his or her clinical care.

- If the visit is conducted in person, obtain a nasal (midturbinate) swab (collected by site staff). Alternatively, if conducted by telehealth, instruct the participant to self-collect a nasal (midturbinate) swab and ship for assessment at the central laboratory.

- Collect COVID-19–related standard-of-care clinical and laboratory information. This includes, but is not limited to:

    - Symptoms and signs, including

        - Clinical signs at rest indicative of severe systemic illness (RR ≥30 breaths per minute, HR ≥125 beats per minute, $SpO_2$ ≤93% on room air at sea level, or $PaO_2/FiO_2$ <300 mm Hg)

        - Evidence of shock (SBP <90 mm Hg, DBP <60 mm Hg, or requiring vasopressors)

        - Significant acute renal, hepatic, or neurologic dysfunction

        - Respiratory failure (defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation, or ECMO)

    - Clinical diagnosis

    - Local laboratory SARS-CoV-2 test result(s). Note that if it is routine practice to perform a repeat local SARS-CoV-2 test for any reason, then a repeat nasal (midturbinate) swab should also be obtained and shipped for assessment at the central laboratory.

- Full blood count
- Blood chemistry, specifically creatinine, urea, liver function tests, and C-reactive protein
- Imaging results (eg, CT or MRI scan) to document neurologic dysfunction
- Number and type of any healthcare contact; duration of hospitalization and ICU stay
- Death

- Schedule an appointment for the participant to return for the potential COVID-19 convalescent visit once he or she has recovered.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs.

### 8.13.2. Potential COVID-19 Convalescent Visit: (28 to 35 Days After Potential COVID-19 Illness Visit)

- Record AEs, as appropriate as described in Section 8.3. Note: Potential COVID-19 illnesses that are consistent with the clinical endpoint definition should not be recorded as AEs. These data will be captured as efficacy assessment data only on the relevant pages of the CRF, as these are expected endpoints.
- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for his or her clinical care.
- Collect a blood sample (approximately 20 mL for participants ≥16 years of age and approximately 10 mL for participants in the 12- to 15-year age stratum) for immunogenicity testing.
- Collect/update COVID-19–related clinical and laboratory information (detailed in Section 8.13.1).
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs.
- Record any AEs that occur within the 48 hours after the blood draw as described in Section 8.3.

## 8.14. Communication and Use of Technology

In a study of this nature that requires illness events to be reported outside of scheduled study visits, it is vital that communication between the study site and the participant or his/her

parent(s)/legal guardian, as appropriate, is maintained to ensure that endpoint events are not missed. This study will employ various methods, tailored to the individual participant, to ensure that communication is maintained and study information can be transmitted securely. Using appropriate technology, such as a study application, a communication pathway between the participant or his/her parent(s)/legal guardian, as appropriate, and the study site staff will be established. The participant or his/her parent(s)/legal guardian, as appropriate, may be able to utilize his or her own devices to access this technology, or use a device provided by the sponsor. Traditional methods of telephone communication will also be available. The technology solution may facilitate the following:

- Contact with the investigator, including the ability of the participant or his/her parent(s)/legal guardian, as appropriate, to report whether or not the participant has experienced symptoms that could represent a potential COVID-19 illness (COVID-19 illness e-diary; see Section 8.13).
- An alert in the event that the participant is hospitalized.
- Visit reminders.
- Messages of thanks and encouragement from the study team.
- A platform for recording local reactions and systemic events (reactogenicity e-diary) – see Section 8.2.2.

If a participant or his/her parent(s)/legal guardian, as appropriate, is not actively completing either the reactogenicity or COVID-19 illness e-diary, the investigator or designee is required to contact the participant or his/her parent(s)/legal guardian, as appropriate, to ascertain why and also to obtain details of any missed events.

### 8.15. SARS-CoV-2 NAAT Results From Visits 1 and 2 and Potential COVID-19 Illness Visits

Nasal (midturbinate) swabs for SARS-CoV-2 NAAT are obtained at:

- Visits 1 and 2: To determine whether a participant will be included in efficacy analyses of those with no serological or virological evidence (up to 7 or 14 days after receipt of the second dose, depending on the objective) of past SARS-CoV-2 infection.
- Potential COVID-19 illness visits: To determine whether symptoms experienced by the participant fulfill the COVID-19 case definition.

Research laboratory–generated positive results from the Visit 1 and Visit 2 swabs, and all results from the illness visit swabs, will be provided to the site once available, but this will not be in real time and cannot be relied upon to direct clinical care. Therefore, the participant should be directed to seek additional testing through his/her primary healthcare providers at a licensed clinical laboratory when exhibiting potential COVID-19 symptoms or otherwise

receiving a positive result and counseled on whether to take any precautionary measures pending confirmatory testing.

Participants who have a positive SARS-CoV-2 NAAT result prior to Visit 2 should be handled as follows:

- Positive SARS-CoV-2 test with no symptoms, either at Visit 1 or any time between Visit 1 and Visit 2: A positive test in an asymptomatic participant does not meet exclusion criterion 5; therefore, Vaccination 2 should proceed as normal.

- Confirmed COVID-19 (ie, symptoms and positive SARS-CoV-2 test): This meets exclusion criterion 5; therefore, Vaccination 2 should not be given but the participant should remain in the study.

# 9. STATISTICAL CONSIDERATIONS

Methodology for summary and statistical analyses of the data collected in this study is described here and further detailed in a statistical analysis plan (SAP), which will be maintained by the sponsor. The SAP may modify what is outlined in the protocol where appropriate; however, any major modifications of the primary endpoint definitions or their analyses will also be reflected in a protocol amendment.

## 9.1. Estimands and Statistical Hypotheses

### 9.1.1. Estimands

The estimand corresponding to each primary, secondary, and tertiary/exploratory objective is described in the table in Section 3.

In the primary safety objective evaluations, missing reactogenicity e-diary data will not be imputed. Missing AE dates will be imputed according to Pfizer safety rules. No other missing information will be imputed in the safety analysis.

The estimands to evaluate the immunogenicity objectives are based on evaluable populations for immunogenicity (Section 9.3). These estimands estimate the vaccine effect in the hypothetical setting where participants follow the study schedules and protocol requirements as directed. Missing antibody results will not be imputed. Immunogenicity results that are below the LLOQ will be set to 0.5 × LLOQ in the analysis; this may be adjusted once additional data on the assay characteristics become available.

The estimands to evaluate the efficacy objectives are based on evaluable populations for efficacy (Section 9.3). These estimands estimate the vaccine effect in the hypothetical setting where participants follow the study schedules and protocol requirements as directed. In addition, VE will also be analyzed by all-available efficacy population. Missing laboratory results will not be imputed for the primary analysis, but missing data imputation for the efficacy endpoint may be performed as a sensitivity analysis.

### 9.1.2. Statistical Hypotheses

#### 9.1.2.1. Statistical Hypothesis Evaluation for Efficacy

Phase 2/3 of the study has 2 primary efficacy endpoints evaluating VE, which is defined as VE = 100 × (1 – IRR). IRR is calculated as the ratio of first confirmed COVID-19 illness rate in the vaccine group to the corresponding illness rate in the placebo group. In Phase 2/3, the assessment of VE will be based on posterior probabilities of $VE_1 > 30\%$ and $VE_2 > 30\%$. $VE_1$ represents VE for prophylactic BNT162b2 against confirmed COVID-19 in participants without evidence of infection before vaccination, and $VE_2$ represents VE for prophylactic BNT162b2 against confirmed COVID-19 in all participants after vaccination.

For participants with multiple confirmed cases, only the first case will contribute to the VE calculation for each hypothesis. $VE_1$ and $VE_2$ will be evaluated sequentially to control the overall type I error to the desired level of 2.5%. VE is demonstrated if there is sufficient evidence (posterior probability) that either $VE_1 > 30\%$ or both $VE_1$ and $VE_2$ are >30%. The assessment for the primary analysis will be based on posterior probability using a Bayesian model.

#### 9.1.2.2. Statistical Hypothesis Evaluation for Immunogenicity

One of the secondary objectives in the Phase 3 part of the study is to evaluate noninferiority of the immune response to prophylactic BNT162b2 in participants 12 to 15 years of age compared to the response in participants 16 to 25 years of age at 1 month after Dose 2. The (Dose 2) evaluable immunogenicity population will be used for the following hypothesis testing:

$H_0$: $\ln(\mu_2) - \ln(\mu_1) \leq \ln(0.67)$

where ln (0.67) corresponds to a 1.5-fold margin for noninferiority, ln(μ2) and ln(μ1) are the natural log of the geometric mean of SARS-CoV-2 neutralizing titers from BNT162b2 recipients 12 to 15 years of age and 16 to 25 years of age, respectively, measured 1 month after Dose 2**.** If the lower limit of the 95% CI for the GMR (12-15 years of age to 16-25 years of age) is >0.67, the noninferiority objective is met.

### 9.2. Sample Size Determination

The study sample size for Phase 1 of the study is not based on any statistical hypothesis testing. Phase 1 comprises 15 participants (randomization ratio of 4:1 so that 12 receive active vaccine and 3 receive placebo) per group; 13 vaccine groups are studied, corresponding to a total of 195 participants.

For Phase 2/3, with assumptions of a true VE of 60% after the second dose of investigational product, a total of approximately 164 first confirmed COVID-19 illness cases will provide 90% power to conclude true VE >30% with high probability, allowing early stopping for efficacy at the IA. This would be achieved with 17,600 evaluable participants per group or 21,999 vaccine recipients randomized in a 1:1 ratio with placebo, for a total sample size of 43,998, based on the assumption of a 1.3% illness rate per year in the placebo group, accrual of 164 first primary-endpoint cases within 6 months, and 20% of the participants being

nonevaluable or having serological evidence of prior infection with SARS-CoV-2, potentially making them immune to further infection. Dependent upon the evolution of the pandemic, it is possible that the COVID-19 attack rate may be much higher, in which case accrual would be expected to be more rapid, enabling the study's primary endpoint to be evaluated much sooner. The total number of participants enrolled in Phase 2/3 may vary depending on the incidence of COVID-19 at the time of the enrollment, the true underlying VE, and a potential early stop for efficacy or futility.

In Phase 3, approximately 2000 participants are anticipated to be 12 to 15 years of age. A random sample of 250 participants will be selected for each of the 2 age groups (12 to 15 years and 16 to 25 years) as an immunogenicity subset for the noninferiority assessment. With the standard deviation and observed GMT difference assumed in the power analysis below, a sample size of 200 evaluable participants (or 250 vaccine recipients) per age group will provide a power of 90.8% to declare the noninferiority of adolescents to 16- to 25-year-olds in terms of neutralizing antibody GMR, 1 month after the second dose (see Table 4).

**Table 4. Power Analysis for Noninferiority Assessment**

| Criteria | Standard Deviation (Log Value)[a] | Assumed Observed GMT Difference (Log Scale) | Number of Evaluable Participants per Age Group | Power[b] |
|---|---|---|---|---|
| Lower limit of 95% CI for GMR (12-15/16-25) >0.67 | 0.623 | -0.2 | 200 | 90.8% |

Abbreviation: GMR = geometric mean ratio.

a. Reference: 1 month after Dose 2, BNT162b2 (30 µg), 18- to 55-year age group (C4591001 Phase 1, N=12). Calculation may be updated if additional information becomes available to better estimate the standard deviation.

b. At 0.05 alpha level (2-sided).

For safety outcomes, Table 5 shows the probability of observing at least 1 AE for a given true event rate of a particular AE, for various sample sizes. For example, if the true AE rate is 10%, with 12 participants in a vaccine group, there is 72% probability of observing at least 1 AE.

**Table 5. Probability of Observing at Least 1 AE by Assumed True Event Rates With Different Sample Sizes**

| Assumed True Event Rate of an AE | N=12 | N=45 | N=180 | N=1000 | N=3000 | N=6000 | N=9000 | N=15000 |
|---|---|---|---|---|---|---|---|---|
| 0.01% | 0.00 | 0.00 | 0.02 | 0.10 | 0.26 | 0.45 | 0.59 | 0.78 |
| 0.02% | 0.00 | 0.01 | 0.04 | 0.18 | 0.45 | 0.70 | 0.83 | 0.95 |
| 0.04% | 0.00 | 0.02 | 0.07 | 0.33 | 0.70 | 0.91 | 0.97 | >0.99 |
| 0.06% | 0.01 | 0.03 | 0.10 | 0.45 | 0.83 | 0.97 | 0.99 | >0.99 |
| 0.08% | 0.01 | 0.04 | 0.13 | 0.55 | 0.91 | 0.99 | 0.99 | >0.99 |
| 0.10% | 0.01 | 0.04 | 0.16 | 0.63 | 0.95 | 0.99 | 0.99 | >0.99 |
| 0.15% | 0.02 | 0.07 | 0.24 | 0.78 | 0.99 | 0.99 | >0.99 | >0.99 |
| 0.20% | 0.02 | 0.09 | 0.30 | 0.86 | >0.99 | >0.99 | >0.99 | >0.99 |
| 0.25% | 0.03 | 0.11 | 0.36 | 0.92 | >0.99 | >0.99 | >0.99 | >0.99 |
| 0.30% | 0.04 | 0.13 | 0.42 | 0.95 | >0.99 | >0.99 | >0.99 | >0.99 |
| 0.35% | 0.04 | 0.15 | 0.47 | 0.97 | >0.99 | >0.99 | >0.99 | >0.99 |
| 0.50% | 0.06 | 0.20 | 0.59 | 0.99 | >0.99 | >0.99 | >0.99 | >0.99 |
| 1.00% | 0.11 | 0.36 | 0.84 | >0.99 | >0.99 | >0.99 | >0.99 | >0.99 |
| 2.00% | 0.22 | 0.60 | 0.97 | >0.99 | >0.99 | >0.99 | >0.99 | >0.99 |
| 3.00% | 0.31 | 0.75 | >0.99 | >0.99 | >0.99 | >0.99 | >0.99 | >0.99 |
| 5.00% | 0.46 | 0.90 | >0.99 | >0.99 | >0.99 | >0.99 | >0.99 | >0.99 |
| 7.00% | 0.58 | 0.96 | >0.99 | >0.99 | >0.99 | >0.99 | >0.99 | >0.99 |
| 10.00% | 0.72 | 0.99 | >0.99 | >0.99 | >0.99 | >0.99 | >0.99 | >0.99 |

Note: N = number in sample.

### 9.3. Analysis Sets

For purposes of analysis, the following populations are defined:

| Population | Description |
|---|---|
| Enrolled | All participants who have a signed ICD. |
| Randomized | All participants who are assigned a randomization number in the IWR system. |
| Dose 1 evaluable immunogenicity | For Phase 1 only, all eligible randomized participants who receive the vaccine to which they are randomly assigned at the first dose, have at least 1 valid and determinate immunogenicity result after Dose 1, have blood collection within an appropriate window after Dose 1, and have no other important protocol deviations as determined by the clinician. |
| Dose 2 evaluable immunogenicity | All eligible randomized participants who receive 2 doses of the vaccine to which they are randomly assigned, within the predefined window, have at least 1 valid and determinate immunogenicity result after Dose 2, have blood collection within an appropriate window after Dose 2, and have no other important protocol deviations as determined by the clinician. |

| Population | Description |
|---|---|
| Dose 1 all-available immunogenicity | For Phase 1 only: all randomized participants who receive at least 1 dose of the study intervention with at least 1 valid and determinate immunogenicity result after Dose 1 but before Dose 2. |
| Dose 2 all-available immunogenicity | All randomized participants who receive at least 1 dose of the study intervention with at least 1 valid and determinate immunogenicity result after Dose 2. |
| Evaluable efficacy | All eligible randomized participants who receive all vaccination(s) as randomized within the predefined window and have no other important protocol deviations as determined by the clinician. |
| All-available efficacy | 1. All randomized participants who receive at least 1 vaccination.<br>2. All randomized participants who complete 2 vaccination doses. |
| Safety | All randomized participants who receive at least 1 dose of the study intervention. |

### 9.4. Statistical Analyses

The SAP will be developed and finalized before database lock for any of the planned analyses in Section 9.5.1. It will describe the participant populations to be included in the analyses and the procedures for accounting for missing, unused, and spurious data. This section provides a summary of the planned statistical analyses of the primary, secondary, and tertiary/exploratory endpoints.

#### 9.4.1. Immunogenicity Analyses

Immunogenicity samples will be drawn for all participants. Immunogenicity analyses will be based upon results from appropriately sized subsets of samples, according to the purpose.

The statistical analysis of immunogenicity results will be primarily based on the evaluable immunogenicity populations as defined in Section 9.3. Serology data after a postbaseline positive SARS-CoV-2 test result will not be included in the analysis based on the evaluable immunogenicity populations.

An additional analysis will be performed based on the all-available populations if there is a large enough difference in sample size between the all-available immunogenicity population and the evaluable immunogenicity population. Participants will be summarized according to the vaccine group to which they were randomized.

| Endpoint | Statistical Analysis Methods |
|---|---|
| Secondary immunogenicity | **Geometric mean titers/concentrations (GMTs/GMCs) of SARS-CoV-2 neutralizing titers, S1-binding IgG level, and RBD-binding IgG level**<br><br>For SARS-CoV-2 neutralizing titers, S1-binding IgG levels, and RBD-binding IgG levels, GMTs/GMCs and 2-sided 95% CIs will be provided for each investigational product within each group before vaccination and at each of the following time points:<br><br>• Phase 1: 7 and 21 days after Dose 1; 7 and 14 days and 1, 6, 12 and 24 months after Dose 2<br><br>Geometric means will be calculated as the mean of the assay results after making the logarithm transformation and then exponentiating the mean to express results on the original scale. Two-sided 95% CIs will be obtained by taking natural log transforms of concentrations/titers, calculating the 95% CI with reference to the t-distribution, and then exponentiating the confidence limits.<br><br>**GMFRs of SARS-CoV-2 neutralizing titers, S1-binding IgG level, and RBD-binding IgG level**<br><br>For SARS-CoV-2 neutralizing titers, S1-binding IgG levels, and RBD-binding IgG levels, the GMFRs and 2-sided 95% CIs will be provided for each investigational product within each group at each of the following time points:<br><br>• Phase 1: 7 and 21 days after Dose 1; 7 and 14 days and 1, 6, 12, and 24 months after Dose 2<br><br>GMFRs will be limited to participants with nonmissing values prior to the first dose and at the postvaccination time point. The GMFR will be calculated as the mean of the difference of logarithmically transformed assay results (later time point – earlier time point) and exponentiating the mean. The associated 2-sided CIs will be obtained by calculating CIs using Student's t-distribution for the mean difference of the logarithmically transformed assay results and exponentiating the confidence limits.<br><br>**Percentage of participants with ≥4-fold rise in SARS-CoV-2 neutralizing titers, S1-binding IgG level, and RBD-binding IgG level**<br><br>For SARS-CoV-2 neutralizing titers, S1-binding IgG levels, and RBD-binding IgG levels, percentages (and 2-sided 95% CIs) of |

| Endpoint | Statistical Analysis Methods |
|---|---|
| | participants with ≥4-fold rise will be provided for each investigational product within each group at each of the following time points:<br><br>• Phase 1: 7 and 21 days after Dose 1; 7 and 14 days and 1, 6, 12, and 24 months after Dose 2<br><br>The Clopper-Pearson method will be used to calculate the CIs.<br><br>**GMR of SARS-CoV-2 neutralizing titer to S1-binding IgG level and to RBD-binding IgG level**<br><br>For SARS-CoV-2 neutralizing titers, S1-binding IgG levels, and RBD-binding IgG levels, the GMRs and 2-sided 95% CIs will be provided for each investigational product within each group at each of the following time points:<br><br>• Phase 1: 7 and 21 days after Dose 1; 7 and 14 days and 1, 6, 12, and 24 months after Dose 2<br><br>GMRs will be limited to participants with nonmissing values for both SARS-CoV-2 neutralizing titers and S1-binding IgG level/RBD-binding IgG level at each time point. The GMR will be calculated as the mean of the difference of logarithmically transformed assay results (eg, SARS-CoV-2 neutralizing titers minus S1-binding IgG level for each participant) and exponentiating the mean. Two-sided CIs will be obtained by calculating CIs using Student's t-distribution for the mean difference of the logarithmically transformed assay results and exponentiating the confidence limits.<br><br>For all the immunogenicity endpoints, the analysis will be based on the Dose 1 and Dose 2 evaluable immunogenicity populations. An additional analysis will be performed based on the all-available immunogenicity populations if there is a large enough difference in sample size between the all-available immunogenicity populations and the evaluable immunogenicity populations. Participants will be summarized according to the vaccine group to which they were randomized. Missing serology data will not be imputed. |
| Secondary immunogenicity (noninferiority in the 12- to 15-year age group compared to the | **GMR of SARS-CoV-2 neutralizing titers in participants 12 to 15 years of age to those 16 to 25 years of age**<br><br>For participants with no serological or virological evidence (up to 1 month after receipt of the second dose) of past SARS-CoV-2 infection, the GMR of SARS-CoV-2 neutralizing titers in participants 12 to 15 years of age to those in participants 16 to 25 years of age and |

| Endpoint | Statistical Analysis Methods |
|---|---|
| 16- to 25-year age group) | 2-sided 95% CIs will be provided at 1 month after Dose 2 for noninferiority assessment.<br><br>The GMR and its 2-sided 95% CI will be derived by calculating differences in means and CIs on the natural log scale of the titers based on the Student's t-distribution and then exponentiating the results. The difference in means on the natural log scale will be 12 to 15 years minus 16 to 25 years. Noninferiority will be declared if the lower bound of the 2-sided 95% CI for the GMR is greater than 0.67.<br><br>This analysis will be based on Dose 2 evaluable immunogenicity populations. An additional analysis may be performed based on the Dose 2 all-available immunogenicity population if needed. Participants will be summarized according to the vaccine group to which they were randomized. Missing serology data will not be imputed. |
| Exploratory immunogenicity | **Geometric mean titers/concentrations (GMTs/GMCs) of SARS-CoV-2 neutralizing titers, S1-binding IgG level, and RBD-binding IgG level**<br><br>For SARS-CoV-2 neutralizing titers, S1-binding IgG levels, and RBD-binding IgG levels, GMTs/GMCs and 2-sided 95% CIs will be provided for each investigational product within each group before vaccination and at each of the following time points in Phase 2/3:<br><br>• 1, 6, 12, and 24 months after completion of vaccination in participants with and without serological or virological evidence of SARS-CoV-2 infection before vaccination<br><br>Geometric means will be calculated as the mean of the assay results after making the logarithm transformation and then exponentiating the mean to express results on the original scale. Two-sided 95% CIs will be obtained by taking natural log transforms of concentrations/titers, calculating the 95% CI with reference to the t-distribution, and then exponentiating the confidence limits.<br><br>**GMFRs of SARS-CoV-2 neutralizing titers, S1-binding IgG level, and RBD-binding IgG level**<br><br>For SARS-CoV-2 neutralizing titers, S1-binding IgG levels, and RBD-binding IgG levels, the GMFRs and 2-sided 95% CIs will be provided for each investigational product within each group at each of the following time points in Phase 2/3: |

| Endpoint | Statistical Analysis Methods |
|---|---|
| | • 1, 6, 12, and 24 months after completion of vaccination in participants with and without serological or virological evidence of SARS-CoV-2 infection before vaccination<br><br>GMFRs will be limited to participants with nonmissing values prior to the first dose and at the postvaccination time point. The GMFR will be calculated as the mean of the difference of logarithmically transformed assay results (later time point – earlier time point) and exponentiating the mean. The associated 2-sided CIs will be obtained by calculating CIs using Student's t-distribution for the mean difference of the logarithmically transformed assay results and exponentiating the confidence limits.<br><br>**Percentage of participants with antibody levels ≥ predefined threshold(s) for SARS-CoV-2 serological parameters**<br><br>For SARS-CoV-2 neutralizing titers, S1-binding IgG levels and/or RBD-binding IgG levels, N-binding antibody, and SARS-CoV-2 detection by NAAT, percentages (and 2-sided 95% CIs) of participants with antibody levels ≥ predefined threshold(s) will be provided for each investigational product within each group at baseline and each of the following time points in Phase 2/3:<br><br>• 1, 6, 12, and 24 months after completion of vaccination in participants with and without serological or virological evidence of SARS-CoV-2 infection before vaccination<br><br>The Clopper-Pearson method will be used to calculate the CIs.<br><br>**Percentage of participants with the immune response (non-S) to SARS-CoV-2 for N-binding antibody at the time points when data are available**<br><br>The Clopper-Pearson method will be used to calculate the CIs.<br><br>For all of the immunogenicity endpoints, the analysis will be based on the Dose 1 and Dose 2 evaluable immunogenicity populations. An additional analysis will be performed based on the all-available immunogenicity populations if there is a large enough difference in sample size between the all-available immunogenicity populations and the evaluable immunogenicity populations. Participants will be summarized according to the vaccine group to which they were randomized. Missing serology data will not be imputed. |

| Endpoint | Statistical Analysis Methods |
|---|---|
| | **RCDCs for immunogenicity results**<br><br>Empirical RCDCs will be provided for SARS-CoV-2 neutralizing titers, S1-binding IgG level, and RBD-binding IgG level after Dose 1 and after Dose 2. |

### 9.4.2. Efficacy Analyses

The evaluable efficacy population will be the primary analysis population for all efficacy analyses. Additional analyses based on the all-available efficacy population will be performed.

| Endpoint | Statistical Analysis Methods |
|---|---|
| Primary efficacy | **Ratio of confirmed COVID-19 illness from 7 days after the second dose per 1000 person-years of follow-up in participants without evidence of infection (prior to 7 days after receipt of the second dose) for the active vaccine group to the placebo group**<br><br>VE will be estimated by 100 × (1 – IRR), where IRR is the calculated ratio of confirmed COVID-19 illness per 1000 person-years follow-up in the active vaccine group to the corresponding illness rate in the placebo group from 7 days after the second dose. VE will be analyzed using a beta-binomial model.<br><br>After the above objective is met, the second primary endpoint will be evaluated as below.<br><br>**Ratio of confirmed COVID-19 illness from 7 days after the second dose per 1000 person-years of follow-up in participants with and without evidence of infection (prior to 7 days after receipt of the second dose) for the active vaccine group to the placebo group**<br><br>VE will be estimated by 100 × (1 – IRR), where IRR is the calculated ratio of confirmed COVID-19 illness per 1000 person-years follow-up in the active vaccine group to the corresponding illness rate in the placebo group from 7 days after the second dose. VE will be analyzed using a beta-binomial model.<br><br>The efficacy analysis for the first primary objective evaluation will be based on the participants without evidence of infection before vaccination and included in the evaluable efficacy population and in the all-available efficacy population. |

| Endpoint | Statistical Analysis Methods |
|---|---|
| | The efficacy analysis for the second primary objective evaluation will be based on all participants included in the evaluable efficacy population and in the all-available efficacy population.<br><br>For the primary endpoint analysis, missing efficacy data will not be imputed. A sensitivity analysis will be performed by imputing missing values with the assumption of MAR. A missing efficacy endpoint may be imputed based on predicted probability using the fully conditional specification method. Other imputation methods without the MAR assumption may be explored. The details will be provided in the SAP. |
| Secondary | **First: Ratio of confirmed COVID-19 illness from 14 days after the second dose per 1000 person-years of follow-up in participants without evidence of infection (prior to 14 days after receipt of the second dose) for the active vaccine group to the placebo group**<br><br>**Second: Ratio of confirmed COVID-19 illness from 14 days after the second dose per 1000 person-years of follow-up in participants with and without evidence of infection (prior to 14 days after receipt of the second dose) for the active vaccine group to the placebo group**<br><br>**Third and fourth: Ratios of confirmed severe COVID-19 illness from 7 days and from 14 days after the second dose per 1000 person-years of follow-up in participants without evidence of infection (prior to 7 days or 14 days after receipt of the second dose) for the active vaccine group to the placebo group**<br><br>**Fifth and sixth: Ratios of confirmed severe COVID-19 illness from 7 days and from 14 days after the second dose per 1000 person-years of follow-up in participants with and without evidence of infection (prior to 7 days or 14 days after receipt of the second dose) for the active vaccine group to the placebo group**<br><br>These secondary efficacy objectives will be evaluated sequentially in the order specified above after the primary objectives are met. The analysis will be based on the evaluable efficacy population and the all-available efficacy population. The analysis methodology used for the primary efficacy endpoints will be applied for the analysis of the above secondary efficacy endpoints.<br><br>The following secondary efficacy endpoints will be evaluated descriptively with 95% CIs.<br><br>**Ratios of confirmed COVID-19 illness (according to the CDC-defined symptoms) from 7 days and from 14 days after the** |

| Endpoint | Statistical Analysis Methods |
|---|---|
| | **second dose per 1000 person-years of follow-up in participants without evidence of infection (prior to 7 days or 14 days after receipt of the second dose) for the active vaccine group to the placebo group**<br><br>**Ratios of confirmed COVID-19 illness (according to the CDC-defined symptoms) from 7 days and from 14 days after the second dose per 1000 person-years of follow-up in participants with and without evidence of infection (prior to 7 days or 14 days after receipt of the second dose) for the active vaccine group to the placebo group**<br><br>VE = 100 × (1 – IRR) will be estimated with confirmed COVID-19 illness according to the CDC-defined symptoms from 7 days or from 14 days after the second dose. The 2-sided 95% CI for VE will be derived using the Clopper-Pearson method as described by Agresti.[9]<br><br>Missing efficacy data will not be imputed. |

### 9.4.3. Safety Analyses

| Endpoint | Statistical Analysis Methods |
|---|---|
| Primary | Descriptive statistics will be provided for each reactogenicity endpoint for each dose and vaccine group. Local reactions and systemic events from Day 1 through Day 7 after each vaccination will be presented by severity and cumulatively across severity levels. Descriptive summary statistics will include counts and percentages of participants with the indicated endpoint and the associated Clopper-Pearson 95% CIs.<br><br>For Phase 1, descriptive statistics will be provided for abnormal hematology and chemistry laboratory values at 1 and 7 days after Dose 1 and 7 days after Dose 2, including grading shifts in hematology and chemistry laboratory assessments between baseline and 1 and 7 days after Dose 1, and before Dose 2 and 7 days after Dose 2. Descriptive summary statistics will include counts and percentages of participants with the indicated endpoint and the associated Clopper-Pearson 2-sided 95% CIs.<br><br>AEs will be categorized according to the Medical Dictionary for Regulatory Activities (MedDRA) terms. A 3-tier approach will be used to summarize AEs in Phase 2/3. Under this approach AEs are classified into 1 of 3 tiers: (1) Tier 1 events are prespecified events of clinical importance and are identified in a list in the product's safety |

| Endpoint | Statistical Analysis Methods |
|---|---|
| | review plan; (2) Tier 2 events are those that are not Tier 1 but are considered "relatively common"; a MedDRA preferred term is defined as a Tier 2 event if there are at least 1% of participants in at least 1 vaccine group reporting the event; and (3) Tier 3 events are those that are neither Tier 1 nor Tier 2 events. For both Tier 1 and Tier 2 events, 2-sided 95% CIs for the difference between the vaccine and placebo groups in the percentage of participants reporting the events based on the Miettinen and Nurminen method[10] will be provided. In addition, for Tier 1 events, the asymptotic p-values will also be presented for the difference between groups in the percentage of participants reporting the events, based on the same test statistic and under the assumption that the test statistic is asymptotically normally distributed.<br><br>Descriptive summary statistics (counts, percentages, and associated Clopper-Pearson 95% CIs) will be provided for any AE events for each vaccine group.<br><br>SAEs will be categorized according to MedDRA terms. Counts, percentages, and the associated Clopper-Pearson 95% CIs of SAEs from Dose 1 to 6 months after the last dose will be provided for each vaccine group.<br><br>The safety analyses are based on the safety population. Participants will be summarized by vaccine group according to the investigational products they actually received. Missing reactogenicity e-diary data will not be imputed; missing AE dates will be handled according to the Pfizer safety rules. |
| Secondary | Not applicable (N/A) |
| Exploratory | N/A |

### 9.4.4. Other Analyses

The ratios of (GMFR A to GMFR B) and (GMFR A to GMFR C) may be explored, where GMFR A is the geometric mean of the ratio of the SARS-CoV-2 neutralizing titer at the postvaccination time point to the corresponding titer at the prevaccination time point, GFMR B is the geometric mean of the ratio of the S1-binding IgG level at the postvaccination time point to the corresponding IgG level at the prevaccination time point, and GMFR C is the geometric mean of the ratio of the RBD-binding IgG level at the postvaccination time point to the corresponding antibody level at the prevaccination time point.

The safety data and immunogenicity results for individuals with confirmed stable HIV disease will be summarized descriptively. Furthermore, VE may be assessed if there is a sufficient number of COVID-19 cases in this group of participants.

The safety and immunogenicity results for individuals 16 to 55 years of age vaccinated with study intervention produced by manufacturing "Process 1" and each lot of "Process 2" will be summarized descriptively. A random sample of 250 participants from those vaccinated with study intervention produced by manufacturing "Process 1" will be selected randomly for the analysis.

### 9.5. Interim Analyses

As this is a sponsor open-label study during Phase 1, the sponsor may conduct unblinded reviews of the data during the course of the study for the purpose of safety assessment, facilitating dose escalation decisions, and/or supporting clinical development.

During Phase 2/3, 4 IAs were planned to be performed by an unblinded statistical team after accrual of at least 32, 62, 92, and 120 cases. However, for operational reasons, the first planned IA was not performed. Consequently, 3 IAs are now planned to be performed after accrual of at least 62, 92, and 120 cases. At these IAs, futility and VE with respect to the first primary endpoint will be assessed as follows:

- VE for the first primary objective will be evaluated. Overwhelming efficacy will be declared if the first primary study objective is met. The criteria for success at an interim analysis are based on the posterior probability (ie, P[VE >30%|data]) at the current number of cases. Overwhelming efficacy will be declared if the posterior probability is higher than the success threshold. The success threshold for each interim analysis will be calibrated to protect overall type I error at 2.5%. Additional details about the success threshold or boundary calculation at each interim analysis will be provided in the SAP.

- The study will stop for lack of benefit (futility) if the predicted probability of success at the final analysis or study success is <5%. The posterior predictive POS will be calculated using a beta-binomial model. The futility assessment will be performed for the first primary endpoint and the futility boundary may be subject to change to reflect subsequent program-related decisions by the sponsor.

- Efficacy and futility boundaries will be applied in a nonbinding way.

Bayesian approaches require specification of a prior distribution for the possible values of the unknown vaccine effect, thereby accounting for uncertainty in its value. A minimally informative beta prior, beta (0.700102, 1), is proposed for $\theta = (1\text{-VE})/(2\text{-VE})$. The prior is centered at $\theta = 0.4118$ (VE=30%) which can be considered pessimistic. The prior allows considerable uncertainty; the 95% interval for $\theta$ is (0.005, 0.964) and the corresponding 95% interval for VE is (-26.2, 0.995).

Table 6 illustrates the boundary for efficacy and futility if, for example, IAs are performed after accrual of 32, 62, 92, and 120 cases in participants without evidence of infection before vaccination. Note that although the first IA was not performed, the statistical criterion for demonstrating success (posterior probability threshold) at the interim (>0.995) and final (>0.986) analyses remains unchanged. Similarly, the futility boundaries are not changed.

**Table 6. Interim Analysis Plan and Boundaries for Efficacy and Futility**

| Analysis | Number of Cases | Success Criteria[a] | Futility Boundary |
|---|---|---|---|
| | | VE Point Estimate (Case Split) | VE Point Estimate (Case Split) |
| IA1 | 32 | 76.9% (6:26) | 11.8% (15:17) |
| IA2 | 62 | 68.1% (15:47) | 27.8% (26:36) |
| IA3 | 92 | 62.7% (25:67) | 38.6% (35:57) |
| IA4 | 120 | 58.8% (35:85) | N/A |
| Final | 164 | 52.3% (53:111) | |

Abbreviations: IA = interim analysis; N/A = not applicable; VE = vaccine efficacy.
Note: Case split = vaccine : placebo.
a. Interim efficacy claim: P(VE >30%|data) > 0.995; success at the final analysis: P(VE >30%|data) > 0.986.

Additional design operating characteristics (the boundary based on the number of cases observed in the vaccine group; the probabilities for efficacy and futility given assumed various VEs with a 1:1 randomization ratio) are listed in Table 7 and Table 8, for IAs conducted at 32, 62, 92, and 120 cases and the final analysis at 164 cases. Although the IA at 32 cases was not performed, the overall Type I error (overall probability of success when true VE=30%) will still be strictly controlled at 0.025 with the originally proposed success/futility boundaries.

**Table 7. Statistical Design Operating Characteristics: Probability of Success or Failure for Interim Analyses**

| Vaccine Efficacy (%) | Interim Analysis 1 (Total Cases = 32) | | Interim Analysis 2 (Total Cases = 62) | | Interim Analysis 3 (Total Cases = 92) | | Interim Analysis 4 (Total Cases = 120) |
|---|---|---|---|---|---|---|---|
| | Probability of Success (Cases in Vaccine Group ≤6) | Probability of Failure (Cases in Vaccine Group ≥15) | Probability of Success (Cases in Vaccine Group ≤15) | Probability of Failure (Cases in Vaccine Group ≥26) | Probability of Success (Cases in Vaccine Group ≤25) | Probability of Failure (Cases in Vaccine Group ≥35) | Probability of Success (Cases Vaccine Group ≤35) |
| 30 | 0.006 | 0.315 | 0.003 | 0.231 | 0.002 | 0.239 | 0.002 |
| 50 | 0.054 | 0.078 | 0.051 | 0.056 | 0.063 | 0.103 | 0.075 |
| 60 | 0.150 | 0.021 | 0.160 | 0.010 | 0.175 | 0.019 | 0.160 |
| 70 | 0.368 | 0.003 | 0.310 | <0.001 | 0.195 | 0.001 | 0.085 |
| 80 | 0.722 | <0.001 | 0.238 | <0.001 | 0.037 | <0.001 | 0.003 |

**Table 8. Statistical Design Operating Characteristics: Probability of Success for Final Analysis and Overall**

| Vaccine Efficacy (%) | Final Analysis (Total Cases = 164) | Overall Probability of Success |
|---|---|---|
| | Probability of Success (Cases in Vaccine Group ≤53) | |
| 30 | 0.007 | 0.021 |
| 50 | 0.196 | 0.439 |
| 60 | 0.220 | 0.866 |
| 70 | 0.036 | >0.999 |
| 80 | <0.001 | >0.999 |

If neither success nor futility has been declared after all IAs, the final analysis will be performed and the first primary objective will have been met if there are 53 or fewer cases observed in the vaccine group out of a total of 164 first confirmed cases from 7 days after receipt of the second dose of investigational product onwards.

Only the first primary endpoint will be analyzed at IA. If the first primary objective is met, the second primary objective will be evaluated at the final analysis. After the primary objectives are met, the first 6 secondary VE endpoints (confirmed COVID-19 occurring from 14 days after the second dose in participants without evidence of infection and in all participants, confirmed severe COVID-19 occurring from 7 days and from 14 days after the second dose in participants without evidence of infection and in all participants) will be evaluated sequentially in the stated order, by the same method used for the evaluation of primary VE endpoints. Success thresholds for secondary VE endpoints will be appropriately chosen to control overall Type I error at 2.5%. Further details will be provided in the SAP. The remaining secondary VE endpoints will be evaluated descriptively to calculate the observed VE with 95% CIs.

### 9.5.1. Analysis Timing

Statistical analyses will be carried out when the following data are available:

- Complete safety and immunogenicity analysis approximately 1 month after Dose 2 for Phase 1.
- Safety data through 7 days after Dose 2 and immunogenicity data through 1 month after Dose 2 from the first 360 participants enrolled (180 to active vaccine and 180 to placebo, stratified equally between 18 to 55 years and >55 to 85 years) in Phase 2/3.
- Safety data through 1 month after Dose 2 from at least 6000 participants enrolled (3000 to active vaccine and 3000 to placebo) in Phase 2/3. Additional analyses of safety data (with longer follow-up and/or additional participants) may be conducted if required for regulatory purposes.
- IAs for efficacy after accrual of at least 62, 92, and 120 cases and futility after accrual of at least 62 and 92 cases.
- Safety data through 1 month after Dose 2 and noninferiority comparison of SARS-CoV-2 neutralizing titers in participants 12 to 15 years of age compared to those in participants 16 to 25 years of age, 1 month after Dose 2.
- Descriptive analysis of immunogenicity and safety of "Process 1" and "Process 2" material, 1 month after Dose 2.
- Complete safety and immunogenicity analysis approximately 6 months after Dose 2 for all participants in Phase 2/3.
- Complete efficacy and persistence-of-immunogenicity analysis after complete data are available or at the end of the study.

All analyses conducted on Phase 2/3 data while the study is ongoing will be performed by an unblinded statistical team.

## 9.6. Data Monitoring Committee or Other Independent Oversight Committee

This study will use an IRC, a DMC, and a group of internal case reviewers. The IRC is independent of the study team and includes only internal members. The DMC is independent of the study team and includes only external members. The IRC and DMC charters describe the role of the IRC and DMC in more detail.

The responsibilities of the IRC are only in Phase 1 and will include:

- Review of safety data to permit dose escalations in the 18- to 55-year age cohort
- Review of safety data in the case of a stopping rule being met

- Review of safety and/or immunogenicity data to:
  - Allow groups of participants of 65 to 85 years of age to proceed
  - Select vaccine candidate/dose level(s) to proceed into Phase 2/3. Data supporting the selection, including results for both binding antibody levels and neutralizing titers, and the ratio between them, will also be submitted to the FDA for review
- Review of any available safety and/or immunogenicity data generated during the course of this study, or the BioNTech study conducted in Germany, to determine:
  - Whether any groups may not be started
  - Whether any groups may be terminated early
  - Whether any groups may be added with dose levels below the lowest stated dose or intermediate between the lowest and highest stated doses
- Contemporaneous review of all NAAT-confirmed COVID-19 illnesses in Phase 1

The DMC will be responsible for ongoing monitoring of the safety of participants in the study according to the charter. This may include, but is not limited to:

- Contemporaneous review of related AEs up to 1 month after completion of the vaccination schedule
- Contemporaneous review of all SAEs up to 6 months after completion of the vaccination schedule
- Contemporaneous review of all NAAT-confirmed COVID-19 illnesses in Phase 1
- At the time of the planned IAs, and ad hoc if requested by the unblinded team, review of cases of COVID-19 for an adverse imbalance of cases of COVID-19 and/or severe COVID-19 between the vaccine and placebo groups

The recommendations made by the DMC to alter the conduct of the study will be forwarded to the appropriate Pfizer personnel for final decision. Pfizer will forward such decisions, which may include summaries of aggregate analyses of safety data, to regulatory authorities, as appropriate.

Three blinded case reviewers (medically qualified Pfizer staff members) will review all potential COVID-19 illness events. If a NAAT-confirmed case in Phase 2/3 may be considered severe, or not, solely on the basis of "significant acute renal, hepatic, or neurologic dysfunction," the blinded data will be reviewed by the case reviewers to assess whether the criterion is met; the majority opinion will prevail.

# 10. SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

## 10.1. Appendix 1: Regulatory, Ethical, and Study Oversight Considerations

### 10.1.1. Regulatory and Ethical Considerations

This study will be conducted in accordance with the protocol and with the following:

- Consensus ethical principles derived from international guidelines including the Declaration of Helsinki and CIOMS International Ethical Guidelines;
- Applicable ICH GCP guidelines;
- Applicable laws and regulations, including applicable privacy laws.

The protocol, protocol amendments, ICD, SRSD(s), and other relevant documents (eg, advertisements) must be reviewed and approved by the sponsor and submitted to an IRB/EC by the investigator and reviewed and approved by the IRB/EC before the study is initiated.

Any amendments to the protocol will require IRB/EC approval before implementation of changes made to the study design, except for changes necessary to eliminate an immediate hazard to study participants.

The investigator will be responsible for the following:

- Providing written summaries of the status of the study to the IRB/EC annually or more frequently in accordance with the requirements, policies, and procedures established by the IRB/EC;
- Notifying the IRB/EC of SAEs or other significant safety findings as required by IRB/EC procedures;
- Providing oversight of the conduct of the study at the site and adherence to requirements of 21 CFR, ICH guidelines, the IRB/EC, European regulation 536/2014 for clinical studies (if applicable), and all other applicable local regulations.

#### 10.1.1.1. Reporting of Safety Issues and Serious Breaches of the Protocol or ICH GCP

In the event of any prohibition or restriction imposed (ie, clinical hold) by an applicable regulatory authority in any area of the world, or if the investigator is aware of any new information that might influence the evaluation of the benefits and risks of the study intervention, Pfizer should be informed immediately.

In addition, the investigator will inform Pfizer immediately of any urgent safety measures taken by the investigator to protect the study participants against any immediate hazard, and of any serious breaches of this protocol or of ICH GCP that the investigator becomes aware of.

### 10.1.2. Informed Consent Process

The investigator or his/her representative will explain the nature of the study to the participant or his or her parent(s)/legal guardian and answer all questions regarding the study. The participant or his or her parent(s)/legal guardian should be given sufficient time and opportunity to ask questions and to decide whether or not to participate in the trial.

Participants must be informed that their participation is voluntary. Participants or their parent(s)/legal guardian will be required to sign a statement of informed consent that meets the requirements of 21 CFR 50, local regulations, ICH guidelines, HIPAA requirements, where applicable, and the IRB/EC or study center.

The investigator must ensure that each study participant or his or her parent(s)/legal guardian is fully informed about the nature and objectives of the study, the sharing of data related to the study, and possible risks associated with participation, including the risks associated with the processing of the participant's personal data.

The participant must be informed that his/her personal study-related data will be used by the sponsor in accordance with local data protection law. The level of disclosure must also be explained to the participant.

The participant must be informed that his/her medical records may be examined by Clinical Quality Assurance auditors or other authorized personnel appointed by the sponsor, by appropriate IRB/EC members, and by inspectors from regulatory authorities.

The investigator further must ensure that each study participant or his or her parent(s)/legal guardian is fully informed about his or her right to access and correct his or her personal data and to withdraw consent for the processing of his or her personal data.

The medical record must include a statement that written informed consent was obtained before the participant was enrolled in the study and the date the written consent was obtained. The authorized person obtaining the informed consent must also sign the ICD.

Participants must be reconsented to the most current version of the ICD(s) during their participation in the study.

A copy of the ICD(s) must be provided to the participant or his or her parent(s)/legal guardian. Participants who are rescreened are required to sign a new ICD.

Unless prohibited by local requirements or IRB/EC decision, the ICD will contain a separate section that addresses the use of samples for optional additional research. The optional additional research does not require the collection of any further samples. The investigator or authorized designee will explain to each participant the objectives of the additional research. Participants will be told that they are free to refuse to participate and may withdraw their consent at any time and for any reason during the storage period.

### 10.1.3. Data Protection

All parties will comply with all applicable laws, including laws regarding the implementation of organizational and technical measures to ensure protection of participant data.

Participants' personal data will be stored at the study site in encrypted electronic and/or paper form and will be password protected or secured in a locked room to ensure that only authorized study staff have access. The study site will implement appropriate technical and organizational measures to ensure that the personal data can be recovered in the event of disaster. In the event of a potential personal data breach, the study site will be responsible for determining whether a personal data breach has in fact occurred and, if so, providing breach notifications as required by law.

To protect the rights and freedoms of participants with regard to the processing of personal data, participants will be assigned a single, participant-specific numerical code. Any participant records or data sets that are transferred to the sponsor will contain the numerical code; participant names will not be transferred. All other identifiable data transferred to the sponsor will be identified by this single, participant-specific code. The study site will maintain a confidential list of participants who participated in the study, linking each participant's numerical code to his or her actual identity and medical record identification. In case of data transfer, the sponsor will protect the confidentiality of participants' personal data consistent with the clinical study agreement and applicable privacy laws.

### 10.1.4. Dissemination of Clinical Study Data

Pfizer fulfills its commitment to publicly disclose clinical study results through posting the results of studies on www.clinicaltrials.gov (ClinicalTrials.gov), the EudraCT, and/or www.pfizer.com, and other public registries in accordance with applicable local laws/regulations. In addition, Pfizer reports study results outside of the requirements of local laws/regulations pursuant to its SOPs.

In all cases, study results are reported by Pfizer in an objective, accurate, balanced, and complete manner and are reported regardless of the outcome of the study or the country in which the study was conducted.

www.clinicaltrials.gov

Pfizer posts clinical trial results on www.clinicaltrials.gov for Pfizer-sponsored interventional studies (conducted in patients) that evaluate the safety and/or efficacy of a product, regardless of the geographical location in which the study is conducted. These results are submitted for posting in accordance with the format and timelines set forth by US law.

EudraCT

Pfizer posts clinical trial results on EudraCT for Pfizer-sponsored interventional studies in accordance with the format and timelines set forth by EU requirements.

www.pfizer.com

Pfizer posts public disclosure synopses (CSR synopses in which any data that could be used to identify individual participants have been removed) on www.pfizer.com for Pfizer-sponsored interventional studies at the same time the corresponding study results are posted to www.clinicaltrials.gov.

Documents within marketing authorization packages/submissions

Pfizer complies with the European Union Policy 0070, the proactive publication of clinical data to the EMA website. Clinical data, under Phase 1 of this policy, includes clinical overviews, clinical summaries, CSRs, and appendices containing the protocol and protocol amendments, sample CRFs, and statistical methods. Clinical data, under Phase 2 of this policy, includes the publishing of individual participant data. Policy 0070 applies to new marketing authorization applications submitted via the centralized procedure since 01 January 2015 and applications for line extensions and for new indications submitted via the centralized procedure since 01 July 2015.

Data Sharing

Pfizer provides researchers secure access to patient-level data or full CSRs for the purposes of "bona-fide scientific research" that contributes to the scientific understanding of the disease, target, or compound class. Pfizer will make available data from these trials 24 months after study completion. Patient-level data will be anonymized in accordance with applicable privacy laws and regulations. CSRs will have personally identifiable information redacted.

Data requests are considered from qualified researchers with the appropriate competencies to perform the proposed analyses. Research teams must include a biostatistician. Data will not be provided to applicants with significant conflicts of interest, including individuals requesting access for commercial/competitive or legal purposes.

### 10.1.5. Data Quality Assurance

All participant data relating to the study will be recorded on printed or electronic CRF unless transmitted to the sponsor or designee electronically (eg, laboratory data). The investigator is responsible for verifying that data entries are accurate and correct by physically or electronically signing the CRF.

The investigator must maintain accurate documentation (source data) that supports the information entered in the CRF.

The investigator must ensure that the CRFs are securely stored at the study site in encrypted electronic and/or paper form and are password protected or secured in a locked room to prevent access by unauthorized third parties.

The investigator must permit study-related monitoring, audits, IRB/EC review, and regulatory agency inspections and provide direct access to source data documents. This verification may also occur after study completion. It is important that the investigator(s)

and their relevant personnel are available during the monitoring visits and possible audits or inspections and that sufficient time is devoted to the process.

Monitoring details describing strategy (eg, risk-based initiatives in operations and quality such as risk management and mitigation strategies and analytical risk-based monitoring), methods, responsibilities, and requirements, including handling of noncompliance issues and monitoring techniques (central, remote, or on-site monitoring), are provided in the monitoring plan.

The sponsor or designee is responsible for the data management of this study, including quality checking of the data.

Study monitors will perform ongoing source data verification to confirm that data entered into the CRF by authorized site personnel are accurate, complete, and verifiable from source documents; that the safety and rights of participants are being protected; and that the study is being conducted in accordance with the currently approved protocol and any other study agreements, ICH GCP, and all applicable regulatory requirements.

Records and documents, including signed ICDs, pertaining to the conduct of this study must be retained by the investigator for 15 years after study completion unless local regulations or institutional policies require a longer retention period. No records may be destroyed during the retention period without the written approval of the sponsor. No records may be transferred to another location or party without written notification to the sponsor. The investigator must ensure that the records continue to be stored securely for as long as they are maintained.

When participant data are to be deleted, the investigator will ensure that all copies of such data are promptly and irrevocably deleted from all systems.

The investigator(s) will notify the sponsor or its agents immediately of any regulatory inspection notification in relation to the study. Furthermore, the investigator will cooperate with the sponsor or its agents to prepare the investigator site for the inspection and will allow the sponsor or its agent, whenever feasible, to be present during the inspection. The investigator site and investigator will promptly resolve any discrepancies that are identified between the study data and the participant's medical records. The investigator will promptly provide copies of the inspection findings to the sponsor or its agent. Before response submission to the regulatory authorities, the investigator will provide the sponsor or its agents with an opportunity to review and comment on responses to any such findings.

### 10.1.6. Source Documents

Source documents provide evidence for the existence of the participant and substantiate the integrity of the data collected. Source documents are filed at the investigator site.

Data reported on the CRF or entered in the eCRF that are from source documents must be consistent with the source documents or the discrepancies must be explained. The

investigator may need to request previous medical records or transfer records, depending on the study. Also, current medical records must be available.

Definition of what constitutes source data can be found in the study monitoring plan.

Description of the use of computerized system is documented in the Data Management Plan.

### 10.1.7. Study and Site Start and Closure

The study start date is the date on which the clinical study will be open for recruitment of participants.

The first act of recruitment is the date of the first participant's first visit and will be the study start date.

The sponsor designee reserves the right to close the study site or terminate the study at any time for any reason at the sole discretion of the sponsor. Study sites will be closed upon study completion. A study site is considered closed when all required documents and study supplies have been collected and a study-site closure visit has been performed.

The investigator may initiate study-site closure at any time upon notification to the sponsor or designee if requested to do so by the responsible IRB/EC or if such termination is required to protect the health of study participants.

Reasons for the early closure of a study site by the sponsor may include but are not limited to:

- Failure of the investigator to comply with the protocol, the requirements of the IRB/EC or local health authorities, the sponsor's procedures, or GCP guidelines;
- Inadequate recruitment of participants by the investigator;
- Discontinuation of further study intervention development.

If the study is prematurely terminated or suspended, the sponsor shall promptly inform the investigators, the ECs/IRBs, the regulatory authorities, and any CRO(s) used in the study of the reason for termination or suspension, as specified by the applicable regulatory requirements. The investigator shall promptly inform the participant and should assure appropriate participant therapy and/or follow-up.

Study termination is also provided for in the clinical study agreement. If there is any conflict between the contract and this protocol, the contract will control as to termination rights.

### 10.1.8. Sponsor's Qualified Medical Personnel

The contact information for the sponsor's appropriately qualified medical personnel for the study is documented in the study contact list located in the supporting study documentation.

To facilitate access to appropriately qualified medical personnel on study-related medical questions or problems, participants are provided with a contact card at the time of informed consent. The contact card contains, at a minimum, protocol and study intervention identifiers, participant numbers, contact information for the investigator site, and contact details for a contact center in the event that the investigator site staff cannot be reached to provide advice on a medical question or problem originating from another healthcare professional not involved in the participant's participation in the study. The contact number can also be used by investigator staff if they are seeking advice on medical questions or problems; however, it should be used only in the event that the established communication pathways between the investigator site and the study team are not available. It is therefore intended to augment, but not replace, the established communication pathways between the investigator site and the study team for advice on medical questions or problems that may arise during the study. The contact number is not intended for use by the participant directly, and if a participant calls that number, he or she will be directed back to the investigator site.

## 10.2. Appendix 2: Clinical Laboratory Tests

The following safety laboratory tests will be performed at times defined in the SoA section of this protocol. Additional laboratory results may be reported on these samples as a result of the method of analysis or the type of analyzer used by the clinical laboratory, or as derived from calculated values. These additional tests would not require additional collection of blood. Unscheduled clinical laboratory measurements may be obtained at any time during the study to assess any perceived safety issues.

| Hematology | Chemistry | Other |
|---|---|---|
| Hemoglobin<br>Hematocrit<br>RBC count<br>MCV<br>MCH<br>MCHC<br>Platelet count<br>WBC count<br>Total neutrophils (Abs)<br>Eosinophils (Abs)<br>Monocytes (Abs)<br>Basophils (Abs)<br>Lymphocytes (Abs) | BUN and creatinine<br>AST, ALT<br>Total bilirubin<br>Alkaline phosphatase | • Urine pregnancy test (β-hCG)<br>At screening only:<br>• Hepatitis B core antibody<br>• Hepatitis B surface antigen<br>• Hepatitis C antibody<br>• Human immunodeficiency virus |

Investigators must document their review of each laboratory safety report.

Clinically significant abnormal laboratory findings should be recorded in the AE CRF in accordance with the following grading scale (Table 9).

**Table 9. Laboratory Abnormality Grading Scale**

| Hematology | Mild (Grade 1) | Moderate (Grade 2) | Severe (Grade 3) | Potentially Life Threatening (Grade 4) |
|---|---|---|---|---|
| Hemoglobin (Female) - g/dL | 11.0 – 12.0 | 9.5 – 10.9 | 8.0 – 9.4 | <8.0 |
| Hemoglobin (Male) - g/dL | 12.5 – 13.5 | 10.5 – 12.4 | 8.5 – 10.4 | <8.5 |
| WBC increase - cells/$mm^3$ | 10,800 – 15,000 | 15,001 – 20,000 | 20,001 – 25, 000 | >25,000 |
| WBC decrease - cells/$mm^3$ | 2,500 – 3,500 | 1,500 – 2,499 | 1,000 – 1,499 | <1,000 |
| Lymphocytes decrease - cells/$mm^3$ | 750 – 1,000 | 500 – 749 | 250 – 499 | <250 |
| Neutrophils decrease - cells/$mm^3$ | 1,500 – 2,000 | 1,000 – 1,499 | 500 – 999 | <500 |
| Eosinophils - cells/$mm^3$ | 650 – 1500 | 1501 - 5000 | >5000 | Hypereosinophilic |
| Platelets decreased - cells/$mm^3$ | 125,000 – 140,000 | 100,000 – 124,000 | 25,000 – 99,000 | <25,000 |

## Table 9. Laboratory Abnormality Grading Scale

| Chemistry | Mild (Grade 1) | Moderate (Grade 2) | Severe (Grade 3) | Potentially Life Threatening (Grade 4) |
|---|---|---|---|---|
| BUN - mg/dL | 23 – 26 | 27 – 31 | > 31 | Requires dialysis |
| Creatinine – mg/dL | 1.5 – 1.7 | 1.8 – 2.0 | 2.1 – 2.5 | > 2.5 or requires dialysis |
| Alkaline phosphate – increase by factor | 1.1 – 2.0 x ULN | 2.1 – 3.0 x ULN | 3.1 – 10 x ULN | >10 x ULN |
| Liver function tests – ALT, AST increase by factor | 1.1 – 2.5 x ULN | 2.6 – 5.0 x ULN | 5.1 – 10 x ULN | >10 x ULN |
| Bilirubin – when accompanied by any increase in liver function test - increase by factor | 1.1 – 1.25 x ULN | 1.26 – 1.5 x ULN | 1.51 – 1.75 x ULN | >1.75 x ULN |
| Bilirubin – when liver function test is normal - increase by factor | 1.1 – 1.5 x ULN | 1.6 – 2.0 x ULN | 2.0 – 3.0 x ULN | >3.0 x ULN |

Abbreviations: ALT = alanine aminotransferase; AST = aspartate aminotransferase; BUN = blood urea nitrogen; ULN = upper limit of normal; WBC = white blood cell.

## 10.3. Appendix 3: Adverse Events: Definitions and Procedures for Recording, Evaluating, Follow-up, and Reporting

### 10.3.1. Definition of AE

**AE Definition**

- An AE is any untoward medical occurrence in a patient or clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention.
- NOTE: An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of study intervention.

**Events Meeting the AE Definition**

- Any abnormal laboratory test results (hematology, clinical chemistry, or urinalysis) or other safety assessments (eg, ECG, radiological scans, vital sign measurements), including those that worsen from baseline, considered clinically significant in the medical and scientific judgment of the investigator Any abnormal laboratory test results that meet any of the conditions below must be recorded as an AE:
  - Is associated with accompanying symptoms.
  - Requires additional diagnostic testing or medical/surgical intervention.
  - Leads to a change in study dosing (outside of any protocol-specified dose adjustments) or discontinuation from the study, significant additional concomitant drug treatment, or other therapy.
- Exacerbation of a chronic or intermittent preexisting condition including either an increase in frequency and/or intensity of the condition.
- New conditions detected or diagnosed after study intervention administration even though it may have been present before the start of the study.
- Signs, symptoms, or the clinical sequelae of a suspected drug-drug interaction.
- Signs, symptoms, or the clinical sequelae of a suspected overdose of either study intervention or a concomitant medication. Overdose per se will not be reported as an AE/SAE unless it is an intentional overdose taken with possible suicidal/self-harming intent. Such overdoses should be reported regardless of sequelae.

| **Events NOT Meeting the AE Definition** |
|---|
| • Any clinically significant abnormal laboratory findings or other abnormal safety assessments which are associated with the underlying disease, unless judged by the investigator to be more severe than expected for the participant's condition.<br><br>• The disease/disorder being studied or expected progression, signs, or symptoms of the disease/disorder being studied, unless more severe than expected for the participant's condition.<br><br>• Medical or surgical procedure (eg, endoscopy, appendectomy): the condition that leads to the procedure is the AE.<br><br>• Situations in which an untoward medical occurrence did not occur (social and/or convenience admission to a hospital).<br><br>• Anticipated day-to-day fluctuations of preexisting disease(s) or condition(s) present or detected at the start of the study that do not worsen. |

### 10.3.2. Definition of SAE

If an event is not an AE per definition above, then it cannot be an SAE even if serious conditions are met (eg, hospitalization for signs/symptoms of the disease under study, death due to progression of disease).

| **An SAE is defined as any untoward medical occurrence that, at any dose:** |
|---|
| **a. Results in death** |
| **b. Is life-threatening**<br><br>The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event. It does not refer to an event that hypothetically might have caused death if it were more severe. |
| **c. Requires inpatient hospitalization or prolongation of existing hospitalization**<br><br>In general, hospitalization signifies that the participant has been detained (usually involving at least an overnight stay) at the hospital or emergency ward for observation and/or treatment that would not have been appropriate in the physician's office or outpatient setting. Complications that occur during hospitalization are AEs. If a complication prolongs hospitalization or fulfills any other serious criteria, the event is serious. When in doubt as to whether "hospitalization" occurred or was necessary, the AE should be considered serious. |

Hospitalization for elective treatment of a preexisting condition that did not worsen from baseline is not considered an AE.

**d. Results in persistent disability/incapacity**

- The term disability means a substantial disruption of a person's ability to conduct normal life functions.
- This definition is not intended to include experiences of relatively minor medical significance such as uncomplicated headache, nausea, vomiting, diarrhea, influenza, and accidental trauma (eg, sprained ankle) which may interfere with or prevent everyday life functions but do not constitute a substantial disruption.

**e. Is a congenital anomaly/birth defect**

**f. Other situations:**

- Medical or scientific judgment should be exercised in deciding whether SAE reporting is appropriate in other situations such as important medical events that may not be immediately life-threatening or result in death or hospitalization but may jeopardize the participant or may require medical or surgical intervention to prevent one of the other outcomes listed in the above definition. These events should usually be considered serious.
- Examples of such events include invasive or malignant cancers, intensive treatment in an emergency room or at home for allergic bronchospasm, blood dyscrasias or convulsions that do not result in hospitalization, or development of drug dependency or drug abuse.
- Suspected transmission via a Pfizer product of an infectious agent, pathogenic or nonpathogenic, is considered serious. The event may be suspected from clinical symptoms or laboratory findings indicating an infection in a patient exposed to a Pfizer product. The terms "suspected transmission" and "transmission" are considered synonymous. These cases are considered unexpected and handled as serious expedited cases by pharmacovigilance personnel. Such cases are also considered for reporting as product defects, if appropriate.

### 10.3.3. Recording/Reporting and Follow-up of AEs and/or SAEs

**AE and SAE Recording/Reporting**

The table below summarizes the requirements for recording adverse events on the CRF and for reporting serious adverse events on the Vaccine SAE Report Form to Pfizer Safety. These requirements are delineated for 3 types of events: (1) SAEs; (2) nonserious adverse events (AEs); and (3) exposure to the study intervention under study during pregnancy or breastfeeding, and occupational exposure.

It should be noted that the Vaccine SAE Report Form for reporting of SAE information is not the same as the AE page of the CRF. When the same data are collected, the forms must be completed in a consistent manner. AEs should be recorded using concise medical terminology and the same AE term should be used on both the CRF and the Vaccine SAE Report Form for reporting of SAE information.

| **Safety Event** | **Recorded on the CRF** | **Reported on the Vaccine SAE Report Form to Pfizer Safety Within 24 Hours of Awareness** |
|---|---|---|
| SAE | All | All |
| Nonserious AE | All | None |
| Exposure to the study intervention under study during pregnancy or breastfeeding, and occupational exposure | All AEs/SAEs associated with exposure during pregnancy or breastfeeding<br><br>Occupational exposure is not recorded. | All (and EDP supplemental form for EDP)<br>Note: Include all SAEs associated with exposure during pregnancy or breastfeeding. Include all AEs/SAEs associated with occupational exposure. |

- When an AE/SAE occurs, it is the responsibility of the investigator to review all documentation (eg, hospital progress notes, laboratory reports, and diagnostic reports) related to the event.
- The investigator will then record all relevant AE/SAE information in the CRF.
- It is **not** acceptable for the investigator to send photocopies of the participant's medical records to Pfizer Safety in lieu of completion of the Vaccine SAE Report Form/AE/SAE CRF page.
- There may be instances when copies of medical records for certain cases are requested by Pfizer Safety. In this case, all participant identifiers, with the

exception of the participant number, will be redacted on the copies of the medical records before submission to Pfizer Safety.

- The investigator will attempt to establish a diagnosis of the event based on signs, symptoms, and/or other clinical information. Whenever possible, the diagnosis (not the individual signs/symptoms) will be documented as the AE/SAE.

**Assessment of Intensity**

The investigator will make an assessment of intensity for each AE and SAE reported during the study and assign it to 1 of the following categories:

| | | |
|---|---|---|
| GRADE | If required on the AE page of the CRF, the investigator will use the adjectives MILD, MODERATE, SEVERE, or LIFE-THREATENING to describe the maximum intensity of the AE. For purposes of consistency, these intensity grades are defined as follows: | |
| 1 | MILD | Does not interfere with participant's usual function. |
| 2 | MODERATE | Interferes to some extent with participant's usual function. |
| 3 | SEVERE | Interferes significantly with participant's usual function. |
| 4 | LIFE-THREATENING | Life-threatening consequences; urgent intervention indicated. |

**Assessment of Causality**

- The investigator is obligated to assess the relationship between study intervention and each occurrence of each AE/SAE.
- A “reasonable possibility” of a relationship conveys that there are facts, evidence, and/or arguments to suggest a causal relationship, rather than a relationship cannot be ruled out.
- The investigator will use clinical judgment to determine the relationship.
- Alternative causes, such as underlying disease(s), concomitant therapy, and other risk factors, as well as the temporal relationship of the event to study intervention administration, will be considered and investigated.

- The investigator will also consult the IB and/or product information, for marketed products, in his/her assessment.

- For each AE/SAE, the investigator **must** document in the medical notes that he/she has reviewed the AE/SAE and has provided an assessment of causality.

- There may be situations in which an SAE has occurred and the investigator has minimal information to include in the initial report to the sponsor. However, **it is very important that the investigator always make an assessment of causality for every event before the initial transmission of the SAE data to the sponsor.**

- The investigator may change his/her opinion of causality in light of follow-up information and send an SAE follow-up report with the updated causality assessment.

- The causality assessment is one of the criteria used when determining regulatory reporting requirements.

- If the investigator does not know whether or not the study intervention caused the event, then the event will be handled as "related to study intervention" for reporting purposes, as defined by the sponsor. In addition, if the investigator determines that an SAE is associated with study procedures, the investigator must record this causal relationship in the source documents and CRF, and report such an assessment in the dedicated section of the Vaccine SAE Report Form and in accordance with the SAE reporting requirements.

**Follow-up of AEs and SAEs**

- The investigator is obligated to perform or arrange for the conduct of supplemental measurements and/or evaluations as medically indicated or as requested by the sponsor to elucidate the nature and/or causality of the AE or SAE as fully as possible. This may include additional laboratory tests or investigations, histopathological examinations, or consultation with other healthcare providers.

- If a participant dies during participation in the study or during a recognized follow-up period, the investigator will provide Pfizer Safety with a copy of any postmortem findings including histopathology.

- New or updated information will be recorded in the originally completed CRF.

- The investigator will submit any updated SAE data to the sponsor within 24 hours of receipt of the information.

### 10.3.4. Reporting of SAEs

| **SAE Reporting to Pfizer Safety via Vaccine SAE Report Form** |
| --- |
| • Facsimile transmission of the Vaccine SAE Report Form is the preferred method to transmit this information to Pfizer Safety.<br><br>• In circumstances when the facsimile is not working, notification by telephone is acceptable with a copy of the Vaccine SAE Report Form sent by overnight mail or courier service.<br><br>• Initial notification via telephone does not replace the need for the investigator to complete and sign the Vaccine SAE Report Form pages within the designated reporting time frames. |

## 10.4. Appendix 4: Contraceptive Guidance

### 10.4.1. Male Participant Reproductive Inclusion Criteria

Male participants are eligible to participate if they agree to the following requirements during the intervention period and for at least 28 days after the last dose of study intervention, which corresponds to the time needed to eliminate reproductive safety risk of the study intervention(s):

- Refrain from donating sperm.

