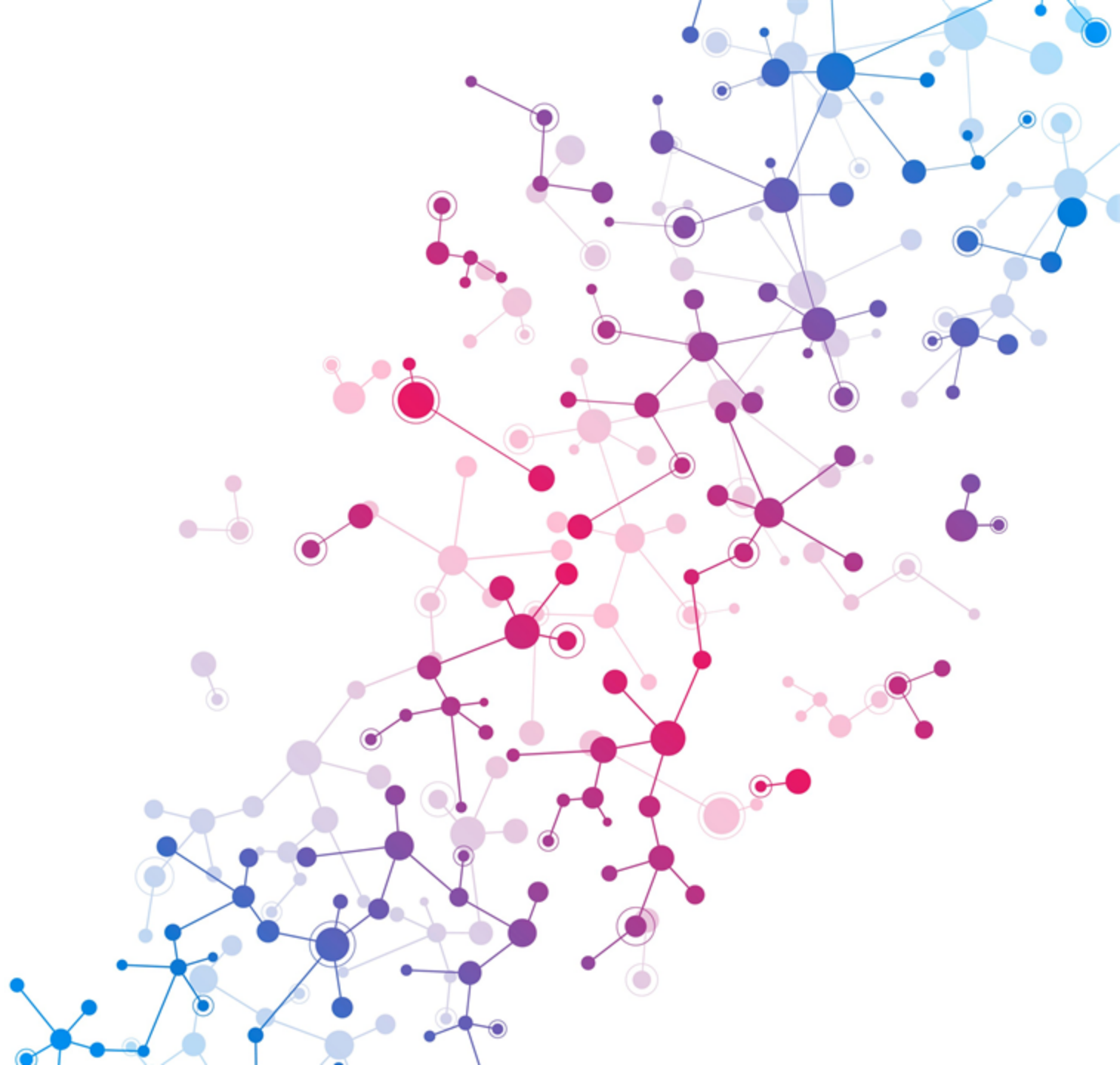


Covid-19 Vaccines

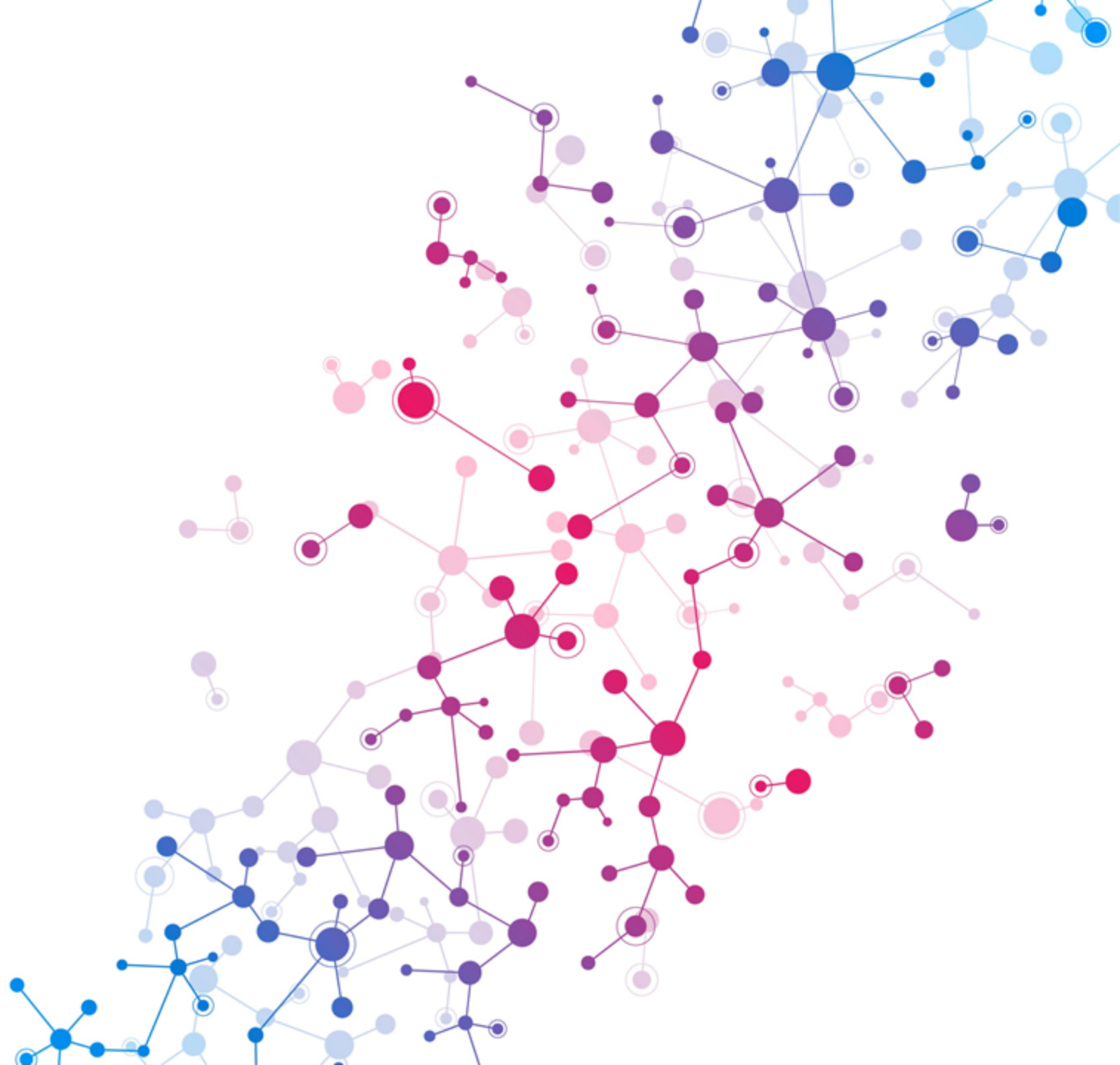
Sabina Vohra-Miller

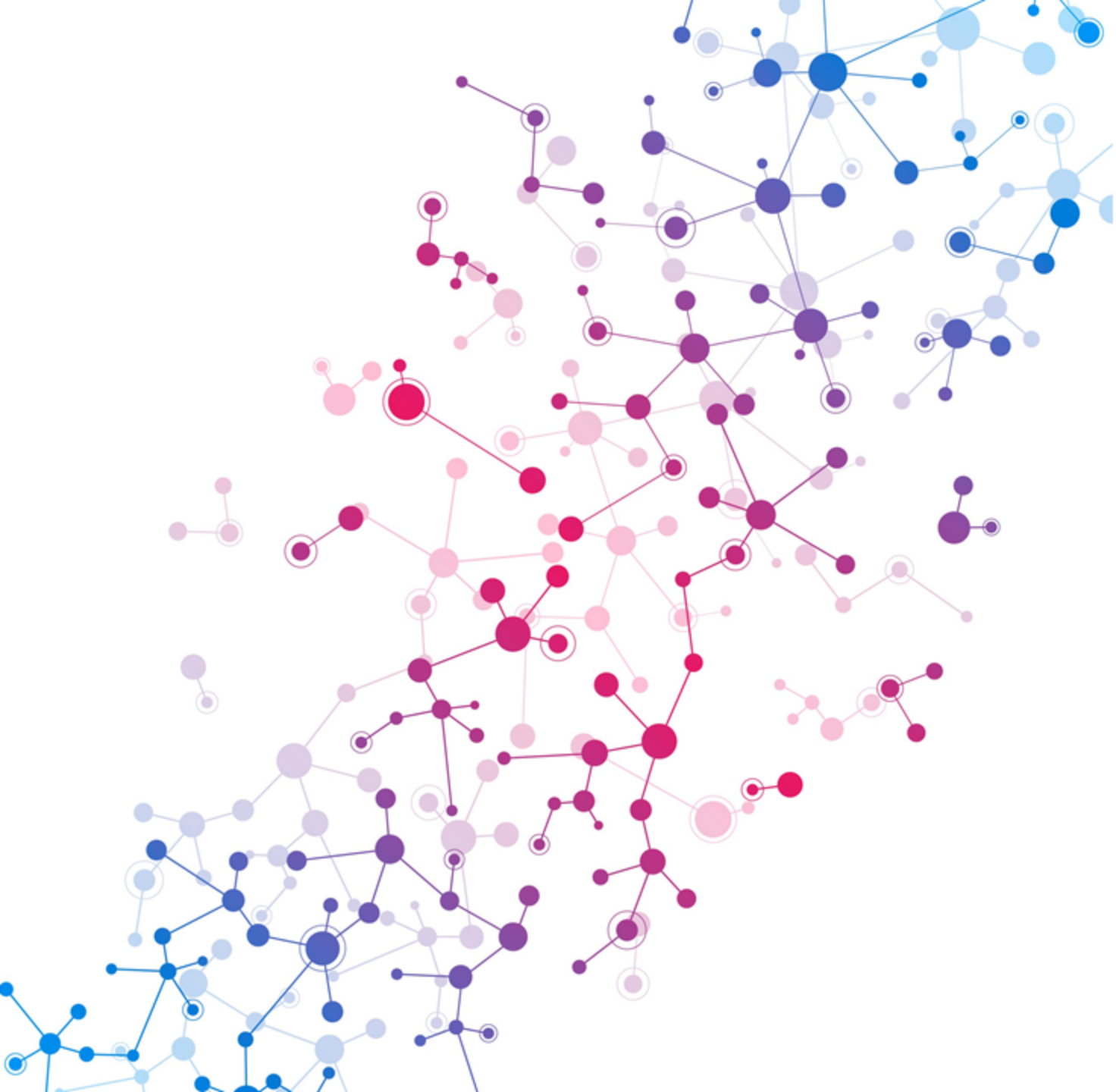
UNAMBIGUOUS
SCIENCE