PLUS either**:**

- Be abstinent from heterosexual intercourse with a female of childbearing potential as their preferred and usual lifestyle (abstinent on a long-term and persistent basis) and agree to remain abstinent.

OR

- Must agree to use a male condom when engaging in any activity that allows for passage of ejaculate to another person.
- In addition to male condom use, a highly effective method of contraception may be considered in WOCBP partners of male participants (refer to the list of highly effective methods below in Section 10.4.4).

### 10.4.2. Female Participant Reproductive Inclusion Criteria

A female participant is eligible to participate if she is not pregnant or breastfeeding, and at least 1 of the following conditions applies:

- Is not a WOCBP (see definitions below in Section 10.4.3).

OR

- Is a WOCBP and using an acceptable contraceptive method as described below during the intervention period (for a minimum of 28 days after the last dose of study intervention). The investigator should evaluate the effectiveness of the contraceptive method in relationship to the first dose of study intervention.

The investigator is responsible for review of medical history, menstrual history, and recent sexual activity to decrease the risk for inclusion of a woman with an early undetected pregnancy.

### 10.4.3. Woman of Childbearing Potential

A woman is considered fertile following menarche and until becoming postmenopausal unless permanently sterile (see below).

If fertility is unclear (eg, amenorrhea in adolescents or athletes) and a menstrual cycle cannot be confirmed before the first dose of study intervention, additional evaluation should be considered.

Women in the following categories are not considered WOCBP:

1. Premenarchal.

2. Premenopausal female with 1 of the following:

    - Documented hysterectomy;

    - Documented bilateral salpingectomy;

    - Documented bilateral oophorectomy.

For individuals with permanent infertility due to an alternate medical cause other than the above, (eg, mullerian agenesis, androgen insensitivity), investigator discretion should be applied to determining study entry.

Note: Documentation for any of the above categories can come from the site personnel's review of the participant's medical records, medical examination, or medical history interview. The method of documentation should be recorded in the participant's medical record for the study.

3. Postmenopausal female:

    - A postmenopausal state is defined as no menses for 12 months without an alternative medical cause. In addition, a

        - high FSH level in the postmenopausal range must be used to confirm a postmenopausal state in women under 60 years of age and not using hormonal contraception or HRT.

        - Female on HRT and whose menopausal status is in doubt will be required to use one of the nonestrogen hormonal highly effective contraception methods if they wish to continue their HRT during the study. Otherwise, they must discontinue HRT to allow confirmation of postmenopausal status before study enrollment.

### 10.4.4. Contraception Methods

Contraceptive use by men or women should be consistent with local availability/regulations regarding the use of contraceptive methods for those participating in clinical trials.

1. Implantable progestogen-only hormone contraception associated with inhibition of ovulation.

2. Intrauterine device.

3. Intrauterine hormone-releasing system.

4. Bilateral tubal occlusion.

5. Vasectomized partner:

    - Vasectomized partner is a highly effective contraceptive method provided that the partner is the sole sexual partner of the woman of childbearing potential and the absence of sperm has been confirmed. If not, an additional highly effective method of contraception should be used. The spermatogenesis cycle is approximately 90 days.

6. Combined (estrogen- and progestogen-containing) hormonal contraception associated with inhibition of ovulation:

    - Oral;

    - Intravaginal;

    - Transdermal;

    - Injectable.

7. Progestogen-only hormone contraception associated with inhibition of ovulation:

    - Oral;

    - Injectable.

8. Sexual abstinence:

    - Sexual abstinence is considered a highly effective method only if defined as refraining from heterosexual intercourse during the entire period of risk associated with the study intervention. The reliability of sexual abstinence needs to be evaluated in relation to the duration of the study and the preferred and usual lifestyle of the participant.

9. Progestogen-only oral hormonal contraception where inhibition of ovulation is not the primary mode of action.

10. Male or female condom with or without spermicide.

11. Cervical cap, diaphragm, or sponge with spermicide.

12. A combination of male condom with either cervical cap, diaphragm, or sponge with spermicide (double-barrier methods).

## 10.5. Appendix 5: Liver Safety: Suggested Actions and Follow-up Assessments

### Potential Cases of Drug-Induced Liver Injury

Humans exposed to a drug who show no sign of liver injury (as determined by elevations in transaminases) are termed “tolerators,” while those who show transient liver injury, but adapt are termed “adaptors.” In some participants, transaminase elevations are a harbinger of a more serious potential outcome. These participants fail to adapt and therefore are "susceptible" to progressive and serious liver injury, commonly referred to as DILI. Participants who experience a transaminase elevation above 3 × ULN should be monitored more frequently to determine if they are an “adaptor” or are “susceptible.”

LFTs are not required as a routine safety monitoring procedure for all participants in this study. However, should an investigator deem it necessary to assess LFTs because a participant presents with clinical signs/symptoms, such LFT results should be managed and followed as described below.

In the majority of DILI cases, elevations in AST and/or ALT precede TBili elevations (>2 × ULN) by several days or weeks. The increase in TBili typically occurs while AST/ALT is/are still elevated above 3 × ULN (ie, AST/ALT and TBili values will be elevated within the same laboratory sample). In rare instances, by the time TBili elevations are detected, AST/ALT values might have decreased. This occurrence is still regarded as a potential DILI. Therefore, abnormal elevations in either AST OR ALT in addition to TBili that meet the criteria outlined below are considered potential DILI (assessed per Hy’s law criteria) cases and should always be considered important medical events, even before all other possible causes of liver injury have been excluded.

The threshold of laboratory abnormalities for a potential DILI case depends on the participant’s individual baseline values and underlying conditions. Participants who present with the following laboratory abnormalities should be evaluated further as potential DILI (Hy’s law) cases to definitively determine the etiology of the abnormal laboratory values:

- Participants with AST/ALT and TBili baseline values within the normal range who subsequently present with AST OR ALT values >3 × ULN AND a TBili value >2 × ULN with no evidence of hemolysis and an alkaline phosphatase value <2 × ULN or not available.

- For participants with baseline AST **OR** ALT **OR** TBili values above the ULN, the following threshold values are used in the definition mentioned above, as needed, depending on which values are above the ULN at baseline:

    - Preexisting AST or ALT baseline values above the normal range: AST or ALT values >2 times the baseline values AND >3 × ULN; or >8 × ULN (whichever is smaller).

- Preexisting values of TBili above the normal range: TBili level increased from baseline value by an amount of at least 1 × ULN **or** if the value reaches >3 × ULN (whichever is smaller).

Rises in AST/ALT and TBili separated by more than a few weeks should be assessed individually based on clinical judgment; any case where uncertainty remains as to whether it represents a potential Hy's law case should be reviewed with the sponsor.

The participant should return to the investigator site and be evaluated as soon as possible, preferably within 48 hours from awareness of the abnormal results. This evaluation should include laboratory tests, detailed history, and physical assessment.

In addition to repeating measurements of AST and ALT and TBili for suspected cases of Hy's law, additional laboratory tests should include albumin, CK, direct and indirect bilirubin, GGT, PT/INR, total bile acids, and alkaline phosphatase. Consideration should also be given to drawing a separate tube of clotted blood and an anticoagulated tube of blood for further testing, as needed, for further contemporaneous analyses at the time of the recognized initial abnormalities to determine etiology. A detailed history, including relevant information, such as review of ethanol, acetaminophen/paracetamol (either by itself or as a coformulated product in prescription or over-the-counter medications), recreational drug, supplement (herbal) use and consumption, family history, sexual history, travel history, history of contact with a jaundiced person, surgery, blood transfusion, history of liver or allergic disease, and potential occupational exposure to chemicals, should be collected. Further testing for acute hepatitis A, B, C, D, and E infection and liver imaging (eg, biliary tract) and collection of serum samples for acetaminophen/paracetamol drug and/or protein adduct levels may be warranted.

All cases demonstrated on repeat testing as meeting the laboratory criteria of AST/ALT and TBili elevation defined above should be considered potential DILI (Hy's law) cases if no other reason for the LFT abnormalities has yet been found. **Such potential DILI (Hy's law) cases are to be reported as SAEs, irrespective of availability of all the results of the investigations performed to determine etiology of the LFT abnormalities.**

A potential DILI (Hy's law) case becomes a confirmed case only after all results of reasonable investigations have been received and have excluded an alternative etiology.

## 10.6. Appendix 6: Abbreviations

The following is a list of abbreviations that may be used in the protocol.

| Abbreviation | Term |
|---|---|
| 2019-nCoV | novel coronavirus 2019 |
| Abs | absolute (in Appendix 2) |
| AE | adverse event |
| ALT | alanine aminotransferase |
| AST | aspartate aminotransferase |
| β-hCG | beta-human chorionic gonadotropin |
| BMI | body mass index |
| BUN | blood urea nitrogen |
| CBER | Center for Biologics Evaluation and Research |
| CDC | Centers for Disease Control and Prevention (United States) |
| CFR | Code of Federal Regulations |
| CI | confidence interval |
| CIOMS | Council for International Organizations of Medical Sciences |
| CLIA | Clinical Laboratory Improvement Amendments |
| CONSORT | Consolidated Standards of Reporting Trials |
| COVID-19 | coronavirus disease 2019 |
| CRF | case report form |
| CRO | contract research organization |
| CSR | clinical study report |
| CT | computed tomography |
| DBP | diastolic blood pressure |
| DILI | drug-induced liver injury |
| DMC | data monitoring committee |
| DNA | deoxyribonucleic acid |
| DU | dosing unit |
| EC | ethics committee |
| ECMO | extracorporeal membrane oxygenation |
| ECG | electrocardiogram |
| eCRF | electronic case report form |
| e-diary | electronic diary |
| EDP | exposure during pregnancy |
| EMA | European Medicines Agency |
| EU | European Union |
| EUA | emergency use authorization |
| EudraCT | European Clinical Trials Database |
| FDA | Food and Drug Administration |
| $FiO_2$ | fraction of inspired oxygen |
| FSH | follicle-stimulating hormone |
| GCP | Good Clinical Practice |
| GGT | gamma-glutamyl transferase |

| Abbreviation | Term |
|---|---|
| GMC | geometric mean concentration |
| GMFR | geometric mean fold rise |
| GMR | geometric mean ratio |
| GMT | geometric mean titer |
| HBc Ab | hepatitis B core antibody |
| HBe | hepatitis B e |
| HBeAg | hepatitis B e antigen |
| HBsAg | hepatitis B surface antigen |
| HBV | hepatitis B virus |
| HCV | hepatitis C virus |
| HCV Ab | hepatitis C virus antibody |
| HIPAA | Health Insurance Portability and Accountability Act |
| HIV | human immunodeficiency virus |
| HR | heart rate |
| HRT | hormone replacement therapy |
| IA | interim analysis |
| IB | investigator's brochure |
| ICD | informed consent document |
| ICH | International Council for Harmonisation |
| ICU | intensive care unit |
| ID | identification |
| Ig | immunoglobulin |
| IgG | immunoglobulin G |
| IgM | immunoglobulin M |
| IMP | investigational medicinal product |
| IND | investigational new drug |
| INR | international normalized ratio |
| IP manual | investigational product manual |
| IPAL | Investigational Product Accountability Log |
| IRB | institutional review board |
| IRC | internal review committee |
| IRR | illness rate ratio |
| IRT | interactive response technology |
| ISO | International Organization for Standardization |
| IV | intravenous(ly) |
| IWR | interactive Web-based response |
| LFT | liver function test |
| LL | lower limit |
| LLOQ | lower limit of quantitation |
| LNP | lipid nanoparticle |
| LPX | lipoplex |
| MAR | missing at random |
| MCH | mean corpuscular hemoglobin |

| Abbreviation | Term |
|---|---|
| MCHC | mean corpuscular hemoglobin concentration |
| MCV | mean corpuscular volume |
| MedDRA | Medical Dictionary for Regulatory Activities |
| MERS | Middle East respiratory syndrome |
| MIS-C | multisystem inflammatory syndrome in children |
| modRNA | nucleoside-modified messenger ribonucleic acid |
| MRI | magnetic resonance imaging |
| N | SARS-CoV-2 nucleoprotein |
| N/A | not applicable |
| NAAT | nucleic acid amplification test |
| non-S | nonspike protein |
| P2 S | SARS-CoV-2 full-length, P2 mutant, prefusion spike glycoprotein |
| $PaO_2$ | partial pressure of oxygen, arterial |
| PCR | polymerase chain reaction |
| PI | principal investigator |
| POS | probability of success |
| PPE | personal protective equipment |
| PT | prothrombin time |
| RBC | red blood cell |
| RBD | receptor-binding domain |
| RCDC | reverse cumulative distribution curve |
| RNA | ribonucleic acid |
| RR | respiratory rate |
| RSV | respiratory syncytial virus |
| RT-PCR | reverse transcription–polymerase chain reaction |
| S1 | spike protein S1 subunit |
| SAE | serious adverse event |
| SAP | statistical analysis plan |
| saRNA | self-amplifying messenger ribonucleic acid |
| SARS | severe acute respiratory syndrome |
| SARS-CoV-2 | severe acute respiratory syndrome coronavirus 2 |
| SBP | systolic blood pressure |
| SoA | schedule of activities |
| SOP | standard operating procedure |
| $SpO_2$ | oxygen saturation as measured by pulse oximetry |
| SRSD | single reference safety document |
| SUSAR | suspected unexpected serious adverse reaction |
| TBD | to be determined |
| TBili | total bilirubin |
| ULN | upper limit of normal |
| uRNA | unmodified messenger ribonucleic acid |
| US | United States |
| vax | vaccination |

| Abbreviation | Term |
|---|---|
| VE | vaccine efficacy |
| WBC | white blood cell |
| WHO | World Health Organization |
| WOCBP | woman/women of childbearing potential |

## 10.7. Appendix 7: Stopping and Alert Rules for Enhanced COVID-19

In Phase 2/3, the unblinded team supporting the DMC (reporting team), including an unblinded medical monitor, will review cases of severe COVID-19 as they are received, and will review AEs at least weekly for additional potential cases of severe COVID-19 and will contact the DMC in the event that the stopping rule or an alert is met. Specifically, the unblinded reporting team will contact the DMC chair, who will then convene the full DMC as soon as possible. The DMC will review all available safety and/or efficacy data at the time of the review. The DMC will make one of the following recommendations to Pfizer: withhold final recommendation until further information/data are provided, continue the study as designed, modify the study and continue, or stop the study. The final decision to accept or reject the committee's recommendation resides with Pfizer management and will be communicated to the committee chairperson in writing.

At any point the unblinded team may discuss with the DMC chair whether the DMC should review cases for an adverse imbalance of cases of COVID-19 and/or severe COVID-19 between the vaccine and placebo groups (see Section 9.6). In addition, at the time of the IAs after accrual of at least 62, 92, and 120 cases, the number of severe COVID-19 cases in the vaccine and placebo groups will be assessed.

Stopping and alert rules will be applied as follows. The stopping rule will be triggered when the 1-sided probability of observing the same or a more extreme case split is 5% or less when the true incidence of severe disease is the same for vaccine and placebo participants, and alert criteria are triggered when this probability is less than 11%. In addition, when the total number of severe cases is low (15 or less), the unblinded team supporting the DMC will implement the alert rule when a reverse case split of 2:1 or worse is observed. For example, at 3 cases 2:1, at 4 cases 3:1, etc. Below 15 cases, this rule is more rigorous than requiring the probability of an observed adverse split or worse be <11%.

The stopping rule and alert rules are illustrated in Table 10 and Table 11, respectively, when the total number of severe cases is 20 or less. For example, when there are 7 severe cases, the adverse split has to be 7:0 to stop the study, but a split of 5:2 would trigger the alert rule. Similarly, when there is a total of 9 severe cases, an adverse split of 9:0 triggers the stopping rule, while a split of 6:3 or worse triggers the alert rule. The alert rule may be triggered with as few as 2 cases, with a split of 2:0.

**Table 10. Stopping Rule: Enrollment Is Stopped if the Number of Severe Cases in the Vaccine Group Is Greater Than or Equal to the Prespecified Stopping Rule Value (S)**

| Total Severe Cases | Prespecified Stopping Rule Value (S): Number of Severe Cases in the Vaccine Group to Stop | If the True Ratio of Severe Cases Between Vaccine and Placebo Groups Is 1:1, Probability of S or More Being Observed in the Vaccine Group |
|---|---|---|
| 4 | 4 | N/A |
| 5 | 5 | 3.13% |
| 6 | 6 | 1.56% |
| 7 | 7 | 0.78% |
| 8 | 7 | 3.52% |
| 9 | 8 | 1.95% |
| 10 | 9 | 1.07% |
| 11 | 9 | 3.27% |
| 12 | 10 | 1.93% |
| 13 | 10 | 4.61% |
| 14 | 11 | 2.87% |
| 15 | 12 | 1.76% |
| 16 | 12 | 3.84% |
| 17 | 13 | 2.45% |
| 18 | 13 | 4.81% |
| 19 | 14 | 3.18% |
| 20 | 15 | 2.07% |

Abbreviation: N/A = not applicable.

**Table 11. Alert Rule: Further Action Is Taken if the Number of Severe Cases in the Vaccine Group Is Greater Than or Equal to the Prespecified Alert Rule Value (A)**

| Total Severe Cases | Prespecified Alert Rule Value (A): Number of Severe Cases in the Vaccine Group to Trigger Further Action | If the True Ratio of Severe Cases Between the Vaccine and Placebo Groups Is 1:1, Probability of A Being Observed in the Vaccine Group | If the True Ratio of Severe Cases Between the Vaccine and Placebo Groups Is 1:1, Probability of A or More Being Observed in the Vaccine Group | If the True Ratio of Severe Cases Between the Vaccine and Placebo Groups Is 2:1, Probability of A or More Being Observed in the Vaccine Group | If the True Ratio of Severe Cases Between the Vaccine and Placebo Groups Is 3:1, Probability of A or More Being Observed in the Vaccine Group | If the True Ratio of Severe Cases Between the Vaccine and Placebo Groups Is 4:1, Probability of A or More Being Observed in the Vaccine Group |
|---|---|---|---|---|---|---|
| 2 | 2 | 25.00% | 25.00% | 44.49% | 56.25% | 64.00% |
| 3 | 2 | 37.50% | 50.00% | 74.12% | 84.38% | 89.60% |
| 4 | 3 | 25.00% | 31.25% | 59.32% | 73.83% | 81.92% |
| 5 | 4 | 15.63% | 18.75% | 46.16% | 63.28% | 73.73% |
| 6 | 4 | 23.44% | 34.38% | 68.10% | 83.06% | 90.11% |
| 7 | 5 | 16.41% | 22.66% | 57.14% | 75.64% | 85.20% |
| 8 | 6 | 10.94% | 14.45% | 46.90% | 67.85% | 79.69% |
| 9 | 6 | 16.41% | 25.39% | 65.11% | 83.43% | 91.44% |
| 10 | 7 | 11.72% | 17.19% | 56.02% | 77.59% | 87.91% |
| 11 | 8 | 8.06% | 11.33% | 47.35% | 71.33% | 83.89% |
| 12 | 8 | 12.08% | 19.38% | 63.25% | 84.24% | 92.74% |
| 13 | 9 | 8.73% | 13.34% | 55.31% | 79.40% | 90.09% |
| 14 | 10 | 6.11% | 8.98% | 47.66% | 74.15% | 87.02% |
| 15 | 10 | 9.16% | 15.09% | 61.94% | 85.16% | 93.89% |
| 16 | 11 | 6.67% | 10.51% | 54.81% | 81.03% | 91.83% |
| 17 | 12 | 4.72% | 7.17% | 47.88% | 76.53% | 89.43% |
| 18 | 13 | 3.27% | 4.81% | 41.34% | 71.75% | 86.71% |
| 19 | 13 | 5.18% | 8.35% | 54.43% | 82.51% | 93.24% |
| 20 | 14 | 3.70% | 5.77% | 48.06% | 78.58% | 91.33% |

## 10.8. Appendix 8: Criteria for Allowing Inclusion of Participants With Chronic Stable HIV, HCV, or HBV Infection

Potential participants with chronic stable HIV, HCV, or HBV infection may be considered for inclusion if they fulfill the following respective criteria.

Known HIV infection

- Confirmed stable HIV disease defined as documented viral load <50 copies/mL and CD4 count >200 cells/$mm^3$ within 6 months before enrollment, and on stable antiretroviral therapy for at least 6 months.

Known HCV infection

- History of chronic HCV with evidence of sustained virological response (defined as undetectable HCV RNA) for ≥12 weeks following HCV treatment or without evidence of HCV RNA viremia (undetectable HCV viral load).

Known HBV infection

Confirmed inactive chronic HBV infection, defined as HBsAg present for ≥6 months and the following:

- HBeAg negative, anti-HBe positive
- Serum HBV DNA <2000 IU/mL
- Persistently normal ALT and/or AST levels
- In those who have had a liver biopsy performed, findings that confirm the absence of significant necroinflammation.

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# A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS

| | |
|---|---|
| **Study Sponsor:** | BioNTech |
| **Study Conducted By:** | Pfizer |
| **Study Intervention Number:** | PF-07302048 |
| **Study Intervention Name:** | RNA-Based COVID-19 Vaccines |
| **US IND Number:** | 19736 |
| **EudraCT Number:** | 2020-002641-42 |
| **Protocol Number:** | C4591001 |
| **Phase:** | 1/2/3 |

**Short Title:** A Phase 1/2/3 Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals

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# 1. PROTOCOL SUMMARY

## 1.1. Synopsis

**Short Title:** A Phase 1/2/3 Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals

### Rationale

A pneumonia of unknown cause detected in Wuhan, China, was first reported in December 2019. On 08 January 2020, the pathogen causing this outbreak was identified as a novel coronavirus 2019. The outbreak was declared a Public Health Emergency of International Concern on 30 January 2020. On 12 February 2020, the virus was officially named as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), and the WHO officially named the disease caused by SARS-CoV-2 as coronavirus disease 2019 (COVID-19). On 11 March 2020, the WHO upgraded the status of the COVID-19 outbreak from epidemic to pandemic, which is now spreading globally at high speed.

There are currently no licensed vaccines to prevent infection with SARS-CoV-2 or COVID-19. Given the rapid transmission of COVID-19 and incidence of disease in the United States and elsewhere, the rapid development of an effective vaccine is of utmost importance.

BioNTech has developed RNA-based vaccine candidates using a platform approach that enables the rapid development of vaccines against emerging viral diseases, including SARS-CoV-2. Each vaccine candidate is based on a platform of nucleoside-modified messenger RNA (modRNA, BNT162b). Each vaccine candidate expresses 1 of 2 antigens: the SARS-CoV-2 full-length, P2 mutant, prefusion spike glycoprotein (P2 S) (version 9) or a trimerized SARS-CoV-2 spike glycoprotein receptor-binding domain (RBD) (version 5). The 2 SARS-CoV-2 vaccine candidates that will be tested in this study are therefore:

BNT162b1 (variant RBP020.3): a modRNA encoding the RBD;

BNT162b2 (variant RBP020.2): a modRNA encoding P2 S.

All candidates are formulated in the same lipid nanoparticle (LNP) composition. This study is intended to investigate the safety, immunogenicity, and efficacy of these prophylactic BNT162 vaccines against COVID-19.

## Objectives, Estimands, and Endpoints

## For Phase 1

| Objectives | Estimands | Endpoints |
|---|---|---|
| **Primary:** | **Primary:** | **Primary:** |
| To describe the safety and tolerability profiles of prophylactic BNT162 vaccines in healthy adults after 1 or 2 doses | In participants receiving at least 1 dose of study intervention, the percentage of participants reporting:<br>• Local reactions for up to 7 days following each dose<br>• Systemic events for up to 7 days following each dose<br>• Adverse events (AEs) from Dose 1 to 1 month after the last dose<br>• Serious AEs (SAEs) from Dose 1 to 6 months after the last dose | • Local reactions (pain at the injection site, redness, and swelling)<br>• Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain)<br>• AEs<br>• SAEs |
| | In addition, the percentage of participants with:<br>• Abnormal hematology and chemistry laboratory values 1 and 7 days after Dose 1; and 7 days after Dose 2<br>• Grading shifts in hematology and chemistry laboratory assessments between baseline and 1 and 7 days after Dose 1; and before Dose 2 and 7 days after Dose 2 | Hematology and chemistry laboratory parameters detailed in Section 10.2 |
| **Secondary:** | **Secondary:** | **Secondary:** |
| To describe the immune responses elicited by prophylactic BNT162 vaccines in healthy adults after 1 or 2 doses | In participants complying with the key protocol criteria (evaluable participants) at the following time points after receipt of study intervention:<br><br>7 and 21 days after Dose 1; 7 and 14 days and 1, 6, 12, and 24 months after Dose 2 | |
| | • Geometric mean titers (GMTs) at each time point<br>• Geometric mean fold rise (GMFR) from before vaccination to each subsequent time point after vaccination<br>• Proportion of participants achieving ≥4-fold rise from before vaccination to each subsequent time point after vaccination | SARS-CoV-2 neutralizing titers |

| Objectives | Estimands | Endpoints |
|---|---|---|
| | • Geometric mean concentrations (GMCs) at each time point<br>• GMFR from before vaccination to each subsequent time point after vaccination<br>• Proportion of participants achieving ≥4-fold rise from before vaccination to each subsequent time point after vaccination | S1-binding IgG levels and RBD-binding IgG levels |
| | • Geometric mean ratio (GMR), estimated by the ratio of the geometric mean of SARS-CoV-2 neutralizing titers to the geometric mean of binding IgG levels at each time point | • SARS-CoV-2 neutralizing titers<br>• S1-binding IgG levels<br>• RBD-binding IgG levels |

## For Phase 2/3

| Objectives[a] | Estimands | Endpoints |
|---|---|---|
| **Primary Efficacy** | | |
| To evaluate the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 7 days after the second dose in participants without evidence of infection before vaccination | In participants complying with the key protocol criteria (evaluable participants) at least 7 days after receipt of the second dose of study intervention:<br>100 × (1 – IRR) [ratio of active vaccine to placebo] | COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT in participants with no serological or virological evidence (up to 7 days after receipt of the second dose) of past SARS-CoV-2 infection |
| To evaluate the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 7 days after the second dose in participants with and without evidence of infection before vaccination | In participants complying with the key protocol criteria (evaluable participants) at least 7 days after receipt of the second dose of study intervention:<br>100 × (1 – IRR) [ratio of active vaccine to placebo] | COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT |
| **Primary Safety** | | |
| To define the safety profile of prophylactic BNT162b2 in the first 360 participants randomized (Phase 2) | In participants receiving at least 1 dose of study intervention, the percentage of participants reporting:<br>• Local reactions for up to 7 days following each dose<br>• Systemic events for up to 7 days following each dose<br>• AEs from Dose 1 to 7 days after the second dose<br>• SAEs from Dose 1 to 7 days after the second dose | • Local reactions (pain at the injection site, redness, and swelling)<br>• Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain)<br>• AEs<br>• SAEs |

| Objectives[a] | Estimands | Endpoints |
|---|---|---|
| To define the safety profile of prophylactic BNT162b2 in all participants randomized in Phase 2/3 | In participants receiving at least 1 dose of study intervention, the percentage of participants reporting:<br>• Local reactions for up to 7 days following each dose<br>• Systemic events for up to 7 days following each dose<br>• AEs from Dose 1 to 1 month after the second dose<br>• SAEs from Dose 1 to 6 months after the second dose | • AEs<br>• SAEs<br>• In a subset of at least 6000 participants:<br>o Local reactions (pain at the injection site, redness, and swelling)<br>o Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain) |
| To define the safety profile of prophylactic BNT162b2 in participants 12 to 15 years of age in Phase 3 | In participants receiving at least 1 dose of study intervention, the percentage of participants reporting:<br>• Local reactions for up to 7 days following each dose<br>• Systemic events for up to 7 days following each dose<br>• AEs from Dose 1 to 1 month after the second dose<br>• SAEs from Dose 1 to 6 months after the second dose | • Local reactions (pain at the injection site, redness, and swelling)<br>• Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain)<br>• AEs<br>• SAEs |
| **Secondary Efficacy** | | |
| To evaluate the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 14 days after the second dose in participants without evidence of infection before vaccination | In participants complying with the key protocol criteria (evaluable participants) at least 14 days after receipt of the second dose of study intervention:<br>100 × (1 – IRR) [ratio of active vaccine to placebo] | COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT in participants with no serological or virological evidence (up to 14 days after receipt of the second dose) of past SARS-CoV-2 infection |
| To evaluate the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 14 days after the second dose in participants with and without evidence of infection before vaccination | In participants complying with the key protocol criteria (evaluable participants) at least 14 days after receipt of the second dose of study intervention:<br>100 × (1 – IRR) [ratio of active vaccine to placebo] | COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT |
| To evaluate the efficacy of prophylactic BNT162b2 against confirmed severe COVID-19 occurring from 7 days and from 14 days after the second dose in participants without evidence of infection before vaccination | In participants complying with the key protocol criteria (evaluable participants)<br>• at least 7 days<br>and<br>• at least 14 days<br>after receipt of the second dose of study intervention:<br>100 × (1 – IRR) [ratio of active vaccine to placebo] | Confirmed severe COVID-19 incidence per 1000 person-years of follow-up in participants with no serological or virological evidence (up to 7 days and up to 14 days after receipt of the second dose) of past SARS-CoV-2 infection |

| Objectives[a] | Estimands | Endpoints |
|---|---|---|
| To evaluate the efficacy of prophylactic BNT162b2 against confirmed severe COVID-19 occurring from 7 days and from 14 days after the second dose in participants with and without evidence of infection before vaccination | In participants complying with the key protocol criteria (evaluable participants)<br>• at least 7 days<br>and<br>• at least 14 days<br>after receipt of the second dose of study intervention:<br>100 × (1 – IRR) [ratio of active vaccine to placebo] | Confirmed severe COVID-19 incidence per 1000 person-years of follow-up |
| To describe the efficacy of prophylactic BNT162b2 against confirmed COVID-19 (according to the CDC-defined symptoms) occurring from 7 days and from 14 days after the second dose in participants without evidence of infection before vaccination | In participants complying with the key protocol criteria (evaluable participants)<br>• at least 7 days<br>and<br>• at least 14 days<br>after receipt of the second dose of study intervention:<br>100 × (1 – IRR) [ratio of active vaccine to placebo] | COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT in participants with no serological or virological evidence (up to 7 days and up to 14 days after receipt of the second dose) of past SARS-CoV-2 infection |
| To describe the efficacy of prophylactic BNT162b2 against confirmed COVID-19 (according to the CDC-defined symptoms) occurring from 7 days and from 14 days after the second dose in participants with and without evidence of infection before vaccination | In participants complying with the key protocol criteria (evaluable participants)<br>• at least 7 days<br>and<br>• at least 14 days<br>after receipt of the second dose of study intervention:<br>100 × (1 – IRR) [ratio of active vaccine to placebo] | COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT |
| **Secondary Immunogenicity** | | |
| To demonstrate the noninferiority of the immune response to prophylactic BNT162b2 in participants 12 to 15 years of age compared to participants 16 to 25 years of age | GMR, estimated by the ratio of the geometric mean of SARS-CoV-2 neutralizing titers in the 2 age groups (12-15 years of age to 16-25 years of age) 1 month after completion of vaccination | SARS-CoV-2 neutralizing titers in participants with no serological or virological evidence (up to 1 month after receipt of the second dose) of past SARS-CoV-2 infection |
| **Exploratory** | | |
| To evaluate the immune response over time to prophylactic BNT162b2 and persistence of immune response in participants with and without serological or virological evidence of SARS-CoV-2 infection before vaccination | GMC/GMT, GMFR, and percentage of participants with titers greater than defined threshold(s), at baseline and 1, 6, 12, and 24 months after completion of vaccination | • S1-binding IgG levels and/or RBD-binding IgG levels<br>• SARS-CoV-2 neutralizing titers |
| To evaluate the immune response (non-S) to SARS-CoV-2 in participants with and without confirmed COVID-19 during the study | | • N-binding antibody |
| To describe the serological responses to the BNT vaccine candidate in cases of:<br>• Confirmed COVID-19<br>• Confirmed severe COVID-19<br>• SARS-CoV-2 infection without confirmed COVID-19 | | • S1-binding IgG levels and/or RBD-binding IgG levels<br>• SARS-CoV-2 neutralizing titers |

| Objectives[a] | Estimands | Endpoints |
|---|---|---|
| To describe the safety, immunogenicity, and efficacy of prophylactic BNT162b2 in individuals with confirmed stable HIV disease | | • All safety, immunogenicity, and efficacy endpoints described above |
| To describe the safety and immunogenicity of prophylactic BNT162b2 in individuals 16 to 55 years of age vaccinated with study intervention produced by manufacturing "Process 1" or "Process 2"[b] | | • All safety endpoints described above<br>• SARS-CoV-2 neutralizing titers |

a. HIV-positive participants in Phase 3 will not be included in analyses of the objectives, with the exception of the specific exploratory objective.
b. See Section 6.1.1 for a description of the manufacturing process.

## Overall Design

This is a Phase 1/2/3, multicenter, multinational, randomized, placebo-controlled, observer-blind, dose-finding, vaccine candidate–selection, and efficacy study in healthy individuals.

The study consists of 2 parts: Phase 1: to identify preferred vaccine candidate(s) and dose level(s); Phase 2/3: an expanded cohort and efficacy part. These parts, and the progression between them, are detailed in the schema (Section 1.2).

The study will evaluate the safety, tolerability, and immunogenicity of 2 different SARS-CoV-2 RNA vaccine candidates against COVID-19 and the efficacy of 1 candidate:

- As a 2-dose (separated by 21 days) schedule;
- At various different dose levels in Phase 1;
- In 3 age groups (Phase 1: 18 to 55 years of age, 65 to 85 years of age; Phase 2/3: ≥12 years of age [stratified as 12-15, 16-55, or >55 years of age]).

Dependent upon safety and/or immunogenicity data generated during the course of this study, or the BioNTech study conducted in Germany (BNT162-01), it is possible that groups in Phase 1 may be started at the next highest dose, groups may not be started, groups may be terminated early, and/or groups may be added with dose levels below the lowest stated dose or intermediate between the lowest and highest stated doses.

The vaccine candidate selected for Phase 2/3 evaluation is BNT162b2 at a dose of 30 µg.

**Number of Participants**

Each group in Phase 1 will comprise 15 participants (12 receiving active vaccine and 3 receiving placebo). In this phase, 13 groups will be studied, corresponding to a total of 195 participants.

The vaccine candidate selected for Phase 2/3, BNT162b2 at a dose of 30 µg, will comprise 21,999 vaccine recipients. The 12- to 15-year stratum will comprise up to approximately 2000 participants (1000 vaccine recipients) enrolled at selected investigational sites. It is intended that a minimum of 40% of participants will be in the >55-year stratum. An equal number of participants will receive placebo, ie, randomized in a 1:1 ratio.

**Intervention Groups and Duration**

The study will evaluate a 2-dose (separated by 21 days) schedule of various different dose levels of 2 investigational RNA vaccine candidates for active immunization against COVID-19 in 3 age groups (Phase 1: 18 to 55 years of age, 65 to 85 years of age; Phase 2/3: ≥12 years of age [stratified as 12-15, 16-55, or >55 years of age]):

- BNT162b1 (BNT162 RNA-LNP vaccine utilizing modRNA and encoding the RBD): 10 µg, 20 µg, 30 µg, 100 µg
- BNT162b2 (BNT162 RNA-LNP vaccine utilizing modRNA and encoding the P2 S): 10 µg, 20 µg, 30 µg

The vaccine candidate selected for Phase 2/3 evaluation is BNT162b2 at a dose of 30 µg.

Participants are expected to participate for up to a maximum of approximately 26 months. The duration of study follow-up may be shorter among participants enrolled in Phase 1 dosing arms that are not evaluated in Phase 2/3.

**Data Monitoring Committee or Other Independent Oversight Committee**

The study will utilize an IRC, an internal Pfizer committee that will review data to allow dose escalation or changes to continuation of specific groups.

An external data monitoring committee (DMC) will be formed and will review cumulative unblinded data throughout the study.

**Statistical Methods**

The sample size for Phase 1 of the study is not based on any statistical hypothesis testing.

For Phase 2/3, the VE evaluation will be the primary objective. The VE is defined as VE = 100 × (1 – IRR), where IRR is calculated as the ratio of the first confirmed COVID-19 illness rate in the vaccine group to the corresponding illness rate in the placebo group. With assumptions of a true VE of 60% and 4 IAs planned, 164 COVID-19 cases will provide 90%

power to conclude true VE >30%. This would be achieved with a total 43,998 participants (21,999 vaccine recipients), based on the assumption of a 1.3% per year incidence in the placebo group, accrual of 164 primary-endpoint cases within 6 months, and 20% of the participants being nonevaluable. If the attack rate is much higher, case accrual would be expected to be more rapid, enabling the study's primary endpoint to be evaluated much sooner. The total number of participants enrolled in Phase 2/3 may vary depending on the incidence of COVID-19 at the time of the enrollment, the true underlying VE, and a potential early stop for efficacy or futility.

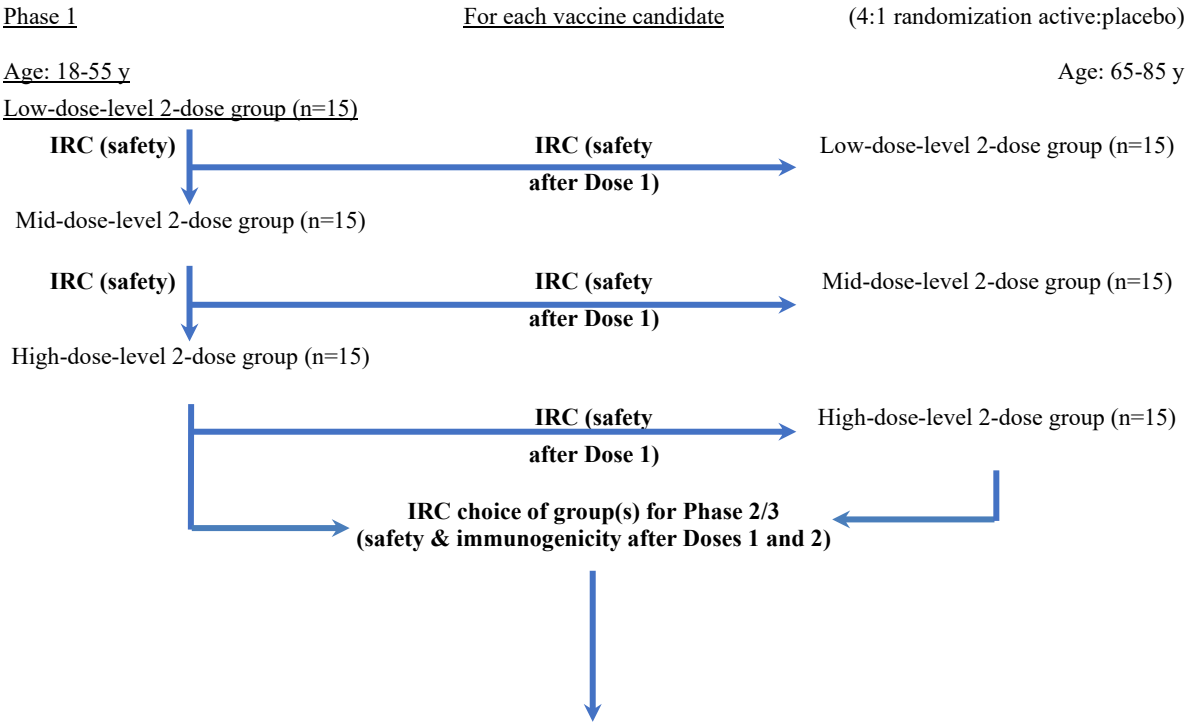
VE will be evaluated using a beta-binomial model and the posterior probability of VE being >30% will be assessed.

In Phase 3, up to approximately 2000 participants are anticipated to be 12 to 15 years of age. Noninferiority of immune response to prophylactic BNT162b2 in participants 12 to 15 years of age to response in participants 16 to 25 years of age will be assessed based on the GMR of SARS-CoV-2 neutralizing titers using a 1.5-fold margin. A sample size of 200 evaluable participants (or 250 vaccine recipients) per age group will provide a power of 90.8% to declare the noninferiority in terms of GMR (lower limit of 95% CI for GMR >0.67).

The primary safety objective will be evaluated by descriptive summary statistics for local reactions, systemic events, AEs/SAEs, and abnormal hematology and chemistry laboratory parameters (Phase 1 only), for each vaccine group. A 3-tier approach will be used to summarize AEs in Phase 2/3.

Except for the objective to assess the noninferiority of immune response in participants 12 to 15 years of age compared to participants 16 to 25 years of age, the other immunogenicity objectives will be evaluated descriptively by GMT, GMC, GMFR, percentage of participants with ≥4-fold rise, percentage of participants with ≥ specified threshold, and GMC ratio, and the associated 95% confidence intervals (CIs), for SARS-CoV-2 neutralizing titers, S1-binding IgG levels, and/or RBD-binding IgG levels at the various time points.

## 1.2. Schema




Abbreviation: IRC = internal review committee.

## 1.3. Schedule of Activities

The SoA table provides an overview of the protocol visits and procedures. Refer to the STUDY ASSESSMENTS AND PROCEDURES section of the protocol for detailed information on each procedure and assessment required for compliance with the protocol.

The investigator may schedule visits (unplanned visits) in addition to those listed in the SoA table, in order to conduct evaluations or assessments required to protect the well-being of the participant.

### 1.3.1. Phase 1

An unplanned potential COVID-19 illness visit and unplanned potential COVID-19 convalescent visit are required at any time between Visit 1 (Vaccination 1) and Visit 10 (24-month follow-up visit) that COVID-19 is suspected.

| Visit Number | Screening | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Unplanned | Unplanned |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Visit Description** | **Screening** | **Vax 1** | **Next-Day Follow-up Visit (Vax 1)** | **1-Week Follow-up Visit (Vax 1)** | **Vax 2** | **1-Week Follow-up Visit (Vax 2)** | **2-Week Follow-up Visit (Vax 2)** | **1-Month Follow-up Visit** | **6-Month Follow-up Visit** | **12-Month Follow-up Visit** | **24-Month Follow-up Visit** | **Potential COVID-19 Illness Visit[a]** | **Potential COVID-19 Convalescent Visit** |
| **Visit Window (Days)** | **0 to 28 Days Before Visit 1** | **Day 1** | **1 to 3 Days After Visit 1** | **6 to 8 Days After Visit 1** | **19 to 23 Days After Visit 1** | **6 to 8 Days After Visit 4** | **12 to 16 Days After Visit 4** | **28 to 35 Days After Visit 4** | **175 to 189 Days After Visit 4** | **350 to 378 Days After Visit 4** | **714 to 742 Days After Visit 4** | **Optimally Within 3 Days After Potential COVID-19 Illness Onset** | **28 to 35 Days After Potential COVID-19 Illness Visit** |
| Obtain informed consent | X | | | | | | | | | | | | |
| Assign participant number | X | | | | | | | | | | | | |
| Obtain demography and medical history data | X | | | | | | | | | | | | |
| Obtain details of medications currently taken | X | | | | | | | | | | | | |
| Perform physical examination | X | X | X | X | X | X | X | | | | | | |

| Visit Number | Screening | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Unplanned | Unplanned |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Visit Description** | **Screening** | **Vax 1** | **Next-Day Follow-up Visit (Vax 1)** | **1-Week Follow-up Visit (Vax 1)** | **Vax 2** | **1-Week Follow-up Visit (Vax 2)** | **2-Week Follow-up Visit (Vax 2)** | **1-Month Follow-up Visit** | **6-Month Follow-up Visit** | **12-Month Follow-up Visit** | **24-Month Follow-up Visit** | **Potential COVID-19 Illness Visit[a]** | **Potential COVID-19 Convalescent Visit** |
| **Visit Window (Days)** | **0 to 28 Days Before Visit 1** | **Day 1** | **1 to 3 Days After Visit 1** | **6 to 8 Days After Visit 1** | **19 to 23 Days After Visit 1** | **6 to 8 Days After Visit 4** | **12 to 16 Days After Visit 4** | **28 to 35 Days After Visit 4** | **175 to 189 Days After Visit 4** | **350 to 378 Days After Visit 4** | **714 to 742 Days After Visit 4** | **Optimally Within 3 Days After Potential COVID-19 Illness Onset** | **28 to 35 Days After Potential COVID-19 Illness Visit** |
| Measure vital signs (including body temperature) | X | X | X | X | X | X | X | | | | | | |
| Collect blood sample for hematology and chemistry laboratory tests[b] | ~10 mL | | ~10 mL | ~10 mL | ~10 mL | ~10 mL | | | | | | | |
| Collect screening blood sample for HIV, HBsAg, HBc Ab, and HCV Ab tests | ~10 mL | | | | | | | | | | | | |
| Serological test for prior COVID-19 infection | ~20 mL | | | | | | | | | | | | |
| Perform urine pregnancy test (if appropriate) | X | X | | | X | | | | | | | | |
| Obtain nasal (midturbinate) swab(s)[c] | | X | | | X | | | | | | | X | |
| Collect nonstudy vaccine information | X | X | X | X | X | X | X | X | X | | | | |
| Confirm eligibility | X | X | | | X | | | | | | | | |
| Collect prohibited medication use | | | X | X | X | X | X | X | X | X | X | X | X |
| Review hematology and chemistry results | | X | | X | X | X | X | | | | | | |
| Review temporary delay criteria | | X | | | X | | | | | | | | |
| Confirm use of contraceptives (if appropriate) | X | X | X | X | X | X | X | X | | | | | |

| Visit Number | Screening | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Unplanned | Unplanned |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Visit Description** | **Screening** | **Vax 1** | **Next-Day Follow-up Visit (Vax 1)** | **1-Week Follow-up Visit (Vax 1)** | **Vax 2** | **1-Week Follow-up Visit (Vax 2)** | **2-Week Follow-up Visit (Vax 2)** | **1-Month Follow-up Visit** | **6-Month Follow-up Visit** | **12-Month Follow-up Visit** | **24-Month Follow-up Visit** | **Potential COVID-19 Illness Visit[a]** | **Potential COVID-19 Convalescent Visit** |
| **Visit Window (Days)** | **0 to 28 Days Before Visit 1** | **Day 1** | **1 to 3 Days After Visit 1** | **6 to 8 Days After Visit 1** | **19 to 23 Days After Visit 1** | **6 to 8 Days After Visit 4** | **12 to 16 Days After Visit 4** | **28 to 35 Days After Visit 4** | **175 to 189 Days After Visit 4** | **350 to 378 Days After Visit 4** | **714 to 742 Days After Visit 4** | **Optimally Within 3 Days After Potential COVID-19 Illness Onset** | **28 to 35 Days After Potential COVID-19 Illness Visit** |
| Obtain randomization number and study intervention allocation | | X | | | | | | | | | | | |
| Collect blood sample for immunogenicity assessment | | ~50 mL | | ~50 mL | ~50 mL | ~50 mL + optional[e] ~170 mL | ~50 mL + optional[e] ~170 mL | ~50 mL + optional[e] ~170 mL | ~20 mL | ~20 mL | ~20 mL | | ~20 mL |
| Administer study intervention | | X | | | X | | | | | | | | |
| Assess acute reactions for at least 30 minutes after study intervention administration[d] | | X | | | X | | | | | | | | |
| Explain participant communication methods (including for e-diary completion), assist the participant with downloading the app, or issue provisioned device, if required | | X | | | | | | | | | | | |
| Provide thermometer and measuring device | | X | | | X | | | | | | | | |
| Review reactogenicity e-diary data (daily review is optimal during the active diary period) | | ◄ | ——— | ► | ◄ | ► | | | | | | | |
| Review ongoing reactogenicity e-diary | | | | | X | | X | | | | | | |

| Visit Number | Screening | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Unplanned | Unplanned |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Visit Description** | **Screening** | **Vax 1** | **Next-Day Follow-up Visit (Vax 1)** | **1-Week Follow-up Visit (Vax 1)** | **Vax 2** | **1-Week Follow-up Visit (Vax 2)** | **2-Week Follow-up Visit (Vax 2)** | **1-Month Follow-up Visit** | **6-Month Follow-up Visit** | **12-Month Follow-up Visit** | **24-Month Follow-up Visit** | **Potential COVID-19 Illness Visit[a]** | **Potential COVID-19 Convalescent Visit** |
| **Visit Window (Days)** | **0 to 28 Days Before Visit 1** | **Day 1** | **1 to 3 Days After Visit 1** | **6 to 8 Days After Visit 1** | **19 to 23 Days After Visit 1** | **6 to 8 Days After Visit 4** | **12 to 16 Days After Visit 4** | **28 to 35 Days After Visit 4** | **175 to 189 Days After Visit 4** | **350 to 378 Days After Visit 4** | **714 to 742 Days After Visit 4** | **Optimally Within 3 Days After Potential COVID-19 Illness Onset** | **28 to 35 Days After Potential COVID-19 Illness Visit** |
| symptoms and obtain stop dates | | | | | | | | | | | | | |
| Collect AEs and SAEs as appropriate | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Collect e-diary or assist the participant to delete application | | | | | | | | | | | X | | |

| Visit Number | Screening | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Unplanned | Unplanned |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Visit Description** | **Screening** | **Vax 1** | **Next-Day Follow-up Visit (Vax 1)** | **1-Week Follow-up Visit (Vax 1)** | **Vax 2** | **1-Week Follow-up Visit (Vax 2)** | **2-Week Follow-up Visit (Vax 2)** | **1-Month Follow-up Visit** | **6-Month Follow-up Visit** | **12-Month Follow-up Visit** | **24-Month Follow-up Visit** | **Potential COVID-19 Illness Visit[a]** | **Potential COVID-19 Convalescent Visit** |
| **Visit Window (Days)** | **0 to 28 Days Before Visit 1** | **Day 1** | **1 to 3 Days After Visit 1** | **6 to 8 Days After Visit 1** | **19 to 23 Days After Visit 1** | **6 to 8 Days After Visit 4** | **12 to 16 Days After Visit 4** | **28 to 35 Days After Visit 4** | **175 to 189 Days After Visit 4** | **350 to 378 Days After Visit 4** | **714 to 742 Days After Visit 4** | **Optimally Within 3 Days After Potential COVID-19 Illness Onset** | **28 to 35 Days After Potential COVID-19 Illness Visit** |
| Collection of COVID-19–related clinical and laboratory information (including local diagnosis) | | | | | | | | | | | | X | X |

Abbreviations: e-diary = electronic diary; HBc Ab = hepatitis B core antibody; HBsAg = hepatitis B surface antigen; HCV Ab = hepatitis C virus antibody; HIV = human immunodeficiency virus; NAAT = nucleic acid amplification test; vax = vaccination.

a. The COVID-19 illness visit may be conducted as an in-person or telehealth visit.
b. Hematology: hemoglobin, complete blood count with differential, and platelets. Blood chemistry: alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase, total bilirubin, blood urea nitrogen (BUN), and creatinine.
c. Two swabs will be taken at Visits 1 and 4. One will be tested (if possible at the site, otherwise at the central laboratory) within 24 hours and vaccination will only proceed if it is NAAT-negative for SARS-CoV-2 genomes. The second will be sent to the central laboratory for potential later testing.
d. The first 5 participants in in each group will be observed at the site for at least 4 hours after study intervention administration. Further vaccination will commence no sooner than 24 hours after the fifth participant received his or her vaccination.
e. An optional blood draw of ~170 mL will be taken at 1 of the visits (from selected participants who consent) for exploratory COVID-19 research.

### 1.3.2. Phase 2/3

An unplanned potential COVID-19 illness visit and unplanned potential COVID-19 convalescent visit are required at any time between Visit 1 (Vaccination 1) and Visit 6 (24-month follow-up visit) that potential COVID-19 symptoms are reported, including MIS-C.

| Visit Number | 1 | 2 | 3 | 4 | 5 | 6 | Unplanned | Unplanned |
|---|---|---|---|---|---|---|---|---|
| **Visit Description** | **Vaccination 1** | **Vaccination 2** | **1-Month Follow-up Visit** | **6-Month Follow-up Visit** | **12-Month Follow-up Visit** | **24-Month Follow-up Visit** | **Potential COVID-19 Illness Visit[a]** | **Potential COVID-19 Convalescent Visit** |
| **Visit Window (Days)** | **Day 1[b]** | **19 to 23 Days After Visit 1** | **28 to 35 Days After Visit 2** | **175 to 189 Days After Visit 2** | **350 to 378 Days After Visit 2** | **714 to 742 Days After Visit 2** | **Optimally Within 3 Days After Potential COVID-19 Illness Onset** | **28 to 35 Days After Potential COVID-19 Illness Visit** |
| Obtain informed consent | X | | | | | | | |
| Assign participant number | X | | | | | | | |
| Obtain demography and medical history data | X | | | | | | | |
| Perform clinical assessment[c] | X | | | | | | | |
| For participants who are HIV-positive, record latest CD4 count and HIV viral load | X | | X | X | X | X | | |
| Measure height and weight | X | | | | | | | |
| Measure temperature (body) | X | X | | | | | | |
| Perform urine pregnancy test (if appropriate) | X | X | | | | | | |
| Confirm use of contraceptives (if appropriate) | X | X | X | | | | | |
| Collect nonstudy vaccine information | X | X | X | X | | | | |
| Collect prohibited medication use | | X | X | X | X | X | X | X |
| Confirm eligibility | X | X | | | | | | |
| Review temporary delay criteria | X | X | | | | | | |
| Collect blood sample for immunogenicity assessment[d] | ~20 mL/ ~10 mL | | ~20 mL/ ~10 mL | ~20 mL/ ~10 mL | ~20 mL/ ~10 mL | ~20 mL/ ~10 mL | | ~20 mL/ ~10 mL |
| Obtain nasal (midturbinate) swab | X | X | | | | | X | |

| Visit Number | 1 | 2 | 3 | 4 | 5 | 6 | Unplanned | Unplanned |
|---|---|---|---|---|---|---|---|---|
| **Visit Description** | **Vaccination 1** | **Vaccination 2** | **1-Month Follow-up Visit** | **6-Month Follow-up Visit** | **12-Month Follow-up Visit** | **24-Month Follow-up Visit** | **Potential COVID-19 Illness Visit[a]** | **Potential COVID-19 Convalescent Visit** |
| **Visit Window (Days)** | **Day 1[b]** | **19 to 23 Days After Visit 1** | **28 to 35 Days After Visit 2** | **175 to 189 Days After Visit 2** | **350 to 378 Days After Visit 2** | **714 to 742 Days After Visit 2** | **Optimally Within 3 Days After Potential COVID-19 Illness Onset** | **28 to 35 Days After Potential COVID-19 Illness Visit** |
| Obtain randomization number and study intervention allocation | X | | | | | | | |
| Administer study intervention | X | X | | | | | | |
| Assess acute reactions for at least 30 minutes after study intervention administration | X | X | | | | | | |
| Explain participant communication methods (including for e-diary completion), assist the participant with downloading the app, or issue provisioned device, if required | X | | | | | | | |
| Provide/ensure the participant has a thermometer (all participants) and measuring device (reactogenicity subset participants only) | X | X | | | | | | |
| Review reactogenicity e-diary data (daily review is optimal during the active diary period)[e] | ◄—► | ◄—► | | | | | | |
| Review ongoing reactogenicity e-diary symptoms and obtain stop dates[e] | | X | X | | | | | |
| Collect AEs and SAEs as appropriate | X | X | X | X[f] | X[f] | X[f] | X | X[f] |
| Collect e-diary or assist the participant to delete application | | | | | | X | | |

| Visit Number | 1 | 2 | 3 | 4 | 5 | 6 | Unplanned | Unplanned |
|---|---|---|---|---|---|---|---|---|
| **Visit Description** | **Vaccination 1** | **Vaccination 2** | **1-Month Follow-up Visit** | **6-Month Follow-up Visit** | **12-Month Follow-up Visit** | **24-Month Follow-up Visit** | **Potential COVID-19 Illness Visit[a]** | **Potential COVID-19 Convalescent Visit** |
| **Visit Window (Days)** | **Day 1[b]** | **19 to 23 Days After Visit 1** | **28 to 35 Days After Visit 2** | **175 to 189 Days After Visit 2** | **350 to 378 Days After Visit 2** | **714 to 742 Days After Visit 2** | **Optimally Within 3 Days After Potential COVID-19 Illness Onset** | **28 to 35 Days After Potential COVID-19 Illness Visit** |
| Collection of COVID-19–related clinical and laboratory information (including local diagnosis) | | | | | | | X | X |

Abbreviations: HIV = human immunodeficiency virus; e-diary = electronic diary.

a. The COVID-19 illness visit may be conducted as an in-person or telehealth visit.
b. The visit may be conducted across 2 consecutive days; if so, all steps from assessing the inclusion and exclusion criteria onwards must be conducted on the same day.
c. Including, if indicated, a physical examination.
d. 20 mL is to be collected from participants ≥16 years of age; 10 mL is to be collected from participants 12 to 15 years of age.
e. Reactogenicity subset participants only.
f. Any AEs occurring up to 48 hours after the blood draw must be recorded (see Section 8.3.1).

# 2. INTRODUCTION

The BNT162 RNA-based COVID-19 vaccines are currently being investigated for prevention of COVID-19 in healthy individuals.

## 2.1. Study Rationale

The purpose of the study is to rapidly describe the safety, tolerability, and immunogenicity of 2 BNT162 RNA-based COVID-19 vaccine candidates against COVID-19, and the efficacy of 1 candidate, in healthy individuals. There are currently no licensed vaccines to prevent infection with SARS-CoV-2 or COVID-19. Given the global crisis of COVID-19 and fast expansion of the disease in the United States and elsewhere, the rapid development of an effective vaccine is of utmost importance.

## 2.2. Background

In December 2019, a pneumonia outbreak of unknown cause occurred in Wuhan, China. In January 2020, it became clear that a novel coronavirus (2019-nCoV) was the underlying cause. Later in January, the genetic sequence of the 2019-nCoV became available to the World Health Organization (WHO) and public (MN908947.3), and the virus was categorized in the *Betacoronavirus* subfamily. By sequence analysis, the phylogenetic tree revealed a closer relationship to severe acute respiratory syndrome (SARS) virus isolates than to another coronavirus infecting humans, the Middle East respiratory syndrome (MERS) virus.

SARS-CoV-2 infections and the resulting disease, COVID-19, have spread globally, affecting a growing number of countries.

On 11 March 2020, the WHO characterized the COVID-19 outbreak as a pandemic.[1] The WHO Situation Update Report dated 30 March 2020 noted 693,224 confirmed cases with 33,106 deaths globally, including 142,081 confirmed cases with 2457 deaths in the Americas.[2] The United States currently has the most reported cases globally. At the time of this communication, the number of confirmed cases continues to rise globally. There are currently no vaccines or effective antiviral drugs to treat SARS-CoV-2 infections or the disease it causes, COVID-19.[3]

A prophylactic, RNA-based SARS-CoV-2 vaccine provides one of the most flexible and fastest approaches available to immunize against the emerging virus.[4,5]

The development of an RNA-based vaccine encoding a viral antigen, which is then expressed by the vaccine recipient as a protein capable of eliciting protective immune responses, provides significant advantages over more traditional vaccine approaches. Unlike live attenuated vaccines, RNA vaccines do not carry the risks associated with infection and may be given to people who cannot be administered live virus (eg, pregnant women and immunocompromised persons). RNA-based vaccines are manufactured via a cell-free in vitro transcription process, which allows an easy and rapid production and the prospect of producing high numbers of vaccination doses within a shorter time period than achieved with traditional vaccine approaches. This capability is pivotal to enable the most effective response in outbreak scenarios.

Two SARS-CoV-2–RNA lipid nanoparticle (RNA-LNP) vaccines based on a platform of nucleoside-modified messenger RNA (modRNA, BNT162b) will be evaluated in this study. Each vaccine candidate expresses 1 of 2 antigens: the SARS-CoV-2 full-length, P2 mutant, prefusion spike glycoprotein (P2 S) (version 9) or a trimerized SARS-CoV-2 spike glycoprotein-receptor binding domain (RBD) (version 5). The 2 SARS-CoV-2 vaccine candidates that will be tested in this study are therefore:

- **BNT162b1** (variant RBP020.3): nucleoside-modified messenger RNA (modRNA) with blunted innate immune sensor–activating capacity and augmented expression encoding the RBD.

- **BNT162b2** (variant RBP020.2): nucleoside-modified messenger RNA (modRNA) as above, but encoding P2 S.

The vaccine candidate selected for Phase 2/3 evaluation is BNT162b2.

### 2.2.1. Clinical Overview

Prior to this study, given clinical data from other similarly formulated uRNA liposomal vaccines from BioNTech in oncology trials[6] and recent published results from clinical trials using modRNA influenza vaccines by Moderna,[7] the BNT162 vaccines were expected to have a favorable safety profile with mild, localized, and transient effects. BNT162 vaccines based on modRNA have now been administered to humans for the first time in this study and the BNT162-01 study conducted in Germany by BioNTech, at doses between 1 µg and 100 µg. The currently available safety and immunogenicity data are presented in the BNT162 IB.

## 2.3. Benefit/Risk Assessment

There is an ongoing global pandemic of COVID-19 with no preventative or therapeutic options available. While there were no data available from clinical trials on the use of BNT162 vaccines in humans at the outset of this study, available nonclinical data with these vaccines, and data from nonclinical studies and clinical trials with the same or related RNA components, or antigens, supported a favorable risk/benefit profile. Anticipated AEs after vaccination were expected to be manageable using routine symptom-driven standard of care as determined by the investigators and, as a result, the profile of these vaccine candidates supported initiation of this Phase 1/2/3 clinical study.

Updates as part of protocol amendment 6:

- In order for the overall Phase 3 study population to be as representative and diverse as possible, the inclusion of participants with known chronic stable HIV, HCV, or HBV infection is permitted. Individuals with chronic viral diseases are at increased risk for COVID-19 complications and severe disease. In addition, with the currently available therapies for their treatment, many individuals with chronic stable HIV, HCV, and HBV infections are unlikely to be at higher safety risk as a

participant in this vaccine study than individuals with other chronic stable medical conditions.

- All participants with chronic stable HIV disease will be included in the reactogenicity subset (see Section 8.2.2).

Updates as part of protocol amendment 7:

- The minimum age for inclusion in Phase 3 is lowered to 12 years, therefore allowing the inclusion of participants 12 to 15 years of age.

- For individuals 12 to 15 years of age, the immune responses in this age group may be higher and reactogenicity is expected to be similar to younger adults 18 to 25 years of age. Inclusion of individuals 12 to 15 years of age was based upon a satisfactory blinded safety profile in participants 18 to 25 years of age.

- All participants 12 to 15 years of age will be included in the reactogenicity subset (see Section 8.2.2).

More detailed information about the known and expected benefits and risks and reasonably expected AEs of BNT162 RNA-based COVID-19 vaccines may be found in the IB, which is the SRSD for this study.

### 2.3.1. Risk Assessment

| Potential Risk of Clinical Significance | Summary of Data/Rationale for Risk | Mitigation Strategy |
|---|---|---|
| **Study Intervention: BNT162 RNA-Based COVID-19 Vaccine** | | |
| Potential for local reactions (injection site redness, injection site swelling, and injection site pain) and systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, muscle pain, and joint pain) following vaccination. | These are common adverse reactions seen with other vaccines, as noted in the FDA Center for Biologics Evaluation and Research (CBER) guidelines on toxicity grading scales for healthy adult volunteers enrolled in preventive vaccine clinical trials.[8] | The Phase 1 study design includes the use of controlled vaccination and dose escalation to closely monitor and limit the rate of enrollment to ensure participant safety. The study employs the use of a reactogenicity e-diary to monitor local reactions and systemic events in real time. Stopping rules are also in place. The first 5 participants in each group in Phase 1 will be observed for 4 hours after vaccination to assess any immediate AEs. All other participants will be observed for at least 30 minutes after vaccination. |
| Unknown AEs and laboratory abnormalities with a novel vaccine. | This study is one of the first 2 parallel-running clinical studies with the BNT162 vaccine candidates and as such there are no clinical data available for this vaccine. | The Phase 1 study design includes the use of controlled vaccination and dose escalation to closely monitor and limit the rate of enrollment to ensure participant safety. An IRC (in Phase 1) and DMC (throughout the study) will also review safety data. Stopping rules are also in place. The first 5 participants in each group in Phase 1 will be observed for 4 hours after vaccination to assess any immediate AEs. All other participants will be observed for at least 30 minutes after vaccination. |
| Potential for COVID-19 enhancement. | Disease enhancement has been seen following vaccination with respiratory syncytial virus (RSV), feline coronavirus, and Dengue virus vaccines. | Phase 1 excludes participants with likely previous or current COVID-19. In Phase 2/3, temporary delay criteria defer vaccination of participants with symptoms of potential COVID-19. All participants are followed for any potential COVID-19 illness, including markers of severity, and have blood samples taken for potential measurement of SARS-CoV-2 antigen-specific antibody and SARS-CoV-2 neutralizing titers. |

| Potential Risk of Clinical Significance | Summary of Data/Rationale for Risk | Mitigation Strategy |
|---|---|---|
| **Study Procedures** | | |
| Participants will be required to attend healthcare facilities during the global SARS-CoV-2 pandemic. | Without appropriate social distancing and PPE, there is a potential for increased exposure to SARS-CoV-2. | Pfizer will work with sites to ensure an appropriate COVID-19 prevention strategy. Potential COVID-19 illness visits can be conducted via telehealth, without the need for an in-person visit, if required, with the participant performing a self-swab. |
| Venipuncture will be performed during the study. | There is the risk of bleeding, bruising, hematoma formation, and infection at the venipuncture site. | Only appropriately qualified personnel would obtain the blood draw. |

### 2.3.2. Benefit Assessment

Benefits to individual participants may include:

- Receipt of a potentially efficacious COVID-19 vaccine during a global pandemic
- Access to COVID-19 diagnostic testing
- Contributing to research to help others in a time of global pandemic

### 2.3.3. Overall Benefit/Risk Conclusion

Taking into account the measures taken to minimize risk to participants participating in this study, the potential risks identified in association with BNT162 RNA-based COVID-19 vaccine are justified by the anticipated benefits that may be afforded to healthy participants.

## 3. OBJECTIVES, ESTIMANDS, AND ENDPOINTS

### 3.1. For Phase 1

| Objectives | Estimands | Endpoints |
|---|---|---|
| **Primary:** | **Primary:** | **Primary:** |
| To describe the safety and tolerability profiles of prophylactic BNT162 vaccines in healthy adults after 1 or 2 doses | In participants receiving at least 1 dose of study intervention, the percentage of participants reporting:<br>• Local reactions for up to 7 days following each dose<br>• Systemic events for up to 7 days following each dose<br>• Adverse events (AEs) from Dose 1 to 1 month after the last dose<br>• Serious AEs (SAEs) from Dose 1 to 6 months after the last dose<br><br>In addition, the percentage of participants with:<br>• Abnormal hematology and chemistry laboratory values 1 and 7 days after Dose 1; and 7 days after Dose 2<br>• Grading shifts in hematology and chemistry laboratory assessments between baseline and 1 and 7 days after Dose 1; and before Dose 2 and 7 days after Dose 2 | • Local reactions (pain at the injection site, redness, and swelling)<br>• Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain)<br>• AEs<br>• SAEs<br><br>Hematology and chemistry laboratory parameters detailed in Section 10.2 |

| Objectives | Estimands | Endpoints |
|---|---|---|
| **Secondary:** | **Secondary:** | **Secondary:** |
| To describe the immune responses elicited by prophylactic BNT162 vaccines in healthy adults after 1 or 2 doses | In participants complying with the key protocol criteria (evaluable participants) at the following time points after receipt of study intervention: 7 and 21 days after Dose 1; 7 and 14 days and 1, 6, 12, and 24 months after Dose 2 | |
| | • Geometric mean titers (GMTs) at each time point<br>• Geometric mean fold rise (GMFR) from before vaccination to each subsequent time point after vaccination<br>• Proportion of participants achieving ≥4-fold rise from before vaccination to each subsequent time point after vaccination | SARS-CoV-2 neutralizing titers |
| | • Geometric mean concentrations (GMCs) at each time point<br>• GMFR from prior to first dose of study intervention to each subsequent time point<br>• Proportion of participants achieving ≥4-fold rise from before vaccination to each subsequent time point after vaccination | S1-binding IgG levels and RBD-binding IgG levels |
| | • Geometric mean ratio (GMR), estimated by the ratio of the geometric mean of SARS-CoV-2 neutralizing titers to the geometric mean of binding IgG levels at each time point | • SARS-CoV-2 neutralizing titers<br>• S1-binding IgG levels<br>• RBD-binding IgG levels |

## 3.2. For Phase 2/3

| Objectives[a] | Estimands | Endpoints |
|---|---|---|
| **Primary Efficacy** | | |
| To evaluate the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 7 days after the second dose in participants without evidence of infection before vaccination | In participants complying with the key protocol criteria (evaluable participants) at least 7 days after receipt of the second dose of study intervention:<br>100 × (1 – IRR) [ratio of active vaccine to placebo] | COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT in participants with no serological or virological evidence (up to 7 days after receipt of the second dose) of past SARS-CoV-2 infection |
| To evaluate the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 7 days after the second dose in participants with and without evidence of infection before vaccination | In participants complying with the key protocol criteria (evaluable participants) at least 7 days after receipt of the second dose of study intervention:<br>100 × (1 – IRR) [ratio of active vaccine to placebo] | COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT |
| **Primary Safety** | | |
| To define the safety profile of prophylactic BNT162b2 in the first 360 participants randomized (Phase 2) | In participants receiving at least 1 dose of study intervention, the percentage of participants reporting:<br>• Local reactions for up to 7 days following each dose<br>• Systemic events for up to 7 days following each dose<br>• AEs from Dose 1 to 7 days after the second dose<br>• SAEs from Dose 1 to 7 days after the second dose | • Local reactions (pain at the injection site, redness, and swelling)<br>• Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain)<br>• AEs<br>• SAEs |
| To define the safety profile of prophylactic BNT162b2 in all participants randomized in Phase 2/3 | In participants receiving at least 1 dose of study intervention, the percentage of participants reporting:<br>• Local reactions for up to 7 days following each dose<br>• Systemic events for up to 7 days following each dose<br>• AEs from Dose 1 to 1 month after the second dose<br>• SAEs from Dose 1 to 6 months after the second dose | • AEs<br>• SAEs<br>• In a subset of at least 6000 participants:<br>o Local reactions (pain at the injection site, redness, and swelling)<br>o Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain) |
| To define the safety profile of prophylactic BNT162b2 in participants 12 to 15 years of age in Phase 3 | In participants receiving at least 1 dose of study intervention, the percentage of participants reporting:<br>• Local reactions for up to 7 days following each dose<br>• Systemic events for up to 7 days following each dose<br>• AEs from Dose 1 to 1 month after the second dose<br>• SAEs from Dose 1 to 6 months after the second dose | • Local reactions (pain at the injection site, redness, and swelling)<br>• Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain)<br>• AEs<br>• SAEs |

| Objectives[a] | Estimands | Endpoints |
|---|---|---|
| **Secondary Efficacy** | | |
| To evaluate the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 14 days after the second dose in participants without evidence of infection before vaccination | In participants complying with the key protocol criteria (evaluable participants) at least 14 days after receipt of the second dose of study intervention:<br>100 × (1 – IRR) [ratio of active vaccine to placebo] | COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT in participants with no serological or virological evidence (up to 14 days after receipt of the second dose) of past SARS-CoV-2 infection |
| To evaluate the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 14 days after the second dose in participants with and without evidence of infection before vaccination | In participants complying with the key protocol criteria (evaluable participants) at least 14 days after receipt of the second dose of study intervention:<br>100 × (1 – IRR) [ratio of active vaccine to placebo] | COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT |
| To evaluate the efficacy of prophylactic BNT162b2 against confirmed severe COVID-19 occurring from 7 days and from 14 days after the second dose in participants without evidence of infection before vaccination | In participants complying with the key protocol criteria (evaluable participants)<br>• at least 7 days<br>and<br>• at least 14 days<br>after receipt of the second dose of study intervention:<br>100 × (1 – IRR) [ratio of active vaccine to placebo] | Confirmed severe COVID-19 incidence per 1000 person-years of follow-up in participants with no serological or virological evidence (up to 7 days and up to 14 days after receipt of the second dose) of past SARS-CoV-2 infection |
| To evaluate the efficacy of prophylactic BNT162b2 against confirmed severe COVID-19 occurring from 7 days and from 14 days after the second dose in participants with and without evidence of infection before vaccination | In participants complying with the key protocol criteria (evaluable participants)<br>• at least 7 days<br>and<br>• at least 14 days<br>after receipt of the second dose of study intervention:<br>100 × (1 – IRR) [ratio of active vaccine to placebo] | Confirmed severe COVID-19 incidence per 1000 person-years of follow-up |
| To describe the efficacy of prophylactic BNT162b2 against confirmed COVID-19 (according to the CDC-defined symptoms) occurring from 7 days and from 14 days after the second dose in participants without evidence of infection before vaccination | In participants complying with the key protocol criteria (evaluable participants)<br>• at least 7 days<br>and<br>• at least 14 days<br>after receipt of the second dose of study intervention:<br>100 × (1 – IRR) [ratio of active vaccine to placebo] | COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT in participants with no serological or virological evidence (up to 7 days and up to 14 days after receipt of the second dose) of past SARS-CoV-2 infection |
| To describe the efficacy of prophylactic BNT162b2 against confirmed COVID-19 (according to the CDC-defined symptoms) occurring from 7 days and from 14 days after the second dose in participants with and without evidence of infection before vaccination | In participants complying with the key protocol criteria (evaluable participants)<br>• at least 7 days<br>and<br>• at least 14 days<br>after receipt of the second dose of study intervention:<br>100 × (1 – IRR) [ratio of active vaccine to placebo] | COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT |

| Objectives[a] | Estimands | Endpoints |
|---|---|---|
| **Secondary Immunogenicity** | | |
| To demonstrate the noninferiority of the immune response to prophylactic BNT162b2 in participants 12 to 15 years of age compared to participants 16 to 25 years of age | GMR, estimated by the ratio of the geometric mean of SARS-CoV-2 neutralizing titers in the 2 age groups (12-15 years of age to 16-25 years of age) 1 month after completion of vaccination | SARS-CoV-2 neutralizing titers in participants with no serological or virological evidence (up to 1 month after receipt of the second dose) of past SARS-CoV-2 infection |
| **Exploratory** | | |
| To evaluate the immune response over time to prophylactic BNT162b2 and persistence of immune response in participants with and without serological or virological evidence of SARS-CoV-2 infection before vaccination | GMC/GMT, GMFR, and percentage of participants with titers greater than defined threshold(s), at baseline and 1, 6, 12, and 24 months after completion of vaccination | • S1-binding IgG levels and/or RBD-binding IgG levels<br>• SARS-CoV-2 neutralizing titers |
| To evaluate the immune response (non-S) to SARS-CoV-2 in participants with and without confirmed COVID-19 during the study | | • N-binding antibody |
| To describe the serological responses to the BNT vaccine candidate in cases of:<br>• Confirmed COVID-19<br>• Confirmed severe COVID-19<br>• SARS-CoV-2 infection without confirmed COVID-19 | | • S1-binding IgG levels and/or RBD-binding IgG levels<br>• SARS-CoV-2 neutralizing titers |
| To describe the safety, immunogenicity, and efficacy of prophylactic BNT162b2 in individuals with confirmed stable HIV disease | | • All safety, immunogenicity, and efficacy endpoints described above |
| To describe the safety and immunogenicity of prophylactic BNT162b2 in individuals 16 to 55 years of age vaccinated with study intervention produced by manufacturing "Process 1" or "Process 2"[b] | | • All safety endpoints described above<br>• SARS-CoV-2 neutralizing titers |

a. HIV-positive participants in Phase 3 will not be included in analyses of the objectives, with the exception of the specific exploratory objective.
b. See Section 6.1.1 for description of the manufacturing process.

This protocol will use a group of internal case reviewers to determine whether certain investigator-reported events meet the definition of disease-related efficacy endpoints, using predefined endpoint criteria.

For those AEs that are handled as disease-related efficacy endpoints (which may include death), a DMC will conduct unblinded reviews on a regular basis throughout the trial (see Section 9.6).

Any AE that is determined by the internal case reviewers NOT to meet endpoint criteria is reported back to the investigator site of incidence. Refer to Section 8.3.1.1 for instructions on how to report any such AE that meets the criteria for seriousness to Pfizer Safety.

# 4. STUDY DESIGN

## 4.1. Overall Design

This is a multicenter, multinational, Phase 1/2/3, randomized, placebo-controlled, observer-blind, dose-finding, vaccine candidate–selection, and efficacy study in healthy individuals.

The study consists of 2 parts. Phase 1: to identify preferred vaccine candidate(s) and dose level(s); Phase 2/3: an expanded cohort and efficacy part. These parts, and the progression between them, are detailed in the schema (Section 1.2).

The study will evaluate the safety, tolerability, and immunogenicity of 2 different SARS-CoV-2 RNA vaccine candidates against COVID-19 and the efficacy of 1 candidate:

- As a 2-dose (separated by 21 days) schedule;
- At various different dose levels in Phase 1;
- In 3 age groups (Phase 1: 18 to 55 years of age, 65 to 85 years of age; Phase 2/3: ≥12 years of age [stratified as 12-15, 16-55, or >55 years of age]).

Dependent upon safety and/or immunogenicity data generated during the course of this study, or the BioNTech study conducted in Germany (BNT162-01), it is possible that groups in Phase 1 may be started at the next highest dose, groups may not be started, groups may be terminated early, and/or groups may be added with dose levels below the lowest stated dose or intermediate between the lowest and highest stated doses.

The study is observer-blinded, as the physical appearance of the investigational vaccine candidates and the placebo may differ. The participant, investigator, study coordinator, and other site staff will be blinded. At the study site, only the dispenser(s)/administrator(s) are unblinded.

To facilitate rapid review of data in real time, sponsor staff will be unblinded to vaccine allocation for the participants in Phase 1.

### 4.1.1. Phase 1

Each group (vaccine candidate/dose level/age group) will comprise 15 participants; 12 participants will be randomized to receive active vaccine and 3 to receive placebo.

For each vaccine candidate/dose level/age group, the following apply:

- Additional safety assessments (see Section 8.2)

- Controlled enrollment (required only for the first candidate and/or dose level studied):
    - No more than 5 participants (4 active, 1 placebo) can be vaccinated on the first day
    - The first 5 participants must be observed by blinded site staff for at least 4 hours after vaccination for any acute reactions
    - Vaccination of the remaining participants will commence no sooner than 24 hours after the fifth participant received his or her vaccination
- Application of stopping rules
- IRC review of safety data to determine escalation to the next dose level in the 18- to 55-year age cohort:
    - Escalation between dose levels will be based on IRC review of at least 7-day post–Dose 1 safety data in this study and/or the BioNTech study conducted in Germany (BNT162-01)
    - Note that, since both candidates are based upon the same RNA platform, dose escalation for the second candidate studied may be based upon the safety profile of the first candidate studied being deemed acceptable at the same, or a higher, dose level by the IRC

Groups of participants 65 to 85 years of age will not be started until safety data for the RNA platform have been deemed acceptable at the same, or a higher, dose level in the 18- to 55-year age cohort by the IRC.

In this phase, 13 groups will be studied, corresponding to a total of 195 participants.

The IRC will select 1 vaccine candidate that, in Phase 1, has an established dose level per age group based on induction of a post–Dose 2 immune response, including neutralizing antibodies, which is expected to be associated with protection against COVID-19, for progression into Phase 2/3.

### 4.1.2. Phase 2/3

On the basis of safety and/or immunogenicity data generated during the course of this study, and/or the BioNTech study conducted in Germany (BNT162-01), 1 vaccine candidate was selected to proceed into Phase 2/3. Participants in this phase will be ≥12 years of age, stratified as follows: 12 to 15 years, 16 to 55 years, or >55 years. The 12- to 15-year stratum will comprise up to approximately 2000 participants enrolled at selected investigational sites. It is intended that a minimum of 40% of participants will be in the >55-year stratum. Commencement of each age stratum will be based upon satisfactory post–Dose 2 safety and immunogenicity data from the 18- to 55-year and 65- to 85-year age groups in Phase 1,

respectively. The vaccine candidate selected for Phase 2/3 evaluation is BNT162b2 at a dose of 30 μg.

Phase 2/3 is event-driven. Under the assumption of a true VE rate of ≥60%, after the second dose of investigational product, a target of 164 primary-endpoint cases of confirmed COVID-19 due to SARS-CoV-2 occurring at least 7 days following the second dose of the primary series of the candidate vaccine will be sufficient to provide 90% power to conclude true VE >30% with high probability. The total number of participants enrolled in Phase 2/3 may vary depending on the incidence of COVID-19 at the time of the enrollment, the true underlying VE, and a potential early stop for efficacy or futility.

Assuming a COVID-19 attack rate of 1.3% per year in the placebo group, accrual of 164 first primary-endpoint cases within 6 months, an estimated 20% nonevaluable rate, and 1:1 randomization, the BNT162b2 vaccine candidate selected for Phase 2/3 is expected to comprise approximately 21,999 vaccine recipients. This is the number of participants initially targeted for Phase 2/3 and may be adjusted based on advice from DMC analyses of case accumulation and the percentage of participants who are seropositive at baseline. Dependent upon the evolution of the pandemic, it is possible that the COVID-19 attack rate may be much higher, in which case accrual would be expected to be more rapid, enabling the study's primary endpoint to be evaluated much sooner.

The first 360 participants enrolled (180 to active vaccine and 180 to placebo, stratified equally between 18 to 55 years and >55 to 85 years) will comprise the "Phase 2" portion. Safety data through 7 days after Dose 2 and immunogenicity data through 1 month after Dose 2 from these 360 participants will be analyzed by the unblinded statistical team, reviewed by the DMC, and submitted to appropriate regulatory authorities for review. Enrollment may continue during this period and these participants would be included in the efficacy evaluation in the "Phase 3" portion of the study.

In Phase 3, up to approximately 2000 participants, enrolled at selected sites, are anticipated to be 12 to 15 years of age. Noninferiority of immune response to prophylactic BNT162b2 in participants 12 to 15 years of age to response in participants 16 to 25 years of age will be assessed based on the GMR of SARS-CoV-2 neutralizing titers using a 1.5-fold margin. A sample size of 200 evaluable participants (or 250 vaccine recipients) per age group will provide a power of 90.8% to declare the noninferiority in terms of GMR (lower limit of 95% CI for GMR >0.67). A random sample of 250 participants from each of the 2 age groups (12 to 15 years and 16 to 25 years) will be selected as an immunogenicity subset for the noninferiority assessment.

The initial BNT162b2 was manufactured using "Process 1"; however, "Process 2" was developed to support an increased scale of manufacture. In the study, each lot of "Process 2"-manufactured BNT162b2 will be administered to approximately 250 participants 16 to 55 years of age. The safety and immunogenicity of prophylactic BNT162b2 in individuals 16 to 55 years of age vaccinated with "Process 1" and each lot of "Process 2" study intervention will be described. A random sample of 250 participants from those

vaccinated with study intervention produced by manufacturing "Process 1" will be selected for this descriptive analysis.

Participants are expected to participate for up to a maximum of approximately 26 months. The duration of study follow-up may be shorter among participants enrolled in Phase 1 dosing arms that are not evaluated in Phase 2/3.

### 4.2. Scientific Rationale for Study Design

Additional surveillance for COVID-19 will be conducted as part of the study, given the potential risk of disease enhancement. If a participant experiences symptoms, as detailed in Section 8.13, a COVID-19 illness and subsequent convalescent visit will occur. As part of these visits, samples (nasal [midturbinate] swab and blood) will be taken for antigen and antibody assessment as well as recording of COVID-19–related clinical and laboratory information (including local diagnosis).

Human reproductive safety data are not available for BNT162 RNA-based COVID-19 vaccines, but there is no suspicion of human teratogenicity based on the intended mechanism of action of the compound. Therefore, the use of a highly effective method of contraception is required (see Appendix 4).

### 4.3. Justification for Dose

Because of the requirement for a rapid response to the newly emerged COVID-19 pandemic, sufficient data were not available to experimentally validate the dose selection and initial starting dose. Therefore, the original planned starting dose of 10 µg (for both BNT162b1 and BNT162b2) in this study was based on nonclinical experience with the same RNAs encoding other viral antigens (such as influenza and HIV antigens). The general safety and effectiveness of uRNA and modRNA platforms have been demonstrated in oncological clinical trials with different administration routes (NCT02410733, NCT03871348). Doses of up to 400 µg total uRNA have been administered IV as RNA lipoplex (RNA-LPX) and doses of up to 1000 µg total naked modRNA have been administered intratumorally, both without signs of unpredictable overstimulation of the immune system.

Based on nonclinical data of the RNA components, with other liposomes or in conjunction with the lipid nanoparticles as will be tested clinically in this study, it was expected that doses in the 1- to 5-µg range would be immunogenic and induce neutralizing antibodies; however, it was anticipated that 3- to 10-fold higher doses would likely be required to elicit a stronger antibody response. Based on previous clinical and nonclinical experience, it was expected that doses of up to 100 µg would be well tolerated.

Update as part of protocol amendment 2: preliminary experience in this study and the BioNTech study conducted in Germany (BNT162-01) suggests that, for vaccine candidates based on the modRNA platform, a dose level between 30 µg and 100 µg warrants consideration. Therefore, a 50-µg dose level is formally included for BNT162b1 and BNT162b2.

Update as part of protocol amendment 3: as data have become available from this study and the BNT162-01 study in Germany, it was decided:

- To not study the BNT162a1 and BNT162c2 vaccine candidates at this time, so these candidates have been removed from the protocol; and
- That lower dose levels of BNT162b1 and BNT162b2 warrant consideration. Therefore, a 20-µg dose level is formally included for both candidates.

Update as part of protocol amendment 4: the 50-µg dose level for BNT162b1 and BNT162b2 is removed and the 100-µg dose level for BNT162b2 is removed; similar dose levels of BNT162b3 may be studied as for BNT162b1 and BNT162b2.

Update as part of protocol amendment 5: the vaccine candidate selected for Phase 2/3 evaluation is BNT162b2 at a dose of 30 µg. BNT162b3 will not be studied.

### 4.4. End of Study Definition

A participant is considered to have completed the study if he/she has completed all phases of the study, including the last visit. Note that participants enrolled in Phase 1 in groups that do not proceed to Phase 2/3 may be followed for fewer than 24 months (but no less than 6 months after the last vaccination).

The end of the study is defined as the date of last visit of the last participant in the study.

## 5. STUDY POPULATION

This study can fulfill its objectives only if appropriate participants are enrolled. The following eligibility criteria are designed to select participants for whom participation in the study is considered appropriate. All relevant medical and nonmedical conditions should be taken into consideration when deciding whether a particular participant is suitable for this protocol.

Prospective approval of protocol deviations to recruitment and enrollment criteria, also known as protocol waivers or exemptions, is not permitted.

### 5.1. Inclusion Criteria

Participants are eligible to be included in the study only if all of the following criteria apply:

**Age and Sex:**

1. Male or female participants between the ages of 18 and 55 years, inclusive, and 65 and 85 years, inclusive (Phase 1), or ≥12 years (Phase 2/3), at randomization. Note that participants <18 years of age cannot be enrolled in the EU.
    - Refer to Appendix 4 for reproductive criteria for male (Section 10.4.1) and female (Section 10.4.2) participants.

**Type of Participant and Disease Characteristics:**

2. Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures.

3. Healthy participants who are determined by medical history, physical examination (if required), and clinical judgment of the investigator to be eligible for inclusion in the study.

   **Note**: Healthy participants with preexisting stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment, can be included. Specific criteria for Phase 3 participants with known stable infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) can be found in Section 10.8.

4. **Phase 2/3 only:** Participants who, in the judgment of the investigator, are at higher risk for acquiring COVID-19 (including, but not limited to, use of mass transportation, relevant demographics, and frontline essential workers).

**Informed Consent:**

5. Capable of giving personal signed informed consent/have parent(s)/legal guardian capable of giving signed informed consent as described in Appendix 1, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol.

### 5.2. Exclusion Criteria

Participants are excluded from the study if any of the following criteria apply:

**Medical Conditions:**

1. Other medical or psychiatric condition including recent (within the past year) or active suicidal ideation/behavior or laboratory abnormality that may increase the risk of study participation or, in the investigator's judgment, make the participant inappropriate for the study.

2. **Phases 1 and 2 only:** Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV).

3. History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s).

4. Receipt of medications intended to prevent COVID-19.

5. Previous clinical (based on COVID-19 symptoms/signs alone, if a SARS-CoV-2 NAAT result was not available) or microbiological (based on COVID-19 symptoms/signs and a positive SARS-CoV-2 NAAT result) diagnosis of COVID-19.

6. **Phase 1 only:** Individuals at high risk for severe COVID-19, including those with any of the following risk factors:

    - Hypertension
    - Diabetes mellitus
    - Chronic pulmonary disease
    - Asthma
    - Current vaping or smoking
    - History of chronic smoking within the prior year
    - Chronic liver disease
    - Stage 3 or worse chronic kidney disease (glomerular filtration rate <60 mL/min/1.73 $m^2$)
    - Resident in a long-term facility
    - BMI >30 $kg/m^2$
    - Anticipating the need for immunosuppressive treatment within the next 6 months

7. **Phase 1 only:** Individuals currently working in occupations with high risk of exposure to SARS-CoV-2 (eg, healthcare worker, emergency response personnel).

8. Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination.

9. **Phase 1 only:** Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention, including but not limited to: systemic or cutaneous lupus erythematosus, autoimmune arthritis/rheumatoid arthritis, Guillain-Barré syndrome, multiple sclerosis, Sjögren's syndrome, idiopathic thrombocytopenia purpura, glomerulonephritis, autoimmune thyroiditis, giant cell arteritis (temporal arteritis), psoriasis, and insulin-dependent diabetes mellitus (type 1).

10. Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection.

11. Women who are pregnant or breastfeeding.

**Prior/Concomitant Therapy:**

12. Previous vaccination with any coronavirus vaccine.

13. Individuals who receive treatment with immunosuppressive therapy, including cytotoxic agents or systemic corticosteroids, eg, for cancer or an autoimmune disease, or planned receipt throughout the study. If systemic corticosteroids have been administered short term (<14 days) for treatment of an acute illness, participants should not be enrolled into

the study until corticosteroid therapy has been discontinued for at least 28 days before study intervention administration. Inhaled/nebulized (except for participants in Phase 1 – see exclusion criterion 14), intra-articular, intrabursal, or topical (skin or eyes) corticosteroids are permitted.

14. **Phase 1 only:** Regular receipt of inhaled/nebulized corticosteroids.

15. Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study.

**Prior/Concurrent Clinical Study Experience:**

16. Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation.

17. Previous participation in other studies involving study intervention containing lipid nanoparticles.

**Diagnostic Assessments:**

18. **Phase 1 only:** Positive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit.

19. **Phase 1 only:** Any screening hematology and/or blood chemistry laboratory value that meets the definition of a ≥ Grade 1 abnormality.

    **Note:** With the exception of bilirubin, participants with any stable Grade 1 abnormalities (according to the toxicity grading scale) may be considered eligible at the discretion of the investigator. (Note: A "stable" Grade 1 laboratory abnormality is defined as a report of Grade 1 on an initial blood sample that remains ≤ Grade 1 upon repeat testing on a second sample from the same participant.)

20. **Phase 1 only:** Positive test for HIV, hepatitis B surface antigen (HBsAg), hepatitis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV Abs) at the screening visit.

21. **Phase 1 only:** SARS-CoV-2 NAAT-positive nasal swab within 24 hours before receipt of study intervention.

**Other Exclusions:**

22. Investigator site staff or Pfizer/BioNTech employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members.

## 5.3. Lifestyle Considerations

### 5.3.1. Contraception

The investigator or his or her designee, in consultation with the participant, will confirm that the participant has selected an appropriate method of contraception for the individual participant and his or her partner(s) from the permitted list of contraception methods (see Appendix 4, Section 10.4.4) and will confirm that the participant has been instructed in its consistent and correct use. At time points indicated in the SoA, the investigator or designee will inform the participant of the need to use highly effective contraception consistently and correctly and document the conversation and the participant's affirmation in the participant's chart (participants need to affirm their consistent and correct use of at least 1 of the selected methods of contraception). In addition, the investigator or designee will instruct the participant to call immediately if the selected contraception method is discontinued or if pregnancy is known or suspected in the participant or partner.

## 5.4. Screen Failures

Screen failures are defined as participants who consent to participate in the clinical study but are not subsequently randomly assigned to study intervention. A minimal set of screen failure information is required to ensure transparent reporting of screen failure participants to meet the CONSORT publishing requirements and to respond to queries from regulatory authorities. Minimal information includes demography, screen failure details, eligibility criteria, and any SAE.

Individuals who do not meet the criteria for participation in this study (screen failure) may be rescreened under a different participant number.

## 5.5. Criteria for Temporarily Delaying Enrollment/Randomization/Study Intervention Administration

The following conditions are temporary or self-limiting and a participant may be vaccinated once the condition(s) has/have resolved and no other exclusion criteria are met.

1. Current febrile illness (body temperature ≥100.4°F [≥38°C]) or other acute illness within 48 hours before study intervention administration. This includes current symptoms that could represent a potential COVID-19 illness:

    - New or increased cough;
    - New or increased shortness of breath;
    - Chills;
    - New or increased muscle pain;
    - New loss of taste/smell;
    - Sore throat;

- Diarrhea;
- Vomiting.

2. Receipt of any seasonal or pandemic influenza vaccine within 14 days, or any other nonstudy vaccine within 28 days, before study intervention administration.

3. Anticipated receipt of any seasonal or pandemic influenza vaccine within 14 days, or any other nonstudy vaccine within 28 days, after study intervention administration.

4. Receipt of short-term (<14 days) systemic corticosteroids. Study intervention administration should be delayed until systemic corticosteroid use has been discontinued for at least 28 days. Inhaled/nebulized, intra-articular, intrabursal, or topical (skin or eyes) corticosteroids are permitted.

## 6. STUDY INTERVENTION

Study intervention is defined as any investigational intervention(s), marketed product(s), placebo, medical device(s), or study procedure(s) intended to be administered to a study participant according to the study protocol.

The study will evaluate a 2-dose (separated by 21 days) schedule of various different dose levels of 2 investigational RNA vaccine candidates for active immunization against COVID-19 in 3 age groups (18 to 55 years of age, 65 to 85 years of age, and ≥12 years of age [stratified as 12-15, 16-55, or >55 years of age]).

These 2 investigational RNA vaccine candidates, with the addition of saline placebo, are the 3 potential study interventions that may be administered to a study participant:

- BNT162b1 (BNT162 RNA-LNP vaccine utilizing modRNA and encoding the RBD): 10 µg, 20 µg, 30 µg, 100 µg
- BNT162b2 (BNT162 RNA-LNP vaccine utilizing modRNA and encoding the P2 S): 10 µg, 20 µg, 30 µg
- Normal saline (0.9% sodium chloride solution for injection)

The vaccine candidate selected for Phase 2/3 evaluation is BNT162b2 at a dose of 30 µg.

## 6.1. Study Intervention(s) Administered

| Intervention Name | BNT162b1 (BNT162 RNA-LNP vaccine utilizing modRNA) | BNT162b2 (BNT162 RNA-LNP vaccine utilizing modRNA) | Saline Placebo |
|---|---|---|---|
| **Type** | Vaccine | Vaccine | Placebo |
| **Dose Formulation** | modRNA | modRNA | Normal saline (0.9% sodium chloride solution for injection) |
| **Unit Dose Strength(s)** | 250 µg/0.5 mL | 250 µg/0.5 mL | N/A |
| **Dosage Level(s)**[a] | 10-, 20-, 30-, 100-µg | 10-, 20-, 30-µg | N/A |
| **Route of Administration** | Intramuscular injection | Intramuscular injection | Intramuscular injection |
| **Use** | Experimental | Experimental | Placebo |
| **IMP or NIMP** | IMP | IMP | IMP |
| **Sourcing** | Provided centrally by the sponsor | Provided centrally by the sponsor | Provided centrally by the sponsor |
| **Packaging and Labeling** | Study intervention will be provided in a glass vial as open-label supply. Each vial will be labeled as required per country requirement | Study intervention will be provided in a glass vial as open-label supply. Each vial will be labeled as required per country requirement | Study intervention will be provided in a glass or plastic vial as open-label supply. Each vial will be labeled as required per country requirement |

a. Dependent upon safety and/or immunogenicity data generated during the course of this study, or the BioNTech study conducted in Germany (BNT162-01), it is possible that groups may be started at the next highest dose, groups may not be started, groups may be terminated early, and/or groups may be added with dose levels below the lowest stated dose or intermediate between the lowest and highest stated doses.

The vaccine candidate selected for Phase 2/3 evaluation is BNT162b2 at a dose of 30 µg.

### 6.1.1. Manufacturing Process

The scale of the BNT162b2 manufacturing has been increased to support future supply. BNT162b2 generated using the manufacturing process supporting an increased supply ("Process 2") will be administered to approximately 250 participants 16 to 55 years of age, per lot, in the study. The safety and immunogenicity of prophylactic BNT162b2 in individuals 16 to 55 years of age vaccinated with material generated using the existing manufacturing process "Process 1," and with material from lots generated using the manufacturing process supporting increased supply, "Process 2," will be described.

In brief, the process changes relate to the method of production for the DNA template that RNA drug substance is transcribed from, and the RNA drug substance purification method. The BNT162b2 drug product is then produced using a scaled-up LNP manufacturing process.

### 6.1.2. Administration

Participants will receive 1 dose of study intervention as randomized at each vaccination visit (Visits 1 and 4 for Phase 1 participants, Visits 1 and 2 for Phase 2/3 participants) in accordance with the study's SoA. The volume to be administered may vary by vaccine candidate and dose level; full details are described in the IP manual.

Study intervention should be administered intramuscularly into the deltoid muscle, preferably of the nondominant arm, by an **unblinded** administrator.

Standard vaccination practices must be observed and vaccine must not be injected into blood vessels. Appropriate medication and other supportive measures for management of an acute hypersensitivity reaction should be available in accordance with local guidelines for standard immunization practices.

Administration of study interventions should be performed by an appropriately qualified, GCP-trained, and vaccine-experienced member of the study staff (eg, physician, nurse, physician's assistant, nurse practitioner, pharmacist, or medical assistant) as allowed by local, state, and institutional guidance.

Study intervention administration details will be recorded on the CRF.

### 6.2. Preparation/Handling/Storage/Accountability

1. The investigator or designee must confirm appropriate temperature conditions have been maintained during transit for all study interventions received and any discrepancies are reported and resolved before use of the study intervention.

2. Only participants enrolled in the study may receive study intervention and only authorized site staff may supply or administer study intervention. All study interventions must be stored in a secure, environmentally controlled, and monitored (manual or automated recording) area in accordance with the labeled storage conditions with access limited to the investigator and authorized site staff. At a minimum, daily minimum and maximum temperatures for all site storage locations must be documented and available upon request. Data for nonworking days must indicate the minimum and maximum temperatures since previously documented for all site storage locations upon return to business.

3. Any excursions from the study intervention label storage conditions should be reported to Pfizer upon discovery along with any actions taken. The site should actively pursue options for returning the study intervention to the storage conditions described in the labeling, as soon as possible. Once an excursion is identified, the study intervention must be quarantined and not used until Pfizer provides permission to use the study intervention. Specific details regarding the definition of an excursion and information the site should report for each excursion will be provided to the site in the IP manual.

4. Any storage conditions stated in the SRSD will be superseded by the storage conditions stated on the label.

5. Study interventions should be stored in their original containers.

6. See the IP manual for storage conditions of the study intervention.

7. The investigator, institution, or the head of the medical institution (where applicable) is responsible for study intervention accountability, reconciliation, and record maintenance (ie, receipt, reconciliation, and final disposition records), such as the IPAL or sponsor-approved equivalent. All study interventions will be accounted for using a study intervention accountability form/record.

8. Further guidance and information for the final disposition of unused study interventions are provided in the IP manual. All destruction must be adequately documented. If destruction is authorized to take place at the investigator site, the investigator must ensure that the materials are destroyed in compliance with applicable environmental regulations, institutional policy, and any special instructions provided by Pfizer.

Upon identification of a product complaint, notify the sponsor within 1 business day of discovery as described in the IP manual.

### 6.2.1. Preparation and Dispensing

See the IP manual for instructions on how to prepare the study intervention for administration. Study intervention should be prepared and dispensed by an appropriately qualified and experienced member of the study staff (eg, physician, nurse, physician's assistant, nurse practitioner, pharmacy assistant/technician, or pharmacist) as allowed by local, state, and institutional guidance. A second staff member will verify the dispensing.

Study intervention and placebo will be prepared by qualified unblinded site personnel according to the IP manual. The study intervention will be administered in such a way to ensure the participants remain blinded.

## 6.3. Measures to Minimize Bias: Randomization and Blinding

### 6.3.1. Allocation to Study Intervention

Allocation (randomization) of participants to vaccine groups will proceed through the use of an IRT system (IWR). The site personnel (study coordinator or specified designee) will be required to enter or select information including but not limited to the user's ID and password, the protocol number, and the participant number. The site personnel will then be provided with a vaccine assignment and randomization number. The IRT system will provide a confirmation report containing the participant number, randomization number, and study intervention allocation assigned. The confirmation report must be stored in the site's files.

The study-specific IRT reference manual and IP manual will provide the contact information and further details on the use of the IRT system.

### 6.3.2. Blinding of Site Personnel

In this observer blinded study, the study staff receiving, storing, dispensing, preparing, and administering the study interventions will be unblinded. All other study and site personnel, including the investigator, investigator staff, and participants, will be blinded to study

intervention assignments. In particular, the individuals who evaluate participant safety will be blinded. Because the BNT162 RNA-based COVID-19 vaccine candidates and placebo are different in physical appearance, the study intervention syringes will be administered in a manner that prevents the study participants from identifying the study intervention type based on its appearance.

The responsibility of the unblinded dispenser and administrator must be assigned to an individual or individuals who will not participate in the evaluation of any study participants. Contact between the unblinded dispenser and study participants and unblinded administrator and study participants should be kept to a minimum. The remaining site personnel must not know study intervention assignments.

### 6.3.3. Blinding of the Sponsor

To facilitate rapid review of data in real time, sponsor staff will be unblinded to study intervention allocation for the participants in Phase 1. The majority of sponsor staff will be blinded to study intervention allocation in Phase 2/3. All laboratory testing personnel performing serology assays will remain blinded to study intervention assigned/received throughout the study. The following sponsor staff, who will have no part in the blinded conduct of the study, will be unblinded in Phase 2/3 (further details will be provided in a data blinding plan):

- Those study team members who are involved in ensuring that protocol requirements for study intervention preparation, handling, allocation, and administration are fulfilled at the site will be unblinded for the duration of the study (eg, unblinded study manager, unblinded clinical research associate).

- Unblinded clinician(s), who are not direct members of the study team and will not participate in any other study-related activities, will review unblinded protocol deviations.

- An unblinded team supporting interactions with, and analyses for, the DMC (see Section 9.6). This will comprise a statistician, programmer(s), a clinical scientist, and a medical monitor who will review cases of severe COVID-19 as they are received, and will review AEs at least weekly for additional potential cases of severe COVID-19 (see Section 8.2.3).

- An unblinded submissions team will be responsible for preparing unblinded analyses and documents to support regulatory activities that may be required while the study is ongoing. This team will only be unblinded at the group level and not have access to individual participant assignments. The programs that produce the summary tables will be developed and validated by the blinded study team, and these programs will be run by the unblinded DMC team. The submissions team will not have access to unblinded COVID-19 cases unless efficacy is achieved in either an interim analysis or the final analysis, as determined by the DMC.

### 6.3.4. Breaking the Blind

The IRT will be programmed with blind-breaking instructions. In case of an emergency, the investigator has the sole responsibility for determining if unblinding of a participant's study intervention assignment is warranted. Participant safety must always be the first consideration in making such a determination. If the investigator decides that unblinding is warranted, the investigator should make every effort to contact the sponsor prior to unblinding a participant's vaccine assignment unless this could delay further management of the participant. If a participant's vaccine assignment is unblinded, the sponsor must be notified within 24 hours after breaking the blind. The date and reason that the blind was broken must be recorded in the source documentation and CRF.

The study-specific IRT reference manual and IP manual will provide the contact information and further details on the use of the IRT system.

## 6.4. Study Intervention Compliance

When participants are dosed at the site, they will receive study intervention directly from the investigator or designee, under medical supervision. The date and time of each dose administered in the clinic will be recorded in the source documents and recorded in the CRF. The dose of study intervention and study participant identification will be confirmed at the time of dosing by a member of the study site staff other than the person administering the study intervention.

## 6.5. Concomitant Therapy

The following concomitant medications and vaccinations will be recorded in the CRF:

- All vaccinations received from 28 days prior to study enrollment until the 6-month follow-up visit (Visit 8 for Phase 1 participants, and Visit 4 for Phase 2/3 participants).
- Prohibited medications listed in Section 6.5.1 will be recorded, to include start and stop dates, name of the medication, dose, unit, route, and frequency.
- In addition, for participants enrolled in Phase 1, all current medication at baseline will be recorded, to include start date, name of the medication, dose, unit, route, and frequency.

### 6.5.1. Prohibited During the Study

Receipt of the following vaccines and medications during the time periods listed below may exclude a participant from the per-protocol analysis from that point onwards, and may require vaccinations to be discontinued in that participant; however, it is anticipated that the participant would not be withdrawn from the study (see Section 7). Medications should not be withheld if required for a participant's medical care.

Unless considered medically necessary, no vaccines other than study intervention should be administered within 28 days before and 28 days after each study vaccination. One exception

to this is that seasonal and pandemic influenza vaccine can be given at least 14 days after, or at least 14 days prior to, the administration of study intervention.

Receipt of chronic systemic treatment with known immunosuppressant medications, or radiotherapy, within 60 days before enrollment through conclusion of the study.

Receipt of systemic corticosteroids (≥20 mg/day of prednisone or equivalent) for ≥14 days is prohibited from 28 days prior to enrollment to Visit 7 for Phase 1 participants, and Visit 3 for Phase 2/3 participants).

Receipt of inhaled/nebulized corticosteroids from 28 days prior to enrollment to Visit 7 (1-month follow-up visit) for Phase 1 participants.

Receipt of blood/plasma products or immunoglobulins within 60 days before enrollment through conclusion of the study.

Receipt of any other (nonstudy) coronavirus vaccine at any time prior to or during study participation is prohibited.

Prophylactic antipyretics and other pain medication to prevent symptoms associated with study intervention administration are not permitted. However, if a participant is taking a medication for another condition, even if it may have antipyretic or pain-relieving properties, it should not be withheld prior to study vaccination.

### 6.5.2. Permitted During the Study

The use of antipyretics and other pain medication to treat symptoms associated with study intervention administration or ongoing conditions is permitted.

Medication other than that described as prohibited in Section 6.5.1 required for treatment of preexisting stable conditions is permitted.

Inhaled (except in Phase 1 participants – see Section 6.5.1), topical, or localized injections of corticosteroids (eg, intra-articular or intrabursal administration) are permitted.

## 6.6. Dose Modification

This protocol allows some alteration of vaccine dose for individual participants and/or dose groups from the currently outlined dosing schedule. For reasons of reactogenicity, tolerability, or safety, the IRC may recommend to reduce the second dose of study intervention and/or increase the interval between doses.

If, due to a medication error, a participant receives 1 dose of BNT162b2 at Visit 1 and 1 dose of placebo at Visit 2 (or vice versa), the participant should be offered the possibility to receive a second dose of BNT162b2 at an unscheduled visit. In this situation:

- Obtain informed consent for administration of the additional dose.

- Measure the participant's body temperature.
- Perform urine pregnancy test on WOCBP as described in Section 8.2.6.
- Discuss contraceptive use as described in Section 10.4.
- Ensure that the participant meets none of the temporary delay criteria as described in Section 5.5.
- Unblinded site staff member(s) will dispense/administer 1 dose of study intervention into the deltoid muscle of the preferably nondominant arm. Please refer to the IP manual for further instruction on this process.
- Blinded site staff must observe the participant for at least 30 minutes after study intervention administration for any acute reactions. Record any acute reactions (including time of onset) in the participant's source documents and on the AE page of the CRF, and on an SAE form as applicable.
- The participant should continue to adhere to the normal visit schedule but must be followed for nonserious AEs for 1 month and SAEs for 6 months after the second dose of BNT162b2. This will require AEs to be elicited either by unscheduled telephone contact(s) and/or in-person visit(s).

### 6.7. Intervention After the End of the Study

No intervention will be provided to study participants at the end of the study.

## 7. DISCONTINUATION OF STUDY INTERVENTION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

### 7.1. Discontinuation of Study Intervention

In rare instances, it may be necessary for a participant to permanently discontinue study intervention (definitive discontinuation). Reasons for definitive discontinuation of study intervention may include the following: AEs; participant request; investigator request; pregnancy; protocol deviation (including no longer meeting all the inclusion criteria, or meeting 1 or more exclusion criteria). In general, unless the investigator considers it unsafe to administer the second dose, or the participant does not wish to receive it, it is preferred that the second dose be administered. Note that a positive SARS-CoV-2 NAAT result without symptoms does not meet exclusion criterion 5 and should not result in discontinuation of study intervention, whereas a COVID-19 diagnosis does meet exclusion criterion 5 and should result in discontinuation of study intervention (see Section 8.15).

Note that discontinuation of study intervention does not represent withdrawal from the study. Per the study estimands, if study intervention is definitively discontinued, the participant will remain in the study to be evaluated for safety, immunogenicity, and efficacy. See the SoA for data to be collected at the time of discontinuation of study intervention and follow-up for any further evaluations that need to be completed.

In the event of discontinuation of study intervention, it must be documented on the appropriate CRF/in the medical records whether the participant is discontinuing further receipt of study intervention or also from study procedures, posttreatment study follow-up, and/or future collection of additional information.

## 7.2. Participant Discontinuation/Withdrawal From the Study

A participant may withdraw from the study at any time at his/her own request. Reasons for discontinuation from the study may include the following:

- Refused further follow-up;
- Lost to follow-up;
- Death;
- Study terminated by sponsor;
- AEs;
- Participant request;
- Investigator request;
- Protocol deviation.

If a participant does not return for a scheduled visit, every effort should be made to contact the participant. All attempts to contact the participant and information received during contact attempts must be documented in the participant's source document. In any circumstance, every effort should be made to document participant outcome, if possible.

The investigator or his or her designee should capture the reason for withdrawal in the CRF for all participants.

If a participant withdraws from the study, he/she may request destruction of any remaining samples taken and not tested, and the investigator must document any such requests in the site study records and notify the sponsor accordingly.

If the participant withdraws from the study and also withdraws consent (see Section 7.2.1) for disclosure of future information, no further evaluations should be performed and no additional data should be collected. The sponsor may retain and continue to use any data collected before such withdrawal of consent.

Lack of completion of all or any of the withdrawal/early termination procedures will not be viewed as protocol deviations so long as the participant's safety was preserved.

### 7.2.1. Withdrawal of Consent

Participants who request to discontinue receipt of study intervention will remain in the study and must continue to be followed for protocol-specified follow-up procedures. The only exception to this is when a participant specifically withdraws consent for any further contact

with him or her or persons previously authorized by the participant to provide this information. Participants should notify the investigator in writing of the decision to withdraw consent from future follow-up, whenever possible. The withdrawal of consent should be explained in detail in the medical records by the investigator, as to whether the withdrawal is only from further receipt of study intervention or also from study procedures and/or posttreatment study follow-up, and entered on the appropriate CRF page. In the event that vital status (whether the participant is alive or dead) is being measured, publicly available information should be used to determine vital status only as appropriately directed in accordance with local law.

### 7.3. Lost to Follow-up

A participant will be considered lost to follow-up if he or she repeatedly fails to return for scheduled visits and is unable to be contacted by the study site.

The following actions must be taken if a participant fails to attend a required study visit:

- The site must attempt to contact the participant and reschedule the missed visit as soon as possible and counsel the participant on the importance of maintaining the assigned visit schedule and ascertain whether or not the participant wishes to and/or should continue in the study;

- Before a participant is deemed lost to follow-up, the investigator or designee must make every effort to regain contact with the participant (where possible, 3 telephone calls and, if necessary, a certified letter to the participant's last known mailing address or local equivalent methods). These contact attempts should be documented in the participant's medical record;

- Should the participant continue to be unreachable, he/she will be considered to have withdrawn from the study.

## 8. STUDY ASSESSMENTS AND PROCEDURES

The investigator (or an appropriate delegate at the investigator site) must obtain a signed and dated ICD before performing any study-specific procedures.

The full date of birth will be collected to critically evaluate the immune response and safety profile by age.

Study procedures and their timing are summarized in the SoA. Protocol waivers or exemptions are not allowed.

Safety issues should be discussed with the sponsor immediately upon occurrence or awareness to determine whether the participant should continue or discontinue study intervention.

Adherence to the study design requirements, including those specified in the SoA, is essential and required for study conduct.

All screening evaluations must be completed and reviewed to confirm that potential participants meet all eligibility criteria. The investigator will maintain a screening log to record details of all participants screened and to confirm eligibility or record reasons for screening failure, as applicable.

Every effort should be made to ensure that protocol-required tests and procedures are completed as described. However, it is anticipated that from time to time there may be circumstances outside the control of the investigator that may make it unfeasible to perform the test. In these cases, the investigator must take all steps necessary to ensure the safety and well-being of the participant. When a protocol-required test cannot be performed, the investigator will document the reason for the missed test and any corrective and preventive actions that he or she has taken to ensure that required processes are adhered to as soon as possible. The study team must be informed of these incidents in a timely manner.

For samples being collected and shipped, detailed collection, processing, storage, and shipment instructions and contact information will be provided to the investigator site prior to initiation of the study.

The total blood sampling volume for individual participants in this study is approximately up to: 515 mL for participants in Phase 1, 110 mL for Phase 2/3 participants ≥16 years of age, and 50 mL for participants in the 12- to 15-year age stratum. Additionally, 20 mL of blood for participants ≥16 years of age and 10 mL for participants in the 12- to 15-year age stratum will be taken at an unplanned convalescent visit at any time a participant develops respiratory symptoms indicating a potential COVID-19 infection. Select participants in Phase 1 will also be asked to provide an additional blood sample of approximately 170 mL at either Visit 5, 6, or 7. These participants would therefore have a total blood sampling volume of 700 mL during the 24-month study period. Other additional blood samples may be taken for safety assessments at times specified by Pfizer, provided the total volume taken during the study does not exceed 550 mL during any period of 60 consecutive days.

### 8.1. Efficacy and/or Immunogenicity Assessments

Efficacy will be assessed throughout a participant's involvement in the study through surveillance for potential cases of COVID-19. If, at any time, a participant develops acute respiratory illness (see Section 8.13), for the purposes of the study he or she will be considered to potentially have COVID-19 illness.[9] In this circumstance, the participant should contact the site, an in-person or telehealth visit should occur, and assessments should be conducted as specified in the SoA. The assessments will include a nasal (midturbinate) swab, which will be tested at a central laboratory using a reverse transcription–polymerase chain reaction (RT-PCR) test (Cepheid; FDA approved under EUA), or other equivalent nucleic acid amplification–based test (ie, NAAT), to detect SARS-CoV-2. In addition, clinical information and results from local standard-of-care tests (as detailed in Section 8.13) will be assessed. The central laboratory NAAT result will be used for the case definition, unless no result is available from the central laboratory, in which case a local NAAT result may be used if it was obtained using 1 of the following assays:

- Cepheid Xpert Xpress SARS-CoV-2

- Roche cobas SARS-CoV-2 real-time RT-PCR test (EUA200009/A001)
- Abbott Molecular/RealTime SARS-CoV-2 assay (EUA200023/A001)

Two definitions of SARS-CoV-2–related cases, and SARS-CoV-2–related severe cases, will be considered (for both, the onset date of the case will be the date that symptoms were first experienced by the participant; if new symptoms are reported within 4 days after resolution of all previous symptoms, they will be considered as part of a single illness):

- Confirmed COVID-19: presence of at least 1 of the following symptoms and SARS-CoV-2 NAAT-positive during, or within 4 days before or after, the symptomatic period, either at the central laboratory or at a local testing facility (using an acceptable test):
    - Fever;
    - New or increased cough;
    - New or increased shortness of breath;
    - Chills;
    - New or increased muscle pain;
    - New loss of taste or smell;
    - Sore throat;
    - Diarrhea;
    - Vomiting.

  The second definition, which may be updated as more is learned about COVID-19, will include the following additional symptoms defined by the CDC (listed at https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html):

    - Fatigue;
    - Headache;
    - Nasal congestion or runny nose;
    - Nausea.
- Confirmed severe COVID-19: confirmed COVID-19 and presence of at least 1 of the following:

- Clinical signs at rest indicative of severe systemic illness (RR ≥30 breaths per minute, HR ≥125 beats per minute, $SpO_2$ ≤93% on room air at sea level, or $PaO_2/FiO_2$ <300 mm Hg);
- Respiratory failure (defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation, or ECMO);
- Evidence of shock (SBP <90 mm Hg, DBP <60 mm Hg, or requiring vasopressors);
- Significant acute renal, hepatic, or neurologic dysfunction*;
- Admission to an ICU;
- Death.

The DMC may recommend modification of the definition of severe disease according to emerging information.

* Three blinded case reviewers (medically qualified Pfizer staff members) will review all potential COVID-19 illness events. If a NAAT-confirmed case in Phase 2/3 may be considered severe, or not, solely on the basis of this criterion, the blinded data will be reviewed by the case reviewers to assess whether the criterion is met; the majority opinion will prevail.

In addition, a serological definition will be used for participants without clinical presentation of COVID-19:

- Confirmed seroconversion to SARS-CoV-2 without confirmed COVID-19: positive N-binding antibody result in a participant with a prior negative N-binding antibody result

Serum samples will be obtained for immunogenicity testing at the visits specified in the SoA. The following assays will be performed:

- SARS-CoV-2 neutralization assay
- S1-binding IgG level assay
- RBD-binding IgG level assay
- N-binding antibody assay

Note that all immunogenicity analyses will be based upon samples analyzed at the central laboratory; the rapid test will only be performed at screening by all sites recruiting participants in Phase 1 (see Section 8.11.1.1) to determine eligibility.

Serum obtained from the additional ~170-mL blood sample from select participants in Phase 1 at either Visit 5, 6, or 7 will be used for exploratory COVID-19 research, intended to establish a surrogate endpoint that is reasonably likely to predict clinical benefit.

### 8.1.1. Biological Samples

Blood and nasal swab samples will be used only for scientific research. Each sample will be labeled with a code so that the laboratory personnel testing the samples will not know the participant's identity. Samples that remain after performing assays outlined in the protocol may be stored by Pfizer. Unless a time limitation is required by local regulations or ethical requirements, the samples will be stored for up to 15 years after the end of the study and then destroyed. If allowed by the ICD, stored samples may be used for additional testing to better understand the immune responses to the vaccine(s) under study in this protocol, to inform the development of other products, and/or for vaccine-related assay work supporting vaccine programs. No testing of the participant's DNA will be performed.

The participant may request that his or her samples, if still identifiable, be destroyed at any time; however, any data already collected from those samples will still be used for this research. The biological samples may be shared with other researchers as long as confidentiality is maintained and no testing of the participant's DNA is performed.

## 8.2. Safety Assessments

Planned time points for all safety assessments are provided in the SoA. Unscheduled clinical laboratory measurements may be obtained at any time during the study to assess any perceived safety issues.

A clinical assessment, including medical history, will be performed on all participants at his/her first visit to establish a baseline. Significant medical history and observations from any physical examination, if performed, will be documented in the CRF.

AEs and SAEs are collected, recorded, and reported as defined in Section 8.3.

Acute reactions within the first 4 hours after administration of the study intervention (for the first 5 participants vaccinated in each Phase 1 group), and within the first 30 minutes (for the remainder of participants), will be assessed and documented in the AE CRF.

The safety parameters also include reactogenicity e-diary reports of local reactions and systemic events (including fever), and use of antipyretic medication that occur in the 7 days after administration of the study intervention in a subset of participants. These prospectively self-collected occurrences of local reactions and systemic events are graded as described in Section 8.2.2. For participants who are not in the reactogenicity subset, these local reactions and systemic events should be detected and reported as AEs, in accordance with Section 8.3.2.

### 8.2.1. Clinical Safety Laboratory Assessments (Phase 1 Participants Only)

See Appendix 2 for the list of clinical safety laboratory tests to be performed and the SoA for the timing and frequency. All protocol-required laboratory assessments, as defined in Appendix 2, must be conducted in accordance with the laboratory manual and the SoA. Unscheduled clinical laboratory measurements may be obtained at any time during the study to assess any perceived safety issues.

The investigator must review the laboratory report, document this review, and record any clinically relevant changes occurring during the study in the AE section of the CRF. See Appendix 2 for the grading scale for assessment of clinically significant abnormal laboratory findings. Clinically significant abnormal laboratory findings are those which are not associated with the underlying disease, unless judged by the investigator to be more severe than expected for the participant's condition.

All laboratory tests with values considered clinically significantly abnormal during participation in the study or within 28 days after the last dose of study intervention should be repeated until the values return to normal or baseline or are no longer considered clinically significant by the investigator or medical monitor.

If such values do not return to normal/baseline within a period of time judged reasonable by the investigator, the etiology should be identified and the sponsor notified.

See Appendix 5 for suggested actions and follow-up assessments in the event of potential drug-induced liver injury (DILI).

### 8.2.2. Electronic Diary

Participants will be required to complete a reactogenicity e-diary through an application (see Section 8.14) installed on a provisioned device or on the participant's own personal device. All participants in Phase 1, and a subset of at least the first 6000 randomized in Phase 2/3, will be asked to monitor and record local reactions, systemic events, and antipyretic medication usage for 7 days following administration of the study intervention. All participants in Phase 3 who are HIV-positive or 12 to 15 years of age will be included in this subset. In addition, participants 16 through 17 years of age enrolled under protocol amendment 9 and onwards will be included in the reactogenicity subset. The reactogenicity e-diary allows recording of these assessments only within a fixed time window, thus providing the accurate representation of the participant's experience at that time. Data on local reactions and systemic events reported in the reactogenicity e-diary will be transferred electronically to a third-party vendor, where they will be available for review by investigators and the Pfizer clinicians at all times via an internet-based portal.

At intervals agreed to by the vendor and Pfizer, these data will be transferred electronically into Pfizer's database for analysis and reporting. These data do not need to be reported by the investigator in the CRF as AEs.

Investigators (or designee) will be required to review the reactogenicity e-diary data online at frequent intervals as part of the ongoing safety review.

The investigator or designee must obtain stop dates from the participant for any ongoing local reactions, systemic events, or use of antipyretic medication on the last day that the reactogenicity e-diary was completed. The stop dates should be documented in the source documents and the information entered in the CRF.

#### 8.2.2.1. Grading Scales

The grading scales used in this study to assess local reactions and systemic events as described below are derived from the FDA Center for Biologics Evaluation and Research (CBER) guidelines on toxicity grading scales for healthy adult volunteers enrolled in preventive vaccine clinical trials.[8]

#### 8.2.2.2. Local Reactions

During the reactogenicity e-diary reporting period, participants will be asked to assess redness, swelling, and pain at the injection site and to record the symptoms in the reactogenicity e-diary. If a local reaction persists beyond the end of the reactogenicity e-diary period following vaccination, the participant will be requested to report that information. The investigator will enter this additional information in the CRF.

Redness and swelling will be measured and recorded in measuring device units (range: 1 to 21) and then categorized during analysis as absent, mild, moderate, or severe based on the grading scale in Table 1. Measuring device units can be converted to centimeters according to the following formula: 1 measuring device unit = 0.5 cm. Pain at the injection site will be assessed by the participant as absent, mild, moderate, or severe according the grading scale in Table 1.

If a Grade 3 local reaction is reported in the reactogenicity e-diary, a telephone contact should occur to ascertain further details and determine whether a site visit is clinically indicated. Only an investigator or medically qualified person is able to classify a participant's local reaction as Grade 4. If a participant experiences a confirmed Grade 4 local reaction, the investigator must immediately notify the sponsor and, if it is determined to be related to the administration of the study intervention, further vaccinations will be discontinued in that participant.

**Table 1. Local Reaction Grading Scale**

| | Mild (Grade 1) | Moderate (Grade 2) | Severe (Grade 3) | Potentially Life Threatening (Grade 4) |
|---|---|---|---|---|
| **Pain at the injection site** | Does not interfere with activity | Interferes with activity | Prevents daily activity | Emergency room visit or hospitalization for severe pain |
| **Redness** | >2.0 cm to 5.0 cm (5 to 10 measuring device units) | >5.0 cm to 10.0 cm (11 to 20 measuring device units) | >10 cm (≥21 measuring device units) | Necrosis or exfoliative dermatitis |
| **Swelling** | >2.0 cm to 5.0 cm (5 to 10 measuring device units) | >5.0 cm to 10.0 cm (11 to 20 measuring device units) | >10 cm (≥21 measuring device units) | Necrosis |

### 8.2.2.3. Systemic Events

During the reactogenicity e-diary reporting period, participants will be asked to assess vomiting, diarrhea, headache, fatigue, chills, new or worsened muscle pain, and new or worsened joint pain and to record the symptoms in the reactogenicity e-diary. The symptoms will be assessed by the participant as absent, mild, moderate, or severe according to the grading scale in Table 2.

If a Grade 3 systemic event is reported in the reactogenicity e-diary, a telephone contact should occur to ascertain further details and determine whether a site visit is clinically indicated. Only an investigator or medically qualified person is able to classify a participant's systemic event as Grade 4. If a participant experiences a confirmed Grade 4 systemic event, the investigator must immediately notify the sponsor and, if it is determined to be related to the administration of the study intervention, further vaccinations will be discontinued in that participant.

**Table 2. Systemic Event Grading Scale**

| | Mild (Grade 1) | Moderate (Grade 2) | Severe (Grade 3) | Potentially Life Threatening (Grade 4) |
|---|---|---|---|---|
| **Vomiting** | 1-2 times in 24 hours | >2 times in 24 hours | Requires IV hydration | Emergency room visit or hospitalization for hypotensive shock |
| **Diarrhea** | 2 to 3 loose stools in 24 hours | 4 to 5 loose stools in 24 hours | 6 or more loose stools in 24 hours | Emergency room visit or hospitalization for severe diarrhea |
| **Headache** | Does not interfere with activity | Some interference with activity | Prevents daily routine activity | Emergency room visit or hospitalization for severe headache |
| **Fatigue/ tiredness** | Does not interfere with activity | Some interference with activity | Prevents daily routine activity | Emergency room visit or hospitalization for severe fatigue |
| **Chills** | Does not interfere with activity | Some interference with activity | Prevents daily routine activity | Emergency room visit or hospitalization for severe chills |
| **New or worsened muscle pain** | Does not interfere with activity | Some interference with activity | Prevents daily routine activity | Emergency room visit or hospitalization for severe new or worsened muscle pain |
| **New or worsened joint pain** | Does not interfere with activity | Some interference with activity | Prevents daily routine activity | Emergency room visit or hospitalization for severe new or worsened joint pain |

Abbreviation: IV = intravenous.

#### 8.2.2.4. Fever

In order to record information on fever, a thermometer will be given to participants with instructions on how to measure oral temperature at home. Temperature will be collected in the reactogenicity e-diary in the evening daily during the reactogenicity e-diary reporting period. It will also be collected at any time during the reactogenicity e-diary data collection periods when fever is suspected. Fever is defined as an oral temperature of ≥38.0°C (100.4°F). The highest temperature for each day will be recorded in the reactogenicity e-diary. Temperature will be measured and recorded to 1 decimal place and then categorized during analysis according to the scale shown in Table 3.

If a fever of ≥39.0°C (102.1°F) is reported in the reactogenicity e-diary, a telephone contact should occur to ascertain further details and determine whether a site visit is clinically indicated. Only an investigator or medically qualified person is able to confirm a participant's fever as >40.0°C (>104.0°F). If a participant experiences a confirmed fever >40.0°C (>104.0°F), the investigator must immediately notify the sponsor and, if it is determined to be related to the administration of the study intervention, further vaccinations will be discontinued in that participant.

**Table 3. Scale for Fever**

| |
|---|
| ≥38.0-38.4°C (100.4-101.1°F) |
| >38.4-38.9°C (101.2-102.0°F) |
| >38.9-40.0°C (102.1-104.0°F) |
| >40.0°C (>104.0°F) |

#### 8.2.2.5. Antipyretic Medication

The use of antipyretic medication to treat symptoms associated with study intervention administration will be recorded in the reactogenicity e-diary daily during the reporting period (Day 1 to Day 7).

### 8.2.3. Phase 1 Stopping Rules

The following stopping rules are in place for all Phase 1 participants, based on review of AE data and e-diary reactogenicity data, until the start of Phase 2/3 or 30 days after the last dose of study intervention in Phase 1, whichever is later. These data will be monitored on an ongoing basis by the investigator (or medically qualified designee) and sponsor in order to promptly identify and flag any event that potentially contributes to a stopping rule.

The sponsor study team will be unblinded during Phase 1, so will be able to assess whether or not a stopping rule has been met on the basis of a participant's individual study intervention allocation.

In the event that sponsor personnel confirm that a stopping rule is met, the following actions will commence:

- The IRC will review all appropriate data.
- The stopping rule will PAUSE randomization and study intervention administration for the impacted vaccine candidate all dose levels and age groups.
- The DMC will review all appropriate data.
- For all participants vaccinated, all other routine study conduct activities, including ongoing data entry, reporting of AEs, participant reactogenicity e-diary completion, blood sample collection, and participant follow-up, will continue during the pause.

A stopping rule is met if any of the following rules occur after administration of investigational BNT162 vaccine; data from placebo recipients will not contribute to the stopping rules. Reactogenicity e-diary data confirmed by the investigator as being entered by the participant in error will not contribute toward a stopping rule.

The BNT162b RNA platform will be evaluated for contribution to stopping rules overall; vaccine candidate dose levels within the platform and age groups will contribute to stopping rules together. However, it is possible that the recommendations may include halting or continuing randomization with any of the BNT162 vaccine candidates.

**Stopping Rule Criteria for Each BNT162 Vaccine Candidate:**

1. If any participant vaccinated with the BNT162 candidate (at any dose level) develops an SAE that is assessed by the investigator as possibly related, or for which there is no alternative, plausible, attributable cause.

2. If any participant vaccinated with the BNT162 candidate (at any dose level) develops a Grade 4 local reaction or systemic event after vaccination (see Section 8.2.2) that is assessed as possibly related by the investigator, or for which there is no alternative, plausible, attributable cause.

3. If any participant vaccinated with the BNT162 candidate (at any dose level) develops a fever >40.0°C (>104.0°F) for at least 1 daily measurement after vaccination (see Section 8.2.2.4) that is assessed as possibly related by the investigator, or for which there is no alternative, plausible, attributable cause.

4. If any 2 participants vaccinated with the BNT162 candidate (at any dose level) report the same or similar severe (Grade 3) AE (including laboratory abnormalities) after vaccination, assessed as possibly related by the investigator, or for which there is no alternative, plausible, attributable cause.

5. If any participant dies or requires ICU admission due to SARS-CoV-2 infection; if this stopping rule is met, all available clinical and preclinical safety and immunogenicity data should be reviewed to evaluate for enhanced COVID-19.

### 8.2.4. Surveillance of Events That Could Represent Enhanced COVID-19 and Phase 2/3 Stopping Rule

Participants in all phases of the study will be surveilled for potential COVID-19 illness from Visit 1 onwards (see Section 8.13).

As this is a sponsor open-label study during Phase 1, the sponsor will conduct unblinded reviews of the data during the course of the study, including for the purpose of safety assessment. All NAAT-confirmed cases in Phase 1 will be reviewed contemporaneously by the IRC and the DMC (see Section 9.6).

In Phase 2/3, the unblinded team supporting the DMC, including an unblinded medical monitor, will review cases of severe COVID-19 as they are received and will review AEs at least weekly for additional potential cases of severe COVID-19. At any point, the unblinded team may discuss with the DMC chair whether the DMC should review cases for an adverse imbalance of cases of COVID-19 and/or severe COVID-19 between the vaccine and placebo groups.

The purpose of these reviews will be to identify whether any features of each case appear unusual, in particular greater in severity, compared to available information at the time of review. Indicators of severity may include accelerated deterioration, need for hospitalization, need for ventilation, or death. Observed rates of these indicators will be compared with what could be expected in a similar population to the study participants based upon available information at the time of review.

Stopping and alert rules will be applied as follows. The stopping rule will be triggered when the 1-sided probability of observing the same or a more extreme case split is 5% or less when the true incidence of severe disease is the same for vaccine and placebo participants, and alert criteria are triggered when this probability is less than 11%. In addition, when the total number of severe cases is low (15 or less), the unblinded team supporting the DMC will implement the alert rule when a reverse case split of 2:1 or worse is observed. For example, at 3 cases 2:1, at 4 cases 3:1, etc. Below 15 cases, this rule is more rigorous than requiring the probability of an observed adverse split or worse be <11%. Further details can be found in Section 10.7.

### 8.2.5. Randomization and Vaccination After a Stopping Rule Is Met

Once the IRC (if in Phase 1) and DMC (all phases) have reviewed the safety data and provided guidance, a notification will be sent from the sponsor to the sites with guidance on how to proceed.

### 8.2.6. Pregnancy Testing

Pregnancy tests may be urine or serum tests, but must have a sensitivity of at least 25 mIU/mL. Pregnancy tests will be performed in WOCBP at the times listed in the SoA, immediately before the administration of each vaccine dose. A negative pregnancy test result will be required prior to the participant's receiving the study intervention. Pregnancy tests may also be repeated if requested by IRBs/ECs or if required by local regulations. In the case of a positive confirmed pregnancy, the participant will be withdrawn from administration of study intervention but may remain in the study.

## 8.3. Adverse Events and Serious Adverse Events

The definitions of an AE and an SAE can be found in Appendix 3.

AEs will be reported by the participant (or, when appropriate, by a caregiver, surrogate, or the participant's parent(s)/legal guardian).

The investigator and any qualified designees are responsible for detecting, documenting, and recording events that meet the definition of an AE or SAE and remain responsible to pursue and obtain adequate information both to determine the outcome and to assess whether the event meets the criteria for classification as an SAE or caused the participant to discontinue the study intervention (see Section 7.1).

Each participant/parent(s)/legal guardian will be questioned about the occurrence of AEs in a nonleading manner.

In addition, the investigator may be requested by Pfizer Safety to obtain specific follow-up information in an expedited fashion.

### 8.3.1. Time Period and Frequency for Collecting AE and SAE Information

The time period for actively eliciting and collecting AEs and SAEs ("active collection period") for each participant begins from the time the participant/parent(s)/legal guardian provides informed consent, which is obtained before the participant's participation in the study (ie, before undergoing any study-related procedure and/or receiving study intervention), through and including Visit 7 for Phase 1 participants, and Visit 3 for Phase 2/3 participants. In addition, any AEs occurring up to 48 hours after each subsequent blood draw must be recorded on the CRF.

SAEs will be collected from the time the participant/parent(s)/legal guardian provides informed consent to approximately 6 months after the last dose of study intervention (Visit 8 for Phase 1 participants, and Visit 4 for Phase 2/3 participants).

Follow-up by the investigator continues throughout and after the active collection period and until the AE or SAE or its sequelae resolve or stabilize at a level acceptable to the investigator and Pfizer concurs with that assessment.

For participants who are screen failures, the active collection period ends when screen failure status is determined.

If the participant withdraws from the study and also withdraws consent for the collection of future information, the active collection period ends when consent is withdrawn.

If a participant definitively discontinues or temporarily discontinues study intervention because of an AE or SAE, the AE or SAE must be recorded on the CRF and the SAE reported using the Vaccine SAE Report Form.

Investigators are not obligated to actively seek AEs or SAEs after the participant has concluded study participation. However, if the investigator learns of any SAE, including a death, at any time after a participant has completed the study, and he/she considers the event to be reasonably related to the study intervention, the investigator must promptly report the SAE to Pfizer using the Vaccine SAE Report Form.

#### 8.3.1.1. Reporting SAEs to Pfizer Safety

All SAEs occurring in a participant during the active collection period as described in Section 8.3.1 are reported to Pfizer Safety on the Vaccine SAE Report Form immediately upon awareness and under no circumstance should this exceed 24 hours, as indicated in Appendix 3. The investigator will submit any updated SAE data to the sponsor within 24 hours of it being available.

#### 8.3.1.2. Recording Nonserious AEs and SAEs on the CRF

All nonserious AEs and SAEs occurring in a participant during the active collection period, which begins after obtaining informed consent as described in Section 8.3.1, will be recorded on the AE section of the CRF.

The investigator is to record on the CRF all directly observed and all spontaneously reported AEs and SAEs reported by the participant.

### 8.3.2. Method of Detecting AEs and SAEs

The method of recording, evaluating, and assessing causality of AEs and SAEs and the procedures for completing and transmitting SAE reports are provided in Appendix 3.

Care will be taken not to introduce bias when detecting AEs and/or SAEs. Open-ended and nonleading verbal questioning of the participant is the preferred method to inquire about AE occurrences.

### 8.3.3. Follow-up of AEs and SAEs

After the initial AE/SAE report, the investigator is required to proactively follow each participant at subsequent visits/contacts. For each event, the investigator must pursue and obtain adequate information until resolution, stabilization, the event is otherwise explained, or the participant is lost to follow-up (as defined in Section 7.3).

In general, follow-up information will include a description of the event in sufficient detail to allow for a complete medical assessment of the case and independent determination of possible causality. Any information relevant to the event, such as concomitant medications and illnesses, must be provided. In the case of a participant death, a summary of available autopsy findings must be submitted as soon as possible to Pfizer Safety.