Overview

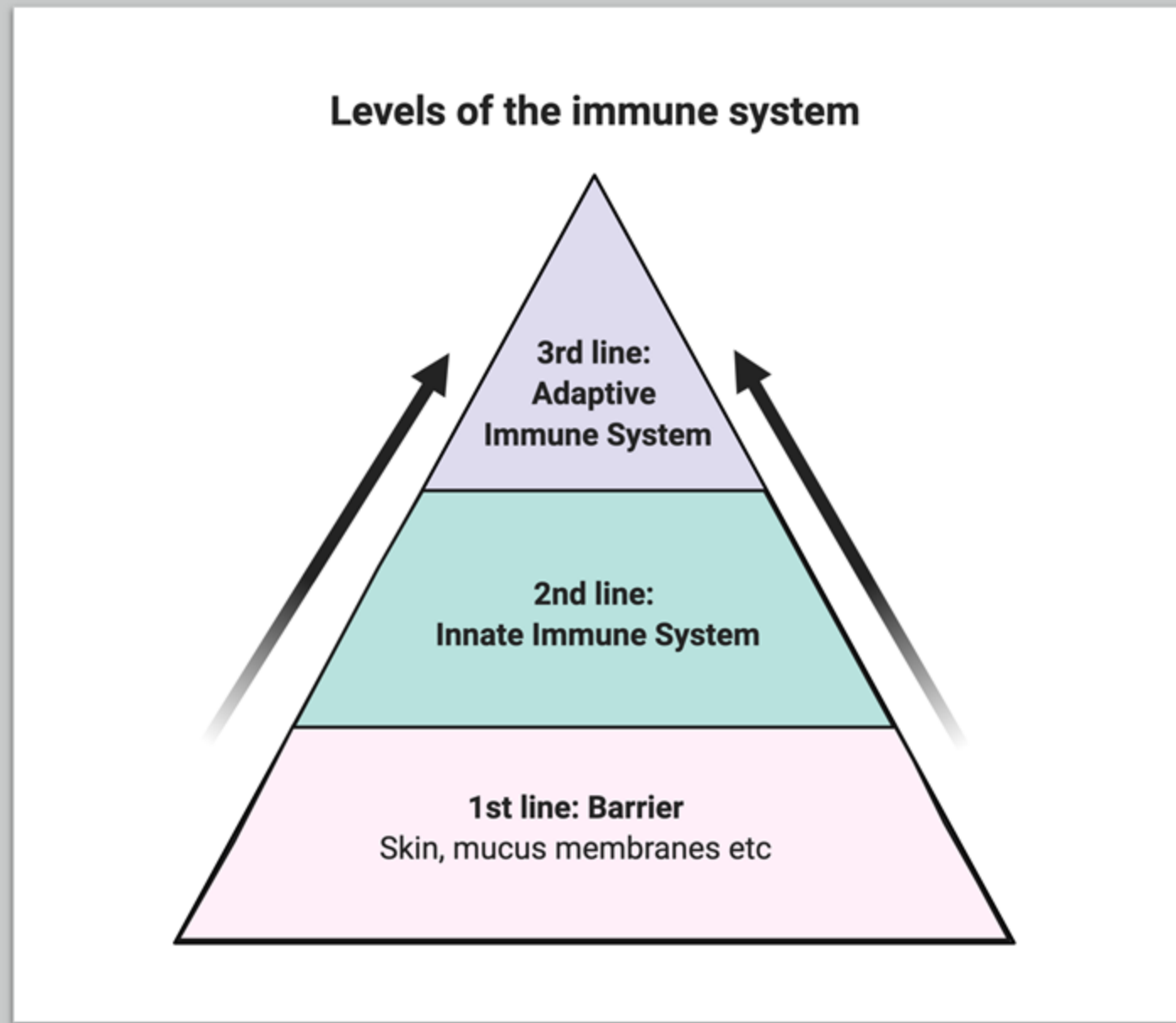
1. The Immune System
2. Current mRNA Vaccines
3. Special Circumstances and Populations
4. Common Questions
5. Other Covid-19 Vaccines



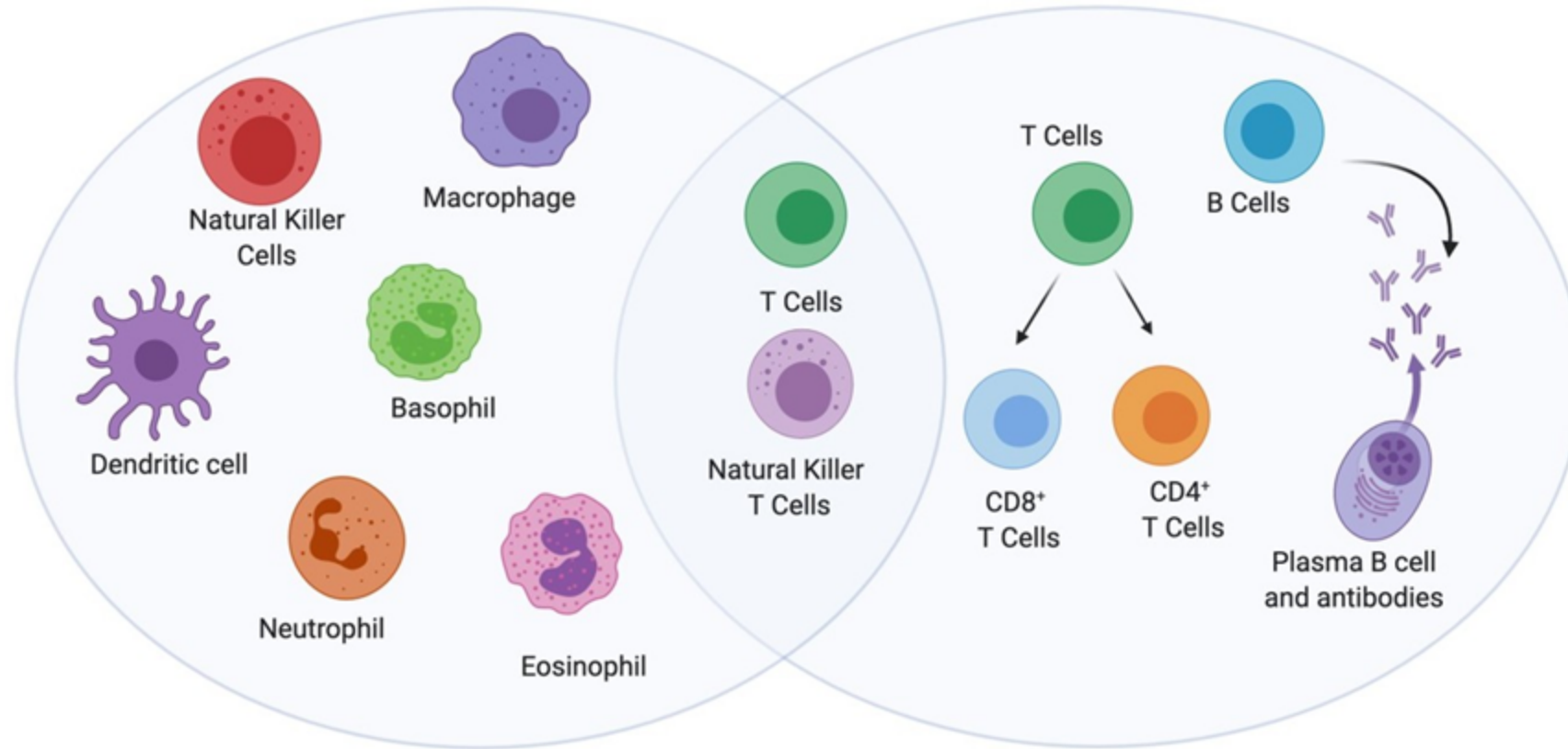


The Immune System

Immune System - Levels



Immune System – Cells Involved



Immune System - Infections



Your immune system is designed to attack anything that is foreign to your body, such as a virus or bacteria.



When it encounters something new, it takes a while for the body to ramp up its immune system defense system.




But, once it fights off that virus, it also produces a special kind of immunity memory that helps it remember the virus. So the next time you come into contact with the virus, your body remembers and is able to quickly assemble its defence system.

Immune System - Infections

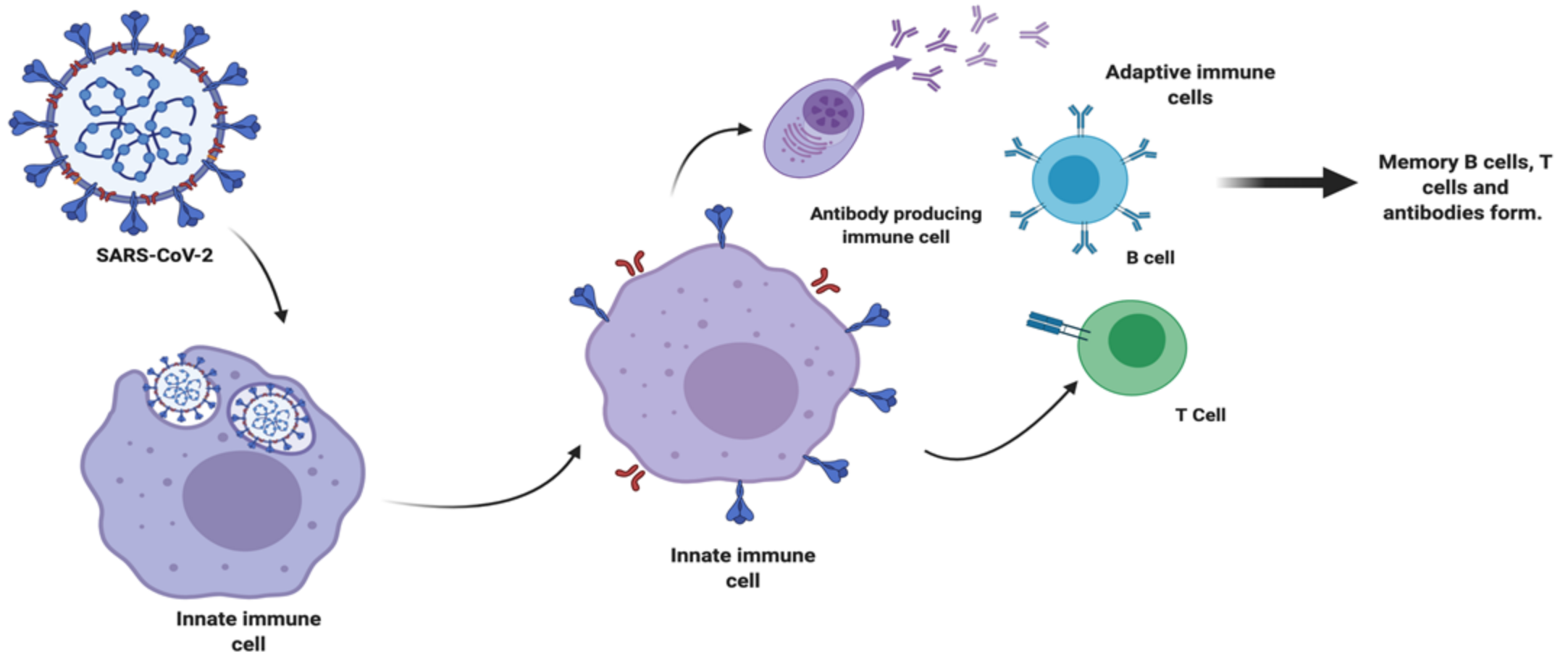
The Innate immune system responds first. This response is non-specific!

The Adaptive immune system takes longer to ramp up, but has specialized cells that will help fight the infection such as antibodies.



The Adaptive immune system will also produce memory cells. These cells remember the disease-causing organism and helps protect you in case you are re-exposed.

Immune System - Infections



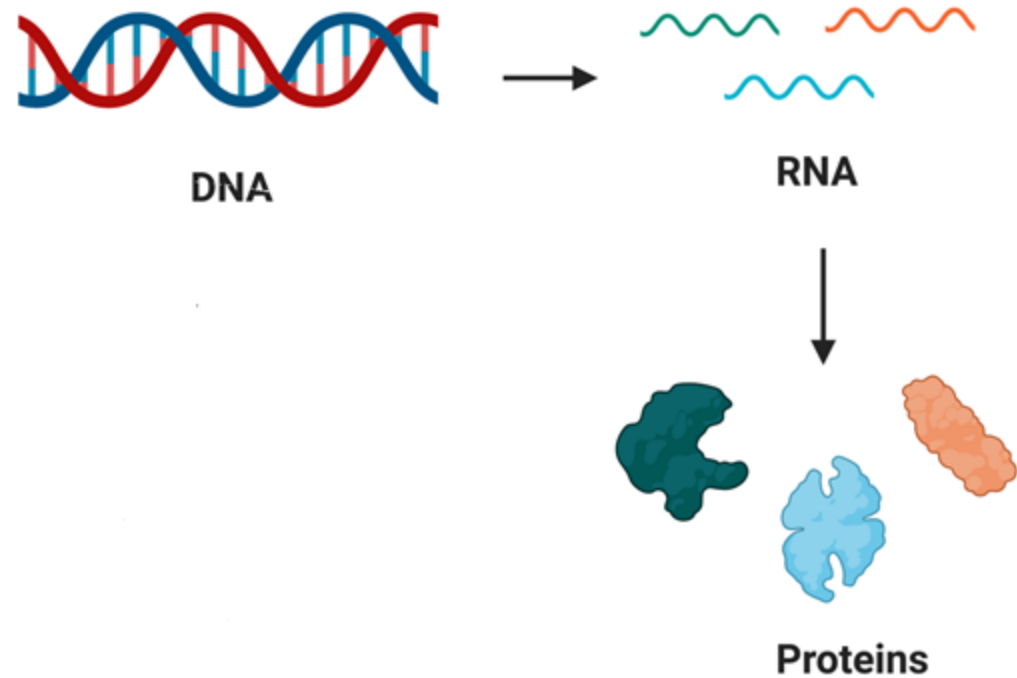
How do vaccines work?

- When you vaccinate, you are essentially putting a small amount of the inactivated or attenuated (weakened) disease-causing organism into the body, so that the body ramps up an immune response against it.
- So later if your body comes across the actual disease-causing organism, it recognizes and responds immediately and fights it off.

Vaccines provide protection because they cause your immune system to make memory cells, so that when you're exposed to the real infection your immune system can quickly protect you.