Further information on follow-up procedures is given in Appendix 3.

### 8.3.4. Regulatory Reporting Requirements for SAEs

Prompt notification by the investigator to the sponsor of an SAE is essential so that legal obligations and ethical responsibilities towards the safety of participants and the safety of a study intervention under clinical investigation are met.

The sponsor has a legal responsibility to notify both the local regulatory authority and other regulatory agencies about the safety of a study intervention under clinical investigation. The sponsor will comply with country-specific regulatory requirements relating to safety reporting to the regulatory authority, IRBs/ECs, and investigators.

Investigator safety reports must be prepared for SUSARs according to local regulatory requirements and sponsor policy and forwarded to investigators as necessary.

An investigator who receives SUSARs or other specific safety information (eg, summary or listing of SAEs) from the sponsor will review and then file it along with the SRSD(s) for the study and will notify the IRB/EC, if appropriate according to local requirements.

### 8.3.5. Exposure During Pregnancy or Breastfeeding, and Occupational Exposure

Exposure to the study intervention under study during pregnancy or breastfeeding and occupational exposure are reportable to Pfizer Safety within 24 hours of investigator awareness.

#### 8.3.5.1. Exposure During Pregnancy

An EDP occurs if:

- A female participant is found to be pregnant while receiving or after discontinuing study intervention.
- A male participant who is receiving or has discontinued study intervention exposes a female partner prior to or around the time of conception.
- A female is found to be pregnant while being exposed or having been exposed to study intervention due to environmental exposure. Below are examples of environmental exposure during pregnancy:
    - A female family member or healthcare provider reports that she is pregnant after having been exposed to the study intervention by inhalation or skin contact.

- A male family member or healthcare provider who has been exposed to the study intervention by inhalation or skin contact then exposes his female partner prior to or around the time of conception.

The investigator must report EDP to Pfizer Safety within 24 hours of the investigator's awareness, irrespective of whether an SAE has occurred. The initial information submitted should include the anticipated date of delivery (see below for information related to termination of pregnancy).

- If EDP occurs in a participant or a participant's partner, the investigator must report this information to Pfizer Safety on the Vaccine SAE Report Form and an EDP Supplemental Form, regardless of whether an SAE has occurred. Details of the pregnancy will be collected after the start of study intervention and until 6 months after the last dose of study intervention.

- If EDP occurs in the setting of environmental exposure, the investigator must report information to Pfizer Safety using the Vaccine SAE Report Form and EDP Supplemental Form. Since the exposure information does not pertain to the participant enrolled in the study, the information is not recorded on a CRF; however, a copy of the completed Vaccine SAE Report Form is maintained in the investigator site file.

Follow-up is conducted to obtain general information on the pregnancy and its outcome for all EDP reports with an unknown outcome. The investigator will follow the pregnancy until completion (or until pregnancy termination) and notify Pfizer Safety of the outcome as a follow-up to the initial EDP Supplemental Form. In the case of a live birth, the structural integrity of the neonate can be assessed at the time of birth. In the event of a termination, the reason(s) for termination should be specified and, if clinically possible, the structural integrity of the terminated fetus should be assessed by gross visual inspection (unless preprocedure test findings are conclusive for a congenital anomaly and the findings are reported).

Abnormal pregnancy outcomes are considered SAEs. If the outcome of the pregnancy meets the criteria for an SAE (ie, ectopic pregnancy, spontaneous abortion, intrauterine fetal demise, neonatal death, or congenital anomaly), the investigator should follow the procedures for reporting SAEs. Additional information about pregnancy outcomes that are reported to Pfizer Safety as SAEs follows:

- Spontaneous abortion including miscarriage and missed abortion;

- Neonatal deaths that occur within 1 month of birth should be reported, without regard to causality, as SAEs. In addition, infant deaths after 1 month should be reported as SAEs when the investigator assesses the infant death as related or possibly related to exposure to the study intervention.

Additional information regarding the EDP may be requested by the sponsor. Further follow-up of birth outcomes will be handled on a case-by-case basis (eg, follow-up on preterm infants to identify developmental delays). In the case of paternal exposure, the investigator will provide the participant with the Pregnant Partner Release of Information Form to deliver to his partner. The investigator must document in the source documents that the participant was given the Pregnant Partner Release of Information Form to provide to his partner.

#### 8.3.5.2. Exposure During Breastfeeding

An exposure during breastfeeding occurs if:

- A female participant is found to be breastfeeding while receiving or after discontinuing study intervention.
- A female is found to be breastfeeding while being exposed or having been exposed to study intervention (ie, environmental exposure). An example of environmental exposure during breastfeeding is a female family member or healthcare provider who reports that she is breastfeeding after having been exposed to the study intervention by inhalation or skin contact.

The investigator must report exposure during breastfeeding to Pfizer Safety within 24 hours of the investigator's awareness, irrespective of whether an SAE has occurred. The information must be reported using the Vaccine SAE Report Form. When exposure during breastfeeding occurs in the setting of environmental exposure, the exposure information does not pertain to the participant enrolled in the study**,** so the information is not recorded on a CRF. However, a copy of the completed Vaccine SAE Report Form is maintained in the investigator site file.

An exposure during breastfeeding report is not created when a Pfizer drug specifically approved for use in breastfeeding women (eg, vitamins) is administered in accord with authorized use. However, if the infant experiences an SAE associated with such a drug, the SAE is reported together with the exposure during breastfeeding.

#### 8.3.5.3. Occupational Exposure

An occupational exposure occurs when a person receives unplanned direct contact with the study intervention, which may or may not lead to the occurrence of an AE. Such persons may include healthcare providers, family members, and other roles that are involved in the trial participant's care.

The investigator must report occupational exposure to Pfizer Safety within 24 hours of the investigator's awareness, regardless of whether there is an associated SAE. The information must be reported using the Vaccine SAE Report Form. Since the information does not pertain to a participant enrolled in the study, the information is not recorded on a CRF; however, a copy of the completed Vaccine SAE Report Form is maintained in the investigator site file.

### 8.3.6. Cardiovascular and Death Events

Not applicable.

### 8.3.7. Disease-Related Events and/or Disease-Related Outcomes Not Qualifying as AEs or SAEs

Potential COVID-19 illnesses and their sequelae that are consistent with the clinical endpoint definition should not be recorded as AEs. These data will be captured as efficacy assessment data only on the relevant pages of the CRF, as these are expected endpoints.

Potential COVID-19 illnesses and their sequelae will not be reported according to the standard process for expedited reporting of SAEs, even though the event may meet the definition of an SAE. These events will be recorded on the COVID-19 illness pages in the participant's CRF within 1 day.

NOTE: However, if either of the following conditions applies, then the event must be recorded and reported as an SAE (instead of a disease-related event):

The event is, in the investigator's opinion, of greater intensity, frequency, or duration than expected for the individual participant.

OR

The investigator considers that there is a reasonable possibility that the event was related to study intervention.

Potential COVID-19 illness events and their sequelae will be reviewed by a group of internal blinded case reviewers. Any SAE that is determined by the internal case reviewers NOT to meet endpoint criteria is reported back to the investigator site of incidence. The investigator must report the SAE to Pfizer Safety within 24 hours of being made aware that the SAE did not meet endpoint criteria. The investigator's SAE awareness date is the date on which the investigator site of incidence receives the SAE back from the internal case reviewers.

### 8.3.8. Adverse Events of Special Interest

Not applicable.

#### 8.3.8.1. Lack of Efficacy

Lack of efficacy is reportable to Pfizer Safety only if associated with an SAE.

### 8.3.9. Medical Device Deficiencies

Not applicable.

### 8.3.10. Medication Errors

Medication errors may result from the administration or consumption of the study intervention by the wrong participant, or at the wrong time, or at the wrong dosage strength.

Exposures to the study intervention under study may occur in clinical trial settings, such as medication errors.

| Safety Event | Recorded on the CRF | Reported on the Vaccine SAE Report Form to Pfizer Safety Within 24 Hours of Awareness |
|---|---|---|
| Medication errors | All (regardless of whether associated with an AE) | Only if associated with an SAE |

Medication errors include:

- Medication errors involving participant exposure to the study intervention;
- Potential medication errors or uses outside of what is foreseen in the protocol that do or do not involve the study participant;
- The administration of expired study intervention;
- The administration of an incorrect study intervention;
- The administration of an incorrect dosage;
- The administration of study intervention that has undergone temperature excursion from the specified storage range, unless it is determined by the sponsor that the study intervention under question is acceptable for use.

Such medication errors occurring to a study participant are to be captured on the medication error page of the CRF, which is a specific version of the AE page.

In the event of a medication dosing error, the sponsor should be notified within 24 hours.

Whether or not the medication error is accompanied by an AE, as determined by the investigator, the medication error is recorded on the medication error page of the CRF and, if applicable, any associated AE(s), serious and nonserious, are recorded on the AE page of the CRF.

Medication errors should be reported to Pfizer Safety within 24 hours on a Vaccine SAE Report Form **only when associated with an SAE.**

### 8.4. Treatment of Overdose

For this study, any dose of study intervention greater than 1 dose of study intervention within a 24-hour time period will be considered an overdose.

Pfizer does not recommend specific treatment for an overdose.

In the event of an overdose, the investigator should:

1. Contact the medical monitor within 24 hours.
2. Closely monitor the participant for any AEs/SAEs.
3. Document the quantity of the excess dose as well as the duration of the overdose in the CRF.
4. Overdose is reportable to Safety **only when associated with an SAE.**

Decisions regarding dose interruptions or modifications will be made by the investigator in consultation with the medical monitor based on the clinical evaluation of the participant.

### 8.5. Pharmacokinetics

Pharmacokinetic parameters are not evaluated in this study.

### 8.6. Pharmacodynamics

Pharmacodynamic parameters are not evaluated in this study.

### 8.7. Genetics

Genetics (specified analyses) are not evaluated in this study.

### 8.8. Biomarkers

Biomarkers are not evaluated in this study.

### 8.9. Immunogenicity Assessments

Immunogenicity assessments are described in Section 8.1.

### 8.10. Health Economics

Health economics/medical resource utilization and health economics parameters are not evaluated in this study.

### 8.11. Study Procedures

#### 8.11.1. Phase 1

##### 8.11.1.1. Screening: (0 to 28 Days Before Visit 1)

Before enrollment and before any study-related procedures are performed, voluntary, written study-specific informed consent will be obtained from the participant. Each signature on the ICD must be personally dated by the signatory. The investigator or his or her designee will also sign the ICD. A copy of the signed and dated ICD must be given to the participant. The source data must reflect that the informed consent was obtained before participation in the study.

It is anticipated that the procedures below will be conducted in a stepwise manner; however, the visit can occur over more than 1 day.

- Assign a single participant number using the IRT system.
- Obtain the participant's demography (including date of birth, sex, race, and ethnicity). The full date of birth will be collected to critically evaluate the immune response and safety profile by age.
- Obtain any medical history of clinical significance.
- Obtain details of any medications currently taken.
- Perform physical examination including vital signs (weight, height, body temperature, pulse rate, and seated blood pressure), evaluating any clinically significant abnormalities within the following body systems: general appearance; skin; head, eyes, ears, nose, and throat; heart; lungs; abdomen; musculoskeletal; extremities; neurological; and lymph nodes.
- Collect a blood sample (approximately 20 mL) for potential future serological assessment and to perform a rapid test for prior COVID-19 infection.
- Collect a blood sample (approximately 10 mL) for hematology and chemistry laboratory tests as described in Section 10.2.
- Collect a blood sample (approximately 10 mL) for HIV, HBsAg, HBc Ab, and HCV Ab tests.
- Perform urine pregnancy test on WOCBP as described in Section 8.2.6.
- Discuss contraceptive use as described in Section 10.4.
- Record nonstudy vaccinations as described in Section 6.5.
- Ensure and document that all of the inclusion criteria and none of the exclusion criteria are met.
- Record AEs as described in Section 8.3. AEs that occur prior to dosing should be noted on the Medical History CRF.
- Ask the participant to contact the site staff or investigator immediately if any significant illness or hospitalization occurs.
- Ask the participant to contact the site staff or investigator immediately if he or she experiences any respiratory symptoms as detailed in Section 8.13.
- Schedule an appointment for the participant to return for the next study visit.

- Complete the source documents.
- Complete the CRF.

#### 8.11.1.2. Visit 1 – Vaccination 1: (Day 1)

It is anticipated that the procedures below will be conducted in a stepwise manner; ensure that procedures listed prior to administration of the vaccine are conducted prior to vaccination.

- Record AEs as described in Section 8.3.
- Measure vital signs (body temperature, pulse rate, and seated blood pressure), and, if indicated by any change in the participant's health since the previous visit, perform a physical examination, evaluating any clinically significant abnormalities within the following body systems: general appearance; skin; head, eyes, ears, nose, and throat; heart; lungs; abdomen; musculoskeletal; extremities; neurological; and lymph nodes.
- Perform urine pregnancy test on WOCBP as described in Section 8.2.6.
- Discuss contraceptive use as described in Section 10.4.
- Record nonstudy vaccinations as described in Section 6.5.
- Review screening laboratory results (hematology and chemistry, and HIV, HBsAg, HBc Ab, and HCV Ab tests).
- Obtain 2 nasal (midturbinate) swabs (collected by site staff). One will be tested (if possible at the site, otherwise at the central laboratory) within 24 hours and vaccination will proceed only if it is NAAT-negative for SARS-CoV-2 genomes. The second will be sent to the central laboratory for potential later testing.
- Ensure and document that all of the inclusion criteria and none of the exclusion criteria are met.
- Ensure that the participant meets none of the temporary delay criteria as described in Section 5.5.
- Obtain the participant's randomization number and study intervention allocation using the IRT system. Only an unblinded site staff member may obtain this information.
- Collect a blood sample (approximately 50 mL) for immunogenicity testing.
- Unblinded site staff member(s) will dispense/administer 1 dose of study intervention into the deltoid muscle of the preferably nondominant arm. Please refer to the IP manual for further instruction on this process.

- The first 5 participants vaccinated in each group must be observed by blinded site staff for any acute reactions for at least 4 hours after vaccination. For participants enrolled thereafter, blinded site staff must observe the participant for at least 30 minutes after study intervention administration for any acute reactions. Record any acute reactions (including time of onset) in the participant's source documents and on the AE page of the CRF, and on an SAE form as applicable.

- Issue a measuring device to measure local reactions at the injection site and a thermometer for recording daily temperatures and provide instructions on their use.

- Explain the e-diary technologies available for this study (see Section 8.14), and assist the participant in downloading the study application onto the participant's own device or issue a provisioned device if required. Provide instructions on e-diary completion and ask the participant to complete the reactogenicity e-diary from Day 1 to Day 7, with Day 1 being the day of vaccination and, if utilized, the COVID-19 illness e-diary (to be completed if the participant is diagnosed with COVID-19 or has possible new or increased symptoms, and when he/she receives a reminder, at least weekly).

- Ask the participant to contact the site staff or investigator immediately if he or she experiences any of the following from Day 1 to Day 7 after vaccination (where Day 1 is the day of vaccination) to determine if an unscheduled reactogenicity visit is required:
  - Fever ≥39.0°C (≥102.1°F).
  - Redness or swelling at the injection site measuring greater than 10 cm (>20 measuring device units).
  - Severe pain at the injection site.
  - Any severe systemic event.
- Ask the participant to contact the site staff or investigator if a medically attended event (eg, doctor's visit, emergency room visit) or hospitalization occurs.
- Ask the participant to contact the site staff or investigator (this could be via the COVID-19 illness e-diary) immediately if he or she experiences any respiratory symptoms as detailed in Section 8.13.
- Schedule an appointment for the participant to return for the next study visit.
- Remind the participant to bring the e-diary to the next visit.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs and an unblinded dispenser/administrator updates the study intervention accountability records.
- The investigator or appropriately qualified designee reviews the reactogenicity e-diary data online following vaccination to evaluate participant compliance and as part of the ongoing safety review. Daily review is optimal during the active diary period.

#### 8.11.1.3. Visit 2 – Next-Day Follow-up Visit (Vaccination 1): (1 to 3 Days After Visit 1)

- Record AEs as described in Section 8.3.
- Measure vital signs (body temperature, pulse rate, and seated blood pressure), and, if indicated by any change in the participant's health since the previous visit, perform a physical examination, evaluating any clinically significant abnormalities within the following body systems: general appearance; skin; head, eyes, ears, nose, and throat; heart; lungs; abdomen; musculoskeletal; extremities; neurological; and lymph nodes.
- Collect a blood sample (approximately 10 mL) for hematology and chemistry laboratory tests as described in Section 10.2.

- Record nonstudy vaccinations as described in Section 6.5.
- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for his or her clinical care.
- Discuss contraceptive use as described in Section 10.4.
- Ask the participant to contact the site staff or investigator immediately if he or she experiences any of the following from Day 1 to Day 7 after vaccination (where Day 1 is the day of vaccination) to determine if an unscheduled reactogenicity visit is required:
  - Fever ≥39.0°C (≥102.1°F).
  - Redness or swelling at the injection site measuring greater than 10 cm (>20 measuring device units).
  - Severe pain at the injection site.
  - Any severe systemic event.
- Ask the participant to contact the site staff or investigator if a medically attended event (eg, doctor's visit, emergency room visit) or hospitalization occurs.
- Ask the participant to contact the site staff or investigator (this could be via the COVID-19 illness e-diary) immediately if he or she experiences any respiratory symptoms as detailed in Section 8.13.
- Schedule an appointment for the participant to return for the next study visit.
- Remind the participant to bring the e-diary to the next visit.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs.
- The investigator or appropriately qualified designee reviews the reactogenicity e-diary data online following vaccination to evaluate participant compliance and as part of the ongoing safety review. Daily review is optimal during the active diary period.

#### 8.11.1.4. Visit 3 – 1-Week Follow-up Visit (Vaccination 1): (6 to 8 Days After Visit 1)

- Record AEs as described in Section 8.3.
- Review hematology and chemistry laboratory results and record any AEs in accordance with Appendix 2.
- Measure vital signs (body temperature, pulse rate, and seated blood pressure), and, if indicated by any change in the participant's health since the previous visit, perform a physical examination, evaluating any clinically significant abnormalities within the following body systems: general appearance; skin; head, eyes, ears, nose, and throat; heart; lungs; abdomen; musculoskeletal; extremities; neurological; and lymph nodes.
- Collect a blood sample (approximately 10 mL) for hematology and chemistry laboratory tests as described in Section 10.2.
- Record nonstudy vaccinations as described in Section 6.5.
- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for his or her clinical care.
- Discuss contraceptive use as described in Section 10.4.
- Collect a blood sample (approximately 50 mL) for immunogenicity testing.
- Ask the participant to contact the site staff or investigator immediately if he or she experiences any of the following from Day 1 to Day 7 after vaccination (where Day 1 is the day of vaccination) to determine if an unscheduled reactogenicity visit is required:
  - Fever ≥39.0°C (≥102.1°F).
  - Redness or swelling at the injection site measuring greater than 10 cm (>20 measuring device units).
  - Severe pain at the injection site.
  - Any severe systemic event.
- Ask the participant to contact the site staff or investigator if a medically attended event (eg, doctor's visit, emergency room visit) or hospitalization occurs.
- Ask the participant to contact the site staff or investigator (this could be via the COVID-19 illness e-diary) immediately if he or she experiences any respiratory symptoms as detailed in Section 8.13.
- Schedule an appointment for the participant to return for the next study visit.

- Remind the participant to bring the e-diary to the next visit.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs.
- The investigator or appropriately qualified designee reviews the reactogenicity e-diary data online following vaccination to evaluate participant compliance and as part of the ongoing safety review. Daily review is optimal during the active diary period.

#### 8.11.1.5. Visit 4 – Vaccination 2: (19 to 23 Days After Visit 1)

It is anticipated that the procedures below will be conducted in a stepwise manner; ensure that procedures listed prior to administration of the vaccine are conducted prior to vaccination.

- Record AEs as described in Section 8.3.
- Review the participant's reactogenicity e-diary data. Collect stop dates of any reactogenicity e-diary events ongoing on the last day that the reactogenicity e-diary was completed and record stop dates in the CRF if required.
- Review hematology and chemistry laboratory results and record any AEs in accordance with Appendix 2.
- Measure vital signs (body temperature, pulse rate, and seated blood pressure), and, if indicated by any change in the participant's health since the previous visit, perform a physical examination, evaluating any clinically significant abnormalities within the following body systems: general appearance; skin; head, eyes, ears, nose, and throat; heart; lungs; abdomen; musculoskeletal; extremities; neurological; and lymph nodes.
- Perform urine pregnancy test on WOCBP as described in Section 8.2.6.
- Discuss contraceptive use as described in Section 10.4.
- Record nonstudy vaccinations as described in Section 6.5.
- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for his or her clinical care.
- Obtain 2 nasal (midturbinate) swabs (collected by site staff). One will be tested (if possible at the site, otherwise at the central laboratory) within 24 hours and vaccination will only proceed if it is NAAT-negative for SARS-CoV-2 genomes. The second will be sent to the central laboratory for potential later testing.
- Ensure and document that all of the inclusion criteria and none of the exclusion criteria are met. If not, the participant should not receive further study intervention

but will remain in the study to be evaluated for safety, immunogenicity, and efficacy (see Section 7.1).

- Ensure that the participant meets none of the temporary delay criteria as described in Section 5.5.
- Collect a blood sample (approximately 10 mL) for hematology and chemistry laboratory tests as described in Section 10.2.
- Collect a blood sample (approximately 50 mL) for immunogenicity testing.
- Unblinded site staff member(s) will dispense/administer 1 dose of study intervention into the deltoid muscle of the preferably nondominant arm. Please refer to the IP manual for further instruction on this process.
- Blinded site staff must observe the participant for at least 30 minutes after study intervention administration for any acute reactions. Record any acute reactions (including time of onset) in the participant's source documents and on the AE page of the CRF, and on an SAE form as applicable.
- Ensure the participant has a measuring device to measure local reactions at the injection site and a thermometer for recording daily temperatures.
- Ensure the participant remains comfortable with his or her chosen e-diary platform, confirm instructions on e-diary completion, and ask the participant to complete the reactogenicity e-diary from Day 1 to Day 7, with Day 1 being the day of vaccination.
- Ask the participant to contact the site staff or investigator immediately if he or she experiences any of the following from Day 1 to Day 7 after vaccination (where Day 1 is the day of vaccination) to determine if an unscheduled reactogenicity visit is required:
  - Fever ≥39.0°C (≥102.1°F).
  - Redness or swelling at the injection site measuring greater than 10 cm (>20 measuring device units).
  - Severe pain at the injection site.
  - Any severe systemic event.
- Ask the participant to contact the site staff or investigator if a medically attended event (eg, doctor's visit, emergency room visit) or hospitalization occurs.
- Ask the participant to contact the site staff or investigator (this could be via the COVID-19 illness e-diary) immediately if he or she experiences any respiratory symptoms as detailed in Section 8.13.

- Schedule an appointment for the participant to return for the next study visit.
- Remind the participant to bring the e-diary to the next visit.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs and an unblinded dispenser/administrator updates the study intervention accountability records.
- The investigator or appropriately qualified designee reviews the reactogenicity e-diary data online following vaccination to evaluate participant compliance and as part of the ongoing safety review. Daily review is optimal during the active diary period.

#### 8.11.1.6. Visit 5 – 1-Week Follow-up Visit (Vaccination 2): (6 to 8 Days After Visit 4)

- Record AEs as described in Section 8.3.
- Review hematology and chemistry laboratory results and record any AEs in accordance with Appendix 2.
- Measure vital signs (body temperature, pulse rate, and seated blood pressure), and, if indicated by any change in the participant's health since the previous visit, perform a physical examination, evaluating any clinically significant abnormalities within the following body systems: general appearance; skin; head, eyes, ears, nose, and throat; heart; lungs; abdomen; musculoskeletal; extremities; neurological; and lymph nodes.
- Collect a blood sample (approximately 10 mL) for hematology and chemistry laboratory tests as described in Section 10.2.
- Record nonstudy vaccinations as described in Section 6.5.
- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for his or her clinical care.
- Discuss contraceptive use as described in Section 10.4.
- Collect a blood sample (approximately 50 mL) for immunogenicity testing.
- If the participant (select participants only, details will be provided by the sponsor) consents, collect an additional 170 mL blood sample for exploratory COVID-19 research.
- Ask the participant to contact the site staff or investigator immediately if he or she experiences any of the following from Day 1 to Day 7 after vaccination (where Day 1 is the day of vaccination) to determine if an unscheduled reactogenicity visit is required:

- Fever ≥39.0°C (≥102.1°F).
- Redness or swelling at the injection site measuring greater than 10 cm (>20 measuring device units).
- Severe pain at the injection site.
- Any severe systemic event.

- Ask the participant to contact the site staff or investigator if a medically attended event (eg, doctor's visit, emergency room visit) or hospitalization occurs.
- Ask the participant to contact the site staff or investigator immediately if he or she experiences any respiratory symptoms as detailed in Section 8.13.
- Schedule an appointment for the participant to return for the next study visit.
- Remind the participant to bring the e-diary to the next visit.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs.
- The investigator or appropriately qualified designee reviews the reactogenicity e-diary data online following vaccination to evaluate participant compliance and as part of the ongoing safety review. Daily review is optimal during the active diary period.

#### 8.11.1.7. Visit 6 – 2-Week Follow-up Visit (Vaccination 2): (12 to 16 Days After Visit 4)

- Record AEs as described in Section 8.3.
- Review the participant's reactogenicity e-diary data. Collect stop dates of any reactogenicity e-diary events ongoing on the last day that the reactogenicity e-diary was completed and record stop dates in the CRF if required.
- Review hematology and chemistry laboratory results and record any AEs in accordance with Appendix 2.
- Measure vital signs (body temperature, pulse rate, and seated blood pressure), and, if indicated by any change in the participant's health since the previous visit, perform a physical examination, evaluating any clinically significant abnormalities within the following body systems: general appearance; skin; head, eyes, ears, nose, and throat; heart; lungs; abdomen; musculoskeletal; extremities; neurological; and lymph nodes.
- Record nonstudy vaccinations as described in Section 6.5.

- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for his or her clinical care.
- Discuss contraceptive use as described in Section 10.4.
- Collect a blood sample (approximately 50 mL) for immunogenicity testing.
- If not collected at Visit 5, and the participant (select participants only, details will be provided by the sponsor) consents, collect an additional 170-mL blood sample for exploratory COVID-19 research.
- Ask the participant to contact the site staff or investigator if a medically attended event (eg, doctor's visit, emergency room visit) or hospitalization occurs.
- Ask the participant to contact the site staff or investigator immediately (this could be via the COVID-19 illness e-diary) if he or she experiences any respiratory symptoms as detailed in Section 8.13.
- Schedule an appointment for the participant to return for the next study visit.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs.

#### 8.11.1.8. Visit 7 – 1-Month Follow-up Visit: (28 to 35 Days After Visit 4)

- Record AEs as described in Section 8.3.
- Record nonstudy vaccinations as described in Section 6.5.
- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for his or her clinical care.
- Discuss contraceptive use as described in Section 10.4.
- Collect a blood sample (approximately 50 mL) for immunogenicity testing.
- If not collected at Visit 5 or 6, and the participant (select participants only, details will be provided by the sponsor) consents, collect an additional 170-mL blood sample for exploratory COVID-19 research.
- Ask the participant to contact the site staff or investigator if a medically attended event (eg, doctor's visit, emergency room visit) or hospitalization occurs.
- Ask the participant to contact the site staff or investigator (this could be via the COVID-19 illness e-diary) immediately if he or she experiences any respiratory symptoms as detailed in Section 8.13.

- Schedule an appointment for the participant to return for the next study visit.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs.

#### 8.11.1.9. Visit 8 – 6-Month Follow-up Visit: (175 to 189 Days After Visit 4)

- Record SAEs as described in Section 8.3.
- Record nonstudy vaccinations as described in Section 6.5.
- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for his or her clinical care.
- Collect a blood sample (approximately 20 mL) for immunogenicity testing.
- Ask the participant to contact the site staff or investigator if a medically attended event (eg, doctor's visit, emergency room visit) or hospitalization occurs.
- Ask the participant to contact the site staff or investigator (this could be via the COVID-19 illness e-diary) immediately if he or she experiences any respiratory symptoms as detailed in Section 8.13.
- Schedule an appointment for the participant to return for the next study visit.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs.
- Record any AEs that occur within the 48 hours after the blood draw as described in Section 8.3.

#### 8.11.1.10. Visit 9 – 12-Month Follow-up Visit: (350 to 378 Days After Visit 4)

- Collect a blood sample (approximately 20 mL) for immunogenicity testing.
- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for his or her clinical care.
- Ask the participant to contact the site staff or investigator (this could be via the COVID-19 illness e-diary) immediately if he or she experiences any respiratory symptoms as detailed in Section 8.13.
- Schedule an appointment for the participant to return for the next study visit.
- Complete the source documents.

- The investigator or an authorized designee completes the CRFs.
- Record any AEs that occur within the 48 hours after the blood draw as described in Section 8.3.

#### 8.11.1.11. Visit 10 – 24-Month Follow-up Visit: (714 to 742 Days After Visit 4)

- Collect a blood sample (approximately 20 mL) for immunogenicity testing.
- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for his or her clinical care.
- Collect the participant's e-diary or assist the participant to remove the study application from his or her own personal device.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs.
- Record any AEs that occur within the 48 hours after the blood draw as described in Section 8.3.

### 8.11.2. Phase 2/3

#### 8.11.2.1. Visit 1 – Vaccination 1: (Day 1)

Before enrollment and before any study-related procedures are performed, voluntary, written, study-specific informed consent will be obtained from the participant or his/her parent(s)/legal guardian, as appropriate. Each signature on the ICD must be personally dated by the signatory. The investigator or his or her designee will also sign the ICD. A copy of the signed and dated ICD must be given to the participant/participant's parent(s)/legal guardian. The source data must reflect that the informed consent was obtained before participation in the study.

It is anticipated that the procedures below will be conducted in a stepwise manner. The visit may be conducted across 2 consecutive days; if so, all steps from assessing the inclusion and exclusion criteria onwards must be conducted on the same day.

- Assign a single participant number using the IRT system.
- Obtain the participant's demography (including date of birth, sex, race, and ethnicity). The full date of birth will be collected to critically evaluate the immune response and safety profile by age.
- Obtain any medical history of clinical significance. For participants who are HIV-positive, record HIV viral load and CD4 count results from the most recent test performed in the previous 6 months.

- Perform a clinical assessment. If the clinical assessment indicates that a physical examination is necessary to comprehensively evaluate the participant, perform a physical examination and record any findings in the source documents and, if clinically significant, record on the medical history CRF.
- Measure the participant's height and weight.
- Measure the participant's body temperature.
- Perform urine pregnancy test on WOCBP as described in Section 8.2.6.
- Discuss contraceptive use as described in Section 10.4.
- Record nonstudy vaccinations as described in Section 6.5.
- Ensure and document that all of the inclusion criteria and none of the exclusion criteria are met.
- Ensure that the participant meets none of the temporary delay criteria as described in Section 5.5.
- Record AEs as described in Section 8.3.
- Collect a blood sample (approximately 20 mL for participants ≥16 years of age and approximately 10 mL for participants in the 12- to 15-year age stratum) for immunogenicity testing.
- Obtain a nasal (midturbinate) swab (collected by site staff).
- Obtain the participant's randomization number and study intervention allocation number using the IRT system. Only an unblinded site staff member may obtain this information.
- Unblinded site staff member(s) will dispense/administer 1 dose of study intervention into the deltoid muscle of the preferably nondominant arm. Please refer to the IP manual for further instruction on this process.
- Blinded site staff must observe the participant for at least 30 minutes after study intervention administration for any acute reactions. Record any acute reactions (including time of onset) in the participant's source documents and on the AE page of the CRF, and on an SAE form as applicable.
- For participants in the reactogenicity subset, issue a measuring device to measure local reactions at the injection site and a thermometer for recording daily temperatures and provide instructions on their use.

- For participants not in the reactogenicity subset, issue a thermometer to monitor for fever (for COVID-19 surveillance) and provide instructions on its use.

- Explain the e-diary technologies available for this study (see Section 8.14), and assist the participant or his/her parent(s)/legal guardian, as appropriate, in downloading the study application onto the participant's own device or issue a provisioned device if required.

    - For participants in the reactogenicity subset, provide instructions on reactogenicity e-diary completion and ask the participant or his/her parent(s)/legal guardian, as appropriate, to complete the reactogenicity e-diary from Day 1 to Day 7, with Day 1 being the day of vaccination.

    - For all participants, provide instructions on COVID-19 illness e-diary completion and ask the participant or his/her parent(s)/legal guardian, as appropriate, to complete the COVID-19 illness e-diary if the participant is diagnosed with COVID-19 or has possible new or increased symptoms, and when he/she receives a reminder, at least weekly. See Section 8.14 for further details.

- If the participant is part of the reactogenicity subset, ask the participant or his/her parent(s)/legal guardian, as appropriate, to contact the site staff or investigator immediately if the participant experiences any of the following from Day 1 to Day 7 after vaccination (where Day 1 is the day of vaccination) to determine if an unscheduled reactogenicity visit is required:

    - Fever ≥39.0°C (≥102.1°F).

    - Redness or swelling at the injection site measuring greater than 10 cm (>20 measuring device units).

    - Severe pain at the injection site.

    - Any severe systemic event.

- Ask the participant or his/her parent(s)/legal guardian, as appropriate, to contact the site staff or investigator if a medically attended event (eg, doctor's visit, emergency room visit) or hospitalization occurs.

- Ask the participant or his/her parent(s)/legal guardian, as appropriate, to contact the site staff or investigator (this could be via the COVID-19 illness e-diary) immediately if he or she experiences any respiratory symptoms as detailed in Section 8.13.

- Schedule an appointment for the participant to return for the next study visit.

- Remind the participant or his/her parent(s)/legal guardian, as appropriate, to bring the e-diary to the next visit.

- Complete the source documents.
- The investigator or an authorized designee completes the CRFs and an unblinded dispenser/administrator updates the study intervention accountability records.

If the participant is part of the reactogenicity subset, the investigator or appropriately qualified designee reviews the reactogenicity e-diary data online following vaccination to evaluate participant compliance and as part of the ongoing safety review. Daily review is optimal during the active diary period.

#### 8.11.2.2. Visit 2 – Vaccination 2: (19 to 23 Days After Visit 1)

It is anticipated that the procedures below will be conducted in a stepwise manner; ensure that procedures listed prior to administration of the vaccine are conducted prior to vaccination.

- Record AEs as described in Section 8.3.
- If the participant is part of the reactogenicity subset, review the participant's reactogenicity e-diary data. Collect stop dates of any reactogenicity e-diary events ongoing on the last day that the reactogenicity e-diary was completed and record stop dates in the CRF if required.
- Perform urine pregnancy test on WOCBP as described in Section 8.2.6.
- Discuss contraceptive use as described in Section 10.4.
- Record nonstudy vaccinations as described in Section 6.5.
- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for his or her clinical care.
- Ensure and document that all of the inclusion criteria and none of the exclusion criteria are met. If not, the participant may not receive further study intervention but will remain in the study to be evaluated for safety, immunogenicity, and efficacy (see Section 7.1).
- Measure the participant's body temperature.
- Ensure that the participant meets none of the temporary delay criteria as described in Section 5.5.
- Obtain a nasal (midturbinate) swab (collected by site staff).
- Unblinded site staff member(s) will dispense/administer 1 dose of study intervention into the deltoid muscle of the preferably nondominant arm. Please refer to the IP manual for further instruction on this process.

- Blinded site staff must observe the participant for at least 30 minutes after study intervention administration for any acute reactions. Record any acute reactions (including time of onset) in the participant's source documents and on the AE page of the CRF, and on an SAE form as applicable.

- Ensure the participant or his/her parent(s)/legal guardian, as appropriate, has a measuring device to measure local reactions at the injection site and a thermometer for recording daily temperatures.

- Ensure the participant or his/her parent(s)/legal guardian, as appropriate, remains comfortable with the chosen e-diary platform, confirm instructions on e-diary completion, and, if the participant is part of the reactogenicity subset, ask the participant or his/her parent(s)/legal guardian, as appropriate, to complete the reactogenicity e-diary from Day 1 to Day 7, with Day 1 being the day of vaccination.

- If the participant is part of the reactogenicity subset, ask the participant or his/her parent(s)/legal guardian, as appropriate, to contact the site staff or investigator immediately if the participant experiences any of the following from Day 1 to Day 7 after vaccination (where Day 1 is the day of vaccination) to determine if an unscheduled reactogenicity visit is required:

  - Fever ≥39.0°C (≥102.1°F).

  - Redness or swelling at the injection site measuring greater than 10 cm (>20 measuring device units).

  - Severe pain at the injection site.

  - Any severe systemic event.

- Ask the participant or his/her parent(s)/legal guardian, as appropriate, to contact the site staff or investigator if a medically attended event (eg, doctor's visit, emergency room visit) or hospitalization occurs.

- Ask the participant or his/her parent(s)/legal guardian, as appropriate, to contact the site staff or investigator (this could be via the COVID-19 illness e-diary) immediately if the participant experiences any respiratory symptoms as detailed in Section 8.13.

- Schedule an appointment for the participant to return for the next study visit.

- Remind the participant or his/her parent(s)/legal guardian, as appropriate, to bring the e-diary to the next visit.

- Complete the source documents.

- The investigator or an authorized designee completes the CRFs and an unblinded dispenser/administrator updates the study intervention accountability records.

If the participant is part of the reactogenicity subset, the investigator or appropriately qualified designee reviews the reactogenicity e-diary data online following vaccination to evaluate participant compliance and as part of the ongoing safety review. Daily review is optimal during the active diary period.

#### 8.11.2.3. Visit 3 – 1-Month Follow-up Visit (After Vaccination 2): (28 to 35 Days After Visit 2)

- Record AEs as described in Section 8.3.
- Review the participant's reactogenicity e-diary data. If the participant is part of the reactogenicity subset, review the participant's reactogenicity e-diary data. Collect stop dates of any reactogenicity e-diary events ongoing on the last day that the reactogenicity e-diary was completed and record stop dates in the CRF if required.
- Record nonstudy vaccinations as described in Section 6.5.
- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for his or her clinical care.
- For participants who are HIV-positive, record HIV viral load and CD4 count results from the most recent test performed since Visit 1 (if any).
- Discuss contraceptive use as described in Section 10.4.
- Collect a blood sample (approximately 20 mL for participants ≥16 years of age, and approximately 10 mL for participants in the 12- to 15-year age stratum) for immunogenicity testing.
- Ask the participant or his/her parent(s)/legal guardian, as appropriate, to contact the site staff or investigator if a medically attended event (eg, doctor's visit, emergency room visit) or hospitalization occurs.
- Ask the participant or his/her parent(s)/legal guardian, as appropriate, to contact the site staff or investigator (this could be via the COVID-19 illness e-diary) immediately if the participant experiences any respiratory symptoms as detailed in Section 8.13.
- Schedule an appointment for the participant to return for the next study visit.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs.

#### 8.11.2.4. Visit 4 – 6-Month Follow-up Visit: (175 to 189 Days After Visit 2)

- Record SAEs as described in Section 8.3.
- Record nonstudy vaccinations as described in Section 6.5.
- For participants who are HIV-positive, record HIV viral load and CD4 count results from the most recent test performed since Visit 3 (if any).
- Collect a blood sample (approximately 20 mL for participants ≥16 years of age and approximately 10 mL for participants in the 12- to 15-year age stratum) for immunogenicity testing.
- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for his or her clinical care.
- Ask the participant or his/her parent(s)/legal guardian, as appropriate, to contact the site staff or investigator (this could be via the COVID-19 illness e-diary) immediately if the participant experiences any respiratory symptoms as detailed in Section 8.3.
- Schedule an appointment for the participant to return for the next study visit.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs.
- Record any AEs that occur within the 48 hours after the blood draw as described in Section 8.3.

#### 8.11.2.5. Visit 5 – 12-Month Follow-up Visit: (350 to 378 Days After Visit 2)

- Collect a blood sample (approximately 20 mL for participants ≥16 years of age and approximately 10 mL for participants in the 12- to 15-year age stratum) for immunogenicity testing.
- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for his or her clinical care.
- For participants who are HIV-positive, record HIV viral load and CD4 count results from the most recent test performed since Visit 4 (if any).
- Ask the participant or his/her parent(s)/legal guardian, as appropriate, to contact the site staff or investigator (this could be via the COVID-19 illness e-diary) immediately if the participant experiences any respiratory symptoms as detailed in Section 8.13.
- Schedule an appointment for the participant to return for the next study visit.
- Complete the source documents.

- The investigator or an authorized designee completes the CRFs.
- Record any AEs that occur within the 48 hours after the blood draw as described in Section 8.3.

#### 8.11.2.6. Visit 6 – 24-Month Follow-up Visit: (714 to 742 Days After Visit 2)

- Collect a blood sample (approximately 20 mL for participants ≥16 years of age and approximately 10 mL for participants in the 12- to 15-year age stratum) for immunogenicity testing.
- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for his or her clinical care.
- For participants who are HIV-positive, record HIV viral load and CD4 count results from the most recent test performed since Visit 5 (if any).
- Collect the participant's e-diary or assist the participant to remove the study application from his or her own personal device.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs.
- Record any AEs that occur within the 48 hours after the blood draw as described in Section 8.3.

### 8.12. Unscheduled Visit for a Grade 3 or Suspected Grade 4 Reaction

If a Grade 3 local reaction (Section 8.2.2.2), systemic event (Section 8.2.2.3), or fever (Section 8.2.2.4) is reported in the reactogenicity e-diary, a telephone contact should occur to ascertain further details and determine whether a site visit is clinically indicated. If suspected Grade 4 local reaction (Section 8.2.2.2), systemic event (Section 8.2.2.3), or fever (Section 8.2.2.4) is reported in the reactogenicity e-diary, a telephone contact or site visit should occur to confirm whether the event meets the criteria for Grade 4.

A site visit must be scheduled as soon as possible to assess the participant unless any of the following is true:

- The participant is unable to attend the unscheduled visit.
- The local reaction/systemic event is no longer present at the time of the telephone contact.
- The participant or his/her parent(s)/legal guardian, as appropriate, recorded an incorrect value in the reactogenicity e-diary (confirmation of a reactogenicity e-diary data entry error).

- The PI or authorized designee determined it was not needed.

This telephone contact will be recorded in the participant's source documentation and the CRF.

If the participant is unable to attend the unscheduled visit, or the PI or authorized designee determined it was not needed, any ongoing local reactions/systemic events must be assessed at the next study visit.

During the unscheduled visit, the reactions should be assessed by the investigator or a medically qualified member of the study staff such as a study physician or a study nurse, as applicable to the investigator's local practice, who will:

- Measure body temperature (°F/°C).
- Measure minimum and maximum diameters of redness (if present).
- Measure minimum and maximum diameters of swelling (if present).
- Assess injection site pain (if present) in accordance with the grades provided in Section 8.2.2.2.
- Assess systemic events (if present) in accordance with the grades provided in Section 8.2.2.3.
- Assess for other findings associated with the reaction and record on the AE page of the CRF, if appropriate.

The investigator or an authorized designee will complete the unscheduled visit assessment page of the CRF.

### 8.13. COVID-19 Surveillance (All Participants)

If a participant experiences any of the following (irrespective of perceived etiology or clinical significance), he or she is instructed to contact the site immediately and, if confirmed, participate in an in-person or telehealth visit as soon as possible, optimally within 3 days of symptom onset (and at the latest 4 days after symptom resolution). Note that:

- If new symptoms are reported within 4 days after resolution of all previous symptoms, they will be considered as part of a single illness and a second illness visit is not required;
- Surveillance of potential COVID-19 symptoms should continue even if a participant has a positive SARS-CoV-2 test earlier in the study.

During the 7 days following each vaccination, potential COVID-19 symptoms that overlap with specific systemic events (ie, fever, chills, new or increased muscle pain, diarrhea, vomiting) should not trigger a potential COVID-19 illness visit unless, in the investigator's

opinion, the clinical picture is more indicative of a possible COVID-19 illness than vaccine reactogenicity. If, in the investigator's opinion, the symptoms are considered more likely to be vaccine reactogenicity, but a participant is required to demonstrate that they are SARS-CoV-2–negative, a local SARS-CoV-2 test may be performed: if positive, the symptoms should be recorded as a potential COVID-19 illness; if not, the symptoms should be recorded as AEs (unless already captured in the reactogenicity e-diary).

Participants may utilize a COVID-19 illness e-diary through an application (see Section 8.14) installed on a provisioned device or on the participant's own personal device to prompt him/her to report any symptoms. Note that this does not substitute for a participant's routine medical care. Therefore, participants should be encouraged to seek care, if appropriate, from their usual provider.

- A diagnosis of COVID-19;
- Fever;
- New or increased cough;
- New or increased shortness of breath;
- Chills;
- New or increased muscle pain;
- New loss of taste/smell;
- Sore throat;
- Diarrhea;
- Vomiting.

### 8.13.1. Potential COVID-19 Illness Visit: (Optimally Within 3 Days After Potential COVID-19 Illness Onset)

This visit may be conducted as an in-person or telehealth visit; a telehealth visit involves the sharing of healthcare information and services via telecommunication technologies (eg, audio, video, video-conferencing software) remotely, thus allowing the participant and investigator to communicate on aspects of clinical care.

As a participant's COVID-19 illness may evolve over time, several contacts may be required to obtain the following information:

- Record AEs, as appropriate as described in Section 8.3. Note: Potential COVID-19 illnesses that are consistent with the clinical endpoint definition should not be recorded as AEs. These data will be captured as efficacy assessment data only on the relevant pages of the CRF, as these are expected endpoints.

- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for his or her clinical care.

- If the visit is conducted in person, obtain a nasal (midturbinate) swab (collected by site staff). Alternatively, if conducted by telehealth, instruct the participant to self-collect a nasal (midturbinate) swab and ship for assessment at the central laboratory.

- Collect COVID-19–related standard-of-care clinical and laboratory information. This includes, but is not limited to:

    - Symptoms and signs, including

        - Clinical signs at rest indicative of severe systemic illness (RR ≥30 breaths per minute, HR ≥125 beats per minute, $SpO_2$ ≤93% on room air at sea level, or $PaO_2/FiO_2$ <300 mm Hg)

        - Evidence of shock (SBP <90 mm Hg, DBP <60 mm Hg, or requiring vasopressors)

        - Significant acute renal, hepatic, or neurologic dysfunction

        - Respiratory failure (defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation, or ECMO)

    - Clinical diagnosis

    - Local laboratory SARS-CoV-2 test result(s). Note that if it is routine practice to perform a repeat local SARS-CoV-2 test for any reason, then a repeat nasal (midturbinate) swab should also be obtained and shipped for assessment at the central laboratory.

- Full blood count
- Blood chemistry, specifically creatinine, urea, liver function tests, and C-reactive protein
- Imaging results (eg, CT or MRI scan) to document neurologic dysfunction
- Number and type of any healthcare contact; duration of hospitalization and ICU stay
- Death

- Schedule an appointment for the participant to return for the potential COVID-19 convalescent visit once he or she has recovered.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs.

### 8.13.2. Potential COVID-19 Convalescent Visit: (28 to 35 Days After Potential COVID-19 Illness Visit)

- Record AEs, as appropriate as described in Section 8.3. Note: Potential COVID-19 illnesses that are consistent with the clinical endpoint definition should not be recorded as AEs. These data will be captured as efficacy assessment data only on the relevant pages of the CRF, as these are expected endpoints.
- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for his or her clinical care.
- Collect a blood sample (approximately 20 mL for participants ≥16 years of age and approximately 10 mL for participants in the 12- to 15-year age stratum) for immunogenicity testing.
- Collect/update COVID-19–related clinical and laboratory information (detailed in Section 8.13.1).
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs.
- Record any AEs that occur within the 48 hours after the blood draw as described in Section 8.3.

## 8.14. Communication and Use of Technology

In a study of this nature that requires illness events to be reported outside of scheduled study visits, it is vital that communication between the study site and the participant or his/her

parent(s)/legal guardian, as appropriate, is maintained to ensure that endpoint events are not missed. This study will employ various methods, tailored to the individual participant, to ensure that communication is maintained and study information can be transmitted securely. Using appropriate technology, such as a study application, a communication pathway between the participant or his/her parent(s)/legal guardian, as appropriate, and the study site staff will be established. The participant or his/her parent(s)/legal guardian, as appropriate, may be able to utilize his or her own devices to access this technology, or use a device provided by the sponsor. Traditional methods of telephone communication will also be available. The technology solution may facilitate the following:

- Contact with the investigator, including the ability of the participant or his/her parent(s)/legal guardian, as appropriate, to report whether or not the participant has experienced symptoms that could represent a potential COVID-19 illness (COVID-19 illness e-diary; see Section 8.13).
- An alert in the event that the participant is hospitalized.
- Visit reminders.
- Messages of thanks and encouragement from the study team.
- A platform for recording local reactions and systemic events (reactogenicity e-diary) – see Section 8.2.2.

If a participant or his/her parent(s)/legal guardian, as appropriate, is not actively completing either the reactogenicity or COVID-19 illness e-diary, the investigator or designee is required to contact the participant or his/her parent(s)/legal guardian, as appropriate, to ascertain why and also to obtain details of any missed events.

### 8.15. SARS-CoV-2 NAAT Results From Visits 1 and 2 and Potential COVID-19 Illness Visits

Nasal (midturbinate) swabs for SARS-CoV-2 NAAT are obtained at:

- Visits 1 and 2: To determine whether a participant will be included in efficacy analyses of those with no serological or virological evidence (up to 7 or 14 days after receipt of the second dose, depending on the objective) of past SARS-CoV-2 infection.
- Potential COVID-19 illness visits: To determine whether symptoms experienced by the participant fulfill the COVID-19 case definition.

Research laboratory–generated positive results from the Visit 1 and Visit 2 swabs, and all results from the illness visit swabs, will be provided to the site once available, but this will not be in real time and cannot be relied upon to direct clinical care. Therefore, the participant should be directed to seek additional testing through his/her primary healthcare providers at a licensed clinical laboratory when exhibiting potential COVID-19 symptoms or otherwise

receiving a positive result and counseled on whether to take any precautionary measures pending confirmatory testing.

Participants who have a positive SARS-CoV-2 NAAT result prior to Visit 2 should be handled as follows:

- Positive SARS-CoV-2 test with no symptoms, either at Visit 1 or any time between Visit 1 and Visit 2: A positive test in an asymptomatic participant does not meet exclusion criterion 5; therefore, Vaccination 2 should proceed as normal.

- Confirmed COVID-19 (ie, symptoms and positive SARS-CoV-2 test): This meets exclusion criterion 5; therefore, Vaccination 2 should not be given but the participant should remain in the study.

# 9. STATISTICAL CONSIDERATIONS

Methodology for summary and statistical analyses of the data collected in this study is described here and further detailed in a statistical analysis plan (SAP), which will be maintained by the sponsor. The SAP may modify what is outlined in the protocol where appropriate; however, any major modifications of the primary endpoint definitions or their analyses will also be reflected in a protocol amendment.

## 9.1. Estimands and Statistical Hypotheses

### 9.1.1. Estimands

The estimand corresponding to each primary, secondary, and tertiary/exploratory objective is described in the table in Section 3.

In the primary safety objective evaluations, missing reactogenicity e-diary data will not be imputed. Missing AE dates will be imputed according to Pfizer safety rules. No other missing information will be imputed in the safety analysis.

The estimands to evaluate the immunogenicity objectives are based on evaluable populations for immunogenicity (Section 9.3). These estimands estimate the vaccine effect in the hypothetical setting where participants follow the study schedules and protocol requirements as directed. Missing antibody results will not be imputed. Immunogenicity results that are below the LLOQ will be set to 0.5 × LLOQ in the analysis; this may be adjusted once additional data on the assay characteristics become available.

The estimands to evaluate the efficacy objectives are based on evaluable populations for efficacy (Section 9.3). These estimands estimate the vaccine effect in the hypothetical setting where participants follow the study schedules and protocol requirements as directed. In addition, VE will also be analyzed by all-available efficacy population. Missing laboratory results will not be imputed for the primary analysis, but missing data imputation for the efficacy endpoint may be performed as a sensitivity analysis.

### 9.1.2. Statistical Hypotheses

#### 9.1.2.1. Statistical Hypothesis Evaluation for Efficacy

Phase 2/3 of the study has 2 primary efficacy endpoints evaluating VE, which is defined as VE = 100 × (1 – IRR). IRR is calculated as the ratio of first confirmed COVID-19 illness rate in the vaccine group to the corresponding illness rate in the placebo group. In Phase 2/3, the assessment of VE will be based on posterior probabilities of $VE_1 > 30\%$ and $VE_2 > 30\%$. $VE_1$ represents VE for prophylactic BNT162b2 against confirmed COVID-19 in participants without evidence of infection before vaccination, and $VE_2$ represents VE for prophylactic BNT162b2 against confirmed COVID-19 in all participants after vaccination.

For participants with multiple confirmed cases, only the first case will contribute to the VE calculation for each hypothesis. $VE_1$ and $VE_2$ will be evaluated sequentially to control the overall type I error to the desired level of 2.5%. VE is demonstrated if there is sufficient evidence (posterior probability) that either $VE_1 > 30\%$ or both $VE_1$ and $VE_2$ are >30%. The assessment for the primary analysis will be based on posterior probability using a Bayesian model.

#### 9.1.2.2. Statistical Hypothesis Evaluation for Immunogenicity

One of the secondary objectives in the Phase 3 part of the study is to evaluate noninferiority of the immune response to prophylactic BNT162b2 in participants 12 to 15 years of age compared to the response in participants 16 to 25 years of age at 1 month after Dose 2. The (Dose 2) evaluable immunogenicity population will be used for the following hypothesis testing:

$H_0$: $\ln(\mu_2) - \ln(\mu_1) \leq \ln(0.67)$

where ln (0.67) corresponds to a 1.5-fold margin for noninferiority, ln(μ2) and ln(μ1) are the natural log of the geometric mean of SARS-CoV-2 neutralizing titers from BNT162b2 recipients 12 to 15 years of age and 16 to 25 years of age, respectively, measured 1 month after Dose 2**.** If the lower limit of the 95% CI for the GMR (12-15 years of age to 16-25 years of age) is >0.67, the noninferiority objective is met.

### 9.2. Sample Size Determination

The study sample size for Phase 1 of the study is not based on any statistical hypothesis testing. Phase 1 comprises 15 participants (randomization ratio of 4:1 so that 12 receive active vaccine and 3 receive placebo) per group; 13 vaccine groups are studied, corresponding to a total of 195 participants.

For Phase 2/3, with assumptions of a true VE of 60% after the second dose of investigational product, a total of approximately 164 first confirmed COVID-19 illness cases will provide 90% power to conclude true VE >30% with high probability, allowing early stopping for efficacy at the IA. This would be achieved with 17,600 evaluable participants per group or 21,999 vaccine recipients randomized in a 1:1 ratio with placebo, for a total sample size of 43,998, based on the assumption of a 1.3% illness rate per year in the placebo group, accrual of 164 first primary-endpoint cases within 6 months, and 20% of the participants being

nonevaluable or having serological evidence of prior infection with SARS-CoV-2, potentially making them immune to further infection. Dependent upon the evolution of the pandemic, it is possible that the COVID-19 attack rate may be much higher, in which case accrual would be expected to be more rapid, enabling the study's primary endpoint to be evaluated much sooner. The total number of participants enrolled in Phase 2/3 may vary depending on the incidence of COVID-19 at the time of the enrollment, the true underlying VE, and a potential early stop for efficacy or futility.

In Phase 3, approximately 2000 participants are anticipated to be 12 to 15 years of age. A random sample of 250 participants will be selected for each of the 2 age groups (12 to 15 years and 16 to 25 years) as an immunogenicity subset for the noninferiority assessment. With the standard deviation and observed GMT difference assumed in the power analysis below, a sample size of 200 evaluable participants (or 250 vaccine recipients) per age group will provide a power of 90.8% to declare the noninferiority of adolescents to 16- to 25-year-olds in terms of neutralizing antibody GMR, 1 month after the second dose (see Table 4).

**Table 4. Power Analysis for Noninferiority Assessment**

| Criteria | Standard Deviation (Log Value)[a] | Assumed Observed GMT Difference (Log Scale) | Number of Evaluable Participants per Age Group | Power[b] |
|---|---|---|---|---|
| Lower limit of 95% CI for GMR (12-15/16-25) >0.67 | 0.623 | -0.2 | 200 | 90.8% |

Abbreviation: GMR = geometric mean ratio.

a. Reference: 1 month after Dose 2, BNT162b2 (30 µg), 18- to 55-year age group (C4591001 Phase 1, N=12). Calculation may be updated if additional information becomes available to better estimate the standard deviation.

b. At 0.05 alpha level (2-sided).

For safety outcomes, Table 5 shows the probability of observing at least 1 AE for a given true event rate of a particular AE, for various sample sizes. For example, if the true AE rate is 10%, with 12 participants in a vaccine group, there is 72% probability of observing at least 1 AE.

**Table 5. Probability of Observing at Least 1 AE by Assumed True Event Rates With Different Sample Sizes**

| Assumed True Event Rate of an AE | N=12 | N=45 | N=180 | N=1000 | N=3000 | N=6000 | N=9000 | N=15000 |
|---|---|---|---|---|---|---|---|---|
| 0.01% | 0.00 | 0.00 | 0.02 | 0.10 | 0.26 | 0.45 | 0.59 | 0.78 |
| 0.02% | 0.00 | 0.01 | 0.04 | 0.18 | 0.45 | 0.70 | 0.83 | 0.95 |
| 0.04% | 0.00 | 0.02 | 0.07 | 0.33 | 0.70 | 0.91 | 0.97 | >0.99 |
| 0.06% | 0.01 | 0.03 | 0.10 | 0.45 | 0.83 | 0.97 | 0.99 | >0.99 |
| 0.08% | 0.01 | 0.04 | 0.13 | 0.55 | 0.91 | 0.99 | 0.99 | >0.99 |
| 0.10% | 0.01 | 0.04 | 0.16 | 0.63 | 0.95 | 0.99 | 0.99 | >0.99 |
| 0.15% | 0.02 | 0.07 | 0.24 | 0.78 | 0.99 | 0.99 | >0.99 | >0.99 |
| 0.20% | 0.02 | 0.09 | 0.30 | 0.86 | >0.99 | >0.99 | >0.99 | >0.99 |
| 0.25% | 0.03 | 0.11 | 0.36 | 0.92 | >0.99 | >0.99 | >0.99 | >0.99 |
| 0.30% | 0.04 | 0.13 | 0.42 | 0.95 | >0.99 | >0.99 | >0.99 | >0.99 |
| 0.35% | 0.04 | 0.15 | 0.47 | 0.97 | >0.99 | >0.99 | >0.99 | >0.99 |
| 0.50% | 0.06 | 0.20 | 0.59 | 0.99 | >0.99 | >0.99 | >0.99 | >0.99 |
| 1.00% | 0.11 | 0.36 | 0.84 | >0.99 | >0.99 | >0.99 | >0.99 | >0.99 |
| 2.00% | 0.22 | 0.60 | 0.97 | >0.99 | >0.99 | >0.99 | >0.99 | >0.99 |
| 3.00% | 0.31 | 0.75 | >0.99 | >0.99 | >0.99 | >0.99 | >0.99 | >0.99 |
| 5.00% | 0.46 | 0.90 | >0.99 | >0.99 | >0.99 | >0.99 | >0.99 | >0.99 |
| 7.00% | 0.58 | 0.96 | >0.99 | >0.99 | >0.99 | >0.99 | >0.99 | >0.99 |
| 10.00% | 0.72 | 0.99 | >0.99 | >0.99 | >0.99 | >0.99 | >0.99 | >0.99 |

Note: N = number in sample.

### 9.3. Analysis Sets

For purposes of analysis, the following populations are defined:

| Population | Description |
|---|---|
| Enrolled | All participants who have a signed ICD. |
| Randomized | All participants who are assigned a randomization number in the IWR system. |
| Dose 1 evaluable immunogenicity | For Phase 1 only, all eligible randomized participants who receive the vaccine to which they are randomly assigned at the first dose, have at least 1 valid and determinate immunogenicity result after Dose 1, have blood collection within an appropriate window after Dose 1, and have no other important protocol deviations as determined by the clinician. |
| Dose 2 evaluable immunogenicity | All eligible randomized participants who receive 2 doses of the vaccine to which they are randomly assigned, within the predefined window, have at least 1 valid and determinate immunogenicity result after Dose 2, have blood collection within an appropriate window after Dose 2, and have no other important protocol deviations as determined by the clinician. |

| Population | Description |
|---|---|
| Dose 1 all-available immunogenicity | For Phase 1 only: all randomized participants who receive at least 1 dose of the study intervention with at least 1 valid and determinate immunogenicity result after Dose 1 but before Dose 2. |
| Dose 2 all-available immunogenicity | All randomized participants who receive at least 1 dose of the study intervention with at least 1 valid and determinate immunogenicity result after Dose 2. |
| Evaluable efficacy | All eligible randomized participants who receive all vaccination(s) as randomized within the predefined window and have no other important protocol deviations as determined by the clinician. |
| All-available efficacy | 1. All randomized participants who receive at least 1 vaccination.<br>2. All randomized participants who complete 2 vaccination doses. |
| Safety | All randomized participants who receive at least 1 dose of the study intervention. |

### 9.4. Statistical Analyses

The SAP will be developed and finalized before database lock for any of the planned analyses in Section 9.5.1. It will describe the participant populations to be included in the analyses and the procedures for accounting for missing, unused, and spurious data. This section provides a summary of the planned statistical analyses of the primary, secondary, and tertiary/exploratory endpoints.

#### 9.4.1. Immunogenicity Analyses

Immunogenicity samples will be drawn for all participants. Immunogenicity analyses will be based upon results from appropriately sized subsets of samples, according to the purpose.

The statistical analysis of immunogenicity results will be primarily based on the evaluable immunogenicity populations as defined in Section 9.3. Serology data after a postbaseline positive SARS-CoV-2 test result will not be included in the analysis based on the evaluable immunogenicity populations.

An additional analysis will be performed based on the all-available populations if there is a large enough difference in sample size between the all-available immunogenicity population and the evaluable immunogenicity population. Participants will be summarized according to the vaccine group to which they were randomized.

| Endpoint | Statistical Analysis Methods |
|---|---|
| Secondary immunogenicity | **Geometric mean titers/concentrations (GMTs/GMCs) of SARS-CoV-2 neutralizing titers, S1-binding IgG level, and RBD-binding IgG level**<br><br>For SARS-CoV-2 neutralizing titers, S1-binding IgG levels, and RBD-binding IgG levels, GMTs/GMCs and 2-sided 95% CIs will be provided for each investigational product within each group before vaccination and at each of the following time points:<br><br>• Phase 1: 7 and 21 days after Dose 1; 7 and 14 days and 1, 6, 12 and 24 months after Dose 2<br><br>Geometric means will be calculated as the mean of the assay results after making the logarithm transformation and then exponentiating the mean to express results on the original scale. Two-sided 95% CIs will be obtained by taking natural log transforms of concentrations/titers, calculating the 95% CI with reference to the t-distribution, and then exponentiating the confidence limits.<br><br>**GMFRs of SARS-CoV-2 neutralizing titers, S1-binding IgG level, and RBD-binding IgG level**<br><br>For SARS-CoV-2 neutralizing titers, S1-binding IgG levels, and RBD-binding IgG levels, the GMFRs and 2-sided 95% CIs will be provided for each investigational product within each group at each of the following time points:<br><br>• Phase 1: 7 and 21 days after Dose 1; 7 and 14 days and 1, 6, 12, and 24 months after Dose 2<br><br>GMFRs will be limited to participants with nonmissing values prior to the first dose and at the postvaccination time point. The GMFR will be calculated as the mean of the difference of logarithmically transformed assay results (later time point – earlier time point) and exponentiating the mean. The associated 2-sided CIs will be obtained by calculating CIs using Student's t-distribution for the mean difference of the logarithmically transformed assay results and exponentiating the confidence limits.<br><br>**Percentage of participants with ≥4-fold rise in SARS-CoV-2 neutralizing titers, S1-binding IgG level, and RBD-binding IgG level**<br><br>For SARS-CoV-2 neutralizing titers, S1-binding IgG levels, and RBD-binding IgG levels, percentages (and 2-sided 95% CIs) of |

| Endpoint | Statistical Analysis Methods |
|---|---|
| | participants with ≥4-fold rise will be provided for each investigational product within each group at each of the following time points:<br><br>• Phase 1: 7 and 21 days after Dose 1; 7 and 14 days and 1, 6, 12, and 24 months after Dose 2<br><br>The Clopper-Pearson method will be used to calculate the CIs.<br><br>**GMR of SARS-CoV-2 neutralizing titer to S1-binding IgG level and to RBD-binding IgG level**<br><br>For SARS-CoV-2 neutralizing titers, S1-binding IgG levels, and RBD-binding IgG levels, the GMRs and 2-sided 95% CIs will be provided for each investigational product within each group at each of the following time points:<br><br>• Phase 1: 7 and 21 days after Dose 1; 7 and 14 days and 1, 6, 12, and 24 months after Dose 2<br><br>GMRs will be limited to participants with nonmissing values for both SARS-CoV-2 neutralizing titers and S1-binding IgG level/RBD-binding IgG level at each time point. The GMR will be calculated as the mean of the difference of logarithmically transformed assay results (eg, SARS-CoV-2 neutralizing titers minus S1-binding IgG level for each participant) and exponentiating the mean. Two-sided CIs will be obtained by calculating CIs using Student's t-distribution for the mean difference of the logarithmically transformed assay results and exponentiating the confidence limits.<br><br>For all the immunogenicity endpoints, the analysis will be based on the Dose 1 and Dose 2 evaluable immunogenicity populations. An additional analysis will be performed based on the all-available immunogenicity populations if there is a large enough difference in sample size between the all-available immunogenicity populations and the evaluable immunogenicity populations. Participants will be summarized according to the vaccine group to which they were randomized. Missing serology data will not be imputed. |
| Secondary immunogenicity (noninferiority in the 12- to 15-year age group compared to the | **GMR of SARS-CoV-2 neutralizing titers in participants 12 to 15 years of age to those 16 to 25 years of age**<br><br>For participants with no serological or virological evidence (up to 1 month after receipt of the second dose) of past SARS-CoV-2 infection, the GMR of SARS-CoV-2 neutralizing titers in participants 12 to 15 years of age to those in participants 16 to 25 years of age and |

| Endpoint | Statistical Analysis Methods |
|---|---|
| 16- to 25-year age group) | 2-sided 95% CIs will be provided at 1 month after Dose 2 for noninferiority assessment.<br><br>The GMR and its 2-sided 95% CI will be derived by calculating differences in means and CIs on the natural log scale of the titers based on the Student's t-distribution and then exponentiating the results. The difference in means on the natural log scale will be 12 to 15 years minus 16 to 25 years. Noninferiority will be declared if the lower bound of the 2-sided 95% CI for the GMR is greater than 0.67.<br><br>This analysis will be based on Dose 2 evaluable immunogenicity populations. An additional analysis may be performed based on the Dose 2 all-available immunogenicity population if needed. Participants will be summarized according to the vaccine group to which they were randomized. Missing serology data will not be imputed. |
| Exploratory immunogenicity | **Geometric mean titers/concentrations (GMTs/GMCs) of SARS-CoV-2 neutralizing titers, S1-binding IgG level, and RBD-binding IgG level**<br><br>For SARS-CoV-2 neutralizing titers, S1-binding IgG levels, and RBD-binding IgG levels, GMTs/GMCs and 2-sided 95% CIs will be provided for each investigational product within each group before vaccination and at each of the following time points in Phase 2/3:<br><br>• 1, 6, 12, and 24 months after completion of vaccination in participants with and without serological or virological evidence of SARS-CoV-2 infection before vaccination<br><br>Geometric means will be calculated as the mean of the assay results after making the logarithm transformation and then exponentiating the mean to express results on the original scale. Two-sided 95% CIs will be obtained by taking natural log transforms of concentrations/titers, calculating the 95% CI with reference to the t-distribution, and then exponentiating the confidence limits.<br><br>**GMFRs of SARS-CoV-2 neutralizing titers, S1-binding IgG level, and RBD-binding IgG level**<br><br>For SARS-CoV-2 neutralizing titers, S1-binding IgG levels, and RBD-binding IgG levels, the GMFRs and 2-sided 95% CIs will be provided for each investigational product within each group at each of the following time points in Phase 2/3: |

| Endpoint | Statistical Analysis Methods |
|---|---|
| | • 1, 6, 12, and 24 months after completion of vaccination in participants with and without serological or virological evidence of SARS-CoV-2 infection before vaccination<br><br>GMFRs will be limited to participants with nonmissing values prior to the first dose and at the postvaccination time point. The GMFR will be calculated as the mean of the difference of logarithmically transformed assay results (later time point – earlier time point) and exponentiating the mean. The associated 2-sided CIs will be obtained by calculating CIs using Student's t-distribution for the mean difference of the logarithmically transformed assay results and exponentiating the confidence limits.<br><br>**Percentage of participants with antibody levels ≥ predefined threshold(s) for SARS-CoV-2 serological parameters**<br><br>For SARS-CoV-2 neutralizing titers, S1-binding IgG levels and/or RBD-binding IgG levels, N-binding antibody, and SARS-CoV-2 detection by NAAT, percentages (and 2-sided 95% CIs) of participants with antibody levels ≥ predefined threshold(s) will be provided for each investigational product within each group at baseline and each of the following time points in Phase 2/3:<br><br>• 1, 6, 12, and 24 months after completion of vaccination in participants with and without serological or virological evidence of SARS-CoV-2 infection before vaccination<br><br>The Clopper-Pearson method will be used to calculate the CIs.<br><br>**Percentage of participants with the immune response (non-S) to SARS-CoV-2 for N-binding antibody at the time points when data are available**<br><br>The Clopper-Pearson method will be used to calculate the CIs.<br><br>For all of the immunogenicity endpoints, the analysis will be based on the Dose 1 and Dose 2 evaluable immunogenicity populations. An additional analysis will be performed based on the all-available immunogenicity populations if there is a large enough difference in sample size between the all-available immunogenicity populations and the evaluable immunogenicity populations. Participants will be summarized according to the vaccine group to which they were randomized. Missing serology data will not be imputed. |

| Endpoint | Statistical Analysis Methods |
|---|---|
| | **RCDCs for immunogenicity results**<br><br>Empirical RCDCs will be provided for SARS-CoV-2 neutralizing titers, S1-binding IgG level, and RBD-binding IgG level after Dose 1 and after Dose 2. |

### 9.4.2. Efficacy Analyses

The evaluable efficacy population will be the primary analysis population for all efficacy analyses. Additional analyses based on the all-available efficacy population will be performed.

| Endpoint | Statistical Analysis Methods |
|---|---|
| Primary efficacy | **Ratio of confirmed COVID-19 illness from 7 days after the second dose per 1000 person-years of follow-up in participants without evidence of infection (prior to 7 days after receipt of the second dose) for the active vaccine group to the placebo group**<br><br>VE will be estimated by 100 × (1 – IRR), where IRR is the calculated ratio of confirmed COVID-19 illness per 1000 person-years follow-up in the active vaccine group to the corresponding illness rate in the placebo group from 7 days after the second dose. VE will be analyzed using a beta-binomial model.<br><br>After the above objective is met, the second primary endpoint will be evaluated as below.<br><br>**Ratio of confirmed COVID-19 illness from 7 days after the second dose per 1000 person-years of follow-up in participants with and without evidence of infection (prior to 7 days after receipt of the second dose) for the active vaccine group to the placebo group**<br><br>VE will be estimated by 100 × (1 – IRR), where IRR is the calculated ratio of confirmed COVID-19 illness per 1000 person-years follow-up in the active vaccine group to the corresponding illness rate in the placebo group from 7 days after the second dose. VE will be analyzed using a beta-binomial model.<br><br>The efficacy analysis for the first primary objective evaluation will be based on the participants without evidence of infection before vaccination and included in the evaluable efficacy population and in the all-available efficacy population. |

| Endpoint | Statistical Analysis Methods |
|---|---|
| | The efficacy analysis for the second primary objective evaluation will be based on all participants included in the evaluable efficacy population and in the all-available efficacy population.<br><br>For the primary endpoint analysis, missing efficacy data will not be imputed. A sensitivity analysis will be performed by imputing missing values with the assumption of MAR. A missing efficacy endpoint may be imputed based on predicted probability using the fully conditional specification method. Other imputation methods without the MAR assumption may be explored. The details will be provided in the SAP. |
| Secondary | **First: Ratio of confirmed COVID-19 illness from 14 days after the second dose per 1000 person-years of follow-up in participants without evidence of infection (prior to 14 days after receipt of the second dose) for the active vaccine group to the placebo group**<br><br>**Second: Ratio of confirmed COVID-19 illness from 14 days after the second dose per 1000 person-years of follow-up in participants with and without evidence of infection (prior to 14 days after receipt of the second dose) for the active vaccine group to the placebo group**<br><br>**Third and fourth: Ratios of confirmed severe COVID-19 illness from 7 days and from 14 days after the second dose per 1000 person-years of follow-up in participants without evidence of infection (prior to 7 days or 14 days after receipt of the second dose) for the active vaccine group to the placebo group**<br><br>**Fifth and sixth: Ratios of confirmed severe COVID-19 illness from 7 days and from 14 days after the second dose per 1000 person-years of follow-up in participants with and without evidence of infection (prior to 7 days or 14 days after receipt of the second dose) for the active vaccine group to the placebo group**<br><br>These secondary efficacy objectives will be evaluated sequentially in the order specified above after the primary objectives are met. The analysis will be based on the evaluable efficacy population and the all-available efficacy population. The analysis methodology used for the primary efficacy endpoints will be applied for the analysis of the above secondary efficacy endpoints.<br><br>The following secondary efficacy endpoints will be evaluated descriptively with 95% CIs.<br><br>**Ratios of confirmed COVID-19 illness (according to the CDC-defined symptoms) from 7 days and from 14 days after the** |

| Endpoint | Statistical Analysis Methods |
|---|---|
| | **second dose per 1000 person-years of follow-up in participants without evidence of infection (prior to 7 days or 14 days after receipt of the second dose) for the active vaccine group to the placebo group**<br><br>**Ratios of confirmed COVID-19 illness (according to the CDC-defined symptoms) from 7 days and from 14 days after the second dose per 1000 person-years of follow-up in participants with and without evidence of infection (prior to 7 days or 14 days after receipt of the second dose) for the active vaccine group to the placebo group**<br><br>VE = 100 × (1 – IRR) will be estimated with confirmed COVID-19 illness according to the CDC-defined symptoms from 7 days or from 14 days after the second dose. The 2-sided 95% CI for VE will be derived using the Clopper-Pearson method as described by Agresti.[9]<br><br>Missing efficacy data will not be imputed. |

### 9.4.3. Safety Analyses

| Endpoint | Statistical Analysis Methods |
|---|---|
| Primary | Descriptive statistics will be provided for each reactogenicity endpoint for each dose and vaccine group. Local reactions and systemic events from Day 1 through Day 7 after each vaccination will be presented by severity and cumulatively across severity levels. Descriptive summary statistics will include counts and percentages of participants with the indicated endpoint and the associated Clopper-Pearson 95% CIs.<br><br>For Phase 1, descriptive statistics will be provided for abnormal hematology and chemistry laboratory values at 1 and 7 days after Dose 1 and 7 days after Dose 2, including grading shifts in hematology and chemistry laboratory assessments between baseline and 1 and 7 days after Dose 1, and before Dose 2 and 7 days after Dose 2. Descriptive summary statistics will include counts and percentages of participants with the indicated endpoint and the associated Clopper-Pearson 2-sided 95% CIs.<br><br>AEs will be categorized according to the Medical Dictionary for Regulatory Activities (MedDRA) terms. A 3-tier approach will be used to summarize AEs in Phase 2/3. Under this approach AEs are classified into 1 of 3 tiers: (1) Tier 1 events are prespecified events of clinical importance and are identified in a list in the product's safety |

| Endpoint | Statistical Analysis Methods |
|---|---|
| | review plan; (2) Tier 2 events are those that are not Tier 1 but are considered "relatively common"; a MedDRA preferred term is defined as a Tier 2 event if there are at least 1% of participants in at least 1 vaccine group reporting the event; and (3) Tier 3 events are those that are neither Tier 1 nor Tier 2 events. For both Tier 1 and Tier 2 events, 2-sided 95% CIs for the difference between the vaccine and placebo groups in the percentage of participants reporting the events based on the Miettinen and Nurminen method[10] will be provided. In addition, for Tier 1 events, the asymptotic p-values will also be presented for the difference between groups in the percentage of participants reporting the events, based on the same test statistic and under the assumption that the test statistic is asymptotically normally distributed.<br><br>Descriptive summary statistics (counts, percentages, and associated Clopper-Pearson 95% CIs) will be provided for any AE events for each vaccine group.<br><br>SAEs will be categorized according to MedDRA terms. Counts, percentages, and the associated Clopper-Pearson 95% CIs of SAEs from Dose 1 to 6 months after the last dose will be provided for each vaccine group.<br><br>The safety analyses are based on the safety population. Participants will be summarized by vaccine group according to the investigational products they actually received. Missing reactogenicity e-diary data will not be imputed; missing AE dates will be handled according to the Pfizer safety rules. |
| Secondary | Not applicable (N/A) |
| Exploratory | N/A |

### 9.4.4. Other Analyses

The ratios of (GMFR A to GMFR B) and (GMFR A to GMFR C) may be explored, where GMFR A is the geometric mean of the ratio of the SARS-CoV-2 neutralizing titer at the postvaccination time point to the corresponding titer at the prevaccination time point, GFMR B is the geometric mean of the ratio of the S1-binding IgG level at the postvaccination time point to the corresponding IgG level at the prevaccination time point, and GMFR C is the geometric mean of the ratio of the RBD-binding IgG level at the postvaccination time point to the corresponding antibody level at the prevaccination time point.

The safety data and immunogenicity results for individuals with confirmed stable HIV disease will be summarized descriptively. Furthermore, VE may be assessed if there is a sufficient number of COVID-19 cases in this group of participants.

The safety and immunogenicity results for individuals 16 to 55 years of age vaccinated with study intervention produced by manufacturing "Process 1" and each lot of "Process 2" will be summarized descriptively. A random sample of 250 participants from those vaccinated with study intervention produced by manufacturing "Process 1" will be selected randomly for the analysis.

### 9.5. Interim Analyses

As this is a sponsor open-label study during Phase 1, the sponsor may conduct unblinded reviews of the data during the course of the study for the purpose of safety assessment, facilitating dose escalation decisions, and/or supporting clinical development.

During Phase 2/3, 4 IAs were planned to be performed by an unblinded statistical team after accrual of at least 32, 62, 92, and 120 cases. However, for operational reasons, the first planned IA was not performed. Consequently, 3 IAs are now planned to be performed after accrual of at least 62, 92, and 120 cases. At these IAs, futility and VE with respect to the first primary endpoint will be assessed as follows:

- VE for the first primary objective will be evaluated. Overwhelming efficacy will be declared if the first primary study objective is met. The criteria for success at an interim analysis are based on the posterior probability (ie, P[VE >30%|data]) at the current number of cases. Overwhelming efficacy will be declared if the posterior probability is higher than the success threshold. The success threshold for each interim analysis will be calibrated to protect overall type I error at 2.5%. Additional details about the success threshold or boundary calculation at each interim analysis will be provided in the SAP.

- The study will stop for lack of benefit (futility) if the predicted probability of success at the final analysis or study success is <5%. The posterior predictive POS will be calculated using a beta-binomial model. The futility assessment will be performed for the first primary endpoint and the futility boundary may be subject to change to reflect subsequent program-related decisions by the sponsor.

- Efficacy and futility boundaries will be applied in a nonbinding way.

Bayesian approaches require specification of a prior distribution for the possible values of the unknown vaccine effect, thereby accounting for uncertainty in its value. A minimally informative beta prior, beta (0.700102, 1), is proposed for $\theta = (1\text{-VE})/(2\text{-VE})$. The prior is centered at $\theta = 0.4118$ (VE=30%) which can be considered pessimistic. The prior allows considerable uncertainty; the 95% interval for $\theta$ is (0.005, 0.964) and the corresponding 95% interval for VE is (-26.2, 0.995).

Table 6 illustrates the boundary for efficacy and futility if, for example, IAs are performed after accrual of 32, 62, 92, and 120 cases in participants without evidence of infection before vaccination. Note that although the first IA was not performed, the statistical criterion for demonstrating success (posterior probability threshold) at the interim (>0.995) and final (>0.986) analyses remains unchanged. Similarly, the futility boundaries are not changed.

**Table 6. Interim Analysis Plan and Boundaries for Efficacy and Futility**

| Analysis | Number of Cases | Success Criteria[a] | Futility Boundary |
|---|---|---|---|
| | | VE Point Estimate (Case Split) | VE Point Estimate (Case Split) |
| IA1 | 32 | 76.9% (6:26) | 11.8% (15:17) |
| IA2 | 62 | 68.1% (15:47) | 27.8% (26:36) |
| IA3 | 92 | 62.7% (25:67) | 38.6% (35:57) |
| IA4 | 120 | 58.8% (35:85) | N/A |
| Final | 164 | 52.3% (53:111) | |

Abbreviations: IA = interim analysis; N/A = not applicable; VE = vaccine efficacy.
Note: Case split = vaccine : placebo.
a. Interim efficacy claim: P(VE >30%|data) > 0.995; success at the final analysis: P(VE >30%|data) > 0.986.

Additional design operating characteristics (the boundary based on the number of cases observed in the vaccine group; the probabilities for efficacy and futility given assumed various VEs with a 1:1 randomization ratio) are listed in Table 7 and Table 8, for IAs conducted at 32, 62, 92, and 120 cases and the final analysis at 164 cases. Although the IA at 32 cases was not performed, the overall Type I error (overall probability of success when true VE=30%) will still be strictly controlled at 0.025 with the originally proposed success/futility boundaries.

**Table 7. Statistical Design Operating Characteristics: Probability of Success or Failure for Interim Analyses**

| Vaccine Efficacy (%) | Interim Analysis 1 (Total Cases = 32) | | Interim Analysis 2 (Total Cases = 62) | | Interim Analysis 3 (Total Cases = 92) | | Interim Analysis 4 (Total Cases = 120) |
|---|---|---|---|---|---|---|---|
| | Probability of Success (Cases in Vaccine Group ≤6) | Probability of Failure (Cases in Vaccine Group ≥15) | Probability of Success (Cases in Vaccine Group ≤15) | Probability of Failure (Cases in Vaccine Group ≥26) | Probability of Success (Cases in Vaccine Group ≤25) | Probability of Failure (Cases in Vaccine Group ≥35) | Probability of Success (Cases Vaccine Group ≤35) |
| 30 | 0.006 | 0.315 | 0.003 | 0.231 | 0.002 | 0.239 | 0.002 |
| 50 | 0.054 | 0.078 | 0.051 | 0.056 | 0.063 | 0.103 | 0.075 |
| 60 | 0.150 | 0.021 | 0.160 | 0.010 | 0.175 | 0.019 | 0.160 |
| 70 | 0.368 | 0.003 | 0.310 | <0.001 | 0.195 | 0.001 | 0.085 |
| 80 | 0.722 | <0.001 | 0.238 | <0.001 | 0.037 | <0.001 | 0.003 |

**Table 8. Statistical Design Operating Characteristics: Probability of Success for Final Analysis and Overall**

| Vaccine Efficacy (%) | Final Analysis (Total Cases = 164) | Overall Probability of Success |
|---|---|---|
| | Probability of Success (Cases in Vaccine Group ≤53) | |
| 30 | 0.007 | 0.021 |
| 50 | 0.196 | 0.439 |
| 60 | 0.220 | 0.866 |
| 70 | 0.036 | >0.999 |
| 80 | <0.001 | >0.999 |

If neither success nor futility has been declared after all IAs, the final analysis will be performed and the first primary objective will have been met if there are 53 or fewer cases observed in the vaccine group out of a total of 164 first confirmed cases from 7 days after receipt of the second dose of investigational product onwards.

Only the first primary endpoint will be analyzed at IA. If the first primary objective is met, the second primary objective will be evaluated at the final analysis. After the primary objectives are met, the first 6 secondary VE endpoints (confirmed COVID-19 occurring from 14 days after the second dose in participants without evidence of infection and in all participants, confirmed severe COVID-19 occurring from 7 days and from 14 days after the second dose in participants without evidence of infection and in all participants) will be evaluated sequentially in the stated order, by the same method used for the evaluation of primary VE endpoints. Success thresholds for secondary VE endpoints will be appropriately chosen to control overall Type I error at 2.5%. Further details will be provided in the SAP. The remaining secondary VE endpoints will be evaluated descriptively to calculate the observed VE with 95% CIs.

### 9.5.1. Analysis Timing

Statistical analyses will be carried out when the following data are available:

- Complete safety and immunogenicity analysis approximately 1 month after Dose 2 for Phase 1.
- Safety data through 7 days after Dose 2 and immunogenicity data through 1 month after Dose 2 from the first 360 participants enrolled (180 to active vaccine and 180 to placebo, stratified equally between 18 to 55 years and >55 to 85 years) in Phase 2/3.
- Safety data through 1 month after Dose 2 from at least 6000 participants enrolled (3000 to active vaccine and 3000 to placebo) in Phase 2/3. Additional analyses of safety data (with longer follow-up and/or additional participants) may be conducted if required for regulatory purposes.
- IAs for efficacy after accrual of at least 62, 92, and 120 cases and futility after accrual of at least 62 and 92 cases.
- Safety data through 1 month after Dose 2 and noninferiority comparison of SARS-CoV-2 neutralizing titers in participants 12 to 15 years of age compared to those in participants 16 to 25 years of age, 1 month after Dose 2.
- Descriptive analysis of immunogenicity and safety of "Process 1" and "Process 2" material, 1 month after Dose 2.
- Complete safety and immunogenicity analysis approximately 6 months after Dose 2 for all participants in Phase 2/3.
- Complete efficacy and persistence-of-immunogenicity analysis after complete data are available or at the end of the study.

All analyses conducted on Phase 2/3 data while the study is ongoing will be performed by an unblinded statistical team.

## 9.6. Data Monitoring Committee or Other Independent Oversight Committee

This study will use an IRC, a DMC, and a group of internal case reviewers. The IRC is independent of the study team and includes only internal members. The DMC is independent of the study team and includes only external members. The IRC and DMC charters describe the role of the IRC and DMC in more detail.

The responsibilities of the IRC are only in Phase 1 and will include:

- Review of safety data to permit dose escalations in the 18- to 55-year age cohort
- Review of safety data in the case of a stopping rule being met

- Review of safety and/or immunogenicity data to:
  - Allow groups of participants of 65 to 85 years of age to proceed
  - Select vaccine candidate/dose level(s) to proceed into Phase 2/3. Data supporting the selection, including results for both binding antibody levels and neutralizing titers, and the ratio between them, will also be submitted to the FDA for review
- Review of any available safety and/or immunogenicity data generated during the course of this study, or the BioNTech study conducted in Germany, to determine:
  - Whether any groups may not be started
  - Whether any groups may be terminated early
  - Whether any groups may be added with dose levels below the lowest stated dose or intermediate between the lowest and highest stated doses
- Contemporaneous review of all NAAT-confirmed COVID-19 illnesses in Phase 1

The DMC will be responsible for ongoing monitoring of the safety of participants in the study according to the charter. This may include, but is not limited to:

- Contemporaneous review of related AEs up to 1 month after completion of the vaccination schedule
- Contemporaneous review of all SAEs up to 6 months after completion of the vaccination schedule
- Contemporaneous review of all NAAT-confirmed COVID-19 illnesses in Phase 1
- At the time of the planned IAs, and ad hoc if requested by the unblinded team, review of cases of COVID-19 for an adverse imbalance of cases of COVID-19 and/or severe COVID-19 between the vaccine and placebo groups

The recommendations made by the DMC to alter the conduct of the study will be forwarded to the appropriate Pfizer personnel for final decision. Pfizer will forward such decisions, which may include summaries of aggregate analyses of safety data, to regulatory authorities, as appropriate.

Three blinded case reviewers (medically qualified Pfizer staff members) will review all potential COVID-19 illness events. If a NAAT-confirmed case in Phase 2/3 may be considered severe, or not, solely on the basis of "significant acute renal, hepatic, or neurologic dysfunction," the blinded data will be reviewed by the case reviewers to assess whether the criterion is met; the majority opinion will prevail.

# 10. SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

## 10.1. Appendix 1: Regulatory, Ethical, and Study Oversight Considerations

### 10.1.1. Regulatory and Ethical Considerations

This study will be conducted in accordance with the protocol and with the following:

- Consensus ethical principles derived from international guidelines including the Declaration of Helsinki and CIOMS International Ethical Guidelines;
- Applicable ICH GCP guidelines;
- Applicable laws and regulations, including applicable privacy laws.

The protocol, protocol amendments, ICD, SRSD(s), and other relevant documents (eg, advertisements) must be reviewed and approved by the sponsor and submitted to an IRB/EC by the investigator and reviewed and approved by the IRB/EC before the study is initiated.

Any amendments to the protocol will require IRB/EC approval before implementation of changes made to the study design, except for changes necessary to eliminate an immediate hazard to study participants.

The investigator will be responsible for the following:

- Providing written summaries of the status of the study to the IRB/EC annually or more frequently in accordance with the requirements, policies, and procedures established by the IRB/EC;
- Notifying the IRB/EC of SAEs or other significant safety findings as required by IRB/EC procedures;
- Providing oversight of the conduct of the study at the site and adherence to requirements of 21 CFR, ICH guidelines, the IRB/EC, European regulation 536/2014 for clinical studies (if applicable), and all other applicable local regulations.

#### 10.1.1.1. Reporting of Safety Issues and Serious Breaches of the Protocol or ICH GCP

In the event of any prohibition or restriction imposed (ie, clinical hold) by an applicable regulatory authority in any area of the world, or if the investigator is aware of any new information that might influence the evaluation of the benefits and risks of the study intervention, Pfizer should be informed immediately.

In addition, the investigator will inform Pfizer immediately of any urgent safety measures taken by the investigator to protect the study participants against any immediate hazard, and of any serious breaches of this protocol or of ICH GCP that the investigator becomes aware of.

### 10.1.2. Informed Consent Process

The investigator or his/her representative will explain the nature of the study to the participant or his or her parent(s)/legal guardian and answer all questions regarding the study. The participant or his or her parent(s)/legal guardian should be given sufficient time and opportunity to ask questions and to decide whether or not to participate in the trial.

Participants must be informed that their participation is voluntary. Participants or their parent(s)/legal guardian will be required to sign a statement of informed consent that meets the requirements of 21 CFR 50, local regulations, ICH guidelines, HIPAA requirements, where applicable, and the IRB/EC or study center.

The investigator must ensure that each study participant or his or her parent(s)/legal guardian is fully informed about the nature and objectives of the study, the sharing of data related to the study, and possible risks associated with participation, including the risks associated with the processing of the participant's personal data.

The participant must be informed that his/her personal study-related data will be used by the sponsor in accordance with local data protection law. The level of disclosure must also be explained to the participant.

The participant must be informed that his/her medical records may be examined by Clinical Quality Assurance auditors or other authorized personnel appointed by the sponsor, by appropriate IRB/EC members, and by inspectors from regulatory authorities.

The investigator further must ensure that each study participant or his or her parent(s)/legal guardian is fully informed about his or her right to access and correct his or her personal data and to withdraw consent for the processing of his or her personal data.

The medical record must include a statement that written informed consent was obtained before the participant was enrolled in the study and the date the written consent was obtained. The authorized person obtaining the informed consent must also sign the ICD.

Participants must be reconsented to the most current version of the ICD(s) during their participation in the study.

A copy of the ICD(s) must be provided to the participant or his or her parent(s)/legal guardian. Participants who are rescreened are required to sign a new ICD.

Unless prohibited by local requirements or IRB/EC decision, the ICD will contain a separate section that addresses the use of samples for optional additional research. The optional additional research does not require the collection of any further samples. The investigator or authorized designee will explain to each participant the objectives of the additional research. Participants will be told that they are free to refuse to participate and may withdraw their consent at any time and for any reason during the storage period.

### 10.1.3. Data Protection

All parties will comply with all applicable laws, including laws regarding the implementation of organizational and technical measures to ensure protection of participant data.

Participants' personal data will be stored at the study site in encrypted electronic and/or paper form and will be password protected or secured in a locked room to ensure that only authorized study staff have access. The study site will implement appropriate technical and organizational measures to ensure that the personal data can be recovered in the event of disaster. In the event of a potential personal data breach, the study site will be responsible for determining whether a personal data breach has in fact occurred and, if so, providing breach notifications as required by law.

To protect the rights and freedoms of participants with regard to the processing of personal data, participants will be assigned a single, participant-specific numerical code. Any participant records or data sets that are transferred to the sponsor will contain the numerical code; participant names will not be transferred. All other identifiable data transferred to the sponsor will be identified by this single, participant-specific code. The study site will maintain a confidential list of participants who participated in the study, linking each participant's numerical code to his or her actual identity and medical record identification. In case of data transfer, the sponsor will protect the confidentiality of participants' personal data consistent with the clinical study agreement and applicable privacy laws.

### 10.1.4. Dissemination of Clinical Study Data

Pfizer fulfills its commitment to publicly disclose clinical study results through posting the results of studies on www.clinicaltrials.gov (ClinicalTrials.gov), the EudraCT, and/or www.pfizer.com, and other public registries in accordance with applicable local laws/regulations. In addition, Pfizer reports study results outside of the requirements of local laws/regulations pursuant to its SOPs.

In all cases, study results are reported by Pfizer in an objective, accurate, balanced, and complete manner and are reported regardless of the outcome of the study or the country in which the study was conducted.

www.clinicaltrials.gov

Pfizer posts clinical trial results on www.clinicaltrials.gov for Pfizer-sponsored interventional studies (conducted in patients) that evaluate the safety and/or efficacy of a product, regardless of the geographical location in which the study is conducted. These results are submitted for posting in accordance with the format and timelines set forth by US law.

EudraCT

Pfizer posts clinical trial results on EudraCT for Pfizer-sponsored interventional studies in accordance with the format and timelines set forth by EU requirements.

www.pfizer.com

Pfizer posts public disclosure synopses (CSR synopses in which any data that could be used to identify individual participants have been removed) on www.pfizer.com for Pfizer-sponsored interventional studies at the same time the corresponding study results are posted to www.clinicaltrials.gov.

Documents within marketing authorization packages/submissions

Pfizer complies with the European Union Policy 0070, the proactive publication of clinical data to the EMA website. Clinical data, under Phase 1 of this policy, includes clinical overviews, clinical summaries, CSRs, and appendices containing the protocol and protocol amendments, sample CRFs, and statistical methods. Clinical data, under Phase 2 of this policy, includes the publishing of individual participant data. Policy 0070 applies to new marketing authorization applications submitted via the centralized procedure since 01 January 2015 and applications for line extensions and for new indications submitted via the centralized procedure since 01 July 2015.

Data Sharing

Pfizer provides researchers secure access to patient-level data or full CSRs for the purposes of "bona-fide scientific research" that contributes to the scientific understanding of the disease, target, or compound class. Pfizer will make available data from these trials 24 months after study completion. Patient-level data will be anonymized in accordance with applicable privacy laws and regulations. CSRs will have personally identifiable information redacted.

Data requests are considered from qualified researchers with the appropriate competencies to perform the proposed analyses. Research teams must include a biostatistician. Data will not be provided to applicants with significant conflicts of interest, including individuals requesting access for commercial/competitive or legal purposes.

### 10.1.5. Data Quality Assurance

All participant data relating to the study will be recorded on printed or electronic CRF unless transmitted to the sponsor or designee electronically (eg, laboratory data). The investigator is responsible for verifying that data entries are accurate and correct by physically or electronically signing the CRF.

The investigator must maintain accurate documentation (source data) that supports the information entered in the CRF.

The investigator must ensure that the CRFs are securely stored at the study site in encrypted electronic and/or paper form and are password protected or secured in a locked room to prevent access by unauthorized third parties.

The investigator must permit study-related monitoring, audits, IRB/EC review, and regulatory agency inspections and provide direct access to source data documents. This verification may also occur after study completion. It is important that the investigator(s)

and their relevant personnel are available during the monitoring visits and possible audits or inspections and that sufficient time is devoted to the process.

Monitoring details describing strategy (eg, risk-based initiatives in operations and quality such as risk management and mitigation strategies and analytical risk-based monitoring), methods, responsibilities, and requirements, including handling of noncompliance issues and monitoring techniques (central, remote, or on-site monitoring), are provided in the monitoring plan.

The sponsor or designee is responsible for the data management of this study, including quality checking of the data.

Study monitors will perform ongoing source data verification to confirm that data entered into the CRF by authorized site personnel are accurate, complete, and verifiable from source documents; that the safety and rights of participants are being protected; and that the study is being conducted in accordance with the currently approved protocol and any other study agreements, ICH GCP, and all applicable regulatory requirements.

Records and documents, including signed ICDs, pertaining to the conduct of this study must be retained by the investigator for 15 years after study completion unless local regulations or institutional policies require a longer retention period. No records may be destroyed during the retention period without the written approval of the sponsor. No records may be transferred to another location or party without written notification to the sponsor. The investigator must ensure that the records continue to be stored securely for as long as they are maintained.

When participant data are to be deleted, the investigator will ensure that all copies of such data are promptly and irrevocably deleted from all systems.

The investigator(s) will notify the sponsor or its agents immediately of any regulatory inspection notification in relation to the study. Furthermore, the investigator will cooperate with the sponsor or its agents to prepare the investigator site for the inspection and will allow the sponsor or its agent, whenever feasible, to be present during the inspection. The investigator site and investigator will promptly resolve any discrepancies that are identified between the study data and the participant's medical records. The investigator will promptly provide copies of the inspection findings to the sponsor or its agent. Before response submission to the regulatory authorities, the investigator will provide the sponsor or its agents with an opportunity to review and comment on responses to any such findings.

### 10.1.6. Source Documents

Source documents provide evidence for the existence of the participant and substantiate the integrity of the data collected. Source documents are filed at the investigator site.

Data reported on the CRF or entered in the eCRF that are from source documents must be consistent with the source documents or the discrepancies must be explained. The

investigator may need to request previous medical records or transfer records, depending on the study. Also, current medical records must be available.

Definition of what constitutes source data can be found in the study monitoring plan.

Description of the use of computerized system is documented in the Data Management Plan.

### 10.1.7. Study and Site Start and Closure

The study start date is the date on which the clinical study will be open for recruitment of participants.

The first act of recruitment is the date of the first participant's first visit and will be the study start date.

The sponsor designee reserves the right to close the study site or terminate the study at any time for any reason at the sole discretion of the sponsor. Study sites will be closed upon study completion. A study site is considered closed when all required documents and study supplies have been collected and a study-site closure visit has been performed.

The investigator may initiate study-site closure at any time upon notification to the sponsor or designee if requested to do so by the responsible IRB/EC or if such termination is required to protect the health of study participants.

Reasons for the early closure of a study site by the sponsor may include but are not limited to:

- Failure of the investigator to comply with the protocol, the requirements of the IRB/EC or local health authorities, the sponsor's procedures, or GCP guidelines;
- Inadequate recruitment of participants by the investigator;
- Discontinuation of further study intervention development.

If the study is prematurely terminated or suspended, the sponsor shall promptly inform the investigators, the ECs/IRBs, the regulatory authorities, and any CRO(s) used in the study of the reason for termination or suspension, as specified by the applicable regulatory requirements. The investigator shall promptly inform the participant and should assure appropriate participant therapy and/or follow-up.

Study termination is also provided for in the clinical study agreement. If there is any conflict between the contract and this protocol, the contract will control as to termination rights.

### 10.1.8. Sponsor's Qualified Medical Personnel

The contact information for the sponsor's appropriately qualified medical personnel for the study is documented in the study contact list located in the supporting study documentation.

To facilitate access to appropriately qualified medical personnel on study-related medical questions or problems, participants are provided with a contact card at the time of informed consent. The contact card contains, at a minimum, protocol and study intervention identifiers, participant numbers, contact information for the investigator site, and contact details for a contact center in the event that the investigator site staff cannot be reached to provide advice on a medical question or problem originating from another healthcare professional not involved in the participant's participation in the study. The contact number can also be used by investigator staff if they are seeking advice on medical questions or problems; however, it should be used only in the event that the established communication pathways between the investigator site and the study team are not available. It is therefore intended to augment, but not replace, the established communication pathways between the investigator site and the study team for advice on medical questions or problems that may arise during the study. The contact number is not intended for use by the participant directly, and if a participant calls that number, he or she will be directed back to the investigator site.

## 10.2. Appendix 2: Clinical Laboratory Tests

The following safety laboratory tests will be performed at times defined in the SoA section of this protocol. Additional laboratory results may be reported on these samples as a result of the method of analysis or the type of analyzer used by the clinical laboratory, or as derived from calculated values. These additional tests would not require additional collection of blood. Unscheduled clinical laboratory measurements may be obtained at any time during the study to assess any perceived safety issues.

| Hematology | Chemistry | Other |
|---|---|---|
| Hemoglobin<br>Hematocrit<br>RBC count<br>MCV<br>MCH<br>MCHC<br>Platelet count<br>WBC count<br>Total neutrophils (Abs)<br>Eosinophils (Abs)<br>Monocytes (Abs)<br>Basophils (Abs)<br>Lymphocytes (Abs) | BUN and creatinine<br>AST, ALT<br>Total bilirubin<br>Alkaline phosphatase | • Urine pregnancy test (β-hCG)<br>At screening only:<br>• Hepatitis B core antibody<br>• Hepatitis B surface antigen<br>• Hepatitis C antibody<br>• Human immunodeficiency virus |

Investigators must document their review of each laboratory safety report.

Clinically significant abnormal laboratory findings should be recorded in the AE CRF in accordance with the following grading scale (Table 9).

**Table 9. Laboratory Abnormality Grading Scale**

| Hematology | Mild (Grade 1) | Moderate (Grade 2) | Severe (Grade 3) | Potentially Life Threatening (Grade 4) |
|---|---|---|---|---|
| Hemoglobin (Female) - g/dL | 11.0 – 12.0 | 9.5 – 10.9 | 8.0 – 9.4 | <8.0 |
| Hemoglobin (Male) - g/dL | 12.5 – 13.5 | 10.5 – 12.4 | 8.5 – 10.4 | <8.5 |
| WBC increase - cells/$mm^3$ | 10,800 – 15,000 | 15,001 – 20,000 | 20,001 – 25, 000 | >25,000 |
| WBC decrease - cells/$mm^3$ | 2,500 – 3,500 | 1,500 – 2,499 | 1,000 – 1,499 | <1,000 |
| Lymphocytes decrease - cells/$mm^3$ | 750 – 1,000 | 500 – 749 | 250 – 499 | <250 |
| Neutrophils decrease - cells/$mm^3$ | 1,500 – 2,000 | 1,000 – 1,499 | 500 – 999 | <500 |
| Eosinophils - cells/$mm^3$ | 650 – 1500 | 1501 - 5000 | >5000 | Hypereosinophilic |
| Platelets decreased - cells/$mm^3$ | 125,000 – 140,000 | 100,000 – 124,000 | 25,000 – 99,000 | <25,000 |

## Table 9. Laboratory Abnormality Grading Scale

| Chemistry | Mild (Grade 1) | Moderate (Grade 2) | Severe (Grade 3) | Potentially Life Threatening (Grade 4) |
|---|---|---|---|---|
| BUN - mg/dL | 23 – 26 | 27 – 31 | > 31 | Requires dialysis |
| Creatinine – mg/dL | 1.5 – 1.7 | 1.8 – 2.0 | 2.1 – 2.5 | > 2.5 or requires dialysis |
| Alkaline phosphate – increase by factor | 1.1 – 2.0 x ULN | 2.1 – 3.0 x ULN | 3.1 – 10 x ULN | >10 x ULN |
| Liver function tests – ALT, AST increase by factor | 1.1 – 2.5 x ULN | 2.6 – 5.0 x ULN | 5.1 – 10 x ULN | >10 x ULN |
| Bilirubin – when accompanied by any increase in liver function test - increase by factor | 1.1 – 1.25 x ULN | 1.26 – 1.5 x ULN | 1.51 – 1.75 x ULN | >1.75 x ULN |
| Bilirubin – when liver function test is normal - increase by factor | 1.1 – 1.5 x ULN | 1.6 – 2.0 x ULN | 2.0 – 3.0 x ULN | >3.0 x ULN |

Abbreviations: ALT = alanine aminotransferase; AST = aspartate aminotransferase; BUN = blood urea nitrogen; ULN = upper limit of normal; WBC = white blood cell.

## 10.3. Appendix 3: Adverse Events: Definitions and Procedures for Recording, Evaluating, Follow-up, and Reporting

### 10.3.1. Definition of AE

**AE Definition**

- An AE is any untoward medical occurrence in a patient or clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention.
- NOTE: An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of study intervention.

**Events Meeting the AE Definition**

- Any abnormal laboratory test results (hematology, clinical chemistry, or urinalysis) or other safety assessments (eg, ECG, radiological scans, vital sign measurements), including those that worsen from baseline, considered clinically significant in the medical and scientific judgment of the investigator Any abnormal laboratory test results that meet any of the conditions below must be recorded as an AE:
  - Is associated with accompanying symptoms.
  - Requires additional diagnostic testing or medical/surgical intervention.
  - Leads to a change in study dosing (outside of any protocol-specified dose adjustments) or discontinuation from the study, significant additional concomitant drug treatment, or other therapy.
- Exacerbation of a chronic or intermittent preexisting condition including either an increase in frequency and/or intensity of the condition.
- New conditions detected or diagnosed after study intervention administration even though it may have been present before the start of the study.
- Signs, symptoms, or the clinical sequelae of a suspected drug-drug interaction.
- Signs, symptoms, or the clinical sequelae of a suspected overdose of either study intervention or a concomitant medication. Overdose per se will not be reported as an AE/SAE unless it is an intentional overdose taken with possible suicidal/self-harming intent. Such overdoses should be reported regardless of sequelae.

| **Events NOT Meeting the AE Definition** |
|---|
| • Any clinically significant abnormal laboratory findings or other abnormal safety assessments which are associated with the underlying disease, unless judged by the investigator to be more severe than expected for the participant's condition.<br><br>• The disease/disorder being studied or expected progression, signs, or symptoms of the disease/disorder being studied, unless more severe than expected for the participant's condition.<br><br>• Medical or surgical procedure (eg, endoscopy, appendectomy): the condition that leads to the procedure is the AE.<br><br>• Situations in which an untoward medical occurrence did not occur (social and/or convenience admission to a hospital).<br><br>• Anticipated day-to-day fluctuations of preexisting disease(s) or condition(s) present or detected at the start of the study that do not worsen. |

### 10.3.2. Definition of SAE

If an event is not an AE per definition above, then it cannot be an SAE even if serious conditions are met (eg, hospitalization for signs/symptoms of the disease under study, death due to progression of disease).

| **An SAE is defined as any untoward medical occurrence that, at any dose:** |
|---|
| **a. Results in death** |
| **b. Is life-threatening**<br><br>The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event. It does not refer to an event that hypothetically might have caused death if it were more severe. |
| **c. Requires inpatient hospitalization or prolongation of existing hospitalization**<br><br>In general, hospitalization signifies that the participant has been detained (usually involving at least an overnight stay) at the hospital or emergency ward for observation and/or treatment that would not have been appropriate in the physician's office or outpatient setting. Complications that occur during hospitalization are AEs. If a complication prolongs hospitalization or fulfills any other serious criteria, the event is serious. When in doubt as to whether "hospitalization" occurred or was necessary, the AE should be considered serious. |

Hospitalization for elective treatment of a preexisting condition that did not worsen from baseline is not considered an AE.

**d. Results in persistent disability/incapacity**

- The term disability means a substantial disruption of a person's ability to conduct normal life functions.
- This definition is not intended to include experiences of relatively minor medical significance such as uncomplicated headache, nausea, vomiting, diarrhea, influenza, and accidental trauma (eg, sprained ankle) which may interfere with or prevent everyday life functions but do not constitute a substantial disruption.

**e. Is a congenital anomaly/birth defect**

**f. Other situations:**

- Medical or scientific judgment should be exercised in deciding whether SAE reporting is appropriate in other situations such as important medical events that may not be immediately life-threatening or result in death or hospitalization but may jeopardize the participant or may require medical or surgical intervention to prevent one of the other outcomes listed in the above definition. These events should usually be considered serious.
- Examples of such events include invasive or malignant cancers, intensive treatment in an emergency room or at home for allergic bronchospasm, blood dyscrasias or convulsions that do not result in hospitalization, or development of drug dependency or drug abuse.
- Suspected transmission via a Pfizer product of an infectious agent, pathogenic or nonpathogenic, is considered serious. The event may be suspected from clinical symptoms or laboratory findings indicating an infection in a patient exposed to a Pfizer product. The terms "suspected transmission" and "transmission" are considered synonymous. These cases are considered unexpected and handled as serious expedited cases by pharmacovigilance personnel. Such cases are also considered for reporting as product defects, if appropriate.

### 10.3.3. Recording/Reporting and Follow-up of AEs and/or SAEs

**AE and SAE Recording/Reporting**

The table below summarizes the requirements for recording adverse events on the CRF and for reporting serious adverse events on the Vaccine SAE Report Form to Pfizer Safety. These requirements are delineated for 3 types of events: (1) SAEs; (2) nonserious adverse events (AEs); and (3) exposure to the study intervention under study during pregnancy or breastfeeding, and occupational exposure.

It should be noted that the Vaccine SAE Report Form for reporting of SAE information is not the same as the AE page of the CRF. When the same data are collected, the forms must be completed in a consistent manner. AEs should be recorded using concise medical terminology and the same AE term should be used on both the CRF and the Vaccine SAE Report Form for reporting of SAE information.

| **Safety Event** | **Recorded on the CRF** | **Reported on the Vaccine SAE Report Form to Pfizer Safety Within 24 Hours of Awareness** |
|---|---|---|
| SAE | All | All |
| Nonserious AE | All | None |
| Exposure to the study intervention under study during pregnancy or breastfeeding, and occupational exposure | All AEs/SAEs associated with exposure during pregnancy or breastfeeding<br><br>Occupational exposure is not recorded. | All (and EDP supplemental form for EDP)<br>Note: Include all SAEs associated with exposure during pregnancy or breastfeeding. Include all AEs/SAEs associated with occupational exposure. |

- When an AE/SAE occurs, it is the responsibility of the investigator to review all documentation (eg, hospital progress notes, laboratory reports, and diagnostic reports) related to the event.
- The investigator will then record all relevant AE/SAE information in the CRF.
- It is **not** acceptable for the investigator to send photocopies of the participant's medical records to Pfizer Safety in lieu of completion of the Vaccine SAE Report Form/AE/SAE CRF page.
- There may be instances when copies of medical records for certain cases are requested by Pfizer Safety. In this case, all participant identifiers, with the

exception of the participant number, will be redacted on the copies of the medical records before submission to Pfizer Safety.

- The investigator will attempt to establish a diagnosis of the event based on signs, symptoms, and/or other clinical information. Whenever possible, the diagnosis (not the individual signs/symptoms) will be documented as the AE/SAE.

**Assessment of Intensity**

The investigator will make an assessment of intensity for each AE and SAE reported during the study and assign it to 1 of the following categories:

| | | |
|---|---|---|
| GRADE | If required on the AE page of the CRF, the investigator will use the adjectives MILD, MODERATE, SEVERE, or LIFE-THREATENING to describe the maximum intensity of the AE. For purposes of consistency, these intensity grades are defined as follows: | |
| 1 | MILD | Does not interfere with participant's usual function. |
| 2 | MODERATE | Interferes to some extent with participant's usual function. |
| 3 | SEVERE | Interferes significantly with participant's usual function. |
| 4 | LIFE-THREATENING | Life-threatening consequences; urgent intervention indicated. |

**Assessment of Causality**

- The investigator is obligated to assess the relationship between study intervention and each occurrence of each AE/SAE.
- A “reasonable possibility” of a relationship conveys that there are facts, evidence, and/or arguments to suggest a causal relationship, rather than a relationship cannot be ruled out.
- The investigator will use clinical judgment to determine the relationship.
- Alternative causes, such as underlying disease(s), concomitant therapy, and other risk factors, as well as the temporal relationship of the event to study intervention administration, will be considered and investigated.

- The investigator will also consult the IB and/or product information, for marketed products, in his/her assessment.

- For each AE/SAE, the investigator **must** document in the medical notes that he/she has reviewed the AE/SAE and has provided an assessment of causality.

- There may be situations in which an SAE has occurred and the investigator has minimal information to include in the initial report to the sponsor. However, **it is very important that the investigator always make an assessment of causality for every event before the initial transmission of the SAE data to the sponsor.**

- The investigator may change his/her opinion of causality in light of follow-up information and send an SAE follow-up report with the updated causality assessment.

- The causality assessment is one of the criteria used when determining regulatory reporting requirements.

- If the investigator does not know whether or not the study intervention caused the event, then the event will be handled as "related to study intervention" for reporting purposes, as defined by the sponsor. In addition, if the investigator determines that an SAE is associated with study procedures, the investigator must record this causal relationship in the source documents and CRF, and report such an assessment in the dedicated section of the Vaccine SAE Report Form and in accordance with the SAE reporting requirements.

**Follow-up of AEs and SAEs**

- The investigator is obligated to perform or arrange for the conduct of supplemental measurements and/or evaluations as medically indicated or as requested by the sponsor to elucidate the nature and/or causality of the AE or SAE as fully as possible. This may include additional laboratory tests or investigations, histopathological examinations, or consultation with other healthcare providers.

- If a participant dies during participation in the study or during a recognized follow-up period, the investigator will provide Pfizer Safety with a copy of any postmortem findings including histopathology.

- New or updated information will be recorded in the originally completed CRF.

- The investigator will submit any updated SAE data to the sponsor within 24 hours of receipt of the information.

### 10.3.4. Reporting of SAEs

| **SAE Reporting to Pfizer Safety via Vaccine SAE Report Form** |
| --- |
| • Facsimile transmission of the Vaccine SAE Report Form is the preferred method to transmit this information to Pfizer Safety.<br><br>• In circumstances when the facsimile is not working, notification by telephone is acceptable with a copy of the Vaccine SAE Report Form sent by overnight mail or courier service.<br><br>• Initial notification via telephone does not replace the need for the investigator to complete and sign the Vaccine SAE Report Form pages within the designated reporting time frames. |

## 10.4. Appendix 4: Contraceptive Guidance

### 10.4.1. Male Participant Reproductive Inclusion Criteria

Male participants are eligible to participate if they agree to the following requirements during the intervention period and for at least 28 days after the last dose of study intervention, which corresponds to the time needed to eliminate reproductive safety risk of the study intervention(s):

- Refrain from donating sperm.

PLUS either**:**

- Be abstinent from heterosexual intercourse with a female of childbearing potential as their preferred and usual lifestyle (abstinent on a long-term and persistent basis) and agree to remain abstinent.

OR

- Must agree to use a male condom when engaging in any activity that allows for passage of ejaculate to another person.
- In addition to male condom use, a highly effective method of contraception may be considered in WOCBP partners of male participants (refer to the list of highly effective methods below in Section 10.4.4).

### 10.4.2. Female Participant Reproductive Inclusion Criteria

A female participant is eligible to participate if she is not pregnant or breastfeeding, and at least 1 of the following conditions applies:

- Is not a WOCBP (see definitions below in Section 10.4.3).

OR

- Is a WOCBP and using an acceptable contraceptive method as described below during the intervention period (for a minimum of 28 days after the last dose of study intervention). The investigator should evaluate the effectiveness of the contraceptive method in relationship to the first dose of study intervention.

The investigator is responsible for review of medical history, menstrual history, and recent sexual activity to decrease the risk for inclusion of a woman with an early undetected pregnancy.

### 10.4.3. Woman of Childbearing Potential

A woman is considered fertile following menarche and until becoming postmenopausal unless permanently sterile (see below).

If fertility is unclear (eg, amenorrhea in adolescents or athletes) and a menstrual cycle cannot be confirmed before the first dose of study intervention, additional evaluation should be considered.

Women in the following categories are not considered WOCBP:

1. Premenarchal.

2. Premenopausal female with 1 of the following:

    - Documented hysterectomy;

    - Documented bilateral salpingectomy;

    - Documented bilateral oophorectomy.

For individuals with permanent infertility due to an alternate medical cause other than the above, (eg, mullerian agenesis, androgen insensitivity), investigator discretion should be applied to determining study entry.

Note: Documentation for any of the above categories can come from the site personnel's review of the participant's medical records, medical examination, or medical history interview. The method of documentation should be recorded in the participant's medical record for the study.

3. Postmenopausal female:

    - A postmenopausal state is defined as no menses for 12 months without an alternative medical cause. In addition, a

        - high FSH level in the postmenopausal range must be used to confirm a postmenopausal state in women under 60 years of age and not using hormonal contraception or HRT.

        - Female on HRT and whose menopausal status is in doubt will be required to use one of the nonestrogen hormonal highly effective contraception methods if they wish to continue their HRT during the study. Otherwise, they must discontinue HRT to allow confirmation of postmenopausal status before study enrollment.

### 10.4.4. Contraception Methods

Contraceptive use by men or women should be consistent with local availability/regulations regarding the use of contraceptive methods for those participating in clinical trials.

1. Implantable progestogen-only hormone contraception associated with inhibition of ovulation.

2. Intrauterine device.

3. Intrauterine hormone-releasing system.

4. Bilateral tubal occlusion.

5. Vasectomized partner:

    - Vasectomized partner is a highly effective contraceptive method provided that the partner is the sole sexual partner of the woman of childbearing potential and the absence of sperm has been confirmed. If not, an additional highly effective method of contraception should be used. The spermatogenesis cycle is approximately 90 days.

6. Combined (estrogen- and progestogen-containing) hormonal contraception associated with inhibition of ovulation:

    - Oral;

    - Intravaginal;

    - Transdermal;

    - Injectable.

7. Progestogen-only hormone contraception associated with inhibition of ovulation:

    - Oral;

    - Injectable.

8. Sexual abstinence:

    - Sexual abstinence is considered a highly effective method only if defined as refraining from heterosexual intercourse during the entire period of risk associated with the study intervention. The reliability of sexual abstinence needs to be evaluated in relation to the duration of the study and the preferred and usual lifestyle of the participant.

9. Progestogen-only oral hormonal contraception where inhibition of ovulation is not the primary mode of action.

10. Male or female condom with or without spermicide.

11. Cervical cap, diaphragm, or sponge with spermicide.

12. A combination of male condom with either cervical cap, diaphragm, or sponge with spermicide (double-barrier methods).

## 10.5. Appendix 5: Liver Safety: Suggested Actions and Follow-up Assessments

### Potential Cases of Drug-Induced Liver Injury

Humans exposed to a drug who show no sign of liver injury (as determined by elevations in transaminases) are termed “tolerators,” while those who show transient liver injury, but adapt are termed “adaptors.” In some participants, transaminase elevations are a harbinger of a more serious potential outcome. These participants fail to adapt and therefore are "susceptible" to progressive and serious liver injury, commonly referred to as DILI. Participants who experience a transaminase elevation above 3 × ULN should be monitored more frequently to determine if they are an “adaptor” or are “susceptible.”

LFTs are not required as a routine safety monitoring procedure for all participants in this study. However, should an investigator deem it necessary to assess LFTs because a participant presents with clinical signs/symptoms, such LFT results should be managed and followed as described below.

In the majority of DILI cases, elevations in AST and/or ALT precede TBili elevations (>2 × ULN) by several days or weeks. The increase in TBili typically occurs while AST/ALT is/are still elevated above 3 × ULN (ie, AST/ALT and TBili values will be elevated within the same laboratory sample). In rare instances, by the time TBili elevations are detected, AST/ALT values might have decreased. This occurrence is still regarded as a potential DILI. Therefore, abnormal elevations in either AST OR ALT in addition to TBili that meet the criteria outlined below are considered potential DILI (assessed per Hy’s law criteria) cases and should always be considered important medical events, even before all other possible causes of liver injury have been excluded.

The threshold of laboratory abnormalities for a potential DILI case depends on the participant’s individual baseline values and underlying conditions. Participants who present with the following laboratory abnormalities should be evaluated further as potential DILI (Hy’s law) cases to definitively determine the etiology of the abnormal laboratory values:

- Participants with AST/ALT and TBili baseline values within the normal range who subsequently present with AST OR ALT values >3 × ULN AND a TBili value >2 × ULN with no evidence of hemolysis and an alkaline phosphatase value <2 × ULN or not available.

- For participants with baseline AST **OR** ALT **OR** TBili values above the ULN, the following threshold values are used in the definition mentioned above, as needed, depending on which values are above the ULN at baseline:

    - Preexisting AST or ALT baseline values above the normal range: AST or ALT values >2 times the baseline values AND >3 × ULN; or >8 × ULN (whichever is smaller).

- Preexisting values of TBili above the normal range: TBili level increased from baseline value by an amount of at least 1 × ULN **or** if the value reaches >3 × ULN (whichever is smaller).

Rises in AST/ALT and TBili separated by more than a few weeks should be assessed individually based on clinical judgment; any case where uncertainty remains as to whether it represents a potential Hy's law case should be reviewed with the sponsor.

The participant should return to the investigator site and be evaluated as soon as possible, preferably within 48 hours from awareness of the abnormal results. This evaluation should include laboratory tests, detailed history, and physical assessment.

In addition to repeating measurements of AST and ALT and TBili for suspected cases of Hy's law, additional laboratory tests should include albumin, CK, direct and indirect bilirubin, GGT, PT/INR, total bile acids, and alkaline phosphatase. Consideration should also be given to drawing a separate tube of clotted blood and an anticoagulated tube of blood for further testing, as needed, for further contemporaneous analyses at the time of the recognized initial abnormalities to determine etiology. A detailed history, including relevant information, such as review of ethanol, acetaminophen/paracetamol (either by itself or as a coformulated product in prescription or over-the-counter medications), recreational drug, supplement (herbal) use and consumption, family history, sexual history, travel history, history of contact with a jaundiced person, surgery, blood transfusion, history of liver or allergic disease, and potential occupational exposure to chemicals, should be collected. Further testing for acute hepatitis A, B, C, D, and E infection and liver imaging (eg, biliary tract) and collection of serum samples for acetaminophen/paracetamol drug and/or protein adduct levels may be warranted.

All cases demonstrated on repeat testing as meeting the laboratory criteria of AST/ALT and TBili elevation defined above should be considered potential DILI (Hy's law) cases if no other reason for the LFT abnormalities has yet been found. **Such potential DILI (Hy's law) cases are to be reported as SAEs, irrespective of availability of all the results of the investigations performed to determine etiology of the LFT abnormalities.**

A potential DILI (Hy's law) case becomes a confirmed case only after all results of reasonable investigations have been received and have excluded an alternative etiology.

## 10.6. Appendix 6: Abbreviations

The following is a list of abbreviations that may be used in the protocol.

| Abbreviation | Term |
|---|---|
| 2019-nCoV | novel coronavirus 2019 |
| Abs | absolute (in Appendix 2) |
| AE | adverse event |
| ALT | alanine aminotransferase |
| AST | aspartate aminotransferase |
| β-hCG | beta-human chorionic gonadotropin |
| BMI | body mass index |
| BUN | blood urea nitrogen |
| CBER | Center for Biologics Evaluation and Research |
| CDC | Centers for Disease Control and Prevention (United States) |
| CFR | Code of Federal Regulations |
| CI | confidence interval |
| CIOMS | Council for International Organizations of Medical Sciences |
| CLIA | Clinical Laboratory Improvement Amendments |
| CONSORT | Consolidated Standards of Reporting Trials |
| COVID-19 | coronavirus disease 2019 |
| CRF | case report form |
| CRO | contract research organization |
| CSR | clinical study report |
| CT | computed tomography |
| DBP | diastolic blood pressure |
| DILI | drug-induced liver injury |
| DMC | data monitoring committee |
| DNA | deoxyribonucleic acid |
| DU | dosing unit |
| EC | ethics committee |
| ECMO | extracorporeal membrane oxygenation |
| ECG | electrocardiogram |
| eCRF | electronic case report form |
| e-diary | electronic diary |
| EDP | exposure during pregnancy |
| EMA | European Medicines Agency |
| EU | European Union |
| EUA | emergency use authorization |
| EudraCT | European Clinical Trials Database |
| FDA | Food and Drug Administration |
| $FiO_2$ | fraction of inspired oxygen |
| FSH | follicle-stimulating hormone |
| GCP | Good Clinical Practice |
| GGT | gamma-glutamyl transferase |

| Abbreviation | Term |
|---|---|
| GMC | geometric mean concentration |
| GMFR | geometric mean fold rise |
| GMR | geometric mean ratio |
| GMT | geometric mean titer |
| HBc Ab | hepatitis B core antibody |
| HBe | hepatitis B e |
| HBeAg | hepatitis B e antigen |
| HBsAg | hepatitis B surface antigen |
| HBV | hepatitis B virus |
| HCV | hepatitis C virus |
| HCV Ab | hepatitis C virus antibody |
| HIPAA | Health Insurance Portability and Accountability Act |
| HIV | human immunodeficiency virus |
| HR | heart rate |
| HRT | hormone replacement therapy |
| IA | interim analysis |
| IB | investigator's brochure |
| ICD | informed consent document |
| ICH | International Council for Harmonisation |
| ICU | intensive care unit |
| ID | identification |
| Ig | immunoglobulin |
| IgG | immunoglobulin G |
| IgM | immunoglobulin M |
| IMP | investigational medicinal product |
| IND | investigational new drug |
| INR | international normalized ratio |
| IP manual | investigational product manual |
| IPAL | Investigational Product Accountability Log |
| IRB | institutional review board |
| IRC | internal review committee |
| IRR | illness rate ratio |
| IRT | interactive response technology |
| ISO | International Organization for Standardization |
| IV | intravenous(ly) |
| IWR | interactive Web-based response |
| LFT | liver function test |
| LL | lower limit |
| LLOQ | lower limit of quantitation |
| LNP | lipid nanoparticle |
| LPX | lipoplex |
| MAR | missing at random |
| MCH | mean corpuscular hemoglobin |

| Abbreviation | Term |
|---|---|
| MCHC | mean corpuscular hemoglobin concentration |
| MCV | mean corpuscular volume |
| MedDRA | Medical Dictionary for Regulatory Activities |
| MERS | Middle East respiratory syndrome |
| MIS-C | multisystem inflammatory syndrome in children |
| modRNA | nucleoside-modified messenger ribonucleic acid |
| MRI | magnetic resonance imaging |
| N | SARS-CoV-2 nucleoprotein |
| N/A | not applicable |
| NAAT | nucleic acid amplification test |
| non-S | nonspike protein |
| P2 S | SARS-CoV-2 full-length, P2 mutant, prefusion spike glycoprotein |
| $PaO_2$ | partial pressure of oxygen, arterial |
| PCR | polymerase chain reaction |
| PI | principal investigator |
| POS | probability of success |
| PPE | personal protective equipment |
| PT | prothrombin time |
| RBC | red blood cell |
| RBD | receptor-binding domain |
| RCDC | reverse cumulative distribution curve |
| RNA | ribonucleic acid |
| RR | respiratory rate |
| RSV | respiratory syncytial virus |
| RT-PCR | reverse transcription–polymerase chain reaction |
| S1 | spike protein S1 subunit |
| SAE | serious adverse event |
| SAP | statistical analysis plan |
| saRNA | self-amplifying messenger ribonucleic acid |
| SARS | severe acute respiratory syndrome |
| SARS-CoV-2 | severe acute respiratory syndrome coronavirus 2 |
| SBP | systolic blood pressure |
| SoA | schedule of activities |
| SOP | standard operating procedure |
| $SpO_2$ | oxygen saturation as measured by pulse oximetry |
| SRSD | single reference safety document |
| SUSAR | suspected unexpected serious adverse reaction |
| TBD | to be determined |
| TBili | total bilirubin |
| ULN | upper limit of normal |
| uRNA | unmodified messenger ribonucleic acid |
| US | United States |
| vax | vaccination |

| Abbreviation | Term |
|---|---|
| VE | vaccine efficacy |
| WBC | white blood cell |
| WHO | World Health Organization |
| WOCBP | woman/women of childbearing potential |

## 10.7. Appendix 7: Stopping and Alert Rules for Enhanced COVID-19

In Phase 2/3, the unblinded team supporting the DMC (reporting team), including an unblinded medical monitor, will review cases of severe COVID-19 as they are received, and will review AEs at least weekly for additional potential cases of severe COVID-19 and will contact the DMC in the event that the stopping rule or an alert is met. Specifically, the unblinded reporting team will contact the DMC chair, who will then convene the full DMC as soon as possible. The DMC will review all available safety and/or efficacy data at the time of the review. The DMC will make one of the following recommendations to Pfizer: withhold final recommendation until further information/data are provided, continue the study as designed, modify the study and continue, or stop the study. The final decision to accept or reject the committee's recommendation resides with Pfizer management and will be communicated to the committee chairperson in writing.

At any point the unblinded team may discuss with the DMC chair whether the DMC should review cases for an adverse imbalance of cases of COVID-19 and/or severe COVID-19 between the vaccine and placebo groups (see Section 9.6). In addition, at the time of the IAs after accrual of at least 62, 92, and 120 cases, the number of severe COVID-19 cases in the vaccine and placebo groups will be assessed.

Stopping and alert rules will be applied as follows. The stopping rule will be triggered when the 1-sided probability of observing the same or a more extreme case split is 5% or less when the true incidence of severe disease is the same for vaccine and placebo participants, and alert criteria are triggered when this probability is less than 11%. In addition, when the total number of severe cases is low (15 or less), the unblinded team supporting the DMC will implement the alert rule when a reverse case split of 2:1 or worse is observed. For example, at 3 cases 2:1, at 4 cases 3:1, etc. Below 15 cases, this rule is more rigorous than requiring the probability of an observed adverse split or worse be <11%.

The stopping rule and alert rules are illustrated in Table 10 and Table 11, respectively, when the total number of severe cases is 20 or less. For example, when there are 7 severe cases, the adverse split has to be 7:0 to stop the study, but a split of 5:2 would trigger the alert rule. Similarly, when there is a total of 9 severe cases, an adverse split of 9:0 triggers the stopping rule, while a split of 6:3 or worse triggers the alert rule. The alert rule may be triggered with as few as 2 cases, with a split of 2:0.

**Table 10. Stopping Rule: Enrollment Is Stopped if the Number of Severe Cases in the Vaccine Group Is Greater Than or Equal to the Prespecified Stopping Rule Value (S)**

| Total Severe Cases | Prespecified Stopping Rule Value (S): Number of Severe Cases in the Vaccine Group to Stop | If the True Ratio of Severe Cases Between Vaccine and Placebo Groups Is 1:1, Probability of S or More Being Observed in the Vaccine Group |
|---|---|---|
| 4 | 4 | N/A |
| 5 | 5 | 3.13% |
| 6 | 6 | 1.56% |
| 7 | 7 | 0.78% |
| 8 | 7 | 3.52% |
| 9 | 8 | 1.95% |
| 10 | 9 | 1.07% |
| 11 | 9 | 3.27% |
| 12 | 10 | 1.93% |
| 13 | 10 | 4.61% |
| 14 | 11 | 2.87% |
| 15 | 12 | 1.76% |
| 16 | 12 | 3.84% |
| 17 | 13 | 2.45% |
| 18 | 13 | 4.81% |
| 19 | 14 | 3.18% |
| 20 | 15 | 2.07% |

Abbreviation: N/A = not applicable.

**Table 11. Alert Rule: Further Action Is Taken if the Number of Severe Cases in the Vaccine Group Is Greater Than or Equal to the Prespecified Alert Rule Value (A)**

| Total Severe Cases | Prespecified Alert Rule Value (A): Number of Severe Cases in the Vaccine Group to Trigger Further Action | If the True Ratio of Severe Cases Between the Vaccine and Placebo Groups Is 1:1, Probability of A Being Observed in the Vaccine Group | If the True Ratio of Severe Cases Between the Vaccine and Placebo Groups Is 1:1, Probability of A or More Being Observed in the Vaccine Group | If the True Ratio of Severe Cases Between the Vaccine and Placebo Groups Is 2:1, Probability of A or More Being Observed in the Vaccine Group | If the True Ratio of Severe Cases Between the Vaccine and Placebo Groups Is 3:1, Probability of A or More Being Observed in the Vaccine Group | If the True Ratio of Severe Cases Between the Vaccine and Placebo Groups Is 4:1, Probability of A or More Being Observed in the Vaccine Group |
|---|---|---|---|---|---|---|
| 2 | 2 | 25.00% | 25.00% | 44.49% | 56.25% | 64.00% |
| 3 | 2 | 37.50% | 50.00% | 74.12% | 84.38% | 89.60% |
| 4 | 3 | 25.00% | 31.25% | 59.32% | 73.83% | 81.92% |
| 5 | 4 | 15.63% | 18.75% | 46.16% | 63.28% | 73.73% |
| 6 | 4 | 23.44% | 34.38% | 68.10% | 83.06% | 90.11% |
| 7 | 5 | 16.41% | 22.66% | 57.14% | 75.64% | 85.20% |
| 8 | 6 | 10.94% | 14.45% | 46.90% | 67.85% | 79.69% |
| 9 | 6 | 16.41% | 25.39% | 65.11% | 83.43% | 91.44% |
| 10 | 7 | 11.72% | 17.19% | 56.02% | 77.59% | 87.91% |
| 11 | 8 | 8.06% | 11.33% | 47.35% | 71.33% | 83.89% |
| 12 | 8 | 12.08% | 19.38% | 63.25% | 84.24% | 92.74% |
| 13 | 9 | 8.73% | 13.34% | 55.31% | 79.40% | 90.09% |
| 14 | 10 | 6.11% | 8.98% | 47.66% | 74.15% | 87.02% |
| 15 | 10 | 9.16% | 15.09% | 61.94% | 85.16% | 93.89% |
| 16 | 11 | 6.67% | 10.51% | 54.81% | 81.03% | 91.83% |
| 17 | 12 | 4.72% | 7.17% | 47.88% | 76.53% | 89.43% |
| 18 | 13 | 3.27% | 4.81% | 41.34% | 71.75% | 86.71% |
| 19 | 13 | 5.18% | 8.35% | 54.43% | 82.51% | 93.24% |
| 20 | 14 | 3.70% | 5.77% | 48.06% | 78.58% | 91.33% |

## 10.8. Appendix 8: Criteria for Allowing Inclusion of Participants With Chronic Stable HIV, HCV, or HBV Infection

Potential participants with chronic stable HIV, HCV, or HBV infection may be considered for inclusion if they fulfill the following respective criteria.

Known HIV infection

- Confirmed stable HIV disease defined as documented viral load <50 copies/mL and CD4 count >200 cells/$mm^3$ within 6 months before enrollment, and on stable antiretroviral therapy for at least 6 months.

Known HCV infection

- History of chronic HCV with evidence of sustained virological response (defined as undetectable HCV RNA) for ≥12 weeks following HCV treatment or without evidence of HCV RNA viremia (undetectable HCV viral load).

Known HBV infection

Confirmed inactive chronic HBV infection, defined as HBsAg present for ≥6 months and the following:

- HBeAg negative, anti-HBe positive
- Serum HBV DNA <2000 IU/mL
- Persistently normal ALT and/or AST levels
- In those who have had a liver biopsy performed, findings that confirm the absence of significant necroinflammation.

## 11. REFERENCES

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# 5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021



**Report Prepared by:**

**Worldwide Safety**

**Pfizer**

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## LIST OF ABBREVIATIONS

| Acronym | Term |
|---|---|
| AE | adverse event |
| AESI | adverse event of special interest |
| BC | Brighton Collaboration |
| CDC | Centers for Disease Control and Prevention |
| COVID-19 | coronavirus disease 2019 |
| DLP | data lock point |
| EUA | emergency use authorisation |
| HLGT | (MedDRA) High Group Level Term |
| HLT | (MedDRA) High Level Term |
| MAH | marketing authorisation holder |
| MedDRA | medical dictionary for regulatory activities |
| MHRA | Medicines and Healthcare products Regulatory Agency |
| PCR | Polymerase Chain Reaction |
| PT | (MedDRA) Preferred Term |
| PVP | pharmacovigilance plan |
| RT-PCR | Reverse Transcription-Polymerase Chain Reaction |
| RSI | reference safety information |
| TME | targeted medically event |
| SARS-CoV-2 | severe acute respiratory syndrome coronavirus 2 |
| SMQ | standardised MedDRA query |
| SOC | (MedDRA) System Organ Class |
| UK | United Kingdom |
| US | United States |
| VAED | vaccine-associated enhanced disease |
| VAERD | vaccine-associated enhanced respiratory disease |
| VAERS | vaccine adverse event reporting system |

## 1. INTRODUCTION

Reference is made to the Request for Comments and Advice submitted 04 February 2021 regarding Pfizer/BioNTech's proposal for the clinical and post-authorization safety data package for the Biologics License Application (BLA) for our investigational COVID-19 Vaccine (BNT162b2). Further reference is made to the Agency's 09 March 2021 response to this request, and specifically, the following request from the Agency.

*"Monthly safety reports primarily focus on events that occurred during the reporting interval and include information not relevant to a BLA submission such as line lists of adverse events by country. We are most interested in a cumulative analysis of post-authorization safety data to support your future BLA submission. Please submit an integrated analysis of your cumulative post-authorization safety data, including U.S. and foreign post-authorization experience, in your upcoming BLA submission. Please include a cumulative analysis of the Important Identified Risks, Important Potential Risks, and areas of Important Missing Information identified in your Pharmacovigilance Plan, as well as adverse events of special interest and vaccine administration errors (whether or not associated with an adverse event). Please also include distribution data and an analysis of the most common adverse events. In addition, please submit your updated Pharmacovigilance Plan with your BLA submission."*

This document provides an integrated analysis of the cumulative post-authorization safety data, including U.S. and foreign post-authorization adverse event reports received through 28 February 2021.