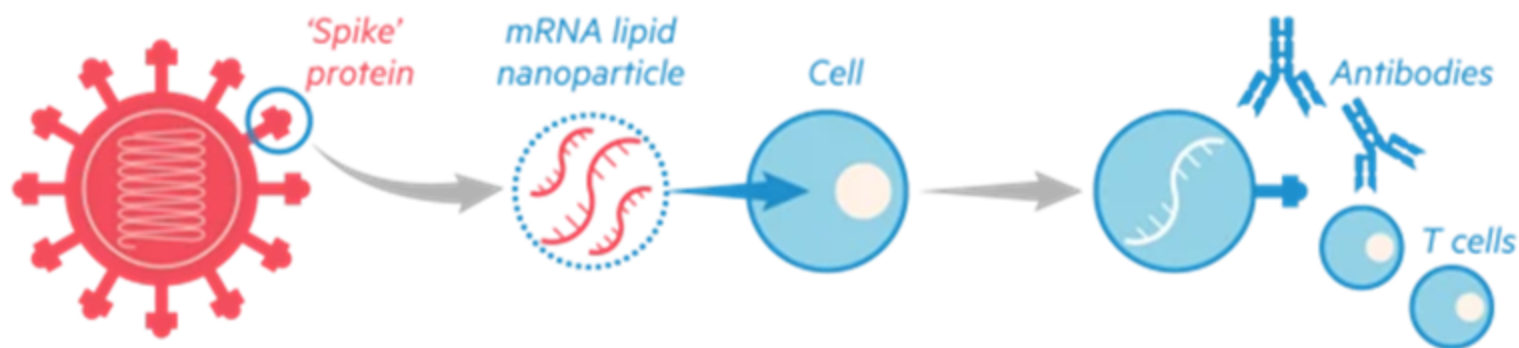
What is mRNA?

- mRNA stands for messenger RNA.
- mRNA gives instructions to our body to make things such as proteins.



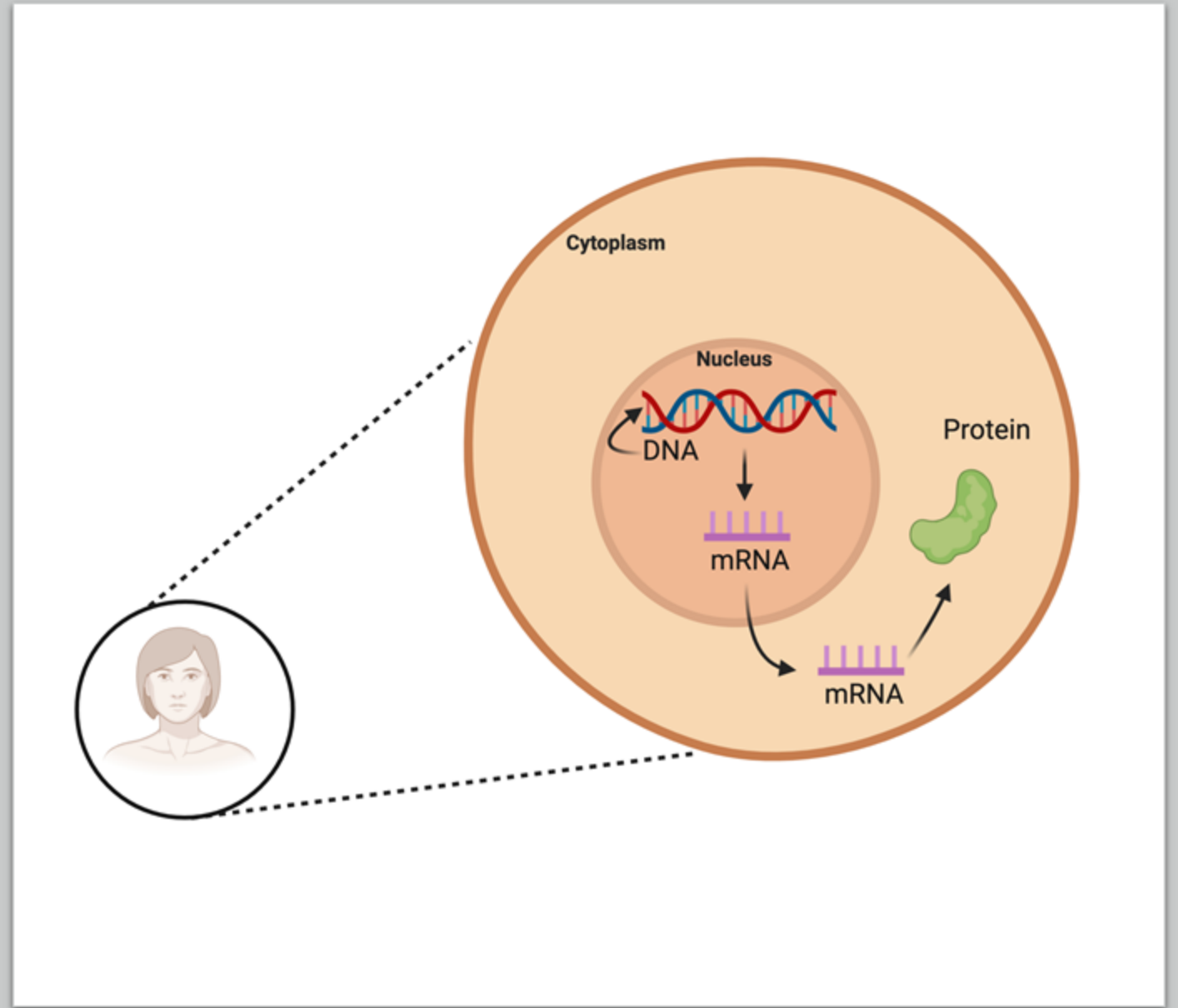
How do mRNA vaccines work?

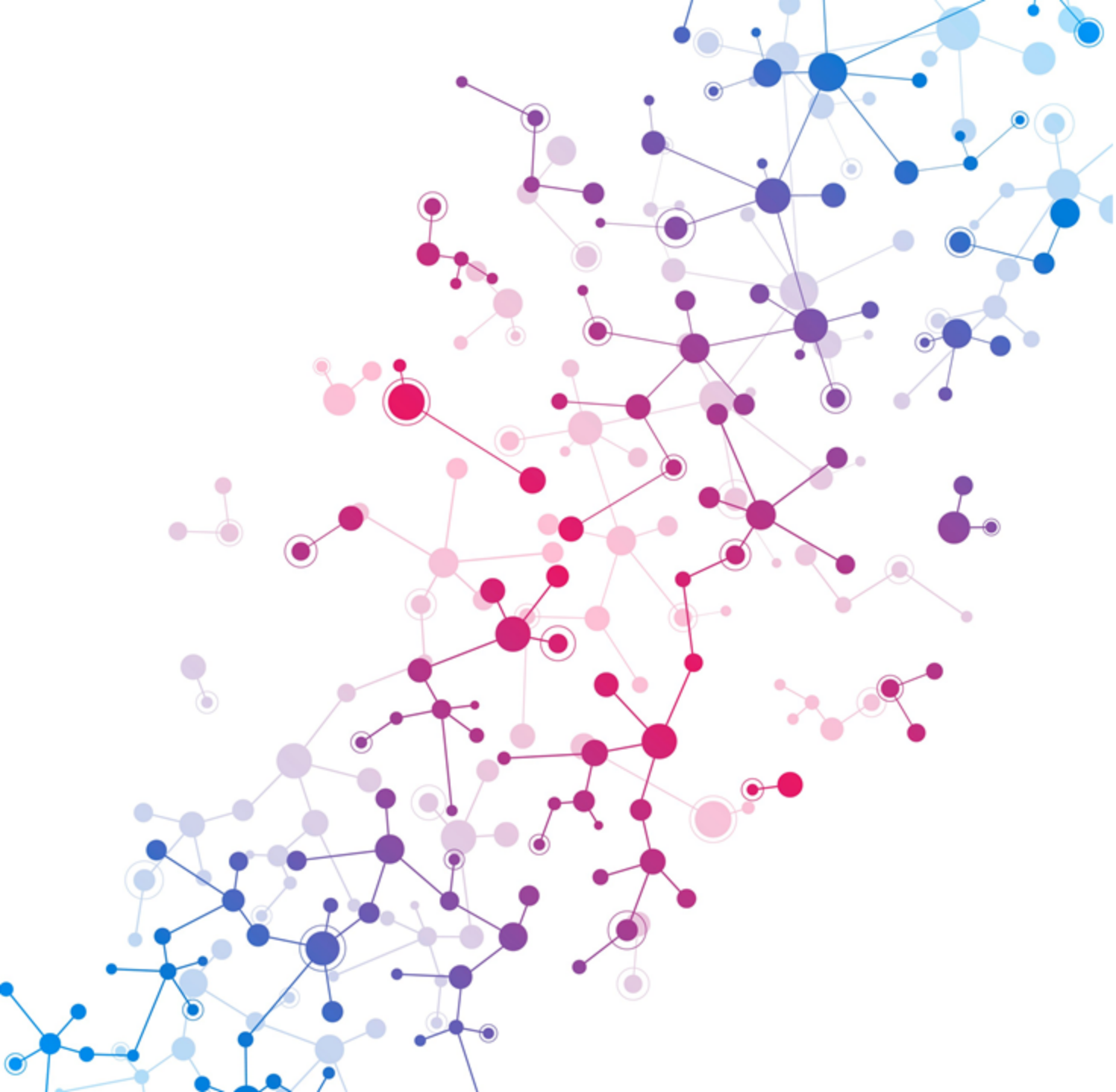
- In these vaccines, synthetic mRNA is used to tell the body to make a harmless piece of the 'spike protein' that is found on the surface of the actual COVID-19 virus.
- These vaccines work by delivering mRNA instructions or a 'recipe card' that direct the body to produce a small amount of the spike protein.
- Our body recognizes that this protein doesn't belong here and ramps up an immune response by producing protective antibodies against the COVID-19 against the 'spike protein' so if later our body comes in contact with the actual COVID-19 causing virus, it knows how to fight it off.



mRNA does not impact your DNA

- mRNA does not change or impact your DNA in any way
- mRNA simply gives instructions to our body to make things such as proteins.
- mRNA also degrades very quickly after.





**Two Covid-19
vaccines are
currently
approved in
Canada:**

**Pfizer-BioNTech
and Moderna**

Pfizer-BioNTech and Moderna Clinical Trial Data

Pfizer-BioNTech	Moderna
>40,000 participants	>30,000 participants
≥ 16 years	≥ 18 years
21 days apart	28 days apart

- Hundreds of thousands of participants, including older adults, through extensive clinical trials
- Have met all the requirements for approval, including safety requirements, and no requirements were overlooked in order to approve them

What is the efficacy in protecting against COVID-19 illness?

Pfizer-BioNTech	Moderna
95%	94.1%

- **Efficacy consistent across age, gender, race and ethnicity demographics**
- **The 5-6% who did get Covid-19 did not have severe disease**



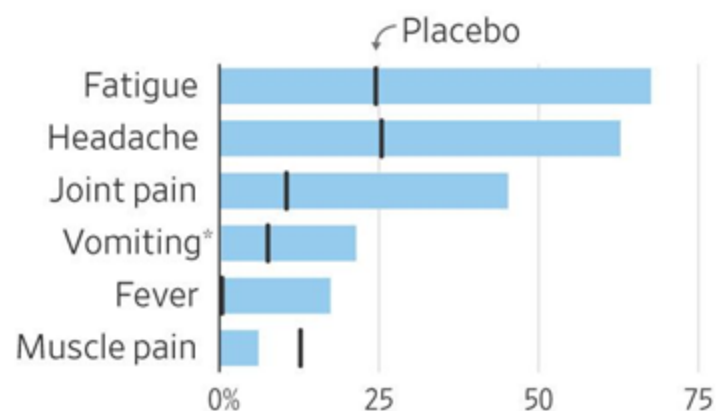
Were the studies diverse and include racialized groups?

	Moderna	Pfizer-BioNTech
White	79.1%	82.9%
Black or African American	10.1%	9.2%
Asian	4.8%	4.2%
American Indian or Alaska Native (Indigenous)	0.8%	0.5%
Native Hawaiian or Pacific Islander	0.2%	0.2
Multi-racial	2.1%	2.1%
Hispanic/Latinx	20.5%	27.9%
Other	2.1%	2.1%

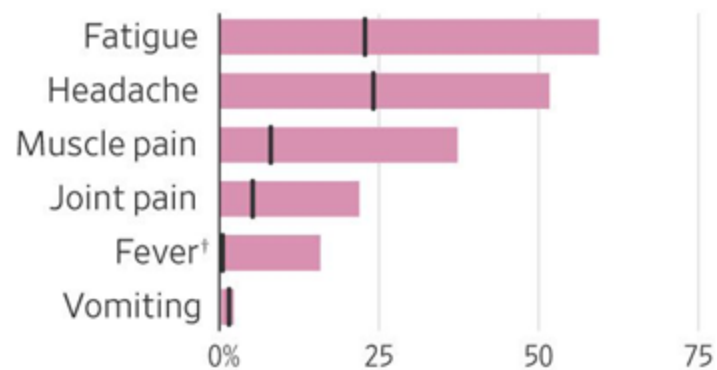
No difference in the effectiveness of the vaccine in different populations

What are the common side-effects?

MODERNA VACCINE



PFIZER



*Including nausea †100.4°F or higher

Note: For ages 18-64 for Moderna, 18-55 for Pfizer

Source: FDA

Very common $\geq 10\%$ (more than 1 in 10 doses)

- pain at the injection site
- headache, feeling tired
- muscle or joint pain
- fever or chills

Common 1%-10% (1 in 100 to 1 in 10 doses)

- redness & swelling at the injection site
- nausea & vomiting

Uncommon 1% (1 in 100 doses)

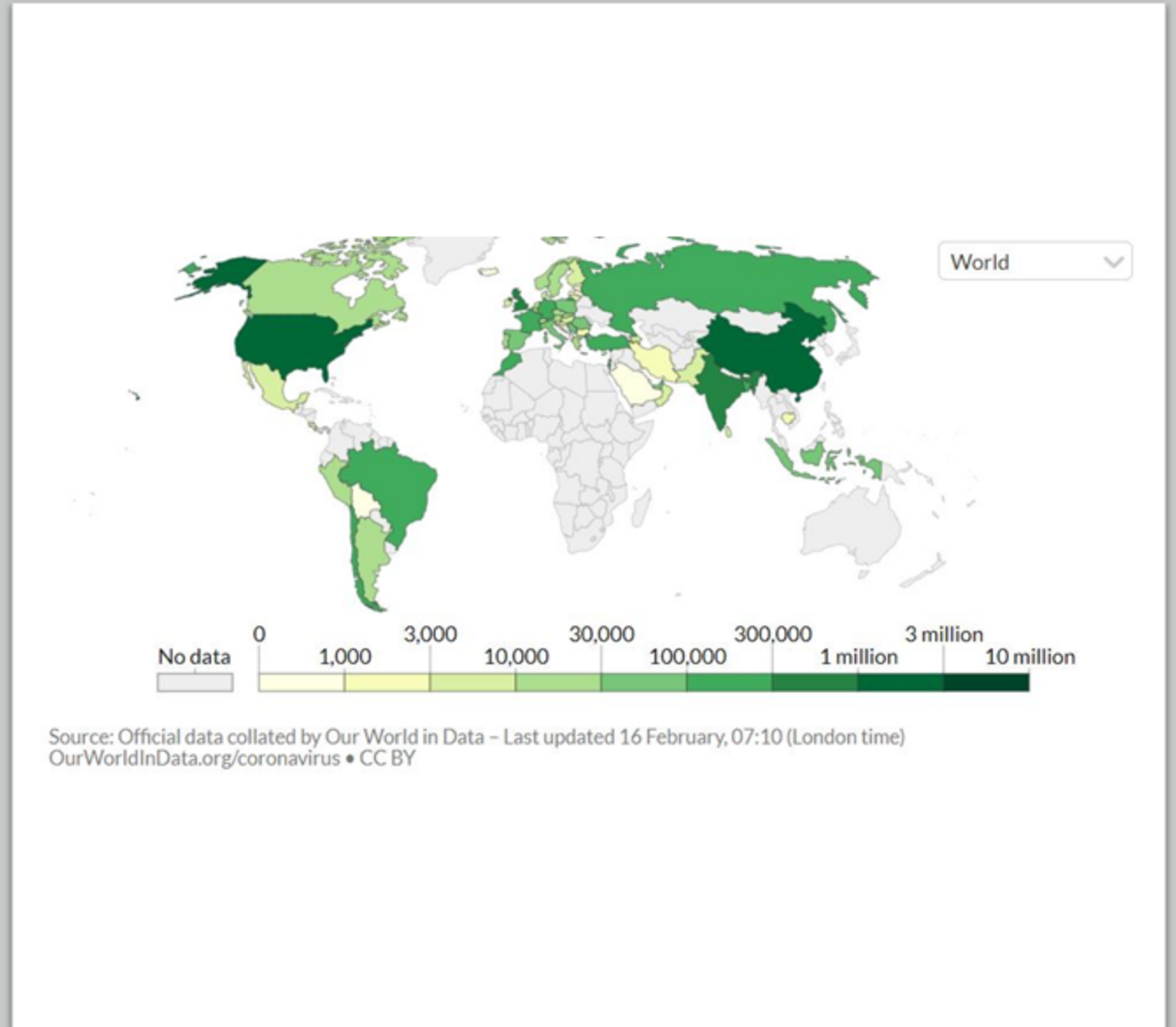
- enlarged lymph nodes

Very rare

- serious allergic reactions such as anaphylaxis

Generally resolve in 1-3 days

As of Feb. 11th,
152 MILLION
DOSES of
Covid-19
vaccines have
been given



Contraindications

- Severe allergic reaction after previous administration of these or any mRNA vaccines.
- Proven immediate or anaphylactic hypersensitivity to any component of the vaccine or its container, including polyethylene glycol and polysorbate.



Precautions

- Symptoms of confirmed or suspected Covid-19 infection – wait until recovered.
- Acute illness, as a precautionary measure.
- Those who have received another vaccine in the past 14 days
- Anyone outside the authorized age group (< 16).