## 2. METHODOLOGY

Pfizer is responsible for the management post-authorization safety data on behalf of the MAH BioNTech according to the Pharmacovigilance Agreement in place. Data from BioNTech are included in the report when applicable.

Pfizer's safety database contains cases of AEs reported spontaneously to Pfizer, cases reported by the health authorities, cases published in the medical literature, cases from Pfizer-sponsored marketing programs, non-interventional studies, and cases of serious AEs reported from clinical studies regardless of causality assessment.

The limitations of post-marketing adverse drug event reporting should be considered when interpreting these data:

- Reports are submitted voluntarily, and the magnitude of underreporting is unknown. Some of the factors that may influence whether an event is reported include: length of time since marketing, market share of the drug, publicity about a drug or an AE, seriousness of the reaction, regulatory actions, awareness by health professionals and consumers of adverse drug event reporting, and litigation.

- Because many external factors influence whether or not an AE is reported, the spontaneous reporting system yields reporting proportions not incidence rates. As a result, it is generally not appropriate to make between-drug comparisons using these

proportions; the spontaneous reporting system should be used for signal detection rather than hypothesis testing.

- In some reports, clinical information (such as medical history, validation of diagnosis, time from drug use to onset of illness, dose, and use of concomitant drugs) is missing or incomplete, and follow-up information may not be available.

- An accumulation of adverse event reports (AERs) does not necessarily indicate that a particular AE was caused by the drug; rather, the event may be due to an underlying disease or some other factor(s) such as past medical history or concomitant medication.

- Among adverse event reports received into the Pfizer safety database during the cumulative period, only those having a complete workflow cycle in the safety database (meaning they progressed to Distribution or Closed workflow status) are included in the monthly SMSR. This approach prevents the inclusion of cases that are not fully processed hence not accurately reflecting final information. Due to the large numbers of spontaneous adverse event reports received for the product, the MAH has prioritised the processing of serious cases, in order to meet expedited regulatory reporting timelines and ensure these reports are available for signal detection and evaluation activity. The increased volume of reports has not impacted case processing for serious reports, and compliance metrics continue to be monitored weekly with prompt action taken as needed to maintain compliance with expedited reporting obligations. Non-serious cases are entered into the safety database no later than 4 calendar days from receipt. Entrance into the database includes the coding of all adverse events; this allow for a manual review of events being received but may not include immediate case processing to completion. Non-serious cases are processed as soon as possible and no later than 90 days from receipt. Pfizer has also taken a multiple actions to help alleviate the large increase of adverse event reports. This includes significant technology enhancements, and process and workflow solutions, as well as increasing the number of data entry and case processing colleagues. To date, Pfizer has onboarded approximately (b) (4) additional full-time employees (FTEs). More are joining each month with an expected total of more than (b) (4) additional resources by the end of June 2021.

## 3. RESULTS

### 3.1. Safety Database

#### 3.1.1. General Overview

It is estimated that approximately (b) (4) doses of BNT162b2 were shipped worldwide from the receipt of the first temporary authorisation for emergency supply on 01 December 2020 through 28 February 2021.

Cumulatively, through 28 February 2021, there was a total of 42,086 case reports (25,379 medically confirmed and 16,707 non-medically confirmed) containing 158,893 events. Most cases (34,762) were received from United States (13,739), United Kingdom (13,404) Italy (2,578), Germany (1913), France (1506), Portugal (866) and Spain (756); the remaining 7,324 were distributed among 56 other countries.

Table 1 below presents the main characteristics of the overall cases.

**Table 1. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval**

| Characteristics | | Relevant cases (N=42086) |
|---|---|---|
| Gender: | Female | 29914 |
| | Male | 9182 |
| | No Data | 2990 |
| Age range (years):<br>0.01 -107 years<br>Mean = 50.9 years<br>n = 34952 | ≤ 17<br>18-30<br>31-50<br>51-64<br>65-74<br>≥ 75<br>Unknown | 175[a]<br>4953<br>13886<br>7884<br>3098<br>5214<br>6876 |
| Case outcome: | Recovered/Recovering | 19582 |
| | Recovered with sequelae | 520 |
| | Not recovered at the time of report | 11361 |
| | Fatal | 1223 |
| | Unknown | 9400 |

a. in 46 cases reported age was <16-year-old and in 34 cases <12-year-old.

As shown in Figure 1, the System Organ Classes (SOCs) that contained the greatest number (≥2%) of events, in the overall dataset, were General disorders and administration site conditions (51,335 AEs), Nervous system disorders (25,957), Musculoskeletal and connective tissue disorders (17,283), Gastrointestinal disorders (14,096), Skin and subcutaneous tissue disorders (8,476), Respiratory, thoracic and mediastinal disorders (8,848), Infections and infestations (4,610), Injury, poisoning and procedural complications (5,590), and Investigations (3,693).

**Figure 1. Total Number of BNT162b2 AEs by System Organ Classes and Event Seriousness**

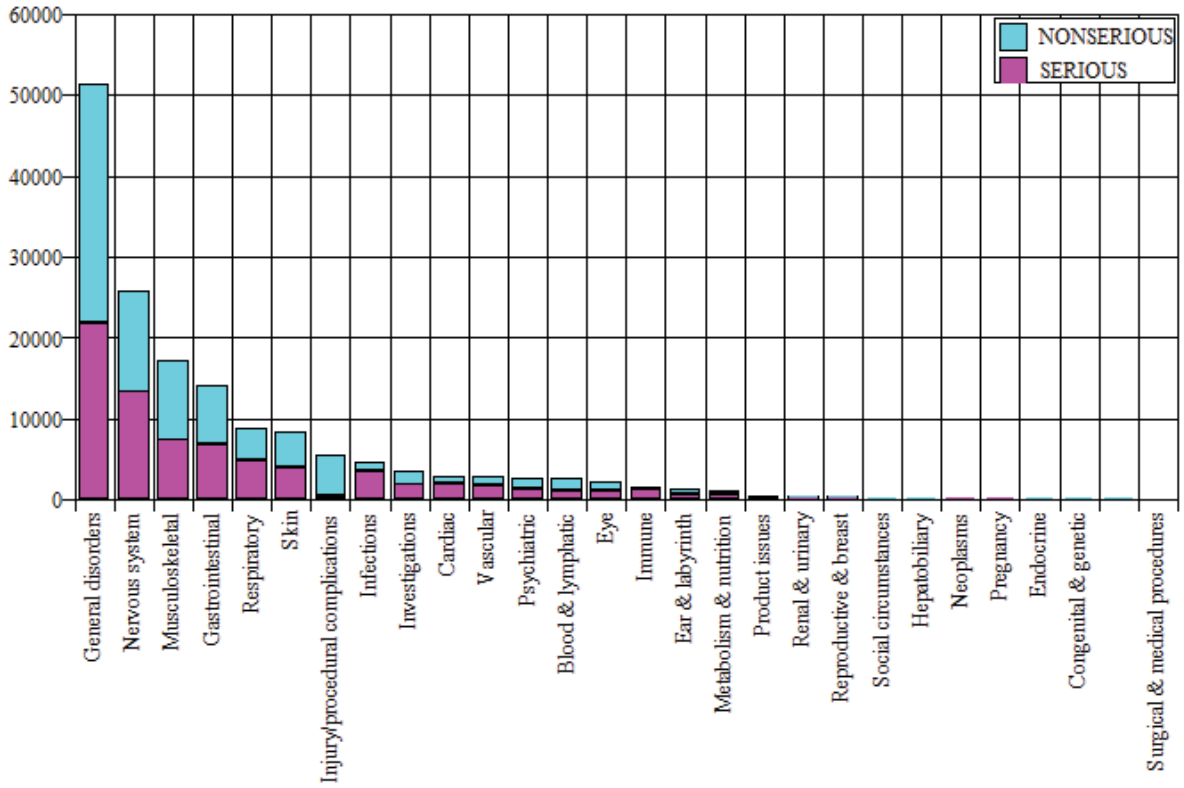


Table 2 shows the most commonly (≥2%) reported MedDRA (v. 23.1) PTs in the overall dataset (through 28 February 2021),

**Table 2. Events Reported in ≥2% Cases**

| | | Cumulatively Through 28 February 2021 |
|---|---|---|
| **MedDRA SOC** | **MedDRA PT** | **AEs (AERP%) N = 42086** |
| **Blood and lymphatic system disorders** | | |
| | Lymphadenopathy | 1972 (4.7%) |
| **Cardiac disorders** | | |
| | Tachycardia | 1098 (2.6%) |
| **Gastrointestinal disorders** | | |
| | Nausea | 5182 (12.3%) |
| | Diarrhoea | 1880 (4.5%) |
| | Vomiting | 1698 (4.0%) |
| **General disorders and administration site conditions** | | |
| | Pyrexia | 7666 (18.2%) |
| | Fatigue | 7338 (17.4%) |
| | Chills | 5514 (13.1%) |
| | Vaccination site pain | 5181 (12.3%) |

## Table 2. Events Reported in ≥2% Cases

| | | Cumulatively Through 28 February 2021 |
|---|---|---|
| **MedDRA SOC** | **MedDRA PT** | **AEs (AERP%) N = 42086** |
| | Pain | 3691 (8.8%) |
| | Malaise | 2897 (6.9%) |
| | Asthenia | 2285 (5.4%) |
| | Drug ineffective | 2201 (5.2%) |
| | Vaccination site erythema | 930 (2.2%) |
| | Vaccination site swelling | 913 (2.2%) |
| | Influenza like illness | 835 (2%) |
| **Infections and infestations** | | |
| | COVID-19 | 1927 (4.6%) |
| **Injury, poisoning and procedural complications** | | |
| | Off label use | 880 (2.1%) |
| | Product use issue | 828 (2.0%) |
| **Musculoskeletal and connective tissue disorders** | | |
| | Myalgia | 4915 (11.7%) |
| | Pain in extremity | 3959 (9.4%) |
| | Arthralgia | 3525 (8.4%) |
| **Nervous system disorders** | | |
| | Headache | 10131 (24.1%) |
| | Dizziness | 3720 (8.8%) |
| | Paraesthesia | 1500 (3.6%) |
| | Hypoaesthesia | 999 (2.4%) |
| **Respiratory, thoracic and mediastinal disorders** | | |
| | Dyspnoea | 2057 (4.9%) |
| | Cough | 1146 (2.7%) |
| | Oropharyngeal pain | 948 (2.3%) |
| **Skin and subcutaneous tissue disorders** | | |
| | Pruritus | 1447 (3.4%) |
| | Rash | 1404 (3.3%) |
| | Erythema | 1044 (2.5%) |
| | Hyperhidrosis | 900 (2.1%) |
| | Urticaria | 862 (2.1%) |
| **Total number of events** | | **93473** |

## 3.1.2. Summary of Safety Concerns in the US Pharmacovigilance Plan

## Table 3. Safety concerns

| | |
|---|---|
| **Important identified risks** | Anaphylaxis |
| **Important potential risks** | Vaccine-Associated Enhanced Disease (VAED), Including Vaccine-associated Enhanced Respiratory Disease (VAERD) |
| **Missing information** | Use in Pregnancy and lactation<br>Use in Paediatric Individuals <12 Years of Age<br>Vaccine Effectiveness |

## Table 4. Important Identified Risk

<table>
<tr><th>Topic</th><th>Description</th></tr>
<tr><td>Important Identified Risk</td><td>Post Authorization Cases Evaluation (cumulative to 28 Feb 2021)<br>Total Number of Cases in the Reporting Period (N=42086)</td></tr>
<tr><td>Anaphylaxis</td><td>Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021, 1833 potentially relevant cases were retrieved from the Anaphylactic reaction SMQ (Narrow and Broad) search strategy, applying the MedDRA algorithm. These cases were individually reviewed and assessed according to Brighton Collaboration (BC) definition and level of diagnostic certainty as shown in the Table below:<br><br>
<table>
<tr><td>Brighton Collaboration Level</td><td>Number of cases</td></tr>
<tr><td>BC 1</td><td>290</td></tr>
<tr><td>BC 2</td><td>311</td></tr>
<tr><td>BC 3</td><td>10</td></tr>
<tr><td>BC 4</td><td>391</td></tr>
<tr><td>BC 5</td><td>831</td></tr>
<tr><td>Total</td><td>1833</td></tr>
</table>
Level 1 indicates a case with the highest level of diagnostic certainty of anaphylaxis, whereas the diagnostic certainty is lowest for Level 3. Level 4 is defined as “reported event of anaphylaxis with insufficient evidence to meet the case definition” and Level 5 as not a case of anaphylaxis.<br><br>
There were 1002 cases (54.0% of the potentially relevant cases retrieved), 2958 potentially relevant events, from the Anaphylactic reaction SMQ (Broad and Narrow) search strategy, meeting BC Level 1 to 4:<br><br>
Country of incidence: UK (261), US (184), Mexico (99), Italy (82), Germany (67), Spain (38), France (36), Portugal (22), Denmark (20), Finland, Greece (19 each), Sweden (17), Czech Republic , Netherlands (16 each), Belgium, Ireland (13 each), Poland (12), Austria (11); the remaining 57 cases originated from 15 different countries.<br>
Relevant event seriousness: Serious (2341), Non-Serious (617);<br>
Gender: Females (876), Males (106), Unknown (20);<br>
Age (n=961) ranged from 16 to 98 years (mean = 54.8 years, median = 42.5 years);<br>
Relevant even outcome[a]: fatal (9)[b], resolved/resolving (1922), not resolved (229), resolved with sequelae (48), unknown (754);<br>
Most frequently reported relevant PTs (≥2%), from the Anaphylactic reaction SMQ (Broad and Narrow) search strategy: Anaphylactic reaction (435), Dyspnoea (356), Rash (190), Pruritus (175), Erythema (159), Urticaria (133), Cough (115), Respiratory distress, Throat tightness (97 each), Swollen tongue (93), Anaphylactic shock (80), Hypotension (72), Chest discomfort (71), Swelling face (70), Pharyngeal swelling (68), and Lip swelling (64).<br><br>
Conclusion: Evaluation of BC cases Level 1 - 4 did not reveal any significant new safety information. Anaphylaxis is appropriately described in the product labeling as are non-anaphylactic hypersensitivity events. Surveillance will continue.</td></tr>
</table>

a Different clinical outcome may be reported for an event that occurred more than once to the same individual.
b There were 4 individuals in the anaphylaxis evaluation who died on the same day they were vaccinated. Although these patients experienced adverse events (9) that are potential symptoms of anaphylaxis, they all had serious underlying medical conditions, and one individual appeared to also have COVID-19 pneumonia, that likely contributed to their deaths

## Table 5. Important Potential Risk

| Topic | Description |
|---|---|
| **Important Potential Risk** | **Post Authorization Cases Evaluation (cumulative to 28 Feb 2021)<br>Total Number of Cases in the Reporting Period (N=42086)** |
| Vaccine-Associated Enhanced Disease (VAED), including Vaccine-Associated Enhanced Respiratory Disease (VAERD) | No post-authorized AE reports have been identified as cases of VAED/VAERD, therefore, there is no observed data at this time. An expected rate of VAED is difficult to establish so a meaningful observed/expected analysis cannot be conducted at this point based on available data. The feasibility of conducting such an analysis will be re-evaluated on an ongoing basis as data on the virus grows and the vaccine safety data continues to accrue.<br><br>The search criteria utilised to identify potential cases of VAED for this report includes PTs indicating a lack of effect of the vaccine and PTs potentially indicative of severe or atypical COVID-19[a].<br><br>Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021, 138 cases [0.33% of the total PM dataset], reporting 317 potentially relevant events were retrieved:<br><br>Country of incidence: UK (71), US (25), Germany (14), France, Italy, Mexico, Spain, (4 each), Denmark (3); the remaining 9 cases originated from 9 different countries;<br>Cases Seriousness: 138;<br>Seriousness criteria for the total 138 cases: Medically significant (71, of which 8 also serious for disability), Hospitalization required (non-fatal/non-life threatening) (16, of which 1 also serious for disability), Life threatening (13, of which 7 were also serious for hospitalization), Death (38).<br>Gender: Females (73), Males (57), Unknown (8);<br>Age (n=132) ranged from 21 to 100 years (mean = 57.2 years, median = 59.5);<br>Case outcome: fatal (38), resolved/resolving (26), not resolved (65), resolved with sequelae (1), unknown (8);<br>Of the 317 relevant events, the most frequently reported PTs (≥2%) were: Drug ineffective (135), Dyspnoea (53), Diarrhoea (30), COVID-19 pneumonia (23), Vomiting (20), Respiratory failure (8), and Seizure (7).<br><br>Conclusion: VAED may present as severe or unusual clinical manifestations of COVID-19. Overall, there were 37 subjects with suspected COVID-19 and 101 subjects with confirmed COVID-19 following one or both doses of the vaccine; 75 of the 101 cases were severe, resulting in hospitalisation, disability, life-threatening consequences or death. None of the 75 cases could be definitively considered as VAED/VAERD.<br>In this review of subjects with COVID-19 following vaccination, based on the current evidence, VAED/VAERD remains a theoretical risk for the vaccine. Surveillance will continue. |

a. Search criteria: Standard Decreased Therapeutic Response Search AND PTs Dyspnoea; Tachypnoea; Hypoxia; COVID 19 pneumonia; Respiratory Failure; Acute Respiratory Distress Syndrome; Cardiac Failure; Cardiogenic shock; Acute myocardial infarction; Arrhythmia; Myocarditis; Vomiting; Diarrhoea; Abdominal pain; Jaundice; Acute hepatic failure; Deep vein thrombosis; Pulmonary embolism; Peripheral Ischaemia; Vasculitis; Shock; Acute kidney injury; Renal failure; Altered state of consciousness; Seizure; Encephalopathy; Meningitis; Cerebrovascular accident; Thrombocytopenia; Disseminated intravascular coagulation; Chillblains; Erythema multiforme; Multiple organ dysfunction syndrome; Multisystem inflammatory syndrome in children.

## Table 6. Description of Missing Information

| Topic | Description |
|---|---|
| **Missing Information** | **Post Authorization Cases Evaluation (cumulative to 28 Feb 2021)<br>Total Number of Cases in the Reporting Period (N=42086)** |
| Use in Pregnancy and lactation | • Number of cases: 413[a] (0.98% of the total PM dataset); 84 serious and 329 non-serious;<br>• Country of incidence: US (205), UK (64), Canada (31), Germany (30), Poland (13), Israel (11); Italy (9), Portugal (8), Mexico (6), Estonia, Hungary and Ireland, (5 each), Romania (4), Spain (3), Czech Republic and France (2 each), the remaining 10 cases were distributed among 10 other countries.<br><br>Pregnancy cases: 274 cases including:<br><br>• 270 mother cases and 4 foetus/baby cases representing 270 unique pregnancies (the 4 foetus/baby cases were linked to 3 mother cases; 1 mother case involved twins).<br>• Pregnancy outcomes for the 270 pregnancies were reported as spontaneous abortion (23), outcome pending (5), premature birth with neonatal death, spontaneous abortion with intrauterine death (2 each), spontaneous abortion with neonatal death, and normal outcome (1 each). No outcome was provided for 238 pregnancies (note that 2 different outcomes were reported for each twin, and both were counted).<br><br>• 146 non-serious mother cases reported exposure to vaccine in utero without the occurrence of any clinical adverse event. The exposure PTs coded to the PTs Maternal exposure during pregnancy (111), Exposure during pregnancy (29) and Maternal exposure timing unspecified (6). Trimester of exposure was reported in 21 of these cases: 1st trimester (15 cases), 2nd trimester (7), and 3rd trimester (2).<br>• 124 mother cases, 49 non-serious and 75 serious, reported clinical events, which occurred in the vaccinated mothers. Pregnancy related events reported in these cases coded to the PTs Abortion spontaneous (25), Uterine contraction during pregnancy, Premature rupture of membranes, Abortion, Abortion missed, and Foetal death (1 each). Other clinical events which occurred in more than 5 cases coded to the PTs Headache (33), Vaccination site pain (24), Pain in extremity and Fatigue (22 each), Myalgia and Pyrexia (16 each), Chills (13) Nausea (12), Pain (11), Arthralgia (9), Lymphadenopathy and Drug ineffective (7 each), Chest pain, Dizziness and Asthenia (6 each), Malaise and COVID-19 (5 each). Trimester of exposure was reported in 22 of these cases: 1st trimester (19 cases), 2nd trimester (1 case), 3rd trimester (2 cases).<br>• 4 serious foetus/baby cases reported the PTs Exposure during pregnancy, Foetal growth restriction, Maternal exposure during pregnancy, Premature baby (2 each), and Death neonatal (1). Trimester of exposure was reported for 2 cases (twins) as occurring during the 1st trimester.<br><br>Breast feeding baby cases: 133, of which:<br><br>• 116 cases reported exposure to vaccine during breastfeeding (PT Exposure via breast milk) without the occurrence of any clinical adverse events;<br>• 17 cases, 3 serious and 14 non-serious, reported the following clinical events that occurred in the infant/child exposed to vaccine via breastfeeding: Pyrexia (5), Rash (4), Infant irritability (3), Infantile vomiting, Diarrhoea, Insomnia, and Illness (2 each), Poor feeding infant, Lethargy, Abdominal discomfort, Vomiting, Allergy to vaccine, Increased appetite, Anxiety, Crying, Poor quality sleep, Eructation, Agitation, Pain and Urticaria (1 each).<br><br>Breast feeding mother cases (6):<br>• 1 serious case reported 3 clinical events that occurred in a mother during breast feeding (PT Maternal exposure during breast feeding); these events coded to the PTs Chills, Malaise, and Pyrexia<br>• 1 non-serious case reported with very limited information and without associated AEs. |

## Table 6. Description of Missing Information

| Topic | Description |
|---|---|
| **Missing Information** | **Post Authorization Cases Evaluation (cumulative to 28 Feb 2021)<br>Total Number of Cases in the Reporting Period (N=42086)** |
| | • In 4 cases (3 non-serious; 1 serious) Suppressed lactation occurred in a breast feeding women with the following co-reported events: Pyrexia (2), Paresis, Headache, Chills, Vomiting, Pain in extremity, Arthralgia, Breast pain, Scar pain, Nausea, Migraine, Myalgia, Fatigue and Breast milk discolouration (1 each).<br>Conclusion: There were no safety signals that emerged from the review of these cases of use in pregnancy and while breast feeding. |
| Use in Paediatric Individuals <12 Years of Age | <u>Paediatric individuals <12 years of age</u><br>• Number of cases: 34[d] (0.1% of the total PM dataset), indicative of administration in paediatric subjects <12 years of age;<br>• Country of incidence: UK (29), US (3), Germany and Andorra (1 each);<br>• Cases Seriousness: Serious (24), Non-Serious (10);<br>• Gender: Females (25), Males (7), Unknown (2);<br>• Age (n=34) ranged from 2 months to 9 years, mean = 3.7 years, median = 4.0;<br>• Case outcome: resolved/resolving (16), not resolved (13), and unknown (5).<br>• Of the 132 reported events, those reported more than once were as follows: Product administered to patient of inappropriate age (27, see Medication Error), Off label use (11), Pyrexia (6), Product use issue (5), Fatigue, Headache and Nausea (4 each), Vaccination site pain (3), Abdominal pain upper, COVID-19, Facial paralysis, Lymphadenopathy, Malaise, Pruritus and Swelling (2 each).<br><br>Conclusion: No new significant safety information was identified based on a review of these cases compared with the non-paediatric population. |
| Vaccine Effectiveness | Company conventions for coding cases indicative of lack of efficacy:<br><br>The coding conventions for lack of efficacy in the context of administration of the COVID-19 vaccine were revised on 15 February 2021, as shown below:<br>• PT "Vaccination failure" is coded when ALL of the following criteria are met:<br>o The subject has received the series of two doses per the dosing regimen in local labeling.<br>o At least 7 days have elapsed since the second dose of vaccine has been administered.<br>o The subject experiences SARS-CoV-2 infection (confirmed laboratory tests).<br>• PT "Drug ineffective" is coded when either of the following applies:<br>o The infection is not confirmed as SARS-CoV-2 through laboratory tests (irrespective of the vaccination schedule). This includes scenarios where LOE is stated or implied, e.g., "the vaccine did not work", "I got COVID-19".<br>o It is unknown:<br>▪ Whether the subject has received the series of two doses per the dosing regimen in local labeling;<br>▪ How many days have passed since the first dose (including unspecified number of days like" a few days", "some days", etc.);<br>▪ If 7 days have passed since the second dose;<br>o The subject experiences a vaccine preventable illness 14 days after receiving the first dose up to and through 6 days after receipt of the second dose.<br><br>Note: after the immune system as had sufficient time (14 days) to respond to the vaccine, a report of COVID-19 is considered a potential lack of efficacy even if the vaccination course is not complete.<br><br>Summary of the coding conventions for onset of vaccine preventable disease versus the vaccination date: |

## Table 6. Description of Missing Information

| Topic | Description |
|---|---|
| **Missing Information** | **Post Authorization Cases Evaluation (cumulative to 28 Feb 2021)<br>Total Number of Cases in the Reporting Period (N=42086)** |

| | | |
|---|---|---|
| 1st dose (day 1-13) | From day 14 post 1st dose to day 6 post 2nd dose | Day 7 post 2nd dose |
| Code only the events describing the SARS-CoV-2 infection | Code "Drug ineffective" | Code "Vaccination failure" |
| Scenario Not considered LOE | Scenario considered LOE as "Drug ineffective" | Scenario considered LOE as "Vaccination failure" |

***Lack of efficacy cases***

- Number of cases: 1665[b] (3.9 % of the total PM dataset) of which 1100 were medically confirmed and 565 non medically confirmed;
- Number of lack of efficacy events: 1665 [PT: Drug ineffective (1646) and Vaccination failure (19)[f]].
- Country of incidence: US (665), UK (405), Germany (181), France (85), Italy (58), Romania (47), Belgium (33), Israel (30), Poland (28), Spain (21), Austria (18), Portugal (17), Greece (15), Mexico (13), Denmark (8), Canada (7), Hungary, Sweden and United Arab Emirates (5 each), Czech Republic (4), Switzerland (3); the remaining 12 cases originated from 9 different countries.
- COVID-19 infection was suspected in 155 cases, confirmed in 228 cases, in 1 case it was reported that the first dose was not effective (no other information).
- COVID-19 infection (suspected or confirmed) outcome was reported as resolved/resolving (165), not resolved (205) or unknown (1230) at the time of the reporting; there were 65 cases where a fatal outcome was reported.

***Drug ineffective cases (1649)***

- Drug ineffective event seriousness: serious (1625), non-serious (21)[e];
- Lack of efficacy term was reported:
  - after the 1st dose in 788 cases
  - after the 2nd dose in 139 cases
  - in 722 cases it was unknown after which dose the lack of efficacy occurred.
- Latency of lack of efficacy term reported after the first dose was known for 176 cases:
  - Within 9 days: 2 subjects;
  - Within 14 and 21 days: 154 subjects;
  - Within 22 and 50 days: 20 subjects;
- Latency of lack of efficacy term reported after the second dose was known for 69 cases:
  - Within 0 and 7 days: 42 subjects;
  - Within 8 and 21 days: 22 subjects;
  - Within 23 and 36 days: 5 subjects.
- Latency of lack of efficacy term reported in cases where the number of doses administered was not provided, was known in 409 cases:
  - Within 0 and 7 days after vaccination: 281 subjects.
  - Within 8 and 14 days after vaccination: 89 subjects.
  - Within 15 and 44 days after vaccination: 39 subjects.

According to the RSI, individuals may not be fully protected until 7 days after their second dose of vaccine, therefore for the above 1649 cases where lack of efficacy was reported after the 1st dose or the

## Table 6. Description of Missing Information

| Topic | Description |
|---|---|
| **Missing Information** | **Post Authorization Cases Evaluation (cumulative to 28 Feb 2021)<br>Total Number of Cases in the Reporting Period (N=42086)** |
| | 2nd dose, the reported events may represent signs and symptoms of intercurrent or undiagnosed COVID-19 infection or infection in an individual who was not fully vaccinated, rather than vaccine ineffectiveness.<br><br>***Vaccination failure cases (16)***<br>• Vaccination failure seriousness: all serious;<br>• Lack of efficacy term was reported in all cases after the 2nd dose:<br>• Latency of lack of efficacy was known for 14 cases:<br>o Within 7 and 13 days: 8 subjects;<br>o Within 15 and 29 days: 6 subjects.<br>COVID-19 (10) and Asymptomatic COVID-19 (6) were the reported vaccine preventable infections that occurred in these 16 cases.<br><br>Conclusion: No new safety signals of vaccine lack of efficacy have emerged based on a review of these cases. |

a. From a total of 417 cases, 4 cases were excluded from the analysis. In 3 cases, the MAH was informed that a 33-year-old and two unspecified age pregnant female patients were scheduled to receive bnt162b2 (PT reported Off label use and Product use issue in 2 cases; Circumstance or information capable of leading to medication error in one case). One case reported the PT Morning sickness; however, pregnancy was not confirmed in this case.
b. 558 additional cases retrieved in this dataset were excluded from the analysis; upon review, 546 cases cannot be considered true lack of efficacy cases because the PT Drug ineffective was coded but the subjects developed SARS-CoV-2 infection during the early days from the first dose (days 1 – 13); the vaccine has not had sufficient time to stimulate the immune system and, consequently, the development of a vaccine preventable disease during this time is not considered a potential lack of effect of the vaccine; in 5 cases the PT Drug ineffective was removed after data lock point (DLP) because the subjects did not develop COVID-19 infection; in 1 case, reporting Treatment failure and Transient ischaemic attack, the Lack of efficacy PT did not refer to BNT162b2 vaccine; 5 cases have been invalidated in the safety database after DLP; 1 case has been deleted from the discussion because the PTs reported Pathogen resistance and Product preparation issue were not indicative of a lack of efficacy. to be eliminated.
c. Upon review, 31 additional cases were excluded from the analysis as the data reported (e.g. clinical details, height, weight, etc.) were not consistent with paediatric subjects
d. Upon review, 28 additional cases were excluded from the analysis as the data reported (e.g. clinical details, height, weight, etc.) were not consistent with paediatric subjects.
e. Different clinical outcomes may be reported for an event that occurred more than once to the same individual
f. In 2 cases the PT Vaccination failure was replaced with Drug ineffective after DLP. Another case was not included in the discussion of the Vaccination failure cases because correct scheduling (21 days apart between the first and second dose) cannot be confirmed.

### 3.1.3. Review of Adverse Events of Special Interest (AESIs)

Please refer to Appendix 1 for the list of the company's AESIs for BNT162b2.

The company's AESI list takes into consideration the lists of AESIs from the following expert groups and regulatory authorities: Brighton Collaboration (SPEAC), ACCESS protocol, US CDC (preliminary list of AESI for VAERS surveillance), MHRA (unpublished guideline).

The AESI terms are incorporated into a TME list and include events of interest due to their association with severe COVID-19 and events of interest for vaccines in general.

The AESI list is comprised of MedDRA PTs, HLTs, HLGTs or MedDRA SMQs and can be changed as appropriate based on the evolving safety profile of the vaccine.

Table 7 provides a summary review of cumulative cases within AESI categories in the Pfizer safety database. This is distinct from safety signal evaluations which are conducted and included, as appropriate, in the Summary Monthly Safety Reports submitted regularly to the FDA and other Health Authorities.

**Table 7. AESIs Evaluation for BNT162b2**

| **AESIs**[a]<br>**Category** | **Post-Marketing Cases Evaluation**[b]<br>**Total Number of Cases (N=42086)** |
|---|---|
| **Anaphylactic Reactions**<br>*Search criteria: Anaphylactic reaction SMQ (Narrow and Broad, with the algorithm applied), selecting relevant cases according to BC criteria* | Please refer to the Risk 'Anaphylaxis' included above in Table 4. |
| **Cardiovascular AESIs**<br>*Search criteria: PTs Acute myocardial infarction; Arrhythmia; Cardiac failure; Cardiac failure acute; Cardiogenic shock; Coronary artery disease; Myocardial infarction; Postural orthostatic tachycardia syndrome; Stress cardiomyopathy; Tachycardia* | • Number of cases: 1403 (3.3% of the total PM dataset), of which 241 are medically confirmed and 1162 are non-medically confirmed;<br>• Country of incidence: UK (268), US (233), Mexico (196), Italy (141), France (128), Germany (102), Spain (46), Greece (45), Portugal (37), Sweden (20), Ireland (17), Poland (16), Israel (13), Austria, Romania and Finland (12 each), Netherlands (11), Belgium and Norway (10 each), Czech Republic (9), Hungary and Canada (8 each), Croatia and Denmark (7 each), Iceland (5); the remaining 30 cases were distributed among 13 other countries;<br>• Subjects' gender: female (1076), male (291) and unknown (36);<br>• Subjects' age group (n = 1346): Adult[c] (1078), Elderly[d] (266) Child[e] and Adolescent[f] (1 each);<br>• Number of relevant events: 1441, of which 946 serious, 495 non-serious; in the cases reporting relevant serious events;<br>• Reported relevant PTs: Tachycardia (1098), Arrhythmia (102), Myocardial infarction (89), Cardiac failure (80), Acute myocardial infarction (41), Cardiac failure acute (11), Cardiogenic shock and Postural orthostatic tachycardia syndrome (7 each) and Coronary artery disease (6);<br>• Relevant event onset latency (n = 1209): Range from <24 hours to 21 days, median <24 hours; |

**Table 7. AESIs Evaluation for BNT162b2**

| AESIs[a] Category | Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086) |
|---|---|
| | • Relevant event outcome[g]: fatal (136), resolved/resolving (767), resolved with sequelae (21), not resolved (140) and unknown (380);<br><br>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue |
| **COVID-19 AESIs**<br>*Search criteria: Covid-19 SMQ (Narrow and Broad) OR PTs Ageusia; Anosmia* | • Number of cases: 3067 (7.3% of the total PM dataset), of which 1013 are medically confirmed and 2054 are non-medically confirmed;<br>• Country of incidence: US (1272), UK (609), Germany (360), France (161), Italy (94), Spain (69), Romania (62), Portugal (51), Poland (50), Mexico (43), Belgium (42), Israel (41), Sweden (30), Austria (27), Greece (24), Denmark (18), Czech Republic and Hungary (17 each), Canada (12), Ireland (11), Slovakia (9), Latvia and United Arab Emirates (6 each); the remaining 36 cases were distributed among 16 other different countries;<br>• Subjects' gender: female (1650), male (844) and unknown (573);<br>• Subjects' age group (n= 1880): Adult (1315), Elderly (560), Infant[h] and Adolescent (2 each), Child (1);<br>• Number of relevant events: 3359, of which 2585 serious, 774 non-serious;<br>• Most frequently reported relevant PTs (>1 occurrence): COVID-19 (1927), SARS-CoV-2 test positive (415), Suspected COVID-19 (270), Ageusia (228), Anosmia (194), SARS-CoV-2 antibody test negative (83), Exposure to SARS-CoV-2 (62), SARS-CoV-2 antibody test positive (53), COVID-19 pneumonia (51), Asymptomatic COVID-19 (31), Coronavirus infection (13), Occupational exposure to SARS-CoV-2 (11), SARS-CoV-2 test false positive (7), Coronavirus test positive (6), SARS-CoV-2 test negative (3) SARS-CoV-2 antibody test (2);<br>• Relevant event onset latency (n = 2070): Range from <24 hours to 374 days, median 5 days;<br>• Relevant event outcome: fatal (136), not resolved (547), resolved/resolving (558), resolved with sequelae (9) and unknown (2110).<br><br>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue |
| **Dermatological AESIs**<br>*Search criteria: PT Chillblains; Erythema multiforme* | • Number of cases: 20 cases (0.05% of the total PM dataset), of which 15 are medically confirmed and 5 are non-medically confirmed;<br>• Country of incidence: UK (8), France and Poland (2 each), and the remaining 8 cases were distributed among 8 other different countries;<br>• Subjects' gender: female (17) male and unknown (1 each);<br>• Subjects' age group (n=19): Adult (18), Elderly (1);<br>• Number of relevant events: 20 events, 16 serious, 4 non-serious |

**Table 7. AESIs Evaluation for BNT162b2**

| AESIs[a] Category | Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086) |
|---|---|
| | • Reported relevant PTs: Erythema multiforme (13) and Chillblains (7)<br>• Relevant event onset latency (n = 18): Range from <24 hours to 17 days, median 3 days;<br>• Relevant event outcome: resolved/resolving (7), not resolved (8) and unknown (6).<br><br>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue. |
| **Haematological AESIs**<br>*Search criteria: Leukopenias NEC (HLT) (Primary Path) OR Neutropenias (HLT) (Primary Path) OR PTs Immune thrombocytopenia, Thrombocytopenia OR SMQ Haemorrhage terms (excl laboratory terms* | • Number of cases: 932 (2.2 % of the total PM dataset), of which 524 medically confirmed and 408 non-medically confirmed;<br>• Country of incidence: UK (343), US (308), France (50), Germany (43), Italy (37), Spain (27), Mexico and Poland (13 each), Sweden (10), Israel (9), Netherlands (8), Denmark, Finland, Portugal and Ireland (7 each), Austria and Norway (6 each), Croatia (4), Greece, Belgium, Hungary and Switzerland (3 each), Cyprus, Latvia and Serbia (2 each); the remaining 9 cases originated from 9 different countries;<br>• Subjects' gender (n=898): female (676) and male (222);<br>• Subjects' age group (n=837): Adult (543), Elderly (293), Infant (1);<br>• Number of relevant events: 1080, of which 681 serious, 399 non-serious;<br>• Most frequently reported relevant PTs (≥15 occurrences) include: Epistaxis (127), Contusion (112), Vaccination site bruising (96), Vaccination site haemorrhage (51), Petechiae (50), Haemorrhage (42), Haematochezia (34), Thrombocytopenia (33), Vaccination site haematoma (32), Conjunctival haemorrhage and Vaginal haemorrhage (29 each), Haematoma, Haemoptysis and Menorrhagia (27 each), Haematemesis (25), Eye haemorrhage (23), Rectal haemorrhage (22), Immune thrombocytopenia (20), Blood urine present (19), Haematuria, Neutropenia and Purpura (16 each) Diarrhoea haemorrhagic (15);<br>• Relevant event onset latency (n = 787): Range from <24 hours to 33 days, median = 1 day;<br>• Relevant event outcome: fatal (34), resolved/resolving (393), resolved with sequelae (17), not resolved (267) and unknown (371).<br><br>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue |
| **Hepatic AESIs**<br>*Search criteria: Liver related investigations, signs and symptoms (SMQ) (Narrow and Broad) OR PT Liver injury* | • Number of cases: 70 cases (0.2% of the total PM dataset), of which 54 medically confirmed and 16 non-medically confirmed;<br>• Country of incidence: UK (19), US (14), France (7), Italy (5), Germany (4), Belgium, Mexico and Spain (3 each), Austria, and Iceland (2 each); the remaining 8 cases originated from 8 different countries;<br>• Subjects' gender: female (43), male (26) and unknown (1);<br>• Subjects' age group (n=64): Adult (37), Elderly (27); |

**Table 7. AESIs Evaluation for BNT162b2**

| AESIs[a] Category | Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086) |
|---|---|
| | • Number of relevant events: 94, of which 53 serious, 41 non-serious;<br>• Most frequently reported relevant PTs (≥3 occurrences) include: Alanine aminotransferase increased (16), Transaminases increased and Hepatic pain (9 each), Liver function test increased (8), Aspartate aminotransferase increased and Liver function test abnormal (7 each), Gamma-glutamyltransferase increased and Hepatic enzyme increased (6 each), Blood alkaline phosphatase increased and Liver injury (5 each), Ascites, Blood bilirubin increased and Hypertransaminasaemia (3 each);<br>• Relevant event onset latency (n = 57): Range from <24 hours to 20 days, median 3 days;<br>• Relevant event outcome: fatal (5), resolved/resolving (27), resolved with sequelae (1), not resolved (14) and unknown (47).<br><br>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue |
| **Facial Paralysis**<br>*Search criteria: PTs Facial paralysis, Facial paresis* | • Number of cases: 449[i] (1.07% of the total PM dataset), 314 medically confirmed and 135 non-medically confirmed;<br>• Country of incidence: US (124), UK (119), Italy (40), France (27), Israel (20), Spain (18), Germany (13), Sweden (11), Ireland (9), Cyprus (8), Austria (7), Finland and Portugal (6 each), Hungary and Romania (5 each), Croatia and Mexico (4 each), Canada (3),Czech Republic, Malta, Netherlands, Norway, Poland and Puerto Rico (2 each); the remaining 8 cases originated from 8 different countries;<br>• Subjects' gender: female (295), male (133), unknown (21);<br>• Subjects' age group (n=411): Adult (313), Elderly (96), Infant[j] and Child (1 each);<br>• Number of relevant events[k]: 453, of which 399 serious, 54 non-serious;<br>• Reported relevant PTs: Facial paralysis (401), Facial paresis (64);<br>• Relevant event onset latency (n = 404): Range from <24 hours to 46 days, median 2 days;<br>• Relevant event outcome: resolved/resolving (184), resolved with sequelae (3), not resolved (183) and unknown (97);<br><br>Overall Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue. Causality assessment will be further evaluated following availability of additional unblinded data from the clinical study C4591001, which will be unblinded for final analysis approximately mid-April 2021. Additionally, non-interventional post-authorisation safety studies, C4591011 and C4591012 are expected to capture data on a sufficiently large vaccinated population to detect an increased risk of Bell's palsy in vaccinated individuals. The timeline for conducting these analyses will be established based on the size of the vaccinated population captured in the study data sources by the first interim reports (due 30 June |

**Table 7. AESIs Evaluation for BNT162b2**

| AESIs[a] Category | Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086) |
|---|---|
| | 2021). Study C4591021, pending protocol endorsement by EMA, is also intended to inform this risk. |
| **Immune-Mediated/Autoimmune AESIs** *Search criteria: Immune-mediated/autoimmune disorders (SMQ) (Broad and Narrow) OR Autoimmune disorders HLGT (Primary Path) OR PTs Cytokine release syndrome; Cytokine storm; Hypersensitivity* | • Number of cases: 1050 (2.5 % of the total PM dataset), of which 760 medically confirmed and 290 non-medically confirmed;<br>• Country of incidence (>10 cases): UK (267), US (257), Italy (70), France and Germany (69 each), Mexico (36), Sweden (35), Spain (32), Greece (31), Israel (21), Denmark (18), Portugal (17), Austria and Czech Republic (16 each), Canada (12), Finland (10). The remaining 74 cases were from 24 different countries.<br>• Subjects' gender (n=682): female (526), male (156).<br>• Subjects' age group (n=944): Adult (746), Elderly (196), Adolescent (2).<br>• Number of relevant events: 1077, of which 780 serious, 297 non-serious.<br>• Most frequently reported relevant PTs (>10 occurrences): Hypersensitivity (596), Neuropathy peripheral (49), Pericarditis (32), Myocarditis (25), Dermatitis (24), Diabetes mellitus and Encephalitis (16 each), Psoriasis (14), Dermatitis Bullous (13), Autoimmune disorder and Raynaud's phenomenon (11 each);<br>• Relevant event onset latency (n = 807): Range from <24 hours to 30 days, median <24 hours.<br>• Relevant event outcome[l]: resolved/resolving (517), not resolved (215), fatal (12), resolved with sequelae (22) and unknown (312).<br><br>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue |
| **Musculoskeletal AESIs** *Search criteria: PTs Arthralgia; Arthritis; Arthritis bacterial[n]; Chronic fatigue syndrome; Polyarthritis; Polyneuropathy; Post viral fatigue syndrome; Rheumatoid arthritis* | • Number of cases: 3600 (8.5% of the total PM dataset), of which 2045 medically confirmed and 1555 non-medically confirmed;<br>• Country of incidence: UK (1406), US (1004), Italy (285), Mexico (236), Germany (72), Portugal (70), France (48), Greece and Poland (46), Latvia (33), Czech Republic (32), Israel and Spain (26), Sweden (25), Romania (24), Denmark (23), Finland and Ireland (19 each), Austria and Belgium (18 each), Canada (16), Netherlands (14), Bulgaria (12), Croatia and Serbia (9 each), Cyprus and Hungary (8 each), Norway (7), Estonia and Puerto Rico (6 each), Iceland and Lithuania (4 each); the remaining 21 cases originated from 11 different countries;<br>• Subjects' gender (n=3471): female (2760), male (711);<br>• Subjects' age group (n=3372): Adult (2850), Elderly (515), Child (4), Adolescent (2), Infant (1);<br>• Number of relevant events: 3640, of which 1614 serious, 2026 non-serious;<br>• Reported relevant PTs: Arthralgia (3525), Arthritis (70), Rheumatoid arthritis (26), Polyarthritis (5), Polyneuropathy, Post viral fatigue syndrome, Chronic fatigue syndrome (4 each), Arthritis bacterial (1);<br>• Relevant event onset latency (n = 2968): Range from <24 hours to 32 days, median 1 day; |

## Table 7. AESIs Evaluation for BNT162b2

| AESIs[a] Category | Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086) |
|---|---|
| | • Relevant event outcome: resolved/resolving (1801), not resolved (959), resolved with sequelae (49), and unknown (853).<br><br>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue. |
| **Neurological AESIs (including demyelination)**<br>*Search criteria: Convulsions (SMQ) (Broad and Narrow) OR Demyelination (SMQ) (Broad and Narrow) OR PTs Ataxia; Cataplexy; Encephalopathy; Fibromyalgia; Intracranial pressure increased; Meningitis; Meningitis aseptic; Narcolepsy* | • Number of cases: 501 (1.2% of the total PM dataset), of which 365 medically confirmed and 136 non-medically confirmed.<br>• Country of incidence (≥9 cases): UK (157), US (68), Germany (49), Mexico (35), Italy (31), France (25), Spain (18), Poland (17), Netherlands and Israel (15 each), Sweden (9). The remaining 71 cases were from 22 different countries.<br>• Subjects' gender (n=478): female (328), male (150).<br>• Subjects' age group (n=478): Adult (329), Elderly (149);<br>• Number of relevant events: 542, of which 515 serious, 27 non-serious.<br>• Most frequently reported relevant PTs (>2 occurrences) included: Seizure (204), Epilepsy (83), Generalised tonic-clonic seizure (33), Guillain-Barre syndrome (24), Fibromyalgia and Trigeminal neuralgia (17 each), Febrile convulsion, (15), Status epilepticus (12), Aura and Myelitis transverse (11 each), Multiple sclerosis relapse and Optic neuritis (10 each), Petit mal epilepsy and Tonic convulsion (9 each), Ataxia (8), Encephalopathy and Tonic clonic movements (7 each), Foaming at mouth (5), Multiple sclerosis, Narcolepsy and Partial seizures (4 each), Bad sensation, Demyelination, Meningitis, Postictal state, Seizure like phenomena and Tongue biting (3 each);<br>• Relevant event onset latency (n = 423): Range from <24 hours to 48 days, median 1 day;<br>• Relevant events outcome: fatal (16), resolved/resolving (265), resolved with sequelae (13), not resolved (89) and unknown (161);<br><br>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue |
| **Other AESIs**<br>*Search criteria: Herpes viral infections (HLT) (Primary Path) OR PTs Adverse event following immunisation; Inflammation; Manufacturing laboratory analytical testing issue; Manufacturing materials issue; Manufacturing production issue; MERS-CoV test; MERS-CoV test negative; MERS-CoV test positive; Middle East respiratory syndrome; Multiple organ dysfunction syndrome; Occupational exposure to communicable disease; Patient* | • Number of cases: 8152 (19.4% of the total PM dataset), of which 4977 were medically confirmed and 3175 non-medically confirmed;<br>• Country of incidence (> 20 occurrences): UK (2715), US (2421), Italy (710), Mexico (223), Portugal (210), Germany (207), France (186), Spain (183), Sweden (133), Denmark (127), Poland (120), Greece (95), Israel (79), Czech Republic (76), Romania (57), Hungary (53), Finland (52), Norway (51), Latvia (49), Austria (47), Croatia (42), Belgium (41), Canada (39), Ireland (34), Serbia (28), Iceland (25), Netherlands (22). The remaining 127 cases were from 21 different countries;<br>• Subjects' gender (n=7829): female (5969), male (1860);<br>• Subjects' age group (n=7479): Adult (6330), Elderly (1125), Adolescent, Child (9 each), Infant (6); |

**Table 7. AESIs Evaluation for BNT162b2**

| **AESIs**[a]<br>**Category** | **Post-Marketing Cases Evaluation**[b]<br>**Total Number of Cases (N=42086)** |
|---|---|
| *isolation; Product availability issue; Product distribution issue; Product supply issue; Pyrexia; Quarantine; SARS-CoV-1 test; SARS-CoV-1 test negative; SARS-CoV-1 test positive* | • Number of relevant events: 8241, of which 3674 serious, 4568 non-serious;<br>• Most frequently reported relevant PTs (≥6 occurrences) included: Pyrexia (7666), Herpes zoster (259), Inflammation (132), Oral herpes (80), Multiple organ dysfunction syndrome (18), Herpes virus infection (17), Herpes simplex (13), Ophthalmic herpes zoster (10), Herpes ophthalmic and Herpes zoster reactivation (6 each);<br>• Relevant event onset latency (n =6836): Range from <24 hours to 61 days, median 1 day;<br>• Relevant events outcome: fatal (96), resolved/resolving (5008), resolved with sequelae (84), not resolved (1429) and unknown (1685).<br><br>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue |
| **Pregnancy Related AESIs**<br>*Search criteria: PTs Amniotic cavity infection; Caesarean section; Congenital anomaly; Death neonatal; Eclampsia; Foetal distress syndrome; Low birth weight baby; Maternal exposure during pregnancy; Placenta praevia; Pre-eclampsia; Premature labour; Stillbirth; Uterine rupture; Vasa praevia* | For relevant cases, please refer to Table 6, Description of Missing Information, *Use in Pregnancy and While Breast Feeding* |
| **Renal AESIs**<br>*Search criteria: PTs Acute kidney injury; Renal failure.* | • Number of cases: 69 cases (0.17% of the total PM dataset), of which 57 medically confirmed, 12 non-medically confirmed;<br>• Country of incidence: Germany (17), France and UK (13 each), US (6), Belgium, Italy and Spain (4 each), Sweden (2), Austria, Canada, Denmark, Finland, Luxembourg and Norway (1 each);<br>• Subjects' gender: female (46), male (23);<br>• Subjects' age group (n=68): Adult (7), Elderly (60), Infant (1);<br>• Number of relevant events: 70, all serious;<br>• Reported relevant PTs: Acute kidney injury (40) and Renal failure (30);<br>• Relevant event onset latency (n = 42): Range from <24 hours to 15 days, median 4 days;<br>• Relevant event outcome: fatal (23), resolved/resolving (10), not resolved (15) and unknown (22).<br><br>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue. |
| **Respiratory AESIs**<br>*Search criteria: Lower respiratory tract infections NEC (HLT)* | • Number of cases: 130 cases (0.3% of the total PM dataset), of which 107 medically confirmed; |

## Table 7. AESIs Evaluation for BNT162b2

| AESIs[a] Category | Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086) |
|---|---|
| *(Primary Path) OR Respiratory failures (excl neonatal) (HLT) (Primary Path) OR Viral lower respiratory tract infections (HLT) (Primary Path) OR PTs: Acute respiratory distress syndrome; Endotracheal intubation; Hypoxia; Pulmonary haemorrhage; Respiratory disorder; Severe acute respiratory syndrome* | • Countries of incidence: United Kingdom (20), France (18), United States (16), Germany (14), Spain (13), Belgium and Italy (9), Denmark (8), Norway (5), Czech Republic, Iceland (3 each); the remaining 12 cases originated from 8 different countries.<br>• Subjects' gender (n=130): female (72), male (58).<br>• Subjects's age group (n=126): Elderly (78), Adult (47), Adolescent (1).<br>• Number of relevant events: 137, of which 126 serious, 11 non-serious;<br>• Reported relevant PTs: Respiratory failure (44), Hypoxia (42), Respiratory disorder (36), Acute respiratory distress syndrome (10), Chronic respiratory syndrome (3), Severe acute respiratory syndrome (2).<br>• Relevant event onset latency (n=102): range from < 24 hours to 18 days, median 1 day;<br>• Relevant events outcome: fatal (41), Resolved/resolving (47), not recovered (18) and unknown (31).<br><br>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue. |
| **Thromboembolic Events**<br>*Search criteria: Embolism and thrombosis (HLGT) (Primary Path), excluding PTs reviewed as Stroke AESIs, OR PTs Deep vein thrombosis; Disseminated intravascular coagulation; Embolism; Embolism venous; Pulmonary embolism* | • Number of cases: 151 (0.3% of the total PM dataset), of which 111 medically confirmed and 40 non-medically confirmed;<br>• Country of incidence: UK (34), US (31), France (20), Germany (15), Italy and Spain (6 each), Denmark and Sweden (5 each), Austria, Belgium and Israel (3 each), Canada, Cyprus, Netherlands and Portugal (2 each); the remaining 12 cases originated from 12 different countries;<br>• Subjects' gender (n= 144): female (89), male (55);<br>• Subjects' age group (n=136): Adult (66), Elderly (70);<br>• Number of relevant events: 168, of which 165 serious, 3 non-serious;<br>• Most frequently reported relevant PTs (>1 occurrence) included: Pulmonary embolism (60), Thrombosis (39), Deep vein thrombosis (35), Thrombophlebitis superficial (6), Venous thrombosis limb (4), Embolism, Microembolism, Thrombophlebitis and Venous thrombosis (3 each) Blue toe syndrome (2);<br>• Relevant event onset latency (n = 124): Range from <24 hours to 28 days, median 4 days;<br>• Relevant event outcome: fatal (18), resolved/resolving (54), resolved with sequelae (6), not resolved (49) and unknown (42).<br><br>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue. |
| **Stroke**<br>*Search criteria: HLT Central nervous system haemorrhages and cerebrovascular accidents* | • Number of cases: 275 (0.6% of the total PM dataset), of which 180 medically confirmed and 95 non-medically confirmed;<br>• Country of incidence: UK (81), US (66), France (32), Germany (21), Norway (14), Netherlands and Spain (11 each), Sweden (9), |

**Table 7. AESIs Evaluation for BNT162b2**

| **AESIs**[a] **Category** | **Post-Marketing Cases Evaluation**[b] **Total Number of Cases (N=42086)** |
|---|---|
| *(Primary Path) OR HLT Cerebrovascular venous and sinus thrombosis (Primary Path)* | Israel (6), Italy (5), Belgium (3), Denmark, Finland, Poland and Switzerland (2 each); the remaining 8 cases originated from 8 different countries;<br>• Subjects' gender (n= 273): female (182), male (91);<br>• Subjects' age group (n=265): Adult (59), Elderly (205), Child[m] (1);<br>• Number of relevant events: 300, all serious;<br>• Most frequently reported relevant PTs (>1 occurrence) included:<br>o PTs indicative of Ischaemic stroke: Cerebrovascular accident (160), Ischaemic stroke (41), Cerebral infarction (15), Cerebral ischaemia, Cerebral thrombosis, Cerebral venous sinus thrombosis, Ischaemic cerebral infarction and Lacunal infarction (3 each) Basal ganglia stroke, Cerebellar infarction and Thrombotic stroke (2 each);<br>o PTs indicative of Haemorrhagic stroke: Cerebral haemorrhage (26), Haemorrhagic stroke (11), Haemorrhage intracranical and Subarachnoid haemorrhage (5 each), Cerebral haematoma (4), Basal ganglia haemorrhage and Cerebellar haemorrhage (2 each);<br>• Relevant event onset latency (n = 241): Range from <24 hours to 41 days, median 2 days;<br>• Relevant event outcome: fatal and resolved/resolving (61 each), resolved with sequelae (10), not resolved (85) and unknown (83).<br><br>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue. |
| **Vasculitic Events**<br>*Search criteria: Vasculitides HLT* | • Number of cases: 32 cases (0.08% of the total PM dataset), of which 26 medically confirmed and 6 non-medically confirmed;<br>• Country of incidence: UK (13), France (4), Portugal, US and Spain (3 each), Cyprus, Germany, Hungary, Italy and Slovakia and Costa rica (1 each);<br>• Subjects' gender: female (26), male (6);<br>• Subjects' age group (n=31): Adult (15), Elderly (16);<br>• Number of relevant events: 34, of which 25 serious, 9 non-serious;<br>• Reported relevant PTs: Vasculitis (14), Cutaneous vasculitis and Vasculitic rash (4 each), (3), Giant cell arteritis and Peripheral ischaemia (3 each), Behcet's syndrome and Hypersensitivity vasculitis (2 each) Palpable purpura, and Takayasu's arteritis (1 each);<br>• Relevant event onset latency (n = 25): Range from <24 hours to 19 days, median 3 days;<br>• Relevant event outcome: fatal (1), resolved/resolving (13), not resolved (12) and unknown (8).<br><br>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue |

## Table 7. AESIs Evaluation for BNT162b2

| AESIs[a] Category | Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086) |
|---|---|

a. For the complete list of the AESIs, please refer to Appendix 5;
b. Please note that this corresponds to evidence from post-EUA/conditional marketing authorisation approval data sources;
c. Subjects with age ranged between 18 and 64 years;
d. Subjects with age equal to or above 65 years;
e. Subjects with age ranged between 2 and 11 years;
f. Subjects with age ranged between 12 and less than 18 years;
g. Multiple episodes of the same PT event were reported with a different clinical outcome within some cases hence the sum of the events outcome exceeds the total number of PT events;
h. Subjects with age ranged between 1 (28 days) and 23 months;
i. Twenty-four additional cases were excluded from the analysis as they were not cases of peripheral facial nerve palsy because they described other disorders (stroke, cerebral haemorrhage or transient ischaemic attack); 1 case was excluded from the analysis because it was invalid due to an unidentifiable reporter;
j. This UK case report received from the UK MHRA described a 1-year-old subject who received the vaccine, and had left postauricular ear pain that progressed to left-sided Bell's palsy 1 day following vaccination that had not resolved at the time of the report;
k. If a case included both PT Facial paresis and PT Facial paralysis, only the PT Facial paralysis was considered in the descriptions of the events as it is most clinically important;
l. Multiple episodes of the same PT event were reported with a different clinical outcome within some cases hence the sum of the events outcome exceeds the total number of PT events
m. This UK case report received from the UK MHRA described a 7-year-old female subject who received the vaccine and had stroke (unknown outcome); no follow-up is possible for clarification.
n. This PT not included in the AESIs/TME list was included in the review as relevant for ACCESS protocol criteria;

### 3.1.4. Medication error

Cases potentially indicative of medication errors[1] that cumulatively occurred are summarized below.

- Number of relevant medication error cases: 2056[2] (4.9%) of which 1569 (3.7%) are medically confirmed.
- Number of relevant events: 2792
- Top 10 countries of incidence:
  - US (1201), France (171), UK (138), Germany (88), Czech Republic (87), Sweden (49), Israel (45), Italy (42), Canada (35), Romania (33), Finland (21), Portugal (20), Norway (14), Puerto Rico (13), Poland (12), Austria and Spain (10 each).

Medication error case outcomes:

- Fatal (7)[3],
- Recovered/recovering (354, of which 4 are serious),
- Recovered with sequelae (8, of which 3 serious)

[1] MedDRA (version 23.1) Higher Level Terms: Accidental exposures to product; Product administration errors and issues; Product confusion errors and issues; Product dispensing errors and issues; Product label issues; Product monitoring errors and issues; Product preparation errors and issues; Product selection errors and issues; Product storage errors and issues in the product use system; Product transcribing errors and communication issues, OR Preferred Terms: Accidental poisoning; Circumstance or information capable of leading to device use error; Circumstance or information capable of leading to medication error; Contraindicated device used; Deprescribing error; Device use error; Dose calculation error; Drug titration error; Expired device used; Exposure via direct contact; Exposure via eye contact; Exposure via mucosa; Exposure via skin contact; Failure of child resistant product closure; Inadequate aseptic technique in use of product; Incorrect disposal of product; Intercepted medication error; Intercepted product prescribing error; Medication error; Multiple use of single-use product; Product advertising issue; Product distribution issue; Product prescribing error; Product prescribing issue; Product substitution error; Product temperature excursion issue; Product use in unapproved therapeutic environment; Radiation underdose; Underdose; Unintentional medical device removal; Unintentional use for unapproved indication; Vaccination error; Wrong device used; Wrong dosage form; Wrong dosage formulation; Wrong dose; Wrong drug; Wrong patient; Wrong product procured; Wrong product stored; Wrong rate; Wrong route; Wrong schedule; Wrong strength; Wrong technique in device usage process; Wrong technique in product usage process.

[2] Thirty-five (35) cases were exclude from the analysis because describing medication errors occurring in an unspecified number of individuals or describing medication errors occurring with co suspects were determined to be non-contributory.

[3] All the medication errors reported in these cases were assessed as non-serious occurrences with an unknown outcome; based on the available information including the causes of death, the relationship between the medication error and the death is weak. .

- Not recovered (189, of which 84 are serious),
- Unknown (1498, of which 33 are serious).

1371 cases reported only MEs without any associated clinical adverse event. The PTs most frequently reported (≥12 occurrences) were: Poor quality product administered (539), Product temperature excursion issue (253), Inappropriate schedule of product administration (225), Product preparation error (206), Underdose (202), Circumstance or information capable of leading to medication error (120), Product preparation issue (119), Wrong technique in product usage process (76), Incorrect route of product administration (66), Accidental overdose (33), Product administered at inappropriate site (27), Incorrect dose administered and Accidental exposure to the product (25 each), Exposure via skin contact (22), Wrong product administered (17), Incomplete course of vaccination, and Product administration error (14 each) Product administered to patient of inappropriate age (12).

In 685 cases, there were co-reported AEs. The most frequently co- associated AEs (> 40 occurrences) were: Headache (187), Pyrexia (161), Fatigue (135), Chills (127), Pain (107), Vaccination site pain (100), Nausea (89), Myalgia (88), Pain in extremity (85) Arthralgia (68), Off label use (57), Dizziness (52), Lymphadenopathy (47), Asthenia (46) and Malaise (41). These cases are summarized in Table 8.

**Table 8. ME PTs by seriousness with or without harm co-association (Through 28 February 2021)**

| | Serious | | Non-Serious | |
|---|---|---|---|---|
| **ME PTs** | **With Harm** | **Without Harm** | **With Harm** | **Without Harm** |
| Accidental exposure to product | 0 | 0 | 0 | 5 |
| Accidental overdose | 4 | 1 | 9 | 6 |
| Booster dose missed | 0 | 0 | 0 | 1 |
| Circumstance or information capable of leading to medication error | 0 | 0 | 5 | 11 |
| Contraindicated product administered | 1 | 0 | 0 | 2 |
| Expired product administered | 0 | 0 | 0 | 2 |
| Exposure via skin contact | 0 | 0 | 0 | 5 |
| Inappropriate schedule of product administration | 0 | 2 | 8 | 264 |
| Incorrect dose administered | 1 | 1 | 0 | 0 |

**Table 8. ME PTs by seriousness with or without harm co-association (Through 28 February 2021)**

| | Serious | | Non-Serious | |
|---|---|---|---|---|
| **ME PTs** | **With Harm** | **Without Harm** | **With Harm** | **Without Harm** |
| Incorrect route of product administration | 2 | 6 | 16 | 127 |
| Lack of vaccination site rotation | 1 | 0 | 0 | 0 |
| Medication error | 0 | 0 | 0 | 1 |
| Poor quality product administered | 1 | 0 | 0 | 34 |
| Product administered at inappropriate site | 2 | 1 | 13 | 29 |
| Product administered to patient of inappropriate age | 0 | 4 | 0 | 40 |
| Product administration error | 1 | 0 | 0 | 3 |
| Product dose omission issue | 0 | 1 | 0 | 3 |
| Product preparation error | 1 | 0 | 4 | 11 |
| Product preparation issue | 1 | 1 | 0 | 14 |

Overall, there were 68 cases with co-reported AEs reporting Harm and 599 cases with co-reported AEs without harm. Additionally, Intercepted medication errors was reported in 1 case (PTs Malaise, clinical outcome unknow) and Potential medication errors were reported in 17 cases.

## 4. DISCUSSION

Pfizer performs frequent and rigorous signal detection on BNT162b2 cases. The findings of these signal detection analyses are consistent with the known safety profile of the vaccine. This cumulative analysis to support the Biologics License Application for BNT162b2, is an integrated analysis of post-authorization safety data, from U.S. and foreign experience, focused on Important Identified Risks, Important Potential Risks, and areas of Important Missing Information identified in the Pharmacovigilance Plan, as well as adverse events of special interest and vaccine administration errors (whether or not associated with an adverse event). The data do not reveal any novel safety concerns or risks requiring label changes and support a favorable benefit risk profile of to the BNT162b2 vaccine.

## 5. SUMMARY AND CONCLUSION

Review of the available data for this cumulative PM experience, confirms a favorable benefit: risk balance for BNT162b2.

Pfizer will continue routine pharmacovigilance activities on behalf of BioNTech according to the Pharmacovigilance Agreement in place, in order to assure patient safety and will inform the Agency if an evaluation of the safety data yields significant new information for BNT162b2.

## APPENDIX 1. LIST OF ADVERSE EVENTS OF SPECIAL INTEREST

1p36 deletion syndrome;2-Hydroxyglutaric aciduria;5'nucleotidase increased;Acoustic neuritis;Acquired C1 inhibitor deficiency;Acquired epidermolysis bullosa;Acquired epileptic aphasia;Acute cutaneous lupus erythematosus;Acute disseminated encephalomyelitis;Acute encephalitis with refractory, repetitive partial seizures;Acute febrile neutrophilic dermatosis;Acute flaccid myelitis;Acute haemorrhagic leukoencephalitis;Acute haemorrhagic oedema of infancy;Acute kidney injury;Acute macular outer retinopathy;Acute motor axonal neuropathy;Acute motor-sensory axonal neuropathy;Acute myocardial infarction;Acute respiratory distress syndrome;Acute respiratory failure;Addison's disease;Administration site thrombosis;Administration site vasculitis;Adrenal thrombosis;Adverse event following immunisation;Ageusia;Agranulocytosis;Air embolism;Alanine aminotransferase abnormal;Alanine aminotransferase increased;Alcoholic seizure;Allergic bronchopulmonary mycosis;Allergic oedema;Alloimmune hepatitis;Alopecia areata;Alpers disease;Alveolar proteinosis;Ammonia abnormal;Ammonia increased;Amniotic cavity infection;Amygdalohippocampectomy;Amyloid arthropathy;Amyloidosis;Amyloidosis senile;Anaphylactic reaction;Anaphylactic shock;Anaphylactic transfusion reaction;Anaphylactoid reaction;Anaphylactoid shock;Anaphylactoid syndrome of pregnancy;Angioedema;Angiopathic neuropathy;Ankylosing spondylitis;Anosmia;Antiacetylcholine receptor antibody positive;Anti-actin antibody positive;Anti-aquaporin-4 antibody positive;Anti-basal ganglia antibody positive;Anti-cyclic citrullinated peptide antibody positive;Anti-epithelial antibody positive;Anti-erythrocyte antibody positive;Anti-exosome complex antibody positive;Anti-GAD antibody negative;Anti-GAD antibody positive;Anti-ganglioside antibody positive;Antigliadin antibody positive;Anti-glomerular basement membrane antibody positive;Anti-glomerular basement membrane disease;Anti-glycyl-tRNA synthetase antibody positive;Anti-HLA antibody test positive;Anti-IA2 antibody positive;Anti-insulin antibody increased;Anti-insulin antibody positive;Anti-insulin receptor antibody increased;Anti-insulin receptor antibody positive;Anti-interferon antibody negative;Anti-interferon antibody positive;Anti-islet cell antibody positive;Antimitochondrial antibody positive;Anti-muscle specific kinase antibody positive;Anti-myelin-associated glycoprotein antibodies positive;Anti-myelin-associated glycoprotein associated polyneuropathy;Antimyocardial antibody positive;Anti-neuronal antibody positive;Antineutrophil cytoplasmic antibody increased;Antineutrophil cytoplasmic antibody positive;Anti-neutrophil cytoplasmic antibody positive vasculitis;Anti-NMDA antibody positive;Antinuclear antibody increased;Antinuclear antibody positive;Antiphospholipid antibodies positive;Antiphospholipid syndrome;Anti-platelet antibody positive;Anti-prothrombin antibody positive;Antiribosomal P antibody positive;Anti-RNA polymerase III antibody positive;Anti-saccharomyces cerevisiae antibody test positive;Anti-sperm antibody positive;Anti-SRP antibody positive;Antisynthetase syndrome;Anti-thyroid antibody positive;Anti-transglutaminase antibody increased;Anti-VGCC antibody positive;Anti-VGKC antibody positive;Anti-vimentin antibody positive;Antiviral prophylaxis;Antiviral treatment;Anti-zinc transporter 8 antibody positive;Aortic embolus;Aortic thrombosis;Aortitis;Aplasia pure red cell;Aplastic anaemia;Application site thrombosis;Application site vasculitis;Arrhythmia;Arterial bypass occlusion;Arterial bypass thrombosis;Arterial thrombosis;Arteriovenous fistula thrombosis;Arteriovenous graft site stenosis;Arteriovenous graft thrombosis;Arteritis;Arteritis

coronary;Arthralgia;Arthritis;Arthritis enteropathic;Ascites;Aseptic cavernous sinus thrombosis;Aspartate aminotransferase abnormal;Aspartate aminotransferase increased;Aspartate-glutamate-transporter deficiency;AST to platelet ratio index increased;AST/ALT ratio abnormal;Asthma;Asymptomatic COVID-19;Ataxia;Atheroembolism;Atonic seizures;Atrial thrombosis;Atrophic thyroiditis;Atypical benign partial epilepsy;Atypical pneumonia;Aura;Autoantibody positive;Autoimmune anaemia;Autoimmune aplastic anaemia;Autoimmune arthritis;Autoimmune blistering disease;Autoimmune cholangitis;Autoimmune colitis;Autoimmune demyelinating disease;Autoimmune dermatitis;Autoimmune disorder;Autoimmune encephalopathy;Autoimmune endocrine disorder;Autoimmune enteropathy;Autoimmune eye disorder;Autoimmune haemolytic anaemia;Autoimmune heparin-induced thrombocytopenia;Autoimmune hepatitis;Autoimmune hyperlipidaemia;Autoimmune hypothyroidism;Autoimmune inner ear disease;Autoimmune lung disease;Autoimmune lymphoproliferative syndrome;Autoimmune myocarditis;Autoimmune myositis;Autoimmune nephritis;Autoimmune neuropathy;Autoimmune neutropenia;Autoimmune pancreatitis;Autoimmune pancytopenia;Autoimmune pericarditis;Autoimmune retinopathy;Autoimmune thyroid disorder;Autoimmune thyroiditis;Autoimmune uveitis;Autoinflammation with infantile enterocolitis;Autoinflammatory disease;Automatism epileptic;Autonomic nervous system imbalance;Autonomic seizure;Axial spondyloarthritis;Axillary vein thrombosis;Axonal and demyelinating polyneuropathy;Axonal neuropathy;Bacterascites;Baltic myoclonic epilepsy;Band sensation;Basedow's disease;Basilar artery thrombosis;Basophilopenia;B-cell aplasia;Behcet's syndrome;Benign ethnic neutropenia;Benign familial neonatal convulsions;Benign familial pemphigus;Benign rolandic epilepsy;Beta-2 glycoprotein antibody positive;Bickerstaff's encephalitis;Bile output abnormal;Bile output decreased;Biliary ascites;Bilirubin conjugated abnormal;Bilirubin conjugated increased;Bilirubin urine present;Biopsy liver abnormal;Biotinidase deficiency;Birdshot chorioretinopathy;Blood alkaline phosphatase abnormal;Blood alkaline phosphatase increased;Blood bilirubin abnormal;Blood bilirubin increased;Blood bilirubin unconjugated increased;Blood cholinesterase abnormal;Blood cholinesterase decreased;Blood pressure decreased;Blood pressure diastolic decreased;Blood pressure systolic decreased;Blue toe syndrome;Brachiocephalic vein thrombosis;Brain stem embolism;Brain stem thrombosis;Bromosulphthalein test abnormal;Bronchial oedema;Bronchitis;Bronchitis mycoplasmal;Bronchitis viral;Bronchopulmonary aspergillosis allergic;Bronchospasm;Budd-Chiari syndrome;Bulbar palsy;Butterfly rash;C1q nephropathy;Caesarean section;Calcium embolism;Capillaritis;Caplan's syndrome;Cardiac amyloidosis;Cardiac arrest;Cardiac failure;Cardiac failure acute;Cardiac sarcoidosis;Cardiac ventricular thrombosis;Cardiogenic shock;Cardiolipin antibody positive;Cardiopulmonary failure;Cardio-respiratory arrest;Cardio-respiratory distress;Cardiovascular insufficiency;Carotid arterial embolus;Carotid artery thrombosis;Cataplexy;Catheter site thrombosis;Catheter site vasculitis;Cavernous sinus thrombosis;CDKL5 deficiency disorder;CEC syndrome;Cement embolism;Central nervous system lupus;Central nervous system vasculitis;Cerebellar artery thrombosis;Cerebellar embolism;Cerebral amyloid angiopathy;Cerebral arteritis;Cerebral artery embolism;Cerebral artery thrombosis;Cerebral gas embolism;Cerebral microembolism;Cerebral septic infarct;Cerebral thrombosis;Cerebral venous sinus thrombosis;Cerebral venous thrombosis;Cerebrospinal thrombotic

tamponade;Cerebrovascular accident;Change in seizure presentation;Chest discomfort;Child-Pugh-Turcotte score abnormal;Child-Pugh-Turcotte score increased;Chillblains;Choking;Choking sensation;Cholangitis sclerosing;Chronic autoimmune glomerulonephritis;Chronic cutaneous lupus erythematosus;Chronic fatigue syndrome;Chronic gastritis;Chronic inflammatory demyelinating polyradiculoneuropathy;Chronic lymphocytic inflammation with pontine perivascular enhancement responsive to steroids;Chronic recurrent multifocal osteomyelitis;Chronic respiratory failure;Chronic spontaneous urticaria;Circulatory collapse;Circumoral oedema;Circumoral swelling;Clinically isolated syndrome;Clonic convulsion;Coeliac disease;Cogan's syndrome;Cold agglutinins positive;Cold type haemolytic anaemia;Colitis;Colitis erosive;Colitis herpes;Colitis microscopic;Colitis ulcerative;Collagen disorder;Collagen-vascular disease;Complement factor abnormal;Complement factor C1 decreased;Complement factor C2 decreased;Complement factor C3 decreased;Complement factor C4 decreased;Complement factor decreased;Computerised tomogram liver abnormal;Concentric sclerosis;Congenital anomaly;Congenital bilateral perisylvian syndrome;Congenital herpes simplex infection;Congenital myasthenic syndrome;Congenital varicella infection;Congestive hepatopathy;Convulsion in childhood;Convulsions local;Convulsive threshold lowered;Coombs positive haemolytic anaemia;Coronary artery disease;Coronary artery embolism;Coronary artery thrombosis;Coronary bypass thrombosis;Coronavirus infection;Coronavirus test;Coronavirus test negative;Coronavirus test positive;Corpus callosotomy;Cough;Cough variant asthma;COVID-19;COVID-19 immunisation;COVID-19 pneumonia;COVID-19 prophylaxis;COVID-19 treatment;Cranial nerve disorder;Cranial nerve palsies multiple;Cranial nerve paralysis;CREST syndrome;Crohn's disease;Cryofibrinogenaemia;Cryoglobulinaemia;CSF oligoclonal band present;CSWS syndrome;Cutaneous amyloidosis;Cutaneous lupus erythematosus;Cutaneous sarcoidosis;Cutaneous vasculitis;Cyanosis;Cyclic neutropenia;Cystitis interstitial;Cytokine release syndrome;Cytokine storm;De novo purine synthesis inhibitors associated acute inflammatory syndrome;Death neonatal;Deep vein thrombosis;Deep vein thrombosis postoperative;Deficiency of bile secretion;Deja vu;Demyelinating polyneuropathy;Demyelination;Dermatitis;Dermatitis bullous;Dermatitis herpetiformis;Dermatomyositis;Device embolisation;Device related thrombosis;Diabetes mellitus;Diabetic ketoacidosis;Diabetic mastopathy;Dialysis amyloidosis;Dialysis membrane reaction;Diastolic hypotension;Diffuse vasculitis;Digital pitting scar;Disseminated intravascular coagulation;Disseminated intravascular coagulation in newborn;Disseminated neonatal herpes simplex;Disseminated varicella;Disseminated varicella zoster vaccine virus infection;Disseminated varicella zoster virus infection;DNA antibody positive;Double cortex syndrome;Double stranded DNA antibody positive;Dreamy state;Dressler's syndrome;Drop attacks;Drug withdrawal convulsions;Dyspnoea;Early infantile epileptic encephalopathy with burst-suppression;Eclampsia;Eczema herpeticum;Embolia cutis medicamentosa;Embolic cerebellar infarction;Embolic cerebral infarction;Embolic pneumonia;Embolic stroke;Embolism;Embolism arterial;Embolism venous;Encephalitis;Encephalitis allergic;Encephalitis autoimmune;Encephalitis brain stem;Encephalitis haemorrhagic;Encephalitis periaxialis diffusa;Encephalitis post immunisation;Encephalomyelitis;Encephalopathy;Endocrine disorder;Endocrine ophthalmopathy;Endotracheal intubation;Enteritis;Enteritis leukopenic;Enterobacter pneumonia;Enterocolitis;Enteropathic spondylitis;Eosinopenia;Eosinophilic

fasciitis;Eosinophilic granulomatosis with polyangiitis;Eosinophilic oesophagitis;Epidermolysis;Epilepsy;Epilepsy surgery;Epilepsy with myoclonic-atonic seizures;Epileptic aura;Epileptic psychosis;Erythema;Erythema induratum;Erythema multiforme;Erythema nodosum;Evans syndrome;Exanthema subitum;Expanded disability status scale score decreased;Expanded disability status scale score increased;Exposure to communicable disease;Exposure to SARS-CoV-2;Eye oedema;Eye pruritus;Eye swelling;Eyelid oedema;Face oedema;Facial paralysis;Facial paresis;Faciobrachial dystonic seizure;Fat embolism;Febrile convulsion;Febrile infection-related epilepsy syndrome;Febrile neutropenia;Felty's syndrome;Femoral artery embolism;Fibrillary glomerulonephritis;Fibromyalgia;Flushing;Foaming at mouth;Focal cortical resection;Focal dyscognitive seizures;Foetal distress syndrome;Foetal placental thrombosis;Foetor hepaticus;Foreign body embolism;Frontal lobe epilepsy;Fulminant type 1 diabetes mellitus;Galactose elimination capacity test abnormal;Galactose elimination capacity test decreased;Gamma-glutamyltransferase abnormal;Gamma-glutamyltransferase increased;Gastritis herpes;Gastrointestinal amyloidosis;Gelastic seizure;Generalised onset non-motor seizure;Generalised tonic-clonic seizure;Genital herpes;Genital herpes simplex;Genital herpes zoster;Giant cell arteritis;Glomerulonephritis;Glomerulonephritis membranoproliferative;Glomerulonephritis membranous;Glomerulonephritis rapidly progressive;Glossopharyngeal nerve paralysis;Glucose transporter type 1 deficiency syndrome;Glutamate dehydrogenase increased;Glycocholic acid increased;GM2 gangliosidosis;Goodpasture's syndrome;Graft thrombosis;Granulocytopenia;Granulocytopenia neonatal;Granulomatosis with polyangiitis;Granulomatous dermatitis;Grey matter heterotopia;Guanase increased;Guillain-Barre syndrome;Haemolytic anaemia;Haemophagocytic lymphohistiocytosis;Haemorrhage;Haemorrhagic ascites;Haemorrhagic disorder;Haemorrhagic pneumonia;Haemorrhagic varicella syndrome;Haemorrhagic vasculitis;Hantavirus pulmonary infection;Hashimoto's encephalopathy;Hashitoxicosis;Hemimegalencephaly;Henoch-Schonlein purpura;Henoch-Schonlein purpura nephritis;Hepaplastin abnormal;Hepaplastin decreased;Heparin-induced thrombocytopenia;Hepatic amyloidosis;Hepatic artery embolism;Hepatic artery flow decreased;Hepatic artery thrombosis;Hepatic enzyme abnormal;Hepatic enzyme decreased;Hepatic enzyme increased;Hepatic fibrosis marker abnormal;Hepatic fibrosis marker increased;Hepatic function abnormal;Hepatic hydrothorax;Hepatic hypertrophy;Hepatic hypoperfusion;Hepatic lymphocytic infiltration;Hepatic mass;Hepatic pain;Hepatic sequestration;Hepatic vascular resistance increased;Hepatic vascular thrombosis;Hepatic vein embolism;Hepatic vein thrombosis;Hepatic venous pressure gradient abnormal;Hepatic venous pressure gradient increased;Hepatitis;Hepatobiliary scan abnormal;Hepatomegaly;Hepatosplenomegaly;Hereditary angioedema with C1 esterase inhibitor deficiency;Herpes dermatitis;Herpes gestationis;Herpes oesophagitis;Herpes ophthalmic;Herpes pharyngitis;Herpes sepsis;Herpes simplex;Herpes simplex cervicitis;Herpes simplex colitis;Herpes simplex encephalitis;Herpes simplex gastritis;Herpes simplex hepatitis;Herpes simplex meningitis;Herpes simplex meningoencephalitis;Herpes simplex meningomyelitis;Herpes simplex necrotising retinopathy;Herpes simplex oesophagitis;Herpes simplex otitis externa;Herpes simplex pharyngitis;Herpes simplex pneumonia;Herpes simplex reactivation;Herpes simplex sepsis;Herpes simplex viraemia;Herpes simplex virus conjunctivitis neonatal;Herpes simplex visceral;Herpes virus

infection;Herpes zoster;Herpes zoster cutaneous disseminated;Herpes zoster infection neurological;Herpes zoster meningitis;Herpes zoster meningoencephalitis;Herpes zoster meningomyelitis;Herpes zoster meningoradiculitis;Herpes zoster necrotising retinopathy;Herpes zoster oticus;Herpes zoster pharyngitis;Herpes zoster reactivation;Herpetic radiculopathy;Histone antibody positive;Hoigne's syndrome;Human herpesvirus 6 encephalitis;Human herpesvirus 6 infection;Human herpesvirus 6 infection reactivation;Human herpesvirus 7 infection;Human herpesvirus 8 infection;Hyperammonaemia;Hyperbilirubinaemia;Hypercholia;Hypergammaglobulinaemia benign monoclonal;Hyperglycaemic seizure;Hypersensitivity;Hypersensitivity vasculitis;Hyperthyroidism;Hypertransaminasaemia;Hyperventilation;Hypoalbuminaemia;Hypocalcaemic seizure;Hypogammaglobulinaemia;Hypoglossal nerve paralysis;Hypoglossal nerve paresis;Hypoglycaemic seizure;Hyponatraemic seizure;Hypotension;Hypotensive crisis;Hypothenar hammer syndrome;Hypothyroidism;Hypoxia;Idiopathic CD4 lymphocytopenia;Idiopathic generalised epilepsy;Idiopathic interstitial pneumonia;Idiopathic neutropenia;Idiopathic pulmonary fibrosis;IgA nephropathy;IgM nephropathy;IIIrd nerve paralysis;IIIrd nerve paresis;Iliac artery embolism;Immune thrombocytopenia;Immune-mediated adverse reaction;Immune-mediated cholangitis;Immune-mediated cholestasis;Immune-mediated cytopenia;Immune-mediated encephalitis;Immune-mediated encephalopathy;Immune-mediated endocrinopathy;Immune-mediated enterocolitis;Immune-mediated gastritis;Immune-mediated hepatic disorder;Immune-mediated hepatitis;Immune-mediated hyperthyroidism;Immune-mediated hypothyroidism;Immune-mediated myocarditis;Immune-mediated myositis;Immune-mediated nephritis;Immune-mediated neuropathy;Immune-mediated pancreatitis;Immune-mediated pneumonitis;Immune-mediated renal disorder;Immune-mediated thyroiditis;Immune-mediated uveitis;Immunoglobulin G4 related disease;Immunoglobulins abnormal;Implant site thrombosis;Inclusion body myositis;Infantile genetic agranulocytosis;Infantile spasms;Infected vasculitis;Infective thrombosis;Inflammation;Inflammatory bowel disease;Infusion site thrombosis;Infusion site vasculitis;Injection site thrombosis;Injection site urticaria;Injection site vasculitis;Instillation site thrombosis;Insulin autoimmune syndrome;Interstitial granulomatous dermatitis;Interstitial lung disease;Intracardiac mass;Intracardiac thrombus;Intracranial pressure increased;Intrapericardial thrombosis;Intrinsic factor antibody abnormal;Intrinsic factor antibody positive;IPEX syndrome;Irregular breathing;IRVAN syndrome;IVth nerve paralysis;IVth nerve paresis;JC polyomavirus test positive;JC virus CSF test positive;Jeavons syndrome;Jugular vein embolism;Jugular vein thrombosis;Juvenile idiopathic arthritis;Juvenile myoclonic epilepsy;Juvenile polymyositis;Juvenile psoriatic arthritis;Juvenile spondyloarthritis;Kaposi sarcoma inflammatory cytokine syndrome;Kawasaki's disease;Kayser-Fleischer ring;Keratoderma blenorrhagica;Ketosis-prone diabetes mellitus;Kounis syndrome;Lafora's myoclonic epilepsy;Lambl's excrescences;Laryngeal dyspnoea;Laryngeal oedema;Laryngeal rheumatoid arthritis;Laryngospasm;Laryngotracheal oedema;Latent autoimmune diabetes in adults;LE cells present;Lemierre syndrome;Lennox-Gastaut syndrome;Leucine aminopeptidase increased;Leukoencephalomyelitis;Leukoencephalopathy;Leukopenia;Leukopenia neonatal;Lewis-Sumner syndrome;Lhermitte's sign;Lichen planopilaris;Lichen planus;Lichen sclerosus;Limbic encephalitis;Linear IgA disease;Lip oedema;Lip swelling;Liver function test abnormal;Liver function test decreased;Liver function test increased;Liver induration;Liver injury;Liver iron concentration abnormal;Liver iron concentration

increased;Liver opacity;Liver palpable;Liver sarcoidosis;Liver scan abnormal;Liver tenderness;Low birth weight baby;Lower respiratory tract herpes infection;Lower respiratory tract infection;Lower respiratory tract infection viral;Lung abscess;Lupoid hepatic cirrhosis;Lupus cystitis;Lupus encephalitis;Lupus endocarditis;Lupus enteritis;Lupus hepatitis;Lupus myocarditis;Lupus myositis;Lupus nephritis;Lupus pancreatitis;Lupus pleurisy;Lupus pneumonitis;Lupus vasculitis;Lupus-like syndrome;Lymphocytic hypophysitis;Lymphocytopenia neonatal;Lymphopenia;MAGIC syndrome;Magnetic resonance imaging liver abnormal;Magnetic resonance proton density fat fraction measurement;Mahler sign;Manufacturing laboratory analytical testing issue;Manufacturing materials issue;Manufacturing production issue;Marburg's variant multiple sclerosis;Marchiafava-Bignami disease;Marine Lenhart syndrome;Mastocytic enterocolitis;Maternal exposure during pregnancy;Medical device site thrombosis;Medical device site vasculitis;MELAS syndrome;Meningitis;Meningitis aseptic;Meningitis herpes;Meningoencephalitis herpes simplex neonatal;Meningoencephalitis herpetic;Meningomyelitis herpes;MERS-CoV test;MERS-CoV test negative;MERS-CoV test positive;Mesangioproliferative glomerulonephritis;Mesenteric artery embolism;Mesenteric artery thrombosis;Mesenteric vein thrombosis;Metapneumovirus infection;Metastatic cutaneous Crohn's disease;Metastatic pulmonary embolism;Microangiopathy;Microembolism;Microscopic polyangiitis;Middle East respiratory syndrome;Migraine-triggered seizure;Miliary pneumonia;Miller Fisher syndrome;Mitochondrial aspartate aminotransferase increased;Mixed connective tissue disease;Model for end stage liver disease score abnormal;Model for end stage liver disease score increased;Molar ratio of total branched-chain amino acid to tyrosine;Molybdenum cofactor deficiency;Monocytopenia;Mononeuritis;Mononeuropathy multiplex;Morphoea;Morvan syndrome;Mouth swelling;Moyamoya disease;Multifocal motor neuropathy;Multiple organ dysfunction syndrome;Multiple sclerosis;Multiple sclerosis relapse;Multiple sclerosis relapse prophylaxis;Multiple subpial transection;Multisystem inflammatory syndrome in children;Muscular sarcoidosis;Myasthenia gravis;Myasthenia gravis crisis;Myasthenia gravis neonatal;Myasthenic syndrome;Myelitis;Myelitis transverse;Myocardial infarction;Myocarditis;Myocarditis post infection;Myoclonic epilepsy;Myoclonic epilepsy and ragged-red fibres;Myokymia;Myositis;Narcolepsy;Nasal herpes;Nasal obstruction;Necrotising herpetic retinopathy;Neonatal Crohn's disease;Neonatal epileptic seizure;Neonatal lupus erythematosus;Neonatal mucocutaneous herpes simplex;Neonatal pneumonia;Neonatal seizure;Nephritis;Nephrogenic systemic fibrosis;Neuralgic amyotrophy;Neuritis;Neuritis cranial;Neuromyelitis optica pseudo relapse;Neuromyelitis optica spectrum disorder;Neuromyotonia;Neuronal neuropathy;Neuropathy peripheral;Neuropathy, ataxia, retinitis pigmentosa syndrome;Neuropsychiatric lupus;Neurosarcoidosis;Neutropenia;Neutropenia neonatal;Neutropenic colitis;Neutropenic infection;Neutropenic sepsis;Nodular rash;Nodular vasculitis;Noninfectious myelitis;Noninfective encephalitis;Noninfective encephalomyelitis;Noninfective oophoritis;Obstetrical pulmonary embolism;Occupational exposure to communicable disease;Occupational exposure to SARS-CoV-2;Ocular hyperaemia;Ocular myasthenia;Ocular pemphigoid;Ocular sarcoidosis;Ocular vasculitis;Oculofacial paralysis;Oedema;Oedema blister;Oedema due to hepatic disease;Oedema mouth;Oesophageal achalasia;Ophthalmic artery thrombosis;Ophthalmic herpes simplex;Ophthalmic herpes zoster;Ophthalmic vein thrombosis;Optic neuritis;Optic

neuropathy;Optic perineuritis;Oral herpes;Oral lichen planus;Oropharyngeal oedema;Oropharyngeal spasm;Oropharyngeal swelling;Osmotic demyelination syndrome;Ovarian vein thrombosis;Overlap syndrome;Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection;Paget-Schroetter syndrome;Palindromic rheumatism;Palisaded neutrophilic granulomatous dermatitis;Palmoplantar keratoderma;Palpable purpura;Pancreatitis;Panencephalitis;Papillophlebitis;Paracancerous pneumonia;Paradoxical embolism;Parainfluenzae viral laryngotracheobronchitis;Paraneoplastic dermatomyositis;Paraneoplastic pemphigus;Paraneoplastic thrombosis;Paresis cranial nerve;Parietal cell antibody positive;Paroxysmal nocturnal haemoglobinuria;Partial seizures;Partial seizures with secondary generalisation;Patient isolation;Pelvic venous thrombosis;Pemphigoid;Pemphigus;Penile vein thrombosis;Pericarditis;Pericarditis lupus;Perihepatic discomfort;Periorbital oedema;Periorbital swelling;Peripheral artery thrombosis;Peripheral embolism;Peripheral ischaemia;Peripheral vein thrombus extension;Periportal oedema;Peritoneal fluid protein abnormal;Peritoneal fluid protein decreased;Peritoneal fluid protein increased;Peritonitis lupus;Pernicious anaemia;Petit mal epilepsy;Pharyngeal oedema;Pharyngeal swelling;Pityriasis lichenoides et varioliformis acuta;Placenta praevia;Pleuroparenchymal fibroelastosis;Pneumobilia;Pneumonia;Pneumonia adenoviral;Pneumonia cytomegaloviral;Pneumonia herpes viral;Pneumonia influenzal;Pneumonia measles;Pneumonia mycoplasmal;Pneumonia necrotising;Pneumonia parainfluenzae viral;Pneumonia respiratory syncytial viral;Pneumonia viral;POEMS syndrome;Polyarteritis nodosa;Polyarthritis;Polychondritis;Polyglandular autoimmune syndrome type I;Polyglandular autoimmune syndrome type II;Polyglandular autoimmune syndrome type III;Polyglandular disorder;Polymicrogyria;Polymyalgia rheumatica;Polymyositis;Polyneuropathy;Polyneuropathy idiopathic progressive;Portal pyaemia;Portal vein embolism;Portal vein flow decreased;Portal vein pressure increased;Portal vein thrombosis;Portosplenomesenteric venous thrombosis;Post procedural hypotension;Post procedural pneumonia;Post procedural pulmonary embolism;Post stroke epilepsy;Post stroke seizure;Post thrombotic retinopathy;Post thrombotic syndrome;Post viral fatigue syndrome;Postictal headache;Postictal paralysis;Postictal psychosis;Postictal state;Postoperative respiratory distress;Postoperative respiratory failure;Postoperative thrombosis;Postpartum thrombosis;Postpartum venous thrombosis;Postpericardiotomy syndrome;Post-traumatic epilepsy;Postural orthostatic tachycardia syndrome;Precerebral artery thrombosis;Pre-eclampsia;Preictal state;Premature labour;Premature menopause;Primary amyloidosis;Primary biliary cholangitis;Primary progressive multiple sclerosis;Procedural shock;Proctitis herpes;Proctitis ulcerative;Product availability issue;Product distribution issue;Product supply issue;Progressive facial hemiatrophy;Progressive multifocal leukoencephalopathy;Progressive multiple sclerosis;Progressive relapsing multiple sclerosis;Prosthetic cardiac valve thrombosis;Pruritus;Pruritus allergic;Pseudovasculitis;Psoriasis;Psoriatic arthropathy;Pulmonary amyloidosis;Pulmonary artery thrombosis;Pulmonary embolism;Pulmonary fibrosis;Pulmonary haemorrhage;Pulmonary microemboli;Pulmonary oil microembolism;Pulmonary renal syndrome;Pulmonary sarcoidosis;Pulmonary sepsis;Pulmonary thrombosis;Pulmonary tumour thrombotic microangiopathy;Pulmonary vasculitis;Pulmonary veno-occlusive disease;Pulmonary venous thrombosis;Pyoderma gangrenosum;Pyostomatitis vegetans;Pyrexia;Quarantine;Radiation leukopenia;Radiculitis

brachial;Radiologically isolated syndrome;Rash;Rash erythematous;Rash pruritic;Rasmussen encephalitis;Raynaud's phenomenon;Reactive capillary endothelial proliferation;Relapsing multiple sclerosis;Relapsing-remitting multiple sclerosis;Renal amyloidosis;Renal arteritis;Renal artery thrombosis;Renal embolism;Renal failure;Renal vascular thrombosis;Renal vasculitis;Renal vein embolism;Renal vein thrombosis;Respiratory arrest;Respiratory disorder;Respiratory distress;Respiratory failure;Respiratory paralysis;Respiratory syncytial virus bronchiolitis;Respiratory syncytial virus bronchitis;Retinal artery embolism;Retinal artery occlusion;Retinal artery thrombosis;Retinal vascular thrombosis;Retinal vasculitis;Retinal vein occlusion;Retinal vein thrombosis;Retinol binding protein decreased;Retinopathy;Retrograde portal vein flow;Retroperitoneal fibrosis;Reversible airways obstruction;Reynold's syndrome;Rheumatic brain disease;Rheumatic disorder;Rheumatoid arthritis;Rheumatoid factor increased;Rheumatoid factor positive;Rheumatoid factor quantitative increased;Rheumatoid lung;Rheumatoid neutrophilic dermatosis;Rheumatoid nodule;Rheumatoid nodule removal;Rheumatoid scleritis;Rheumatoid vasculitis;Saccadic eye movement;SAPHO syndrome;Sarcoidosis;SARS-CoV-1 test;SARS-CoV-1 test negative;SARS-CoV-1 test positive;SARS-CoV-2 antibody test;SARS-CoV-2 antibody test negative;SARS-CoV-2 antibody test positive;SARS-CoV-2 carrier;SARS-CoV-2 sepsis;SARS-CoV-2 test;SARS-CoV-2 test false negative;SARS-CoV-2 test false positive;SARS-CoV-2 test negative;SARS-CoV-2 test positive;SARS-CoV-2 viraemia;Satoyoshi syndrome;Schizencephaly;Scleritis;Sclerodactylia;Scleroderma;Scleroderma associated digital ulcer;Scleroderma renal crisis;Scleroderma-like reaction;Secondary amyloidosis;Secondary cerebellar degeneration;Secondary progressive multiple sclerosis;Segmented hyalinising vasculitis;Seizure;Seizure anoxic;Seizure cluster;Seizure like phenomena;Seizure prophylaxis;Sensation of foreign body;Septic embolus;Septic pulmonary embolism;Severe acute respiratory syndrome;Severe myoclonic epilepsy of infancy;Shock;Shock symptom;Shrinking lung syndrome;Shunt thrombosis;Silent thyroiditis;Simple partial seizures;Sjogren's syndrome;Skin swelling;SLE arthritis;Smooth muscle antibody positive;Sneezing;Spinal artery embolism;Spinal artery thrombosis;Splenic artery thrombosis;Splenic embolism;Splenic thrombosis;Splenic vein thrombosis;Spondylitis;Spondyloarthropathy;Spontaneous heparin-induced thrombocytopenia syndrome;Status epilepticus;Stevens-Johnson syndrome;Stiff leg syndrome;Stiff person syndrome;Stillbirth;Still's disease;Stoma site thrombosis;Stoma site vasculitis;Stress cardiomyopathy;Stridor;Subacute cutaneous lupus erythematosus;Subacute endocarditis;Subacute inflammatory demyelinating polyneuropathy;Subclavian artery embolism;Subclavian artery thrombosis;Subclavian vein thrombosis;Sudden unexplained death in epilepsy;Superior sagittal sinus thrombosis;Susac's syndrome;Suspected COVID-19;Swelling;Swelling face;Swelling of eyelid;Swollen tongue;Sympathetic ophthalmia;Systemic lupus erythematosus;Systemic lupus erythematosus disease activity index abnormal;Systemic lupus erythematosus disease activity index decreased;Systemic lupus erythematosus disease activity index increased;Systemic lupus erythematosus rash;Systemic scleroderma;Systemic sclerosis pulmonary;Tachycardia;Tachypnoea;Takayasu's arteritis;Temporal lobe epilepsy;Terminal ileitis;Testicular autoimmunity;Throat tightness;Thromboangiitis obliterans;Thrombocytopenia;Thrombocytopenic purpura;Thrombophlebitis;Thrombophlebitis migrans;Thrombophlebitis

neonatal;Thrombophlebitis septic;Thrombophlebitis superficial;Thromboplastin antibody positive;Thrombosis;Thrombosis corpora cavernosa;Thrombosis in device;Thrombosis mesenteric vessel;Thrombotic cerebral infarction;Thrombotic microangiopathy;Thrombotic stroke;Thrombotic thrombocytopenic purpura;Thyroid disorder;Thyroid stimulating immunoglobulin increased;Thyroiditis;Tongue amyloidosis;Tongue biting;Tongue oedema;Tonic clonic movements;Tonic convulsion;Tonic posturing;Topectomy;Total bile acids increased;Toxic epidermal necrolysis;Toxic leukoencephalopathy;Toxic oil syndrome;Tracheal obstruction;Tracheal oedema;Tracheobronchitis;Tracheobronchitis mycoplasmal;Tracheobronchitis viral;Transaminases abnormal;Transaminases increased;Transfusion-related alloimmune neutropenia;Transient epileptic amnesia;Transverse sinus thrombosis;Trigeminal nerve paresis;Trigeminal neuralgia;Trigeminal palsy;Truncus coeliacus thrombosis;Tuberous sclerosis complex;Tubulointerstitial nephritis and uveitis syndrome;Tumefactive multiple sclerosis;Tumour embolism;Tumour thrombosis;Type 1 diabetes mellitus;Type I hypersensitivity;Type III immune complex mediated reaction;Uhthoff's phenomenon;Ulcerative keratitis;Ultrasound liver abnormal;Umbilical cord thrombosis;Uncinate fits;Undifferentiated connective tissue disease;Upper airway obstruction;Urine bilirubin increased;Urobilinogen urine decreased;Urobilinogen urine increased;Urticaria;Urticaria papular;Urticarial vasculitis;Uterine rupture;Uveitis;Vaccination site thrombosis;Vaccination site vasculitis;Vagus nerve paralysis;Varicella;Varicella keratitis;Varicella post vaccine;Varicella zoster gastritis;Varicella zoster oesophagitis;Varicella zoster pneumonia;Varicella zoster sepsis;Varicella zoster virus infection;Vasa praevia;Vascular graft thrombosis;Vascular pseudoaneurysm thrombosis;Vascular purpura;Vascular stent thrombosis;Vasculitic rash;Vasculitic ulcer;Vasculitis;Vasculitis gastrointestinal;Vasculitis necrotising;Vena cava embolism;Vena cava thrombosis;Venous intravasation;Venous recanalisation;Venous thrombosis;Venous thrombosis in pregnancy;Venous thrombosis limb;Venous thrombosis neonatal;Vertebral artery thrombosis;Vessel puncture site thrombosis;Visceral venous thrombosis;VIth nerve paralysis;VIth nerve paresis;Vitiligo;Vocal cord paralysis;Vocal cord paresis;Vogt-Koyanagi-Harada disease;Warm type haemolytic anaemia;Wheezing;White nipple sign;XIth nerve paralysis;X-ray hepatobiliary abnormal;Young's syndrome;Zika virus associated Guillain Barre syndrome.

# 5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021



**Report Prepared by:**

**Worldwide Safety**

**Pfizer**

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## LIST OF ABBREVIATIONS

| Acronym | Term |
|---|---|
| AE | adverse event |
| AESI | adverse event of special interest |
| BC | Brighton Collaboration |
| CDC | Centers for Disease Control and Prevention |
| COVID-19 | coronavirus disease 2019 |
| DLP | data lock point |
| EUA | emergency use authorisation |
| HLGT | (MedDRA) High Group Level Term |
| HLT | (MedDRA) High Level Term |
| MAH | marketing authorisation holder |
| MedDRA | medical dictionary for regulatory activities |
| MHRA | Medicines and Healthcare products Regulatory Agency |
| PCR | Polymerase Chain Reaction |
| PT | (MedDRA) Preferred Term |
| PVP | pharmacovigilance plan |
| RT-PCR | Reverse Transcription-Polymerase Chain Reaction |
| RSI | reference safety information |
| TME | targeted medically event |
| SARS-CoV-2 | severe acute respiratory syndrome coronavirus 2 |
| SMQ | standardised MedDRA query |
| SOC | (MedDRA) System Organ Class |
| UK | United Kingdom |
| US | United States |
| VAED | vaccine-associated enhanced disease |
| VAERD | vaccine-associated enhanced respiratory disease |
| VAERS | vaccine adverse event reporting system |

## 1. INTRODUCTION

Reference is made to the Request for Comments and Advice submitted 04 February 2021 regarding Pfizer/BioNTech's proposal for the clinical and post-authorization safety data package for the Biologics License Application (BLA) for our investigational COVID-19 Vaccine (BNT162b2). Further reference is made to the Agency's 09 March 2021 response to this request, and specifically, the following request from the Agency.

*"Monthly safety reports primarily focus on events that occurred during the reporting interval and include information not relevant to a BLA submission such as line lists of adverse events by country. We are most interested in a cumulative analysis of post-authorization safety data to support your future BLA submission. Please submit an integrated analysis of your cumulative post-authorization safety data, including U.S. and foreign post-authorization experience, in your upcoming BLA submission. Please include a cumulative analysis of the Important Identified Risks, Important Potential Risks, and areas of Important Missing Information identified in your Pharmacovigilance Plan, as well as adverse events of special interest and vaccine administration errors (whether or not associated with an adverse event). Please also include distribution data and an analysis of the most common adverse events. In addition, please submit your updated Pharmacovigilance Plan with your BLA submission."*

This document provides an integrated analysis of the cumulative post-authorization safety data, including U.S. and foreign post-authorization adverse event reports received through 28 February 2021.

## 2. METHODOLOGY

Pfizer is responsible for the management post-authorization safety data on behalf of the MAH BioNTech according to the Pharmacovigilance Agreement in place. Data from BioNTech are included in the report when applicable.

Pfizer's safety database contains cases of AEs reported spontaneously to Pfizer, cases reported by the health authorities, cases published in the medical literature, cases from Pfizer-sponsored marketing programs, non-interventional studies, and cases of serious AEs reported from clinical studies regardless of causality assessment.

The limitations of post-marketing adverse drug event reporting should be considered when interpreting these data:

- Reports are submitted voluntarily, and the magnitude of underreporting is unknown. Some of the factors that may influence whether an event is reported include: length of time since marketing, market share of the drug, publicity about a drug or an AE, seriousness of the reaction, regulatory actions, awareness by health professionals and consumers of adverse drug event reporting, and litigation.

- Because many external factors influence whether or not an AE is reported, the spontaneous reporting system yields reporting proportions not incidence rates. As a result, it is generally not appropriate to make between-drug comparisons using these

proportions; the spontaneous reporting system should be used for signal detection rather than hypothesis testing.

- In some reports, clinical information (such as medical history, validation of diagnosis, time from drug use to onset of illness, dose, and use of concomitant drugs) is missing or incomplete, and follow-up information may not be available.

- An accumulation of adverse event reports (AERs) does not necessarily indicate that a particular AE was caused by the drug; rather, the event may be due to an underlying disease or some other factor(s) such as past medical history or concomitant medication.

- Among adverse event reports received into the Pfizer safety database during the cumulative period, only those having a complete workflow cycle in the safety database (meaning they progressed to Distribution or Closed workflow status) are included in the monthly SMSR. This approach prevents the inclusion of cases that are not fully processed hence not accurately reflecting final information. Due to the large numbers of spontaneous adverse event reports received for the product, the MAH has prioritised the processing of serious cases, in order to meet expedited regulatory reporting timelines and ensure these reports are available for signal detection and evaluation activity. The increased volume of reports has not impacted case processing for serious reports, and compliance metrics continue to be monitored weekly with prompt action taken as needed to maintain compliance with expedited reporting obligations. Non-serious cases are entered into the safety database no later than 4 calendar days from receipt. Entrance into the database includes the coding of all adverse events; this allow for a manual review of events being received but may not include immediate case processing to completion. Non-serious cases are processed as soon as possible and no later than 90 days from receipt. Pfizer has also taken a multiple actions to help alleviate the large increase of adverse event reports. This includes significant technology enhancements, and process and workflow solutions, as well as increasing the number of data entry and case processing colleagues. To date, Pfizer has onboarded approximately (b) (4) additional full-time employees (FTEs). More are joining each month with an expected total of more than (b) (4) additional resources by the end of June 2021.

## 3. RESULTS

### 3.1. Safety Database

#### 3.1.1. General Overview

It is estimated that approximately (b) (4) doses of BNT162b2 were shipped worldwide from the receipt of the first temporary authorisation for emergency supply on 01 December 2020 through 28 February 2021.

Cumulatively, through 28 February 2021, there was a total of 42,086 case reports (25,379 medically confirmed and 16,707 non-medically confirmed) containing 158,893 events. Most cases (34,762) were received from United States (13,739), United Kingdom (13,404) Italy (2,578), Germany (1913), France (1506), Portugal (866) and Spain (756); the remaining 7,324 were distributed among 56 other countries.

Table 1 below presents the main characteristics of the overall cases.

**Table 1. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval**

| Characteristics | | Relevant cases (N=42086) |
|---|---|---|
| Gender: | Female | 29914 |
| | Male | 9182 |
| | No Data | 2990 |
| Age range (years):<br>0.01 -107 years<br>Mean = 50.9 years<br>n = 34952 | ≤ 17<br>18-30<br>31-50<br>51-64<br>65-74<br>≥ 75<br>Unknown | 175[a]<br>4953<br>13886<br>7884<br>3098<br>5214<br>6876 |
| Case outcome: | Recovered/Recovering | 19582 |
| | Recovered with sequelae | 520 |
| | Not recovered at the time of report | 11361 |
| | Fatal | 1223 |
| | Unknown | 9400 |

a. in 46 cases reported age was <16-year-old and in 34 cases <12-year-old.

As shown in Figure 1, the System Organ Classes (SOCs) that contained the greatest number (≥2%) of events, in the overall dataset, were General disorders and administration site conditions (51,335 AEs), Nervous system disorders (25,957), Musculoskeletal and connective tissue disorders (17,283), Gastrointestinal disorders (14,096), Skin and subcutaneous tissue disorders (8,476), Respiratory, thoracic and mediastinal disorders (8,848), Infections and infestations (4,610), Injury, poisoning and procedural complications (5,590), and Investigations (3,693).

**Figure 1. Total Number of BNT162b2 AEs by System Organ Classes and Event Seriousness**

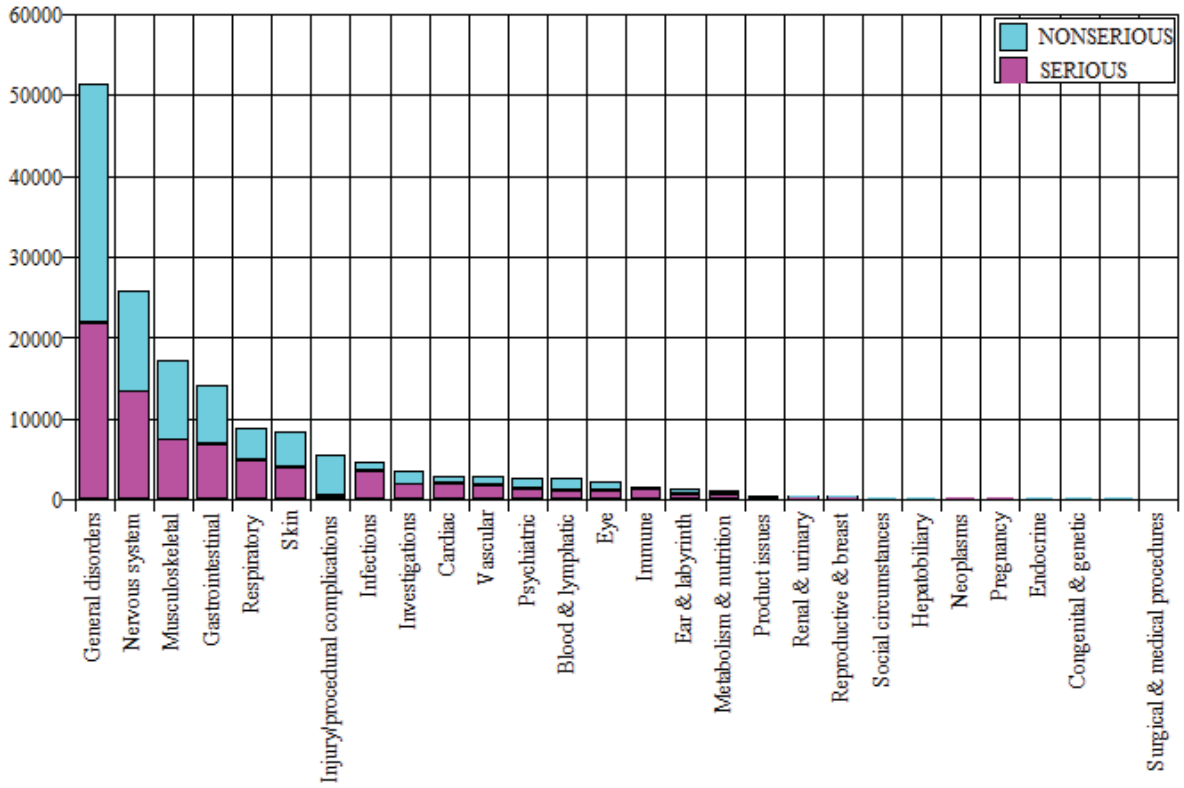


Table 2 shows the most commonly (≥2%) reported MedDRA (v. 23.1) PTs in the overall dataset (through 28 February 2021),

**Table 2. Events Reported in ≥2% Cases**

| | | Cumulatively Through 28 February 2021 |
|---|---|---|
| **MedDRA SOC** | **MedDRA PT** | **AEs (AERP%) N = 42086** |
| **Blood and lymphatic system disorders** | | |
| | Lymphadenopathy | 1972 (4.7%) |
| **Cardiac disorders** | | |
| | Tachycardia | 1098 (2.6%) |
| **Gastrointestinal disorders** | | |
| | Nausea | 5182 (12.3%) |
| | Diarrhoea | 1880 (4.5%) |
| | Vomiting | 1698 (4.0%) |
| **General disorders and administration site conditions** | | |
| | Pyrexia | 7666 (18.2%) |
| | Fatigue | 7338 (17.4%) |
| | Chills | 5514 (13.1%) |
| | Vaccination site pain | 5181 (12.3%) |

## Table 2. Events Reported in ≥2% Cases

| | | Cumulatively Through 28 February 2021 |
|---|---|---|
| **MedDRA SOC** | **MedDRA PT** | **AEs (AERP%) N = 42086** |
| | Pain | 3691 (8.8%) |
| | Malaise | 2897 (6.9%) |
| | Asthenia | 2285 (5.4%) |
| | Drug ineffective | 2201 (5.2%) |
| | Vaccination site erythema | 930 (2.2%) |
| | Vaccination site swelling | 913 (2.2%) |
| | Influenza like illness | 835 (2%) |
| **Infections and infestations** | | |
| | COVID-19 | 1927 (4.6%) |
| **Injury, poisoning and procedural complications** | | |
| | Off label use | 880 (2.1%) |
| | Product use issue | 828 (2.0%) |
| **Musculoskeletal and connective tissue disorders** | | |
| | Myalgia | 4915 (11.7%) |
| | Pain in extremity | 3959 (9.4%) |
| | Arthralgia | 3525 (8.4%) |
| **Nervous system disorders** | | |
| | Headache | 10131 (24.1%) |
| | Dizziness | 3720 (8.8%) |
| | Paraesthesia | 1500 (3.6%) |
| | Hypoaesthesia | 999 (2.4%) |
| **Respiratory, thoracic and mediastinal disorders** | | |
| | Dyspnoea | 2057 (4.9%) |
| | Cough | 1146 (2.7%) |
| | Oropharyngeal pain | 948 (2.3%) |
| **Skin and subcutaneous tissue disorders** | | |
| | Pruritus | 1447 (3.4%) |
| | Rash | 1404 (3.3%) |
| | Erythema | 1044 (2.5%) |
| | Hyperhidrosis | 900 (2.1%) |
| | Urticaria | 862 (2.1%) |
| **Total number of events** | | **93473** |

## 3.1.2. Summary of Safety Concerns in the US Pharmacovigilance Plan

## Table 3. Safety concerns

| | |
|---|---|
| **Important identified risks** | Anaphylaxis |
| **Important potential risks** | Vaccine-Associated Enhanced Disease (VAED), Including Vaccine-associated Enhanced Respiratory Disease (VAERD) |
| **Missing information** | Use in Pregnancy and lactation<br>Use in Paediatric Individuals <12 Years of Age<br>Vaccine Effectiveness |

## Table 4. Important Identified Risk

<table>
<tr><th>Topic</th><th>Description</th></tr>
<tr><td>Important Identified Risk</td><td>Post Authorization Cases Evaluation (cumulative to 28 Feb 2021)<br>Total Number of Cases in the Reporting Period (N=42086)</td></tr>
<tr><td>Anaphylaxis</td><td>Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021, 1833 potentially relevant cases were retrieved from the Anaphylactic reaction SMQ (Narrow and Broad) search strategy, applying the MedDRA algorithm. These cases were individually reviewed and assessed according to Brighton Collaboration (BC) definition and level of diagnostic certainty as shown in the Table below:<br><br>
<table>
<tr><td>Brighton Collaboration Level</td><td>Number of cases</td></tr>
<tr><td>BC 1</td><td>290</td></tr>
<tr><td>BC 2</td><td>311</td></tr>
<tr><td>BC 3</td><td>10</td></tr>
<tr><td>BC 4</td><td>391</td></tr>
<tr><td>BC 5</td><td>831</td></tr>
<tr><td>Total</td><td>1833</td></tr>
</table>
Level 1 indicates a case with the highest level of diagnostic certainty of anaphylaxis, whereas the diagnostic certainty is lowest for Level 3. Level 4 is defined as “reported event of anaphylaxis with insufficient evidence to meet the case definition” and Level 5 as not a case of anaphylaxis.<br><br>
There were 1002 cases (54.0% of the potentially relevant cases retrieved), 2958 potentially relevant events, from the Anaphylactic reaction SMQ (Broad and Narrow) search strategy, meeting BC Level 1 to 4:<br><br>
Country of incidence: UK (261), US (184), Mexico (99), Italy (82), Germany (67), Spain (38), France (36), Portugal (22), Denmark (20), Finland, Greece (19 each), Sweden (17), Czech Republic , Netherlands (16 each), Belgium, Ireland (13 each), Poland (12), Austria (11); the remaining 57 cases originated from 15 different countries.<br>
Relevant event seriousness: Serious (2341), Non-Serious (617);<br>
Gender: Females (876), Males (106), Unknown (20);<br>
Age (n=961) ranged from 16 to 98 years (mean = 54.8 years, median = 42.5 years);<br>
Relevant even outcome[a]: fatal (9)[b], resolved/resolving (1922), not resolved (229), resolved with sequelae (48), unknown (754);<br>
Most frequently reported relevant PTs (≥2%), from the Anaphylactic reaction SMQ (Broad and Narrow) search strategy: Anaphylactic reaction (435), Dyspnoea (356), Rash (190), Pruritus (175), Erythema (159), Urticaria (133), Cough (115), Respiratory distress, Throat tightness (97 each), Swollen tongue (93), Anaphylactic shock (80), Hypotension (72), Chest discomfort (71), Swelling face (70), Pharyngeal swelling (68), and Lip swelling (64).<br><br>
Conclusion: Evaluation of BC cases Level 1 - 4 did not reveal any significant new safety information. Anaphylaxis is appropriately described in the product labeling as are non-anaphylactic hypersensitivity events. Surveillance will continue.</td></tr>
</table>

a Different clinical outcome may be reported for an event that occurred more than once to the same individual.
b There were 4 individuals in the anaphylaxis evaluation who died on the same day they were vaccinated. Although these patients experienced adverse events (9) that are potential symptoms of anaphylaxis, they all had serious underlying medical conditions, and one individual appeared to also have COVID-19 pneumonia, that likely contributed to their deaths

## Table 5. Important Potential Risk

| Topic | Description |
|---|---|
| **Important Potential Risk** | **Post Authorization Cases Evaluation (cumulative to 28 Feb 2021)<br>Total Number of Cases in the Reporting Period (N=42086)** |
| Vaccine-Associated Enhanced Disease (VAED), including Vaccine-Associated Enhanced Respiratory Disease (VAERD) | No post-authorized AE reports have been identified as cases of VAED/VAERD, therefore, there is no observed data at this time. An expected rate of VAED is difficult to establish so a meaningful observed/expected analysis cannot be conducted at this point based on available data. The feasibility of conducting such an analysis will be re-evaluated on an ongoing basis as data on the virus grows and the vaccine safety data continues to accrue.<br><br>The search criteria utilised to identify potential cases of VAED for this report includes PTs indicating a lack of effect of the vaccine and PTs potentially indicative of severe or atypical COVID-19[a].<br><br>Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021, 138 cases [0.33% of the total PM dataset], reporting 317 potentially relevant events were retrieved:<br><br>Country of incidence: UK (71), US (25), Germany (14), France, Italy, Mexico, Spain, (4 each), Denmark (3); the remaining 9 cases originated from 9 different countries;<br>Cases Seriousness: 138;<br>Seriousness criteria for the total 138 cases: Medically significant (71, of which 8 also serious for disability), Hospitalization required (non-fatal/non-life threatening) (16, of which 1 also serious for disability), Life threatening (13, of which 7 were also serious for hospitalization), Death (38).<br>Gender: Females (73), Males (57), Unknown (8);<br>Age (n=132) ranged from 21 to 100 years (mean = 57.2 years, median = 59.5);<br>Case outcome: fatal (38), resolved/resolving (26), not resolved (65), resolved with sequelae (1), unknown (8);<br>Of the 317 relevant events, the most frequently reported PTs (≥2%) were: Drug ineffective (135), Dyspnoea (53), Diarrhoea (30), COVID-19 pneumonia (23), Vomiting (20), Respiratory failure (8), and Seizure (7).<br><br>Conclusion: VAED may present as severe or unusual clinical manifestations of COVID-19. Overall, there were 37 subjects with suspected COVID-19 and 101 subjects with confirmed COVID-19 following one or both doses of the vaccine; 75 of the 101 cases were severe, resulting in hospitalisation, disability, life-threatening consequences or death. None of the 75 cases could be definitively considered as VAED/VAERD.<br>In this review of subjects with COVID-19 following vaccination, based on the current evidence, VAED/VAERD remains a theoretical risk for the vaccine. Surveillance will continue. |

a. Search criteria: Standard Decreased Therapeutic Response Search AND PTs Dyspnoea; Tachypnoea; Hypoxia; COVID 19 pneumonia; Respiratory Failure; Acute Respiratory Distress Syndrome; Cardiac Failure; Cardiogenic shock; Acute myocardial infarction; Arrhythmia; Myocarditis; Vomiting; Diarrhoea; Abdominal pain; Jaundice; Acute hepatic failure; Deep vein thrombosis; Pulmonary embolism; Peripheral Ischaemia; Vasculitis; Shock; Acute kidney injury; Renal failure; Altered state of consciousness; Seizure; Encephalopathy; Meningitis; Cerebrovascular accident; Thrombocytopenia; Disseminated intravascular coagulation; Chillblains; Erythema multiforme; Multiple organ dysfunction syndrome; Multisystem inflammatory syndrome in children.

## Table 6. Description of Missing Information

| Topic | Description |
|---|---|
| **Missing Information** | **Post Authorization Cases Evaluation (cumulative to 28 Feb 2021)<br>Total Number of Cases in the Reporting Period (N=42086)** |
| Use in Pregnancy and lactation | • Number of cases: 413[a] (0.98% of the total PM dataset); 84 serious and 329 non-serious;<br>• Country of incidence: US (205), UK (64), Canada (31), Germany (30), Poland (13), Israel (11); Italy (9), Portugal (8), Mexico (6), Estonia, Hungary and Ireland, (5 each), Romania (4), Spain (3), Czech Republic and France (2 each), the remaining 10 cases were distributed among 10 other countries.<br><br>Pregnancy cases: 274 cases including:<br><br>• 270 mother cases and 4 foetus/baby cases representing 270 unique pregnancies (the 4 foetus/baby cases were linked to 3 mother cases; 1 mother case involved twins).<br>• Pregnancy outcomes for the 270 pregnancies were reported as spontaneous abortion (23), outcome pending (5), premature birth with neonatal death, spontaneous abortion with intrauterine death (2 each), spontaneous abortion with neonatal death, and normal outcome (1 each). No outcome was provided for 238 pregnancies (note that 2 different outcomes were reported for each twin, and both were counted).<br><br>• 146 non-serious mother cases reported exposure to vaccine in utero without the occurrence of any clinical adverse event. The exposure PTs coded to the PTs Maternal exposure during pregnancy (111), Exposure during pregnancy (29) and Maternal exposure timing unspecified (6). Trimester of exposure was reported in 21 of these cases: 1st trimester (15 cases), 2nd trimester (7), and 3rd trimester (2).<br>• 124 mother cases, 49 non-serious and 75 serious, reported clinical events, which occurred in the vaccinated mothers. Pregnancy related events reported in these cases coded to the PTs Abortion spontaneous (25), Uterine contraction during pregnancy, Premature rupture of membranes, Abortion, Abortion missed, and Foetal death (1 each). Other clinical events which occurred in more than 5 cases coded to the PTs Headache (33), Vaccination site pain (24), Pain in extremity and Fatigue (22 each), Myalgia and Pyrexia (16 each), Chills (13) Nausea (12), Pain (11), Arthralgia (9), Lymphadenopathy and Drug ineffective (7 each), Chest pain, Dizziness and Asthenia (6 each), Malaise and COVID-19 (5 each). Trimester of exposure was reported in 22 of these cases: 1st trimester (19 cases), 2nd trimester (1 case), 3rd trimester (2 cases).<br>• 4 serious foetus/baby cases reported the PTs Exposure during pregnancy, Foetal growth restriction, Maternal exposure during pregnancy, Premature baby (2 each), and Death neonatal (1). Trimester of exposure was reported for 2 cases (twins) as occurring during the 1st trimester.<br><br>Breast feeding baby cases: 133, of which:<br><br>• 116 cases reported exposure to vaccine during breastfeeding (PT Exposure via breast milk) without the occurrence of any clinical adverse events;<br>• 17 cases, 3 serious and 14 non-serious, reported the following clinical events that occurred in the infant/child exposed to vaccine via breastfeeding: Pyrexia (5), Rash (4), Infant irritability (3), Infantile vomiting, Diarrhoea, Insomnia, and Illness (2 each), Poor feeding infant, Lethargy, Abdominal discomfort, Vomiting, Allergy to vaccine, Increased appetite, Anxiety, Crying, Poor quality sleep, Eructation, Agitation, Pain and Urticaria (1 each).<br><br>Breast feeding mother cases (6):<br>• 1 serious case reported 3 clinical events that occurred in a mother during breast feeding (PT Maternal exposure during breast feeding); these events coded to the PTs Chills, Malaise, and Pyrexia<br>• 1 non-serious case reported with very limited information and without associated AEs. |

## Table 6. Description of Missing Information

| Topic | Description |
|---|---|
| **Missing Information** | **Post Authorization Cases Evaluation (cumulative to 28 Feb 2021)<br>Total Number of Cases in the Reporting Period (N=42086)** |
| | • In 4 cases (3 non-serious; 1 serious) Suppressed lactation occurred in a breast feeding women with the following co-reported events: Pyrexia (2), Paresis, Headache, Chills, Vomiting, Pain in extremity, Arthralgia, Breast pain, Scar pain, Nausea, Migraine, Myalgia, Fatigue and Breast milk discolouration (1 each).<br>Conclusion: There were no safety signals that emerged from the review of these cases of use in pregnancy and while breast feeding. |
| Use in Paediatric Individuals <12 Years of Age | <u>Paediatric individuals <12 years of age</u><br>• Number of cases: 34[d] (0.1% of the total PM dataset), indicative of administration in paediatric subjects <12 years of age;<br>• Country of incidence: UK (29), US (3), Germany and Andorra (1 each);<br>• Cases Seriousness: Serious (24), Non-Serious (10);<br>• Gender: Females (25), Males (7), Unknown (2);<br>• Age (n=34) ranged from 2 months to 9 years, mean = 3.7 years, median = 4.0;<br>• Case outcome: resolved/resolving (16), not resolved (13), and unknown (5).<br>• Of the 132 reported events, those reported more than once were as follows: Product administered to patient of inappropriate age (27, see Medication Error), Off label use (11), Pyrexia (6), Product use issue (5), Fatigue, Headache and Nausea (4 each), Vaccination site pain (3), Abdominal pain upper, COVID-19, Facial paralysis, Lymphadenopathy, Malaise, Pruritus and Swelling (2 each).<br><br>Conclusion: No new significant safety information was identified based on a review of these cases compared with the non-paediatric population. |
| Vaccine Effectiveness | Company conventions for coding cases indicative of lack of efficacy:<br><br>The coding conventions for lack of efficacy in the context of administration of the COVID-19 vaccine were revised on 15 February 2021, as shown below:<br>• PT "Vaccination failure" is coded when ALL of the following criteria are met:<br>o The subject has received the series of two doses per the dosing regimen in local labeling.<br>o At least 7 days have elapsed since the second dose of vaccine has been administered.<br>o The subject experiences SARS-CoV-2 infection (confirmed laboratory tests).<br>• PT "Drug ineffective" is coded when either of the following applies:<br>o The infection is not confirmed as SARS-CoV-2 through laboratory tests (irrespective of the vaccination schedule). This includes scenarios where LOE is stated or implied, e.g., "the vaccine did not work", "I got COVID-19".<br>o It is unknown:<br>▪ Whether the subject has received the series of two doses per the dosing regimen in local labeling;<br>▪ How many days have passed since the first dose (including unspecified number of days like" a few days", "some days", etc.);<br>▪ If 7 days have passed since the second dose;<br>o The subject experiences a vaccine preventable illness 14 days after receiving the first dose up to and through 6 days after receipt of the second dose.<br><br>Note: after the immune system as had sufficient time (14 days) to respond to the vaccine, a report of COVID-19 is considered a potential lack of efficacy even if the vaccination course is not complete.<br><br>Summary of the coding conventions for onset of vaccine preventable disease versus the vaccination date: |

## Table 6. Description of Missing Information

| Topic | Description |
|---|---|
| **Missing Information** | **Post Authorization Cases Evaluation (cumulative to 28 Feb 2021)<br>Total Number of Cases in the Reporting Period (N=42086)** |

| | | |
|---|---|---|
| 1st dose (day 1-13) | From day 14 post 1st dose to day 6 post 2nd dose | Day 7 post 2nd dose |
| Code only the events describing the SARS-CoV-2 infection | Code "Drug ineffective" | Code "Vaccination failure" |
| Scenario Not considered LOE | Scenario considered LOE as "Drug ineffective" | Scenario considered LOE as "Vaccination failure" |

***Lack of efficacy cases***

- Number of cases: 1665[b] (3.9 % of the total PM dataset) of which 1100 were medically confirmed and 565 non medically confirmed;
- Number of lack of efficacy events: 1665 [PT: Drug ineffective (1646) and Vaccination failure (19)[f]].
- Country of incidence: US (665), UK (405), Germany (181), France (85), Italy (58), Romania (47), Belgium (33), Israel (30), Poland (28), Spain (21), Austria (18), Portugal (17), Greece (15), Mexico (13), Denmark (8), Canada (7), Hungary, Sweden and United Arab Emirates (5 each), Czech Republic (4), Switzerland (3); the remaining 12 cases originated from 9 different countries.
- COVID-19 infection was suspected in 155 cases, confirmed in 228 cases, in 1 case it was reported that the first dose was not effective (no other information).
- COVID-19 infection (suspected or confirmed) outcome was reported as resolved/resolving (165), not resolved (205) or unknown (1230) at the time of the reporting; there were 65 cases where a fatal outcome was reported.

***Drug ineffective cases (1649)***

- Drug ineffective event seriousness: serious (1625), non-serious (21)[e];
- Lack of efficacy term was reported:
  - after the 1st dose in 788 cases
  - after the 2nd dose in 139 cases
  - in 722 cases it was unknown after which dose the lack of efficacy occurred.
- Latency of lack of efficacy term reported after the first dose was known for 176 cases:
  - Within 9 days: 2 subjects;
  - Within 14 and 21 days: 154 subjects;
  - Within 22 and 50 days: 20 subjects;
- Latency of lack of efficacy term reported after the second dose was known for 69 cases:
  - Within 0 and 7 days: 42 subjects;
  - Within 8 and 21 days: 22 subjects;
  - Within 23 and 36 days: 5 subjects.
- Latency of lack of efficacy term reported in cases where the number of doses administered was not provided, was known in 409 cases:
  - Within 0 and 7 days after vaccination: 281 subjects.
  - Within 8 and 14 days after vaccination: 89 subjects.
  - Within 15 and 44 days after vaccination: 39 subjects.

According to the RSI, individuals may not be fully protected until 7 days after their second dose of vaccine, therefore for the above 1649 cases where lack of efficacy was reported after the 1st dose or the

## Table 6. Description of Missing Information

| Topic | Description |
|---|---|
| **Missing Information** | **Post Authorization Cases Evaluation (cumulative to 28 Feb 2021)<br>Total Number of Cases in the Reporting Period (N=42086)** |
| | 2nd dose, the reported events may represent signs and symptoms of intercurrent or undiagnosed COVID-19 infection or infection in an individual who was not fully vaccinated, rather than vaccine ineffectiveness.<br><br>***Vaccination failure cases (16)***<br>• Vaccination failure seriousness: all serious;<br>• Lack of efficacy term was reported in all cases after the 2nd dose:<br>• Latency of lack of efficacy was known for 14 cases:<br>o Within 7 and 13 days: 8 subjects;<br>o Within 15 and 29 days: 6 subjects.<br>COVID-19 (10) and Asymptomatic COVID-19 (6) were the reported vaccine preventable infections that occurred in these 16 cases.<br><br>Conclusion: No new safety signals of vaccine lack of efficacy have emerged based on a review of these cases. |

a. From a total of 417 cases, 4 cases were excluded from the analysis. In 3 cases, the MAH was informed that a 33-year-old and two unspecified age pregnant female patients were scheduled to receive bnt162b2 (PT reported Off label use and Product use issue in 2 cases; Circumstance or information capable of leading to medication error in one case). One case reported the PT Morning sickness; however, pregnancy was not confirmed in this case.
b. 558 additional cases retrieved in this dataset were excluded from the analysis; upon review, 546 cases cannot be considered true lack of efficacy cases because the PT Drug ineffective was coded but the subjects developed SARS-CoV-2 infection during the early days from the first dose (days 1 – 13); the vaccine has not had sufficient time to stimulate the immune system and, consequently, the development of a vaccine preventable disease during this time is not considered a potential lack of effect of the vaccine; in 5 cases the PT Drug ineffective was removed after data lock point (DLP) because the subjects did not develop COVID-19 infection; in 1 case, reporting Treatment failure and Transient ischaemic attack, the Lack of efficacy PT did not refer to BNT162b2 vaccine; 5 cases have been invalidated in the safety database after DLP; 1 case has been deleted from the discussion because the PTs reported Pathogen resistance and Product preparation issue were not indicative of a lack of efficacy. to be eliminated.
c. Upon review, 31 additional cases were excluded from the analysis as the data reported (e.g. clinical details, height, weight, etc.) were not consistent with paediatric subjects
d. Upon review, 28 additional cases were excluded from the analysis as the data reported (e.g. clinical details, height, weight, etc.) were not consistent with paediatric subjects.
e. Different clinical outcomes may be reported for an event that occurred more than once to the same individual
f. In 2 cases the PT Vaccination failure was replaced with Drug ineffective after DLP. Another case was not included in the discussion of the Vaccination failure cases because correct scheduling (21 days apart between the first and second dose) cannot be confirmed.

### 3.1.3. Review of Adverse Events of Special Interest (AESIs)

Please refer to Appendix 1 for the list of the company's AESIs for BNT162b2.

The company's AESI list takes into consideration the lists of AESIs from the following expert groups and regulatory authorities: Brighton Collaboration (SPEAC), ACCESS protocol, US CDC (preliminary list of AESI for VAERS surveillance), MHRA (unpublished guideline).

The AESI terms are incorporated into a TME list and include events of interest due to their association with severe COVID-19 and events of interest for vaccines in general.

The AESI list is comprised of MedDRA PTs, HLTs, HLGTs or MedDRA SMQs and can be changed as appropriate based on the evolving safety profile of the vaccine.

Table 7 provides a summary review of cumulative cases within AESI categories in the Pfizer safety database. This is distinct from safety signal evaluations which are conducted and included, as appropriate, in the Summary Monthly Safety Reports submitted regularly to the FDA and other Health Authorities.