Anaphylaxis Reactions

90% occur within 30 minutes of vaccination.

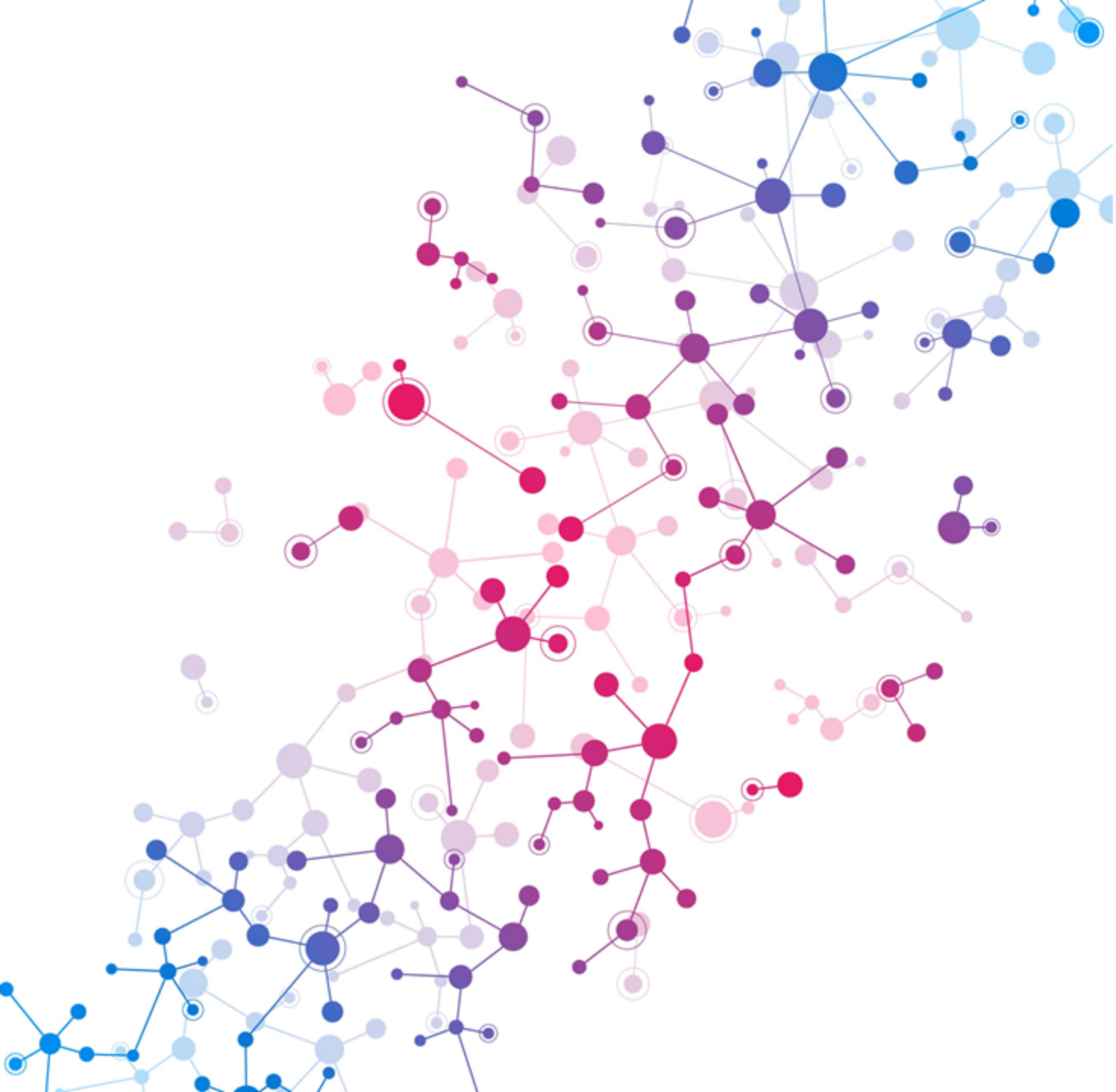
Reported Vaccine doses administered	Anaphylaxis Cases	Reporting Rate (Dec 14 – Jan 18)
Pfizer-BioNTech: 9,943,247	50	5.0 per million doses administered
Moderna: 7,581,429	21	2.8 per million doses administered

CDC advisory report on Jan 29, 2021

Allergic Reactions

- Some people have also experienced non-severe allergic reactions within 4 hours after getting vaccinated (known as immediate allergic reactions), such as hives, swelling, and wheezing (respiratory distress)
- It is possible that some people are allergic to an ingredient in the COVID-19 vaccines; but, it is important to remember these allergic reactions are relatively rare
- It is recommended that if you have allergies, including severe allergies that require you to carry an EpiPen, to discuss the vaccine with your doctor who can assess your risk





Special Circumstances and Populations

Special Populations – Immunocompromised (conditions/meds)

- Currently, there are no data on COVID-19 vaccination in individuals who are immunosuppressed.
- In the vaccine clinical trials, only participants who were not immunosuppressed, such as those with stable HIV infection and those not receiving immunosuppressive therapy were included.
- No safety signals of concern have been noted in these participants.
- Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine.

Talk to your health care provider for further guidance



Special Populations – Pregnancy, Breastfeeding

- NACI, SOGC recommends COVID-19 vaccine should be offered to pregnant and breastfeeding individuals if a risk assessment deems that the benefits outweigh the potential risks, given the elevated risks associated with Covid-19 illness and outcomes in pregnancy.
- As with pretty much any clinical trial on medications or vaccines, pregnant and breastfeeding individuals are excluded. Due to this, we do not have data in pregnancy or breastfeeding.
- There were a few pregnant people in the trials and no adverse effects were noted.
- mRNA vaccines are not live viruses and break down very quickly in the body. There are risks of severe illness from COVID-19 infection during pregnancy

Talk to your health care provider



Source: NACI, SOGC

Special Populations – Children

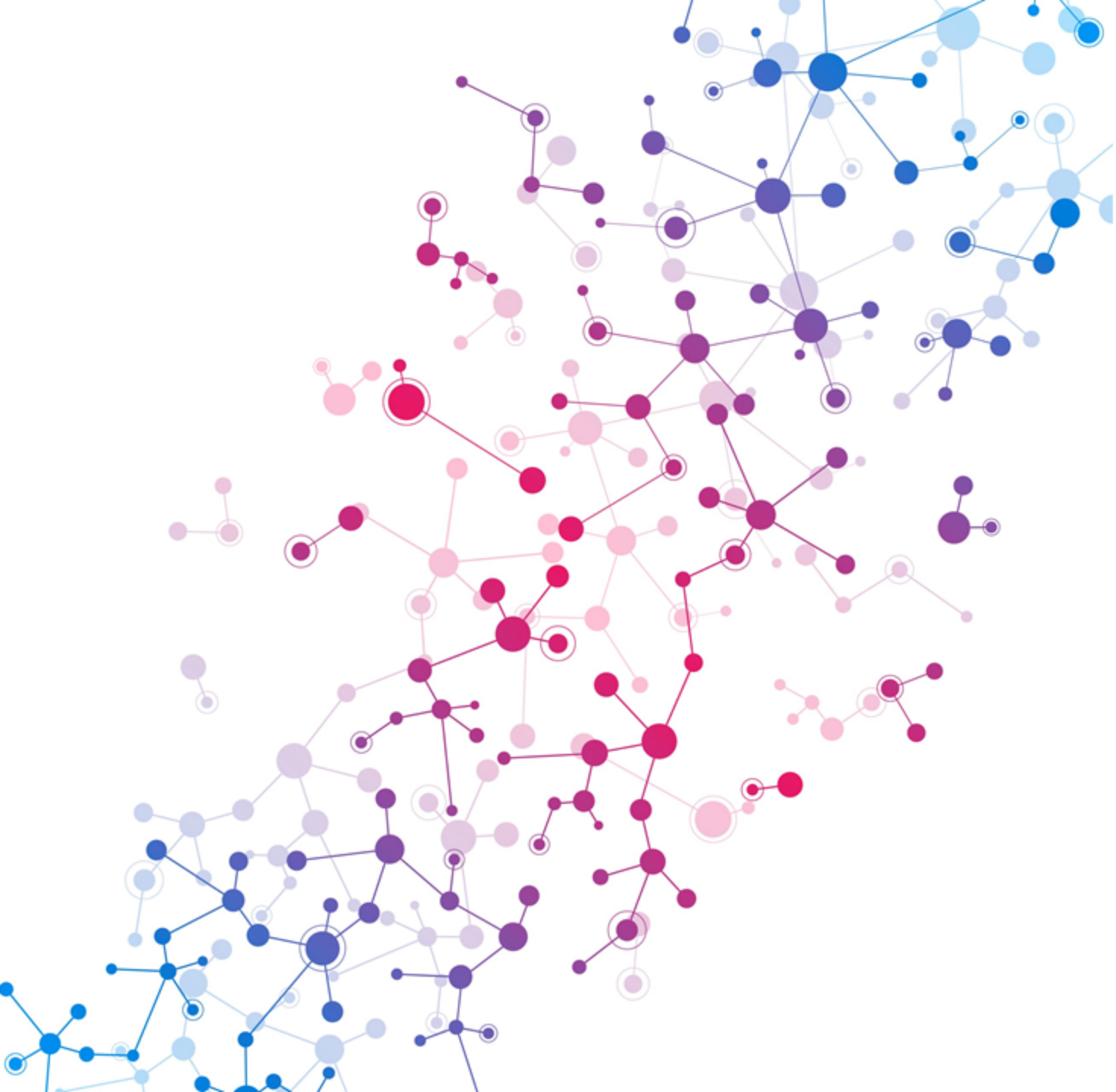
- The vaccine has not been tested in children under age 16.
- Currently, the vaccine is available and recommended in people aged 16+.
- Clinical trials are underway in the adolescent 12-16 age group and data will be available in 2021.