**Table 7. AESIs Evaluation for BNT162b2**

| **AESIs**[a]<br>**Category** | **Post-Marketing Cases Evaluation**[b]<br>**Total Number of Cases (N=42086)** |
|---|---|
| **Anaphylactic Reactions**<br>*Search criteria: Anaphylactic reaction SMQ (Narrow and Broad, with the algorithm applied), selecting relevant cases according to BC criteria* | Please refer to the Risk 'Anaphylaxis' included above in Table 4. |
| **Cardiovascular AESIs**<br>*Search criteria: PTs Acute myocardial infarction; Arrhythmia; Cardiac failure; Cardiac failure acute; Cardiogenic shock; Coronary artery disease; Myocardial infarction; Postural orthostatic tachycardia syndrome; Stress cardiomyopathy; Tachycardia* | • Number of cases: 1403 (3.3% of the total PM dataset), of which 241 are medically confirmed and 1162 are non-medically confirmed;<br>• Country of incidence: UK (268), US (233), Mexico (196), Italy (141), France (128), Germany (102), Spain (46), Greece (45), Portugal (37), Sweden (20), Ireland (17), Poland (16), Israel (13), Austria, Romania and Finland (12 each), Netherlands (11), Belgium and Norway (10 each), Czech Republic (9), Hungary and Canada (8 each), Croatia and Denmark (7 each), Iceland (5); the remaining 30 cases were distributed among 13 other countries;<br>• Subjects' gender: female (1076), male (291) and unknown (36);<br>• Subjects' age group (n = 1346): Adult[c] (1078), Elderly[d] (266) Child[e] and Adolescent[f] (1 each);<br>• Number of relevant events: 1441, of which 946 serious, 495 non-serious; in the cases reporting relevant serious events;<br>• Reported relevant PTs: Tachycardia (1098), Arrhythmia (102), Myocardial infarction (89), Cardiac failure (80), Acute myocardial infarction (41), Cardiac failure acute (11), Cardiogenic shock and Postural orthostatic tachycardia syndrome (7 each) and Coronary artery disease (6);<br>• Relevant event onset latency (n = 1209): Range from <24 hours to 21 days, median <24 hours; |

**Table 7. AESIs Evaluation for BNT162b2**

| AESIs[a] Category | Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086) |
|---|---|
| | • Relevant event outcome[g]: fatal (136), resolved/resolving (767), resolved with sequelae (21), not resolved (140) and unknown (380);<br><br>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue |
| **COVID-19 AESIs**<br>*Search criteria: Covid-19 SMQ (Narrow and Broad) OR PTs Ageusia; Anosmia* | • Number of cases: 3067 (7.3% of the total PM dataset), of which 1013 are medically confirmed and 2054 are non-medically confirmed;<br>• Country of incidence: US (1272), UK (609), Germany (360), France (161), Italy (94), Spain (69), Romania (62), Portugal (51), Poland (50), Mexico (43), Belgium (42), Israel (41), Sweden (30), Austria (27), Greece (24), Denmark (18), Czech Republic and Hungary (17 each), Canada (12), Ireland (11), Slovakia (9), Latvia and United Arab Emirates (6 each); the remaining 36 cases were distributed among 16 other different countries;<br>• Subjects' gender: female (1650), male (844) and unknown (573);<br>• Subjects' age group (n= 1880): Adult (1315), Elderly (560), Infant[h] and Adolescent (2 each), Child (1);<br>• Number of relevant events: 3359, of which 2585 serious, 774 non-serious;<br>• Most frequently reported relevant PTs (>1 occurrence): COVID-19 (1927), SARS-CoV-2 test positive (415), Suspected COVID-19 (270), Ageusia (228), Anosmia (194), SARS-CoV-2 antibody test negative (83), Exposure to SARS-CoV-2 (62), SARS-CoV-2 antibody test positive (53), COVID-19 pneumonia (51), Asymptomatic COVID-19 (31), Coronavirus infection (13), Occupational exposure to SARS-CoV-2 (11), SARS-CoV-2 test false positive (7), Coronavirus test positive (6), SARS-CoV-2 test negative (3) SARS-CoV-2 antibody test (2);<br>• Relevant event onset latency (n = 2070): Range from <24 hours to 374 days, median 5 days;<br>• Relevant event outcome: fatal (136), not resolved (547), resolved/resolving (558), resolved with sequelae (9) and unknown (2110).<br><br>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue |
| **Dermatological AESIs**<br>*Search criteria: PT Chillblains; Erythema multiforme* | • Number of cases: 20 cases (0.05% of the total PM dataset), of which 15 are medically confirmed and 5 are non-medically confirmed;<br>• Country of incidence: UK (8), France and Poland (2 each), and the remaining 8 cases were distributed among 8 other different countries;<br>• Subjects' gender: female (17) male and unknown (1 each);<br>• Subjects' age group (n=19): Adult (18), Elderly (1);<br>• Number of relevant events: 20 events, 16 serious, 4 non-serious |

**Table 7. AESIs Evaluation for BNT162b2**

| AESIs[a] Category | Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086) |
|---|---|
| | • Reported relevant PTs: Erythema multiforme (13) and Chillblains (7)<br>• Relevant event onset latency (n = 18): Range from <24 hours to 17 days, median 3 days;<br>• Relevant event outcome: resolved/resolving (7), not resolved (8) and unknown (6).<br><br>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue. |
| **Haematological AESIs**<br>*Search criteria: Leukopenias NEC (HLT) (Primary Path) OR Neutropenias (HLT) (Primary Path) OR PTs Immune thrombocytopenia, Thrombocytopenia OR SMQ Haemorrhage terms (excl laboratory terms* | • Number of cases: 932 (2.2 % of the total PM dataset), of which 524 medically confirmed and 408 non-medically confirmed;<br>• Country of incidence: UK (343), US (308), France (50), Germany (43), Italy (37), Spain (27), Mexico and Poland (13 each), Sweden (10), Israel (9), Netherlands (8), Denmark, Finland, Portugal and Ireland (7 each), Austria and Norway (6 each), Croatia (4), Greece, Belgium, Hungary and Switzerland (3 each), Cyprus, Latvia and Serbia (2 each); the remaining 9 cases originated from 9 different countries;<br>• Subjects' gender (n=898): female (676) and male (222);<br>• Subjects' age group (n=837): Adult (543), Elderly (293), Infant (1);<br>• Number of relevant events: 1080, of which 681 serious, 399 non-serious;<br>• Most frequently reported relevant PTs (≥15 occurrences) include: Epistaxis (127), Contusion (112), Vaccination site bruising (96), Vaccination site haemorrhage (51), Petechiae (50), Haemorrhage (42), Haematochezia (34), Thrombocytopenia (33), Vaccination site haematoma (32), Conjunctival haemorrhage and Vaginal haemorrhage (29 each), Haematoma, Haemoptysis and Menorrhagia (27 each), Haematemesis (25), Eye haemorrhage (23), Rectal haemorrhage (22), Immune thrombocytopenia (20), Blood urine present (19), Haematuria, Neutropenia and Purpura (16 each) Diarrhoea haemorrhagic (15);<br>• Relevant event onset latency (n = 787): Range from <24 hours to 33 days, median = 1 day;<br>• Relevant event outcome: fatal (34), resolved/resolving (393), resolved with sequelae (17), not resolved (267) and unknown (371).<br><br>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue |
| **Hepatic AESIs**<br>*Search criteria: Liver related investigations, signs and symptoms (SMQ) (Narrow and Broad) OR PT Liver injury* | • Number of cases: 70 cases (0.2% of the total PM dataset), of which 54 medically confirmed and 16 non-medically confirmed;<br>• Country of incidence: UK (19), US (14), France (7), Italy (5), Germany (4), Belgium, Mexico and Spain (3 each), Austria, and Iceland (2 each); the remaining 8 cases originated from 8 different countries;<br>• Subjects' gender: female (43), male (26) and unknown (1);<br>• Subjects' age group (n=64): Adult (37), Elderly (27); |

**Table 7. AESIs Evaluation for BNT162b2**

| AESIs[a] Category | Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086) |
|---|---|
| | • Number of relevant events: 94, of which 53 serious, 41 non-serious;<br>• Most frequently reported relevant PTs (≥3 occurrences) include: Alanine aminotransferase increased (16), Transaminases increased and Hepatic pain (9 each), Liver function test increased (8), Aspartate aminotransferase increased and Liver function test abnormal (7 each), Gamma-glutamyltransferase increased and Hepatic enzyme increased (6 each), Blood alkaline phosphatase increased and Liver injury (5 each), Ascites, Blood bilirubin increased and Hypertransaminasaemia (3 each);<br>• Relevant event onset latency (n = 57): Range from <24 hours to 20 days, median 3 days;<br>• Relevant event outcome: fatal (5), resolved/resolving (27), resolved with sequelae (1), not resolved (14) and unknown (47).<br><br>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue |
| **Facial Paralysis**<br>*Search criteria: PTs Facial paralysis, Facial paresis* | • Number of cases: 449[i] (1.07% of the total PM dataset), 314 medically confirmed and 135 non-medically confirmed;<br>• Country of incidence: US (124), UK (119), Italy (40), France (27), Israel (20), Spain (18), Germany (13), Sweden (11), Ireland (9), Cyprus (8), Austria (7), Finland and Portugal (6 each), Hungary and Romania (5 each), Croatia and Mexico (4 each), Canada (3),Czech Republic, Malta, Netherlands, Norway, Poland and Puerto Rico (2 each); the remaining 8 cases originated from 8 different countries;<br>• Subjects' gender: female (295), male (133), unknown (21);<br>• Subjects' age group (n=411): Adult (313), Elderly (96), Infant[j] and Child (1 each);<br>• Number of relevant events[k]: 453, of which 399 serious, 54 non-serious;<br>• Reported relevant PTs: Facial paralysis (401), Facial paresis (64);<br>• Relevant event onset latency (n = 404): Range from <24 hours to 46 days, median 2 days;<br>• Relevant event outcome: resolved/resolving (184), resolved with sequelae (3), not resolved (183) and unknown (97);<br><br>Overall Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue. Causality assessment will be further evaluated following availability of additional unblinded data from the clinical study C4591001, which will be unblinded for final analysis approximately mid-April 2021. Additionally, non-interventional post-authorisation safety studies, C4591011 and C4591012 are expected to capture data on a sufficiently large vaccinated population to detect an increased risk of Bell's palsy in vaccinated individuals. The timeline for conducting these analyses will be established based on the size of the vaccinated population captured in the study data sources by the first interim reports (due 30 June |

**Table 7. AESIs Evaluation for BNT162b2**

| AESIs[a] Category | Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086) |
|---|---|
| | 2021). Study C4591021, pending protocol endorsement by EMA, is also intended to inform this risk. |
| **Immune-Mediated/Autoimmune AESIs** *Search criteria: Immune-mediated/autoimmune disorders (SMQ) (Broad and Narrow) OR Autoimmune disorders HLGT (Primary Path) OR PTs Cytokine release syndrome; Cytokine storm; Hypersensitivity* | • Number of cases: 1050 (2.5 % of the total PM dataset), of which 760 medically confirmed and 290 non-medically confirmed;<br>• Country of incidence (>10 cases): UK (267), US (257), Italy (70), France and Germany (69 each), Mexico (36), Sweden (35), Spain (32), Greece (31), Israel (21), Denmark (18), Portugal (17), Austria and Czech Republic (16 each), Canada (12), Finland (10). The remaining 74 cases were from 24 different countries.<br>• Subjects' gender (n=682): female (526), male (156).<br>• Subjects' age group (n=944): Adult (746), Elderly (196), Adolescent (2).<br>• Number of relevant events: 1077, of which 780 serious, 297 non-serious.<br>• Most frequently reported relevant PTs (>10 occurrences): Hypersensitivity (596), Neuropathy peripheral (49), Pericarditis (32), Myocarditis (25), Dermatitis (24), Diabetes mellitus and Encephalitis (16 each), Psoriasis (14), Dermatitis Bullous (13), Autoimmune disorder and Raynaud's phenomenon (11 each);<br>• Relevant event onset latency (n = 807): Range from <24 hours to 30 days, median <24 hours.<br>• Relevant event outcome[l]: resolved/resolving (517), not resolved (215), fatal (12), resolved with sequelae (22) and unknown (312).<br><br>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue |
| **Musculoskeletal AESIs** *Search criteria: PTs Arthralgia; Arthritis; Arthritis bacterial[n]; Chronic fatigue syndrome; Polyarthritis; Polyneuropathy; Post viral fatigue syndrome; Rheumatoid arthritis* | • Number of cases: 3600 (8.5% of the total PM dataset), of which 2045 medically confirmed and 1555 non-medically confirmed;<br>• Country of incidence: UK (1406), US (1004), Italy (285), Mexico (236), Germany (72), Portugal (70), France (48), Greece and Poland (46), Latvia (33), Czech Republic (32), Israel and Spain (26), Sweden (25), Romania (24), Denmark (23), Finland and Ireland (19 each), Austria and Belgium (18 each), Canada (16), Netherlands (14), Bulgaria (12), Croatia and Serbia (9 each), Cyprus and Hungary (8 each), Norway (7), Estonia and Puerto Rico (6 each), Iceland and Lithuania (4 each); the remaining 21 cases originated from 11 different countries;<br>• Subjects' gender (n=3471): female (2760), male (711);<br>• Subjects' age group (n=3372): Adult (2850), Elderly (515), Child (4), Adolescent (2), Infant (1);<br>• Number of relevant events: 3640, of which 1614 serious, 2026 non-serious;<br>• Reported relevant PTs: Arthralgia (3525), Arthritis (70), Rheumatoid arthritis (26), Polyarthritis (5), Polyneuropathy, Post viral fatigue syndrome, Chronic fatigue syndrome (4 each), Arthritis bacterial (1);<br>• Relevant event onset latency (n = 2968): Range from <24 hours to 32 days, median 1 day; |

## Table 7. AESIs Evaluation for BNT162b2

| AESIs[a] Category | Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086) |
|---|---|
| | • Relevant event outcome: resolved/resolving (1801), not resolved (959), resolved with sequelae (49), and unknown (853).<br><br>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue. |
| **Neurological AESIs (including demyelination)**<br>*Search criteria: Convulsions (SMQ) (Broad and Narrow) OR Demyelination (SMQ) (Broad and Narrow) OR PTs Ataxia; Cataplexy; Encephalopathy; Fibromyalgia; Intracranial pressure increased; Meningitis; Meningitis aseptic; Narcolepsy* | • Number of cases: 501 (1.2% of the total PM dataset), of which 365 medically confirmed and 136 non-medically confirmed.<br>• Country of incidence (≥9 cases): UK (157), US (68), Germany (49), Mexico (35), Italy (31), France (25), Spain (18), Poland (17), Netherlands and Israel (15 each), Sweden (9). The remaining 71 cases were from 22 different countries.<br>• Subjects' gender (n=478): female (328), male (150).<br>• Subjects' age group (n=478): Adult (329), Elderly (149);<br>• Number of relevant events: 542, of which 515 serious, 27 non-serious.<br>• Most frequently reported relevant PTs (>2 occurrences) included: Seizure (204), Epilepsy (83), Generalised tonic-clonic seizure (33), Guillain-Barre syndrome (24), Fibromyalgia and Trigeminal neuralgia (17 each), Febrile convulsion, (15), Status epilepticus (12), Aura and Myelitis transverse (11 each), Multiple sclerosis relapse and Optic neuritis (10 each), Petit mal epilepsy and Tonic convulsion (9 each), Ataxia (8), Encephalopathy and Tonic clonic movements (7 each), Foaming at mouth (5), Multiple sclerosis, Narcolepsy and Partial seizures (4 each), Bad sensation, Demyelination, Meningitis, Postictal state, Seizure like phenomena and Tongue biting (3 each);<br>• Relevant event onset latency (n = 423): Range from <24 hours to 48 days, median 1 day;<br>• Relevant events outcome: fatal (16), resolved/resolving (265), resolved with sequelae (13), not resolved (89) and unknown (161);<br><br>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue |
| **Other AESIs**<br>*Search criteria: Herpes viral infections (HLT) (Primary Path) OR PTs Adverse event following immunisation; Inflammation; Manufacturing laboratory analytical testing issue; Manufacturing materials issue; Manufacturing production issue; MERS-CoV test; MERS-CoV test negative; MERS-CoV test positive; Middle East respiratory syndrome; Multiple organ dysfunction syndrome; Occupational exposure to communicable disease; Patient* | • Number of cases: 8152 (19.4% of the total PM dataset), of which 4977 were medically confirmed and 3175 non-medically confirmed;<br>• Country of incidence (> 20 occurrences): UK (2715), US (2421), Italy (710), Mexico (223), Portugal (210), Germany (207), France (186), Spain (183), Sweden (133), Denmark (127), Poland (120), Greece (95), Israel (79), Czech Republic (76), Romania (57), Hungary (53), Finland (52), Norway (51), Latvia (49), Austria (47), Croatia (42), Belgium (41), Canada (39), Ireland (34), Serbia (28), Iceland (25), Netherlands (22). The remaining 127 cases were from 21 different countries;<br>• Subjects' gender (n=7829): female (5969), male (1860);<br>• Subjects' age group (n=7479): Adult (6330), Elderly (1125), Adolescent, Child (9 each), Infant (6); |

**Table 7. AESIs Evaluation for BNT162b2**

| **AESIs**[a]<br>**Category** | **Post-Marketing Cases Evaluation**[b]<br>**Total Number of Cases (N=42086)** |
|---|---|
| *isolation; Product availability issue; Product distribution issue; Product supply issue; Pyrexia; Quarantine; SARS-CoV-1 test; SARS-CoV-1 test negative; SARS-CoV-1 test positive* | • Number of relevant events: 8241, of which 3674 serious, 4568 non-serious;<br>• Most frequently reported relevant PTs (≥6 occurrences) included: Pyrexia (7666), Herpes zoster (259), Inflammation (132), Oral herpes (80), Multiple organ dysfunction syndrome (18), Herpes virus infection (17), Herpes simplex (13), Ophthalmic herpes zoster (10), Herpes ophthalmic and Herpes zoster reactivation (6 each);<br>• Relevant event onset latency (n =6836): Range from <24 hours to 61 days, median 1 day;<br>• Relevant events outcome: fatal (96), resolved/resolving (5008), resolved with sequelae (84), not resolved (1429) and unknown (1685).<br><br>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue |
| **Pregnancy Related AESIs**<br>*Search criteria: PTs Amniotic cavity infection; Caesarean section; Congenital anomaly; Death neonatal; Eclampsia; Foetal distress syndrome; Low birth weight baby; Maternal exposure during pregnancy; Placenta praevia; Pre-eclampsia; Premature labour; Stillbirth; Uterine rupture; Vasa praevia* | For relevant cases, please refer to Table 6, Description of Missing Information, *Use in Pregnancy and While Breast Feeding* |
| **Renal AESIs**<br>*Search criteria: PTs Acute kidney injury; Renal failure.* | • Number of cases: 69 cases (0.17% of the total PM dataset), of which 57 medically confirmed, 12 non-medically confirmed;<br>• Country of incidence: Germany (17), France and UK (13 each), US (6), Belgium, Italy and Spain (4 each), Sweden (2), Austria, Canada, Denmark, Finland, Luxembourg and Norway (1 each);<br>• Subjects' gender: female (46), male (23);<br>• Subjects' age group (n=68): Adult (7), Elderly (60), Infant (1);<br>• Number of relevant events: 70, all serious;<br>• Reported relevant PTs: Acute kidney injury (40) and Renal failure (30);<br>• Relevant event onset latency (n = 42): Range from <24 hours to 15 days, median 4 days;<br>• Relevant event outcome: fatal (23), resolved/resolving (10), not resolved (15) and unknown (22).<br><br>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue. |
| **Respiratory AESIs**<br>*Search criteria: Lower respiratory tract infections NEC (HLT)* | • Number of cases: 130 cases (0.3% of the total PM dataset), of which 107 medically confirmed; |

## Table 7. AESIs Evaluation for BNT162b2

| AESIs[a] Category | Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086) |
|---|---|
| *(Primary Path) OR Respiratory failures (excl neonatal) (HLT) (Primary Path) OR Viral lower respiratory tract infections (HLT) (Primary Path) OR PTs: Acute respiratory distress syndrome; Endotracheal intubation; Hypoxia; Pulmonary haemorrhage; Respiratory disorder; Severe acute respiratory syndrome* | • Countries of incidence: United Kingdom (20), France (18), United States (16), Germany (14), Spain (13), Belgium and Italy (9), Denmark (8), Norway (5), Czech Republic, Iceland (3 each); the remaining 12 cases originated from 8 different countries.<br>• Subjects' gender (n=130): female (72), male (58).<br>• Subjects's age group (n=126): Elderly (78), Adult (47), Adolescent (1).<br>• Number of relevant events: 137, of which 126 serious, 11 non-serious;<br>• Reported relevant PTs: Respiratory failure (44), Hypoxia (42), Respiratory disorder (36), Acute respiratory distress syndrome (10), Chronic respiratory syndrome (3), Severe acute respiratory syndrome (2).<br>• Relevant event onset latency (n=102): range from < 24 hours to 18 days, median 1 day;<br>• Relevant events outcome: fatal (41), Resolved/resolving (47), not recovered (18) and unknown (31).<br><br>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue. |
| **Thromboembolic Events**<br>*Search criteria: Embolism and thrombosis (HLGT) (Primary Path), excluding PTs reviewed as Stroke AESIs, OR PTs Deep vein thrombosis; Disseminated intravascular coagulation; Embolism; Embolism venous; Pulmonary embolism* | • Number of cases: 151 (0.3% of the total PM dataset), of which 111 medically confirmed and 40 non-medically confirmed;<br>• Country of incidence: UK (34), US (31), France (20), Germany (15), Italy and Spain (6 each), Denmark and Sweden (5 each), Austria, Belgium and Israel (3 each), Canada, Cyprus, Netherlands and Portugal (2 each); the remaining 12 cases originated from 12 different countries;<br>• Subjects' gender (n= 144): female (89), male (55);<br>• Subjects' age group (n=136): Adult (66), Elderly (70);<br>• Number of relevant events: 168, of which 165 serious, 3 non-serious;<br>• Most frequently reported relevant PTs (>1 occurrence) included: Pulmonary embolism (60), Thrombosis (39), Deep vein thrombosis (35), Thrombophlebitis superficial (6), Venous thrombosis limb (4), Embolism, Microembolism, Thrombophlebitis and Venous thrombosis (3 each) Blue toe syndrome (2);<br>• Relevant event onset latency (n = 124): Range from <24 hours to 28 days, median 4 days;<br>• Relevant event outcome: fatal (18), resolved/resolving (54), resolved with sequelae (6), not resolved (49) and unknown (42).<br><br>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue. |
| **Stroke**<br>*Search criteria: HLT Central nervous system haemorrhages and cerebrovascular accidents* | • Number of cases: 275 (0.6% of the total PM dataset), of which 180 medically confirmed and 95 non-medically confirmed;<br>• Country of incidence: UK (81), US (66), France (32), Germany (21), Norway (14), Netherlands and Spain (11 each), Sweden (9), |

**Table 7. AESIs Evaluation for BNT162b2**

| **AESIs**[a] **Category** | **Post-Marketing Cases Evaluation**[b] **Total Number of Cases (N=42086)** |
|---|---|
| *(Primary Path) OR HLT Cerebrovascular venous and sinus thrombosis (Primary Path)* | Israel (6), Italy (5), Belgium (3), Denmark, Finland, Poland and Switzerland (2 each); the remaining 8 cases originated from 8 different countries;<br>• Subjects' gender (n= 273): female (182), male (91);<br>• Subjects' age group (n=265): Adult (59), Elderly (205), Child[m] (1);<br>• Number of relevant events: 300, all serious;<br>• Most frequently reported relevant PTs (>1 occurrence) included:<br>o PTs indicative of Ischaemic stroke: Cerebrovascular accident (160), Ischaemic stroke (41), Cerebral infarction (15), Cerebral ischaemia, Cerebral thrombosis, Cerebral venous sinus thrombosis, Ischaemic cerebral infarction and Lacunal infarction (3 each) Basal ganglia stroke, Cerebellar infarction and Thrombotic stroke (2 each);<br>o PTs indicative of Haemorrhagic stroke: Cerebral haemorrhage (26), Haemorrhagic stroke (11), Haemorrhage intracranical and Subarachnoid haemorrhage (5 each), Cerebral haematoma (4), Basal ganglia haemorrhage and Cerebellar haemorrhage (2 each);<br>• Relevant event onset latency (n = 241): Range from <24 hours to 41 days, median 2 days;<br>• Relevant event outcome: fatal and resolved/resolving (61 each), resolved with sequelae (10), not resolved (85) and unknown (83).<br><br>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue. |
| **Vasculitic Events**<br>*Search criteria: Vasculitides HLT* | • Number of cases: 32 cases (0.08% of the total PM dataset), of which 26 medically confirmed and 6 non-medically confirmed;<br>• Country of incidence: UK (13), France (4), Portugal, US and Spain (3 each), Cyprus, Germany, Hungary, Italy and Slovakia and Costa rica (1 each);<br>• Subjects' gender: female (26), male (6);<br>• Subjects' age group (n=31): Adult (15), Elderly (16);<br>• Number of relevant events: 34, of which 25 serious, 9 non-serious;<br>• Reported relevant PTs: Vasculitis (14), Cutaneous vasculitis and Vasculitic rash (4 each), (3), Giant cell arteritis and Peripheral ischaemia (3 each), Behcet's syndrome and Hypersensitivity vasculitis (2 each) Palpable purpura, and Takayasu's arteritis (1 each);<br>• Relevant event onset latency (n = 25): Range from <24 hours to 19 days, median 3 days;<br>• Relevant event outcome: fatal (1), resolved/resolving (13), not resolved (12) and unknown (8).<br><br>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue |

## Table 7. AESIs Evaluation for BNT162b2

| AESIs[a] Category | Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086) |
|---|---|

a. For the complete list of the AESIs, please refer to Appendix 5;
b. Please note that this corresponds to evidence from post-EUA/conditional marketing authorisation approval data sources;
c. Subjects with age ranged between 18 and 64 years;
d. Subjects with age equal to or above 65 years;
e. Subjects with age ranged between 2 and 11 years;
f. Subjects with age ranged between 12 and less than 18 years;
g. Multiple episodes of the same PT event were reported with a different clinical outcome within some cases hence the sum of the events outcome exceeds the total number of PT events;
h. Subjects with age ranged between 1 (28 days) and 23 months;
i. Twenty-four additional cases were excluded from the analysis as they were not cases of peripheral facial nerve palsy because they described other disorders (stroke, cerebral haemorrhage or transient ischaemic attack); 1 case was excluded from the analysis because it was invalid due to an unidentifiable reporter;
j. This UK case report received from the UK MHRA described a 1-year-old subject who received the vaccine, and had left postauricular ear pain that progressed to left-sided Bell's palsy 1 day following vaccination that had not resolved at the time of the report;
k. If a case included both PT Facial paresis and PT Facial paralysis, only the PT Facial paralysis was considered in the descriptions of the events as it is most clinically important;
l. Multiple episodes of the same PT event were reported with a different clinical outcome within some cases hence the sum of the events outcome exceeds the total number of PT events
m. This UK case report received from the UK MHRA described a 7-year-old female subject who received the vaccine and had stroke (unknown outcome); no follow-up is possible for clarification.
n. This PT not included in the AESIs/TME list was included in the review as relevant for ACCESS protocol criteria;

### 3.1.4. Medication error

Cases potentially indicative of medication errors[1] that cumulatively occurred are summarized below.

- Number of relevant medication error cases: 2056[2] (4.9%) of which 1569 (3.7%) are medically confirmed.
- Number of relevant events: 2792
- Top 10 countries of incidence:
  - US (1201), France (171), UK (138), Germany (88), Czech Republic (87), Sweden (49), Israel (45), Italy (42), Canada (35), Romania (33), Finland (21), Portugal (20), Norway (14), Puerto Rico (13), Poland (12), Austria and Spain (10 each).

Medication error case outcomes:

- Fatal (7)[3],
- Recovered/recovering (354, of which 4 are serious),
- Recovered with sequelae (8, of which 3 serious)

[1] MedDRA (version 23.1) Higher Level Terms: Accidental exposures to product; Product administration errors and issues; Product confusion errors and issues; Product dispensing errors and issues; Product label issues; Product monitoring errors and issues; Product preparation errors and issues; Product selection errors and issues; Product storage errors and issues in the product use system; Product transcribing errors and communication issues, OR Preferred Terms: Accidental poisoning; Circumstance or information capable of leading to device use error; Circumstance or information capable of leading to medication error; Contraindicated device used; Deprescribing error; Device use error; Dose calculation error; Drug titration error; Expired device used; Exposure via direct contact; Exposure via eye contact; Exposure via mucosa; Exposure via skin contact; Failure of child resistant product closure; Inadequate aseptic technique in use of product; Incorrect disposal of product; Intercepted medication error; Intercepted product prescribing error; Medication error; Multiple use of single-use product; Product advertising issue; Product distribution issue; Product prescribing error; Product prescribing issue; Product substitution error; Product temperature excursion issue; Product use in unapproved therapeutic environment; Radiation underdose; Underdose; Unintentional medical device removal; Unintentional use for unapproved indication; Vaccination error; Wrong device used; Wrong dosage form; Wrong dosage formulation; Wrong dose; Wrong drug; Wrong patient; Wrong product procured; Wrong product stored; Wrong rate; Wrong route; Wrong schedule; Wrong strength; Wrong technique in device usage process; Wrong technique in product usage process.

[2] Thirty-five (35) cases were exclude from the analysis because describing medication errors occurring in an unspecified number of individuals or describing medication errors occurring with co suspects were determined to be non-contributory.

[3] All the medication errors reported in these cases were assessed as non-serious occurrences with an unknown outcome; based on the available information including the causes of death, the relationship between the medication error and the death is weak. .

- Not recovered (189, of which 84 are serious),
- Unknown (1498, of which 33 are serious).

1371 cases reported only MEs without any associated clinical adverse event. The PTs most frequently reported (≥12 occurrences) were: Poor quality product administered (539), Product temperature excursion issue (253), Inappropriate schedule of product administration (225), Product preparation error (206), Underdose (202), Circumstance or information capable of leading to medication error (120), Product preparation issue (119), Wrong technique in product usage process (76), Incorrect route of product administration (66), Accidental overdose (33), Product administered at inappropriate site (27), Incorrect dose administered and Accidental exposure to the product (25 each), Exposure via skin contact (22), Wrong product administered (17), Incomplete course of vaccination, and Product administration error (14 each) Product administered to patient of inappropriate age (12).

In 685 cases, there were co-reported AEs. The most frequently co- associated AEs (> 40 occurrences) were: Headache (187), Pyrexia (161), Fatigue (135), Chills (127), Pain (107), Vaccination site pain (100), Nausea (89), Myalgia (88), Pain in extremity (85) Arthralgia (68), Off label use (57), Dizziness (52), Lymphadenopathy (47), Asthenia (46) and Malaise (41). These cases are summarized in Table 8.

**Table 8. ME PTs by seriousness with or without harm co-association (Through 28 February 2021)**

| | Serious | | Non-Serious | |
|---|---|---|---|---|
| **ME PTs** | **With Harm** | **Without Harm** | **With Harm** | **Without Harm** |
| Accidental exposure to product | 0 | 0 | 0 | 5 |
| Accidental overdose | 4 | 1 | 9 | 6 |
| Booster dose missed | 0 | 0 | 0 | 1 |
| Circumstance or information capable of leading to medication error | 0 | 0 | 5 | 11 |
| Contraindicated product administered | 1 | 0 | 0 | 2 |
| Expired product administered | 0 | 0 | 0 | 2 |
| Exposure via skin contact | 0 | 0 | 0 | 5 |
| Inappropriate schedule of product administration | 0 | 2 | 8 | 264 |
| Incorrect dose administered | 1 | 1 | 0 | 0 |

**Table 8. ME PTs by seriousness with or without harm co-association (Through 28 February 2021)**

| | Serious | | Non-Serious | |
|---|---|---|---|---|
| **ME PTs** | **With Harm** | **Without Harm** | **With Harm** | **Without Harm** |
| Incorrect route of product administration | 2 | 6 | 16 | 127 |
| Lack of vaccination site rotation | 1 | 0 | 0 | 0 |
| Medication error | 0 | 0 | 0 | 1 |
| Poor quality product administered | 1 | 0 | 0 | 34 |
| Product administered at inappropriate site | 2 | 1 | 13 | 29 |
| Product administered to patient of inappropriate age | 0 | 4 | 0 | 40 |
| Product administration error | 1 | 0 | 0 | 3 |
| Product dose omission issue | 0 | 1 | 0 | 3 |
| Product preparation error | 1 | 0 | 4 | 11 |
| Product preparation issue | 1 | 1 | 0 | 14 |

Overall, there were 68 cases with co-reported AEs reporting Harm and 599 cases with co-reported AEs without harm. Additionally, Intercepted medication errors was reported in 1 case (PTs Malaise, clinical outcome unknow) and Potential medication errors were reported in 17 cases.

## 4. DISCUSSION

Pfizer performs frequent and rigorous signal detection on BNT162b2 cases. The findings of these signal detection analyses are consistent with the known safety profile of the vaccine. This cumulative analysis to support the Biologics License Application for BNT162b2, is an integrated analysis of post-authorization safety data, from U.S. and foreign experience, focused on Important Identified Risks, Important Potential Risks, and areas of Important Missing Information identified in the Pharmacovigilance Plan, as well as adverse events of special interest and vaccine administration errors (whether or not associated with an adverse event). The data do not reveal any novel safety concerns or risks requiring label changes and support a favorable benefit risk profile of to the BNT162b2 vaccine.

## 5. SUMMARY AND CONCLUSION

Review of the available data for this cumulative PM experience, confirms a favorable benefit: risk balance for BNT162b2.

Pfizer will continue routine pharmacovigilance activities on behalf of BioNTech according to the Pharmacovigilance Agreement in place, in order to assure patient safety and will inform the Agency if an evaluation of the safety data yields significant new information for BNT162b2.

## APPENDIX 1. LIST OF ADVERSE EVENTS OF SPECIAL INTEREST

1p36 deletion syndrome;2-Hydroxyglutaric aciduria;5'nucleotidase increased;Acoustic neuritis;Acquired C1 inhibitor deficiency;Acquired epidermolysis bullosa;Acquired epileptic aphasia;Acute cutaneous lupus erythematosus;Acute disseminated encephalomyelitis;Acute encephalitis with refractory, repetitive partial seizures;Acute febrile neutrophilic dermatosis;Acute flaccid myelitis;Acute haemorrhagic leukoencephalitis;Acute haemorrhagic oedema of infancy;Acute kidney injury;Acute macular outer retinopathy;Acute motor axonal neuropathy;Acute motor-sensory axonal neuropathy;Acute myocardial infarction;Acute respiratory distress syndrome;Acute respiratory failure;Addison's disease;Administration site thrombosis;Administration site vasculitis;Adrenal thrombosis;Adverse event following immunisation;Ageusia;Agranulocytosis;Air embolism;Alanine aminotransferase abnormal;Alanine aminotransferase increased;Alcoholic seizure;Allergic bronchopulmonary mycosis;Allergic oedema;Alloimmune hepatitis;Alopecia areata;Alpers disease;Alveolar proteinosis;Ammonia abnormal;Ammonia increased;Amniotic cavity infection;Amygdalohippocampectomy;Amyloid arthropathy;Amyloidosis;Amyloidosis senile;Anaphylactic reaction;Anaphylactic shock;Anaphylactic transfusion reaction;Anaphylactoid reaction;Anaphylactoid shock;Anaphylactoid syndrome of pregnancy;Angioedema;Angiopathic neuropathy;Ankylosing spondylitis;Anosmia;Antiacetylcholine receptor antibody positive;Anti-actin antibody positive;Anti-aquaporin-4 antibody positive;Anti-basal ganglia antibody positive;Anti-cyclic citrullinated peptide antibody positive;Anti-epithelial antibody positive;Anti-erythrocyte antibody positive;Anti-exosome complex antibody positive;Anti-GAD antibody negative;Anti-GAD antibody positive;Anti-ganglioside antibody positive;Antigliadin antibody positive;Anti-glomerular basement membrane antibody positive;Anti-glomerular basement membrane disease;Anti-glycyl-tRNA synthetase antibody positive;Anti-HLA antibody test positive;Anti-IA2 antibody positive;Anti-insulin antibody increased;Anti-insulin antibody positive;Anti-insulin receptor antibody increased;Anti-insulin receptor antibody positive;Anti-interferon antibody negative;Anti-interferon antibody positive;Anti-islet cell antibody positive;Antimitochondrial antibody positive;Anti-muscle specific kinase antibody positive;Anti-myelin-associated glycoprotein antibodies positive;Anti-myelin-associated glycoprotein associated polyneuropathy;Antimyocardial antibody positive;Anti-neuronal antibody positive;Antineutrophil cytoplasmic antibody increased;Antineutrophil cytoplasmic antibody positive;Anti-neutrophil cytoplasmic antibody positive vasculitis;Anti-NMDA antibody positive;Antinuclear antibody increased;Antinuclear antibody positive;Antiphospholipid antibodies positive;Antiphospholipid syndrome;Anti-platelet antibody positive;Anti-prothrombin antibody positive;Antiribosomal P antibody positive;Anti-RNA polymerase III antibody positive;Anti-saccharomyces cerevisiae antibody test positive;Anti-sperm antibody positive;Anti-SRP antibody positive;Antisynthetase syndrome;Anti-thyroid antibody positive;Anti-transglutaminase antibody increased;Anti-VGCC antibody positive;Anti-VGKC antibody positive;Anti-vimentin antibody positive;Antiviral prophylaxis;Antiviral treatment;Anti-zinc transporter 8 antibody positive;Aortic embolus;Aortic thrombosis;Aortitis;Aplasia pure red cell;Aplastic anaemia;Application site thrombosis;Application site vasculitis;Arrhythmia;Arterial bypass occlusion;Arterial bypass thrombosis;Arterial thrombosis;Arteriovenous fistula thrombosis;Arteriovenous graft site stenosis;Arteriovenous graft thrombosis;Arteritis;Arteritis

coronary;Arthralgia;Arthritis;Arthritis enteropathic;Ascites;Aseptic cavernous sinus thrombosis;Aspartate aminotransferase abnormal;Aspartate aminotransferase increased;Aspartate-glutamate-transporter deficiency;AST to platelet ratio index increased;AST/ALT ratio abnormal;Asthma;Asymptomatic COVID-19;Ataxia;Atheroembolism;Atonic seizures;Atrial thrombosis;Atrophic thyroiditis;Atypical benign partial epilepsy;Atypical pneumonia;Aura;Autoantibody positive;Autoimmune anaemia;Autoimmune aplastic anaemia;Autoimmune arthritis;Autoimmune blistering disease;Autoimmune cholangitis;Autoimmune colitis;Autoimmune demyelinating disease;Autoimmune dermatitis;Autoimmune disorder;Autoimmune encephalopathy;Autoimmune endocrine disorder;Autoimmune enteropathy;Autoimmune eye disorder;Autoimmune haemolytic anaemia;Autoimmune heparin-induced thrombocytopenia;Autoimmune hepatitis;Autoimmune hyperlipidaemia;Autoimmune hypothyroidism;Autoimmune inner ear disease;Autoimmune lung disease;Autoimmune lymphoproliferative syndrome;Autoimmune myocarditis;Autoimmune myositis;Autoimmune nephritis;Autoimmune neuropathy;Autoimmune neutropenia;Autoimmune pancreatitis;Autoimmune pancytopenia;Autoimmune pericarditis;Autoimmune retinopathy;Autoimmune thyroid disorder;Autoimmune thyroiditis;Autoimmune uveitis;Autoinflammation with infantile enterocolitis;Autoinflammatory disease;Automatism epileptic;Autonomic nervous system imbalance;Autonomic seizure;Axial spondyloarthritis;Axillary vein thrombosis;Axonal and demyelinating polyneuropathy;Axonal neuropathy;Bacterascites;Baltic myoclonic epilepsy;Band sensation;Basedow's disease;Basilar artery thrombosis;Basophilopenia;B-cell aplasia;Behcet's syndrome;Benign ethnic neutropenia;Benign familial neonatal convulsions;Benign familial pemphigus;Benign rolandic epilepsy;Beta-2 glycoprotein antibody positive;Bickerstaff's encephalitis;Bile output abnormal;Bile output decreased;Biliary ascites;Bilirubin conjugated abnormal;Bilirubin conjugated increased;Bilirubin urine present;Biopsy liver abnormal;Biotinidase deficiency;Birdshot chorioretinopathy;Blood alkaline phosphatase abnormal;Blood alkaline phosphatase increased;Blood bilirubin abnormal;Blood bilirubin increased;Blood bilirubin unconjugated increased;Blood cholinesterase abnormal;Blood cholinesterase decreased;Blood pressure decreased;Blood pressure diastolic decreased;Blood pressure systolic decreased;Blue toe syndrome;Brachiocephalic vein thrombosis;Brain stem embolism;Brain stem thrombosis;Bromosulphthalein test abnormal;Bronchial oedema;Bronchitis;Bronchitis mycoplasmal;Bronchitis viral;Bronchopulmonary aspergillosis allergic;Bronchospasm;Budd-Chiari syndrome;Bulbar palsy;Butterfly rash;C1q nephropathy;Caesarean section;Calcium embolism;Capillaritis;Caplan's syndrome;Cardiac amyloidosis;Cardiac arrest;Cardiac failure;Cardiac failure acute;Cardiac sarcoidosis;Cardiac ventricular thrombosis;Cardiogenic shock;Cardiolipin antibody positive;Cardiopulmonary failure;Cardio-respiratory arrest;Cardio-respiratory distress;Cardiovascular insufficiency;Carotid arterial embolus;Carotid artery thrombosis;Cataplexy;Catheter site thrombosis;Catheter site vasculitis;Cavernous sinus thrombosis;CDKL5 deficiency disorder;CEC syndrome;Cement embolism;Central nervous system lupus;Central nervous system vasculitis;Cerebellar artery thrombosis;Cerebellar embolism;Cerebral amyloid angiopathy;Cerebral arteritis;Cerebral artery embolism;Cerebral artery thrombosis;Cerebral gas embolism;Cerebral microembolism;Cerebral septic infarct;Cerebral thrombosis;Cerebral venous sinus thrombosis;Cerebral venous thrombosis;Cerebrospinal thrombotic

tamponade;Cerebrovascular accident;Change in seizure presentation;Chest discomfort;Child-Pugh-Turcotte score abnormal;Child-Pugh-Turcotte score increased;Chillblains;Choking;Choking sensation;Cholangitis sclerosing;Chronic autoimmune glomerulonephritis;Chronic cutaneous lupus erythematosus;Chronic fatigue syndrome;Chronic gastritis;Chronic inflammatory demyelinating polyradiculoneuropathy;Chronic lymphocytic inflammation with pontine perivascular enhancement responsive to steroids;Chronic recurrent multifocal osteomyelitis;Chronic respiratory failure;Chronic spontaneous urticaria;Circulatory collapse;Circumoral oedema;Circumoral swelling;Clinically isolated syndrome;Clonic convulsion;Coeliac disease;Cogan's syndrome;Cold agglutinins positive;Cold type haemolytic anaemia;Colitis;Colitis erosive;Colitis herpes;Colitis microscopic;Colitis ulcerative;Collagen disorder;Collagen-vascular disease;Complement factor abnormal;Complement factor C1 decreased;Complement factor C2 decreased;Complement factor C3 decreased;Complement factor C4 decreased;Complement factor decreased;Computerised tomogram liver abnormal;Concentric sclerosis;Congenital anomaly;Congenital bilateral perisylvian syndrome;Congenital herpes simplex infection;Congenital myasthenic syndrome;Congenital varicella infection;Congestive hepatopathy;Convulsion in childhood;Convulsions local;Convulsive threshold lowered;Coombs positive haemolytic anaemia;Coronary artery disease;Coronary artery embolism;Coronary artery thrombosis;Coronary bypass thrombosis;Coronavirus infection;Coronavirus test;Coronavirus test negative;Coronavirus test positive;Corpus callosotomy;Cough;Cough variant asthma;COVID-19;COVID-19 immunisation;COVID-19 pneumonia;COVID-19 prophylaxis;COVID-19 treatment;Cranial nerve disorder;Cranial nerve palsies multiple;Cranial nerve paralysis;CREST syndrome;Crohn's disease;Cryofibrinogenaemia;Cryoglobulinaemia;CSF oligoclonal band present;CSWS syndrome;Cutaneous amyloidosis;Cutaneous lupus erythematosus;Cutaneous sarcoidosis;Cutaneous vasculitis;Cyanosis;Cyclic neutropenia;Cystitis interstitial;Cytokine release syndrome;Cytokine storm;De novo purine synthesis inhibitors associated acute inflammatory syndrome;Death neonatal;Deep vein thrombosis;Deep vein thrombosis postoperative;Deficiency of bile secretion;Deja vu;Demyelinating polyneuropathy;Demyelination;Dermatitis;Dermatitis bullous;Dermatitis herpetiformis;Dermatomyositis;Device embolisation;Device related thrombosis;Diabetes mellitus;Diabetic ketoacidosis;Diabetic mastopathy;Dialysis amyloidosis;Dialysis membrane reaction;Diastolic hypotension;Diffuse vasculitis;Digital pitting scar;Disseminated intravascular coagulation;Disseminated intravascular coagulation in newborn;Disseminated neonatal herpes simplex;Disseminated varicella;Disseminated varicella zoster vaccine virus infection;Disseminated varicella zoster virus infection;DNA antibody positive;Double cortex syndrome;Double stranded DNA antibody positive;Dreamy state;Dressler's syndrome;Drop attacks;Drug withdrawal convulsions;Dyspnoea;Early infantile epileptic encephalopathy with burst-suppression;Eclampsia;Eczema herpeticum;Embolia cutis medicamentosa;Embolic cerebellar infarction;Embolic cerebral infarction;Embolic pneumonia;Embolic stroke;Embolism;Embolism arterial;Embolism venous;Encephalitis;Encephalitis allergic;Encephalitis autoimmune;Encephalitis brain stem;Encephalitis haemorrhagic;Encephalitis periaxialis diffusa;Encephalitis post immunisation;Encephalomyelitis;Encephalopathy;Endocrine disorder;Endocrine ophthalmopathy;Endotracheal intubation;Enteritis;Enteritis leukopenic;Enterobacter pneumonia;Enterocolitis;Enteropathic spondylitis;Eosinopenia;Eosinophilic

fasciitis;Eosinophilic granulomatosis with polyangiitis;Eosinophilic oesophagitis;Epidermolysis;Epilepsy;Epilepsy surgery;Epilepsy with myoclonic-atonic seizures;Epileptic aura;Epileptic psychosis;Erythema;Erythema induratum;Erythema multiforme;Erythema nodosum;Evans syndrome;Exanthema subitum;Expanded disability status scale score decreased;Expanded disability status scale score increased;Exposure to communicable disease;Exposure to SARS-CoV-2;Eye oedema;Eye pruritus;Eye swelling;Eyelid oedema;Face oedema;Facial paralysis;Facial paresis;Faciobrachial dystonic seizure;Fat embolism;Febrile convulsion;Febrile infection-related epilepsy syndrome;Febrile neutropenia;Felty's syndrome;Femoral artery embolism;Fibrillary glomerulonephritis;Fibromyalgia;Flushing;Foaming at mouth;Focal cortical resection;Focal dyscognitive seizures;Foetal distress syndrome;Foetal placental thrombosis;Foetor hepaticus;Foreign body embolism;Frontal lobe epilepsy;Fulminant type 1 diabetes mellitus;Galactose elimination capacity test abnormal;Galactose elimination capacity test decreased;Gamma-glutamyltransferase abnormal;Gamma-glutamyltransferase increased;Gastritis herpes;Gastrointestinal amyloidosis;Gelastic seizure;Generalised onset non-motor seizure;Generalised tonic-clonic seizure;Genital herpes;Genital herpes simplex;Genital herpes zoster;Giant cell arteritis;Glomerulonephritis;Glomerulonephritis membranoproliferative;Glomerulonephritis membranous;Glomerulonephritis rapidly progressive;Glossopharyngeal nerve paralysis;Glucose transporter type 1 deficiency syndrome;Glutamate dehydrogenase increased;Glycocholic acid increased;GM2 gangliosidosis;Goodpasture's syndrome;Graft thrombosis;Granulocytopenia;Granulocytopenia neonatal;Granulomatosis with polyangiitis;Granulomatous dermatitis;Grey matter heterotopia;Guanase increased;Guillain-Barre syndrome;Haemolytic anaemia;Haemophagocytic lymphohistiocytosis;Haemorrhage;Haemorrhagic ascites;Haemorrhagic disorder;Haemorrhagic pneumonia;Haemorrhagic varicella syndrome;Haemorrhagic vasculitis;Hantavirus pulmonary infection;Hashimoto's encephalopathy;Hashitoxicosis;Hemimegalencephaly;Henoch-Schonlein purpura;Henoch-Schonlein purpura nephritis;Hepaplastin abnormal;Hepaplastin decreased;Heparin-induced thrombocytopenia;Hepatic amyloidosis;Hepatic artery embolism;Hepatic artery flow decreased;Hepatic artery thrombosis;Hepatic enzyme abnormal;Hepatic enzyme decreased;Hepatic enzyme increased;Hepatic fibrosis marker abnormal;Hepatic fibrosis marker increased;Hepatic function abnormal;Hepatic hydrothorax;Hepatic hypertrophy;Hepatic hypoperfusion;Hepatic lymphocytic infiltration;Hepatic mass;Hepatic pain;Hepatic sequestration;Hepatic vascular resistance increased;Hepatic vascular thrombosis;Hepatic vein embolism;Hepatic vein thrombosis;Hepatic venous pressure gradient abnormal;Hepatic venous pressure gradient increased;Hepatitis;Hepatobiliary scan abnormal;Hepatomegaly;Hepatosplenomegaly;Hereditary angioedema with C1 esterase inhibitor deficiency;Herpes dermatitis;Herpes gestationis;Herpes oesophagitis;Herpes ophthalmic;Herpes pharyngitis;Herpes sepsis;Herpes simplex;Herpes simplex cervicitis;Herpes simplex colitis;Herpes simplex encephalitis;Herpes simplex gastritis;Herpes simplex hepatitis;Herpes simplex meningitis;Herpes simplex meningoencephalitis;Herpes simplex meningomyelitis;Herpes simplex necrotising retinopathy;Herpes simplex oesophagitis;Herpes simplex otitis externa;Herpes simplex pharyngitis;Herpes simplex pneumonia;Herpes simplex reactivation;Herpes simplex sepsis;Herpes simplex viraemia;Herpes simplex virus conjunctivitis neonatal;Herpes simplex visceral;Herpes virus

infection;Herpes zoster;Herpes zoster cutaneous disseminated;Herpes zoster infection neurological;Herpes zoster meningitis;Herpes zoster meningoencephalitis;Herpes zoster meningomyelitis;Herpes zoster meningoradiculitis;Herpes zoster necrotising retinopathy;Herpes zoster oticus;Herpes zoster pharyngitis;Herpes zoster reactivation;Herpetic radiculopathy;Histone antibody positive;Hoigne's syndrome;Human herpesvirus 6 encephalitis;Human herpesvirus 6 infection;Human herpesvirus 6 infection reactivation;Human herpesvirus 7 infection;Human herpesvirus 8 infection;Hyperammonaemia;Hyperbilirubinaemia;Hypercholia;Hypergammaglobulinaemia benign monoclonal;Hyperglycaemic seizure;Hypersensitivity;Hypersensitivity vasculitis;Hyperthyroidism;Hypertransaminasaemia;Hyperventilation;Hypoalbuminaemia;Hypocalcaemic seizure;Hypogammaglobulinaemia;Hypoglossal nerve paralysis;Hypoglossal nerve paresis;Hypoglycaemic seizure;Hyponatraemic seizure;Hypotension;Hypotensive crisis;Hypothenar hammer syndrome;Hypothyroidism;Hypoxia;Idiopathic CD4 lymphocytopenia;Idiopathic generalised epilepsy;Idiopathic interstitial pneumonia;Idiopathic neutropenia;Idiopathic pulmonary fibrosis;IgA nephropathy;IgM nephropathy;IIIrd nerve paralysis;IIIrd nerve paresis;Iliac artery embolism;Immune thrombocytopenia;Immune-mediated adverse reaction;Immune-mediated cholangitis;Immune-mediated cholestasis;Immune-mediated cytopenia;Immune-mediated encephalitis;Immune-mediated encephalopathy;Immune-mediated endocrinopathy;Immune-mediated enterocolitis;Immune-mediated gastritis;Immune-mediated hepatic disorder;Immune-mediated hepatitis;Immune-mediated hyperthyroidism;Immune-mediated hypothyroidism;Immune-mediated myocarditis;Immune-mediated myositis;Immune-mediated nephritis;Immune-mediated neuropathy;Immune-mediated pancreatitis;Immune-mediated pneumonitis;Immune-mediated renal disorder;Immune-mediated thyroiditis;Immune-mediated uveitis;Immunoglobulin G4 related disease;Immunoglobulins abnormal;Implant site thrombosis;Inclusion body myositis;Infantile genetic agranulocytosis;Infantile spasms;Infected vasculitis;Infective thrombosis;Inflammation;Inflammatory bowel disease;Infusion site thrombosis;Infusion site vasculitis;Injection site thrombosis;Injection site urticaria;Injection site vasculitis;Instillation site thrombosis;Insulin autoimmune syndrome;Interstitial granulomatous dermatitis;Interstitial lung disease;Intracardiac mass;Intracardiac thrombus;Intracranial pressure increased;Intrapericardial thrombosis;Intrinsic factor antibody abnormal;Intrinsic factor antibody positive;IPEX syndrome;Irregular breathing;IRVAN syndrome;IVth nerve paralysis;IVth nerve paresis;JC polyomavirus test positive;JC virus CSF test positive;Jeavons syndrome;Jugular vein embolism;Jugular vein thrombosis;Juvenile idiopathic arthritis;Juvenile myoclonic epilepsy;Juvenile polymyositis;Juvenile psoriatic arthritis;Juvenile spondyloarthritis;Kaposi sarcoma inflammatory cytokine syndrome;Kawasaki's disease;Kayser-Fleischer ring;Keratoderma blenorrhagica;Ketosis-prone diabetes mellitus;Kounis syndrome;Lafora's myoclonic epilepsy;Lambl's excrescences;Laryngeal dyspnoea;Laryngeal oedema;Laryngeal rheumatoid arthritis;Laryngospasm;Laryngotracheal oedema;Latent autoimmune diabetes in adults;LE cells present;Lemierre syndrome;Lennox-Gastaut syndrome;Leucine aminopeptidase increased;Leukoencephalomyelitis;Leukoencephalopathy;Leukopenia;Leukopenia neonatal;Lewis-Sumner syndrome;Lhermitte's sign;Lichen planopilaris;Lichen planus;Lichen sclerosus;Limbic encephalitis;Linear IgA disease;Lip oedema;Lip swelling;Liver function test abnormal;Liver function test decreased;Liver function test increased;Liver induration;Liver injury;Liver iron concentration abnormal;Liver iron concentration

increased;Liver opacity;Liver palpable;Liver sarcoidosis;Liver scan abnormal;Liver tenderness;Low birth weight baby;Lower respiratory tract herpes infection;Lower respiratory tract infection;Lower respiratory tract infection viral;Lung abscess;Lupoid hepatic cirrhosis;Lupus cystitis;Lupus encephalitis;Lupus endocarditis;Lupus enteritis;Lupus hepatitis;Lupus myocarditis;Lupus myositis;Lupus nephritis;Lupus pancreatitis;Lupus pleurisy;Lupus pneumonitis;Lupus vasculitis;Lupus-like syndrome;Lymphocytic hypophysitis;Lymphocytopenia neonatal;Lymphopenia;MAGIC syndrome;Magnetic resonance imaging liver abnormal;Magnetic resonance proton density fat fraction measurement;Mahler sign;Manufacturing laboratory analytical testing issue;Manufacturing materials issue;Manufacturing production issue;Marburg's variant multiple sclerosis;Marchiafava-Bignami disease;Marine Lenhart syndrome;Mastocytic enterocolitis;Maternal exposure during pregnancy;Medical device site thrombosis;Medical device site vasculitis;MELAS syndrome;Meningitis;Meningitis aseptic;Meningitis herpes;Meningoencephalitis herpes simplex neonatal;Meningoencephalitis herpetic;Meningomyelitis herpes;MERS-CoV test;MERS-CoV test negative;MERS-CoV test positive;Mesangioproliferative glomerulonephritis;Mesenteric artery embolism;Mesenteric artery thrombosis;Mesenteric vein thrombosis;Metapneumovirus infection;Metastatic cutaneous Crohn's disease;Metastatic pulmonary embolism;Microangiopathy;Microembolism;Microscopic polyangiitis;Middle East respiratory syndrome;Migraine-triggered seizure;Miliary pneumonia;Miller Fisher syndrome;Mitochondrial aspartate aminotransferase increased;Mixed connective tissue disease;Model for end stage liver disease score abnormal;Model for end stage liver disease score increased;Molar ratio of total branched-chain amino acid to tyrosine;Molybdenum cofactor deficiency;Monocytopenia;Mononeuritis;Mononeuropathy multiplex;Morphoea;Morvan syndrome;Mouth swelling;Moyamoya disease;Multifocal motor neuropathy;Multiple organ dysfunction syndrome;Multiple sclerosis;Multiple sclerosis relapse;Multiple sclerosis relapse prophylaxis;Multiple subpial transection;Multisystem inflammatory syndrome in children;Muscular sarcoidosis;Myasthenia gravis;Myasthenia gravis crisis;Myasthenia gravis neonatal;Myasthenic syndrome;Myelitis;Myelitis transverse;Myocardial infarction;Myocarditis;Myocarditis post infection;Myoclonic epilepsy;Myoclonic epilepsy and ragged-red fibres;Myokymia;Myositis;Narcolepsy;Nasal herpes;Nasal obstruction;Necrotising herpetic retinopathy;Neonatal Crohn's disease;Neonatal epileptic seizure;Neonatal lupus erythematosus;Neonatal mucocutaneous herpes simplex;Neonatal pneumonia;Neonatal seizure;Nephritis;Nephrogenic systemic fibrosis;Neuralgic amyotrophy;Neuritis;Neuritis cranial;Neuromyelitis optica pseudo relapse;Neuromyelitis optica spectrum disorder;Neuromyotonia;Neuronal neuropathy;Neuropathy peripheral;Neuropathy, ataxia, retinitis pigmentosa syndrome;Neuropsychiatric lupus;Neurosarcoidosis;Neutropenia;Neutropenia neonatal;Neutropenic colitis;Neutropenic infection;Neutropenic sepsis;Nodular rash;Nodular vasculitis;Noninfectious myelitis;Noninfective encephalitis;Noninfective encephalomyelitis;Noninfective oophoritis;Obstetrical pulmonary embolism;Occupational exposure to communicable disease;Occupational exposure to SARS-CoV-2;Ocular hyperaemia;Ocular myasthenia;Ocular pemphigoid;Ocular sarcoidosis;Ocular vasculitis;Oculofacial paralysis;Oedema;Oedema blister;Oedema due to hepatic disease;Oedema mouth;Oesophageal achalasia;Ophthalmic artery thrombosis;Ophthalmic herpes simplex;Ophthalmic herpes zoster;Ophthalmic vein thrombosis;Optic neuritis;Optic

neuropathy;Optic perineuritis;Oral herpes;Oral lichen planus;Oropharyngeal oedema;Oropharyngeal spasm;Oropharyngeal swelling;Osmotic demyelination syndrome;Ovarian vein thrombosis;Overlap syndrome;Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection;Paget-Schroetter syndrome;Palindromic rheumatism;Palisaded neutrophilic granulomatous dermatitis;Palmoplantar keratoderma;Palpable purpura;Pancreatitis;Panencephalitis;Papillophlebitis;Paracancerous pneumonia;Paradoxical embolism;Parainfluenzae viral laryngotracheobronchitis;Paraneoplastic dermatomyositis;Paraneoplastic pemphigus;Paraneoplastic thrombosis;Paresis cranial nerve;Parietal cell antibody positive;Paroxysmal nocturnal haemoglobinuria;Partial seizures;Partial seizures with secondary generalisation;Patient isolation;Pelvic venous thrombosis;Pemphigoid;Pemphigus;Penile vein thrombosis;Pericarditis;Pericarditis lupus;Perihepatic discomfort;Periorbital oedema;Periorbital swelling;Peripheral artery thrombosis;Peripheral embolism;Peripheral ischaemia;Peripheral vein thrombus extension;Periportal oedema;Peritoneal fluid protein abnormal;Peritoneal fluid protein decreased;Peritoneal fluid protein increased;Peritonitis lupus;Pernicious anaemia;Petit mal epilepsy;Pharyngeal oedema;Pharyngeal swelling;Pityriasis lichenoides et varioliformis acuta;Placenta praevia;Pleuroparenchymal fibroelastosis;Pneumobilia;Pneumonia;Pneumonia adenoviral;Pneumonia cytomegaloviral;Pneumonia herpes viral;Pneumonia influenzal;Pneumonia measles;Pneumonia mycoplasmal;Pneumonia necrotising;Pneumonia parainfluenzae viral;Pneumonia respiratory syncytial viral;Pneumonia viral;POEMS syndrome;Polyarteritis nodosa;Polyarthritis;Polychondritis;Polyglandular autoimmune syndrome type I;Polyglandular autoimmune syndrome type II;Polyglandular autoimmune syndrome type III;Polyglandular disorder;Polymicrogyria;Polymyalgia rheumatica;Polymyositis;Polyneuropathy;Polyneuropathy idiopathic progressive;Portal pyaemia;Portal vein embolism;Portal vein flow decreased;Portal vein pressure increased;Portal vein thrombosis;Portosplenomesenteric venous thrombosis;Post procedural hypotension;Post procedural pneumonia;Post procedural pulmonary embolism;Post stroke epilepsy;Post stroke seizure;Post thrombotic retinopathy;Post thrombotic syndrome;Post viral fatigue syndrome;Postictal headache;Postictal paralysis;Postictal psychosis;Postictal state;Postoperative respiratory distress;Postoperative respiratory failure;Postoperative thrombosis;Postpartum thrombosis;Postpartum venous thrombosis;Postpericardiotomy syndrome;Post-traumatic epilepsy;Postural orthostatic tachycardia syndrome;Precerebral artery thrombosis;Pre-eclampsia;Preictal state;Premature labour;Premature menopause;Primary amyloidosis;Primary biliary cholangitis;Primary progressive multiple sclerosis;Procedural shock;Proctitis herpes;Proctitis ulcerative;Product availability issue;Product distribution issue;Product supply issue;Progressive facial hemiatrophy;Progressive multifocal leukoencephalopathy;Progressive multiple sclerosis;Progressive relapsing multiple sclerosis;Prosthetic cardiac valve thrombosis;Pruritus;Pruritus allergic;Pseudovasculitis;Psoriasis;Psoriatic arthropathy;Pulmonary amyloidosis;Pulmonary artery thrombosis;Pulmonary embolism;Pulmonary fibrosis;Pulmonary haemorrhage;Pulmonary microemboli;Pulmonary oil microembolism;Pulmonary renal syndrome;Pulmonary sarcoidosis;Pulmonary sepsis;Pulmonary thrombosis;Pulmonary tumour thrombotic microangiopathy;Pulmonary vasculitis;Pulmonary veno-occlusive disease;Pulmonary venous thrombosis;Pyoderma gangrenosum;Pyostomatitis vegetans;Pyrexia;Quarantine;Radiation leukopenia;Radiculitis

brachial;Radiologically isolated syndrome;Rash;Rash erythematous;Rash pruritic;Rasmussen encephalitis;Raynaud's phenomenon;Reactive capillary endothelial proliferation;Relapsing multiple sclerosis;Relapsing-remitting multiple sclerosis;Renal amyloidosis;Renal arteritis;Renal artery thrombosis;Renal embolism;Renal failure;Renal vascular thrombosis;Renal vasculitis;Renal vein embolism;Renal vein thrombosis;Respiratory arrest;Respiratory disorder;Respiratory distress;Respiratory failure;Respiratory paralysis;Respiratory syncytial virus bronchiolitis;Respiratory syncytial virus bronchitis;Retinal artery embolism;Retinal artery occlusion;Retinal artery thrombosis;Retinal vascular thrombosis;Retinal vasculitis;Retinal vein occlusion;Retinal vein thrombosis;Retinol binding protein decreased;Retinopathy;Retrograde portal vein flow;Retroperitoneal fibrosis;Reversible airways obstruction;Reynold's syndrome;Rheumatic brain disease;Rheumatic disorder;Rheumatoid arthritis;Rheumatoid factor increased;Rheumatoid factor positive;Rheumatoid factor quantitative increased;Rheumatoid lung;Rheumatoid neutrophilic dermatosis;Rheumatoid nodule;Rheumatoid nodule removal;Rheumatoid scleritis;Rheumatoid vasculitis;Saccadic eye movement;SAPHO syndrome;Sarcoidosis;SARS-CoV-1 test;SARS-CoV-1 test negative;SARS-CoV-1 test positive;SARS-CoV-2 antibody test;SARS-CoV-2 antibody test negative;SARS-CoV-2 antibody test positive;SARS-CoV-2 carrier;SARS-CoV-2 sepsis;SARS-CoV-2 test;SARS-CoV-2 test false negative;SARS-CoV-2 test false positive;SARS-CoV-2 test negative;SARS-CoV-2 test positive;SARS-CoV-2 viraemia;Satoyoshi syndrome;Schizencephaly;Scleritis;Sclerodactylia;Scleroderma;Scleroderma associated digital ulcer;Scleroderma renal crisis;Scleroderma-like reaction;Secondary amyloidosis;Secondary cerebellar degeneration;Secondary progressive multiple sclerosis;Segmented hyalinising vasculitis;Seizure;Seizure anoxic;Seizure cluster;Seizure like phenomena;Seizure prophylaxis;Sensation of foreign body;Septic embolus;Septic pulmonary embolism;Severe acute respiratory syndrome;Severe myoclonic epilepsy of infancy;Shock;Shock symptom;Shrinking lung syndrome;Shunt thrombosis;Silent thyroiditis;Simple partial seizures;Sjogren's syndrome;Skin swelling;SLE arthritis;Smooth muscle antibody positive;Sneezing;Spinal artery embolism;Spinal artery thrombosis;Splenic artery thrombosis;Splenic embolism;Splenic thrombosis;Splenic vein thrombosis;Spondylitis;Spondyloarthropathy;Spontaneous heparin-induced thrombocytopenia syndrome;Status epilepticus;Stevens-Johnson syndrome;Stiff leg syndrome;Stiff person syndrome;Stillbirth;Still's disease;Stoma site thrombosis;Stoma site vasculitis;Stress cardiomyopathy;Stridor;Subacute cutaneous lupus erythematosus;Subacute endocarditis;Subacute inflammatory demyelinating polyneuropathy;Subclavian artery embolism;Subclavian artery thrombosis;Subclavian vein thrombosis;Sudden unexplained death in epilepsy;Superior sagittal sinus thrombosis;Susac's syndrome;Suspected COVID-19;Swelling;Swelling face;Swelling of eyelid;Swollen tongue;Sympathetic ophthalmia;Systemic lupus erythematosus;Systemic lupus erythematosus disease activity index abnormal;Systemic lupus erythematosus disease activity index decreased;Systemic lupus erythematosus disease activity index increased;Systemic lupus erythematosus rash;Systemic scleroderma;Systemic sclerosis pulmonary;Tachycardia;Tachypnoea;Takayasu's arteritis;Temporal lobe epilepsy;Terminal ileitis;Testicular autoimmunity;Throat tightness;Thromboangiitis obliterans;Thrombocytopenia;Thrombocytopenic purpura;Thrombophlebitis;Thrombophlebitis migrans;Thrombophlebitis

neonatal;Thrombophlebitis septic;Thrombophlebitis superficial;Thromboplastin antibody positive;Thrombosis;Thrombosis corpora cavernosa;Thrombosis in device;Thrombosis mesenteric vessel;Thrombotic cerebral infarction;Thrombotic microangiopathy;Thrombotic stroke;Thrombotic thrombocytopenic purpura;Thyroid disorder;Thyroid stimulating immunoglobulin increased;Thyroiditis;Tongue amyloidosis;Tongue biting;Tongue oedema;Tonic clonic movements;Tonic convulsion;Tonic posturing;Topectomy;Total bile acids increased;Toxic epidermal necrolysis;Toxic leukoencephalopathy;Toxic oil syndrome;Tracheal obstruction;Tracheal oedema;Tracheobronchitis;Tracheobronchitis mycoplasmal;Tracheobronchitis viral;Transaminases abnormal;Transaminases increased;Transfusion-related alloimmune neutropenia;Transient epileptic amnesia;Transverse sinus thrombosis;Trigeminal nerve paresis;Trigeminal neuralgia;Trigeminal palsy;Truncus coeliacus thrombosis;Tuberous sclerosis complex;Tubulointerstitial nephritis and uveitis syndrome;Tumefactive multiple sclerosis;Tumour embolism;Tumour thrombosis;Type 1 diabetes mellitus;Type I hypersensitivity;Type III immune complex mediated reaction;Uhthoff's phenomenon;Ulcerative keratitis;Ultrasound liver abnormal;Umbilical cord thrombosis;Uncinate fits;Undifferentiated connective tissue disease;Upper airway obstruction;Urine bilirubin increased;Urobilinogen urine decreased;Urobilinogen urine increased;Urticaria;Urticaria papular;Urticarial vasculitis;Uterine rupture;Uveitis;Vaccination site thrombosis;Vaccination site vasculitis;Vagus nerve paralysis;Varicella;Varicella keratitis;Varicella post vaccine;Varicella zoster gastritis;Varicella zoster oesophagitis;Varicella zoster pneumonia;Varicella zoster sepsis;Varicella zoster virus infection;Vasa praevia;Vascular graft thrombosis;Vascular pseudoaneurysm thrombosis;Vascular purpura;Vascular stent thrombosis;Vasculitic rash;Vasculitic ulcer;Vasculitis;Vasculitis gastrointestinal;Vasculitis necrotising;Vena cava embolism;Vena cava thrombosis;Venous intravasation;Venous recanalisation;Venous thrombosis;Venous thrombosis in pregnancy;Venous thrombosis limb;Venous thrombosis neonatal;Vertebral artery thrombosis;Vessel puncture site thrombosis;Visceral venous thrombosis;VIth nerve paralysis;VIth nerve paresis;Vitiligo;Vocal cord paralysis;Vocal cord paresis;Vogt-Koyanagi-Harada disease;Warm type haemolytic anaemia;Wheezing;White nipple sign;XIth nerve paralysis;X-ray hepatobiliary abnormal;Young's syndrome;Zika virus associated Guillain Barre syndrome.

# NEW WORLD ORDER
# UN AGENDA 21 / AGENDA 2030
# MISSION GOALS

- One World Government
- One World Cashless Currency
- One World Central Bank
- One World Military
- The End of National Sovereignty
- The End of All Privately Owned Property
- The End of the Family Unit
- Depopulation. Control of Population Growth and Population Density
- Mandatory Multiple Vaccin.
- Universal Basic Income (Austerity)
- Microchipped Society for purchasing, Travel, Backing and Controlling
- Implementation of a World Social Credit System
- Trillion of Appliances Hooked into the 5G Monitoring System (Internet of Things)
- Government Raised Children
- Government Owned and Controlled Schools, Colleges, Universities
- The End of Private Transportation, Owning Cars, etc.
- All Businesses Owned by Govemment/Corporations
- The Restriction of Nonessential Air Travel
- Human Beings Concentrated into Human Settlement Zones/Smart Cities
- The End of Inigation
- The End of Private Farms and Grazing Livestock
- The End of Single Family Homes
- Restricted Land Use that Serves Human Needs
- The Ban of Natural Non Synthetic Drugs and Naturopathic Medicine
- The End of Fossil Fuels