Special Populations – Elderly

- The vaccine trials included patients aged 65+.
- Efficacy was very similar to the younger age group (95%).
- Older patients experienced slightly fewer side effects.

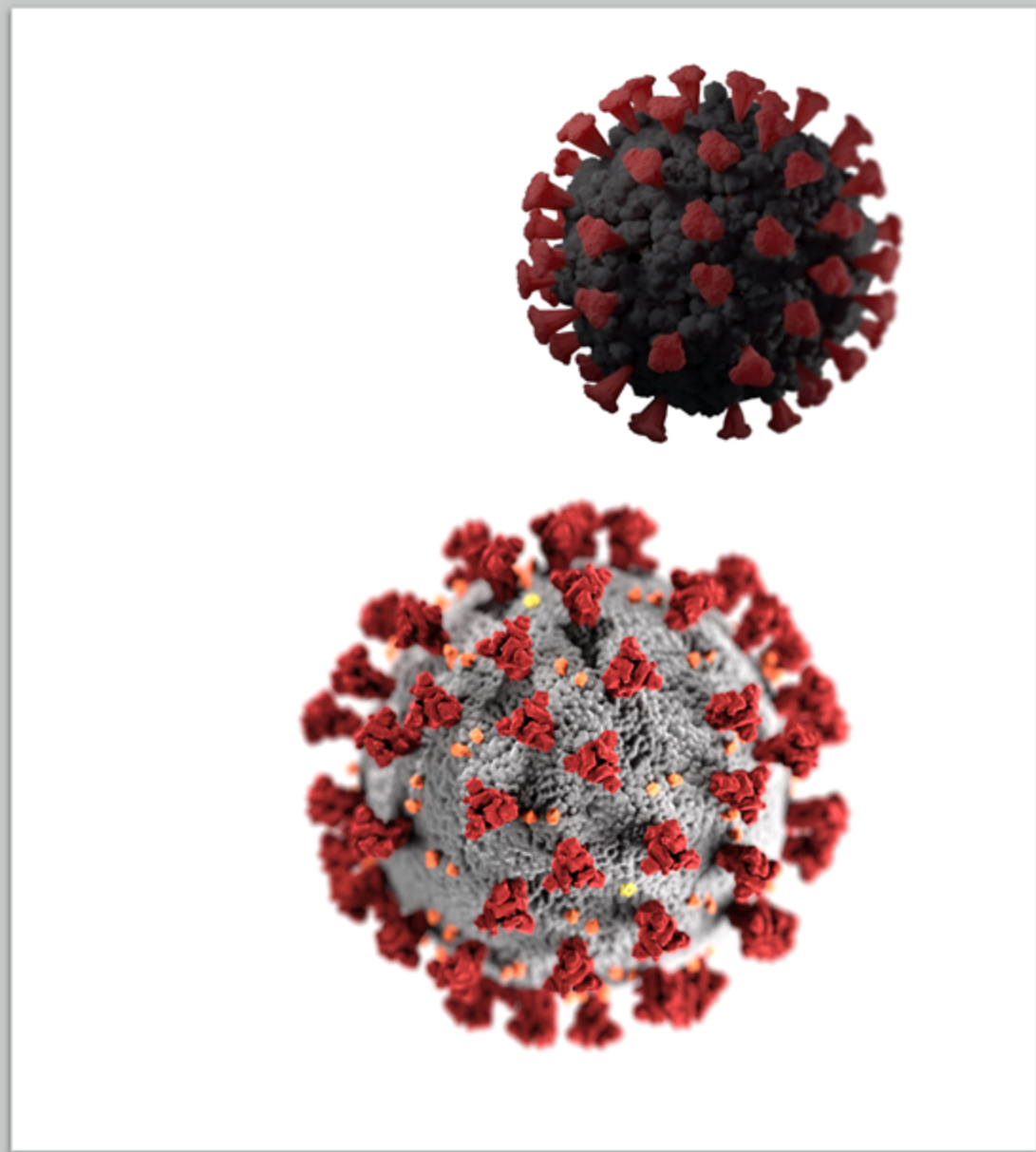




Common Questions

Can you get Covid-19 from the vaccine?

- The vaccines do not contain live virus
- mRNA is used to tell the body to make a harmless piece of the 'spike protein' that is found on the surface of the actual COVID-19 virus
- Although the possible side effects of the vaccine may overlap with symptoms of COVID-19, you cannot get COVID-19 from the vaccine
 - Side effects mean the body's immune system is gearing up!



What's in the mRNA vaccines?

Component	Pfizer	Moderna
mRNA	mRNA for spike protein	mRNA for spike protein
Lipids (Fat bubble)	((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102
Salts, sugars and buffers	2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide	1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 [PEG2000-DMG],
	1,2-distearoyl-snglycero-3-phosphocholine	1,2-distearoyl-snglycero-3-phosphocholine [DSPC])
	cholesterol	cholesterol
	potassium chloride	tromethamine
	monobasic potassium phosphate	tromethamine hydrochloride
	sodium chloride	acetic acid
	dibasic sodium phosphate dihydrate	sodium acetate
	sucrose	sucrose



mRNA - harmless genetic material

Helps build immunity against Covid-19 virus

Lipids and Cholesterol

Forms a bubble around the mRNA and helps it enter our cells



Sugar (sucrose) and salts (sodium, potassium)

Helps to keep the vaccine stable and balanced



No blood or fetal products



No pork or cow or animal products

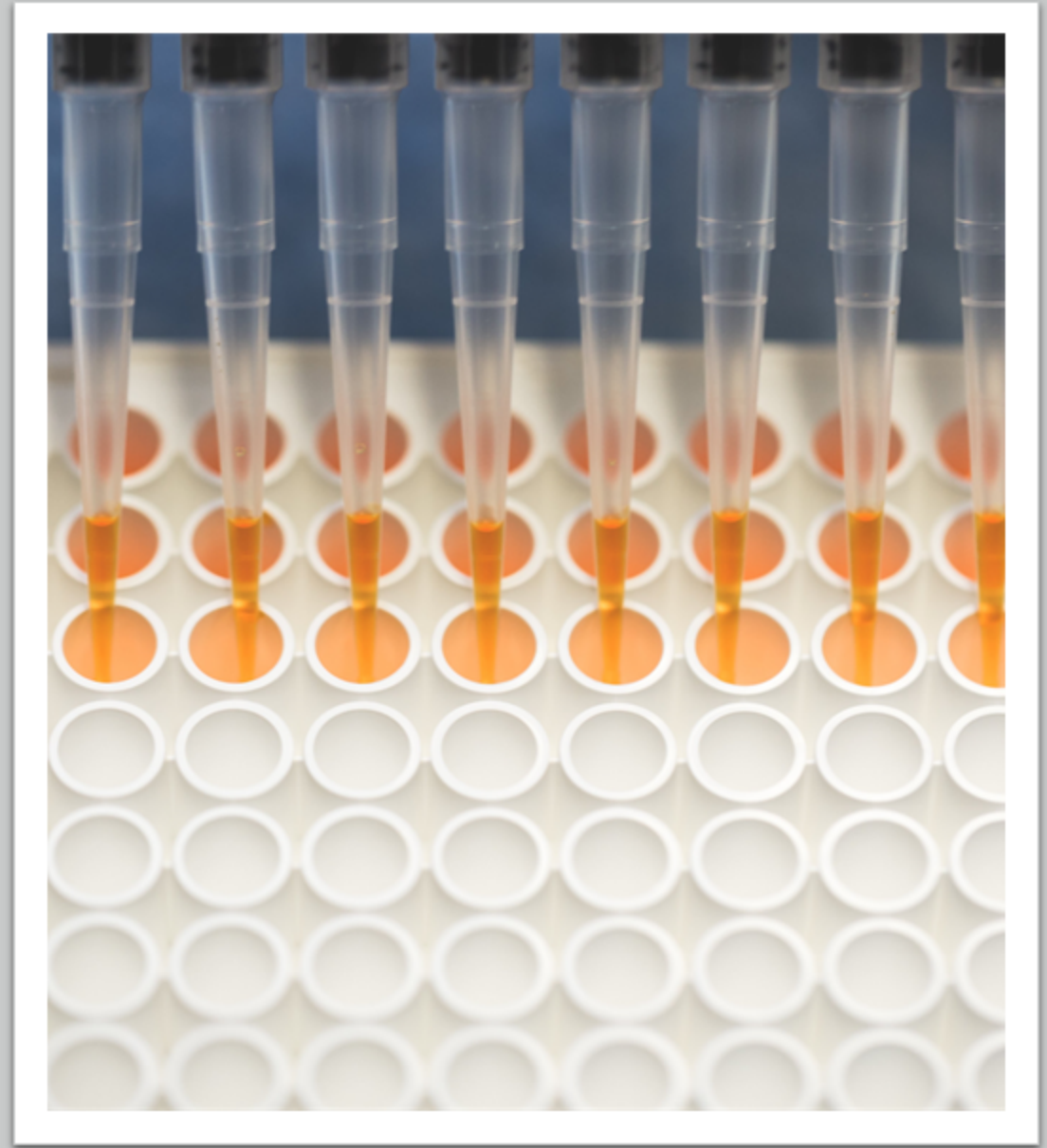
Should I get the vaccine if I already had COVID-19?

- Absolutely
- We do not know how long immunity from a natural infection lasts, current evidence suggests it does not last longer than a few months
- We have seen cases of re-infection occur
- Vaccine offers a more guaranteed, longer and robust level of protection against COVID-19



Is there an impact on fertility?

- Misinformation is being spread that antibodies against the spike protein in the vaccine will also target a protein in the placenta of pregnant mothers called syncytin-1.
- There is no data suggesting that these antibodies will affect syncytin-1.
- If this was true, you would expect COVID-19 infection to be associated with increased rates of miscarriage, but we in fact do not see an increase in miscarriages with Covid-19 infections.



Were the Covid-19 vaccines fast-tracked?

- Strong international collaboration among scientists, health professionals, researchers, industry and governments including ample funding to implement the large clinical trials needed to test the effectiveness of vaccines being developed
- Health agencies allowed for rolling submissions, so this allowed data to be reviewed as it was made available.
- None of this occurred at the expense of safety, and due diligence was absolutely done in the trials.
- mRNA technology has been studied for over a decade, once the virus was genetically sequenced, scientists could get to work to create a variety of vaccines and start clinical trials



Were the Covid-19 vaccines fast-tracked?

- ✓ Funding
- ✓ Existing mRNA technology
- ✓ Virus genetic sequence
- ✓ International collaboration
- ✓ Efficient review processes



Vaccine development



Scientists develop a potential vaccine



Scientists conduct lab and animal studies before testing on humans



10s of volunteers



Phase I

- Is the vaccine safe?
- What is a safe dose?
- Are there any side effects?



100s of volunteers



Phase II

- How well does the vaccine work?
- Is it safe on a larger number of people?
- Safest and most effective dose?



1000s of volunteers



Phase III

- Does the vaccine prevent disease?
- What are the side effects?



Manufacturer submits application to Health Canada for review

Exploratory →


Preclinical →

..... Clinical Trials


..... → Application

Review and approval of vaccines


ROLLING REVIEW PROCESS




Teams of Health Canada experts conduct a thorough and independent review of all vaccine data *




Health Canada approves a vaccine if it is safe, it works, it meets manufacturing standards, and the benefits outweigh the risks



Governments coordinate the purchase, logistics and distribution of vaccines across Canada



All Canadians have access to the vaccine



Continuous monitoring and review to confirm the safety of the vaccine, and that benefits outweigh risks

Scientific Review

Approval

Distribution

Vaccination

Ongoing Monitoring and Review

* For **COVID-19 vaccines**, Health Canada is using a fast-tracked process that allows manufacturers to submit data as it becomes available, and for Health Canada experts to start the review process right away. **Vaccines will only be authorized once we have all necessary evidence.**



Health
Canada

Santé
Canada

Canada 

Will the COVID-19 vaccine protect against the new variants that are emerging?

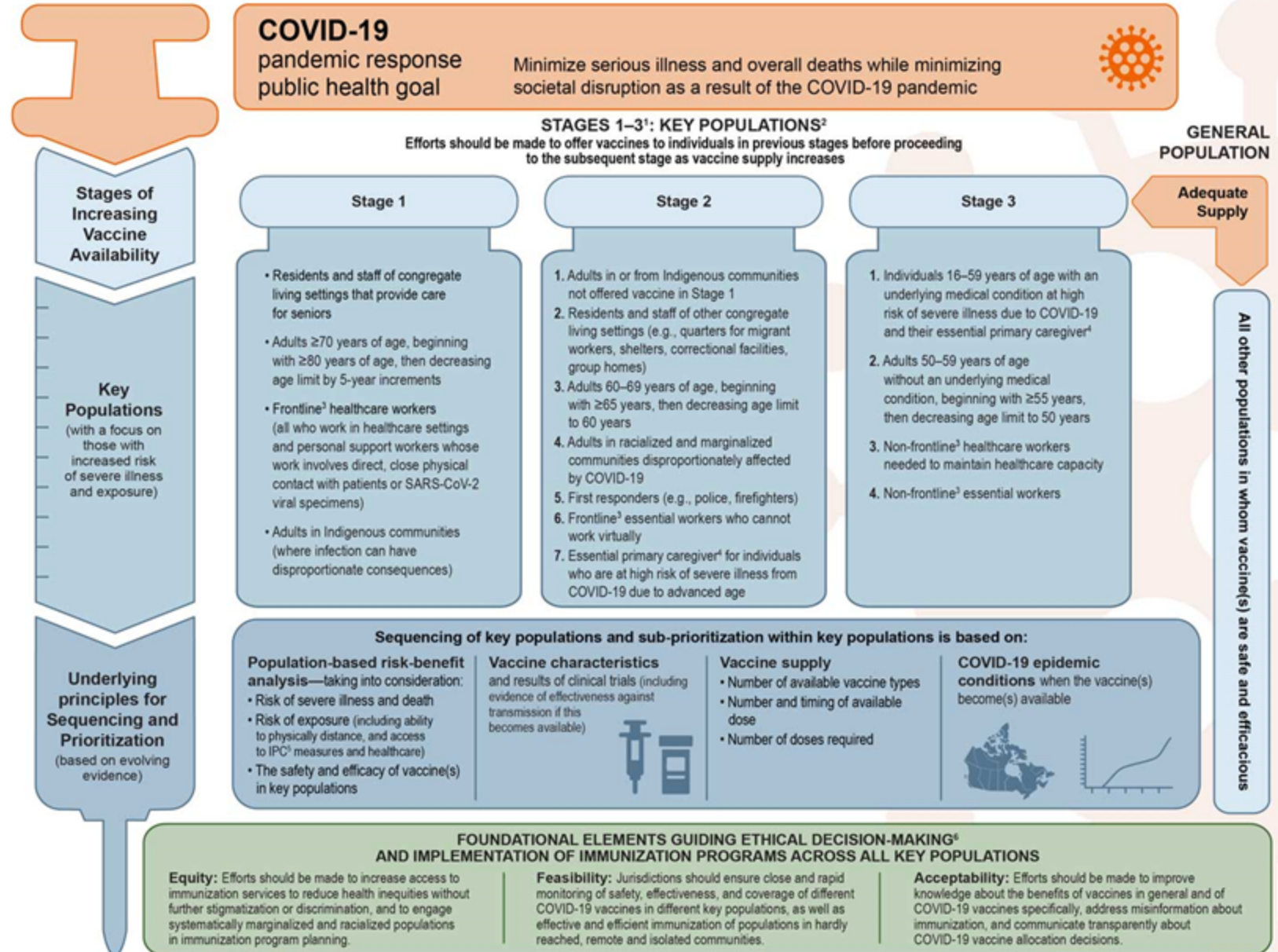
- There are a few COVID-19 variants that have been seen in the UK, South Africa and Brazil.
- The variant first found in the UK improves how well the virus's spike protein can attach to our cell receptors so it makes it more sticky and therefore it can be up to 50 per cent more transmissible.
- The variant first found in South Africa is more sticky but also includes a mutation that helps the virus to disguise part of its signature appearance which allows it to slip past immune response.
- Both Pfizer and Moderna have studied their mRNA vaccines and found that they were effective against the variant first found in the UK, but have seen a modest decrease in efficacy against the variant first found in South Africa.
- Moderna indicated that they are considering adding a booster shot to their vaccine regimen.

Knowledge Gaps

- There are several key knowledge gaps that affect the understanding of immune responses to COVID-19 vaccine:
- How long the immune response lasts after a vaccination, ie the durability of response
- How immune responses differ across populations (e.g., in immunocompromised, children) or by SARS-CoV-2 serostatus (i.e., past COVID-19 infection)
- How immune responses differ based on previous infection with other non-SARS-CoV-2 coronaviruses



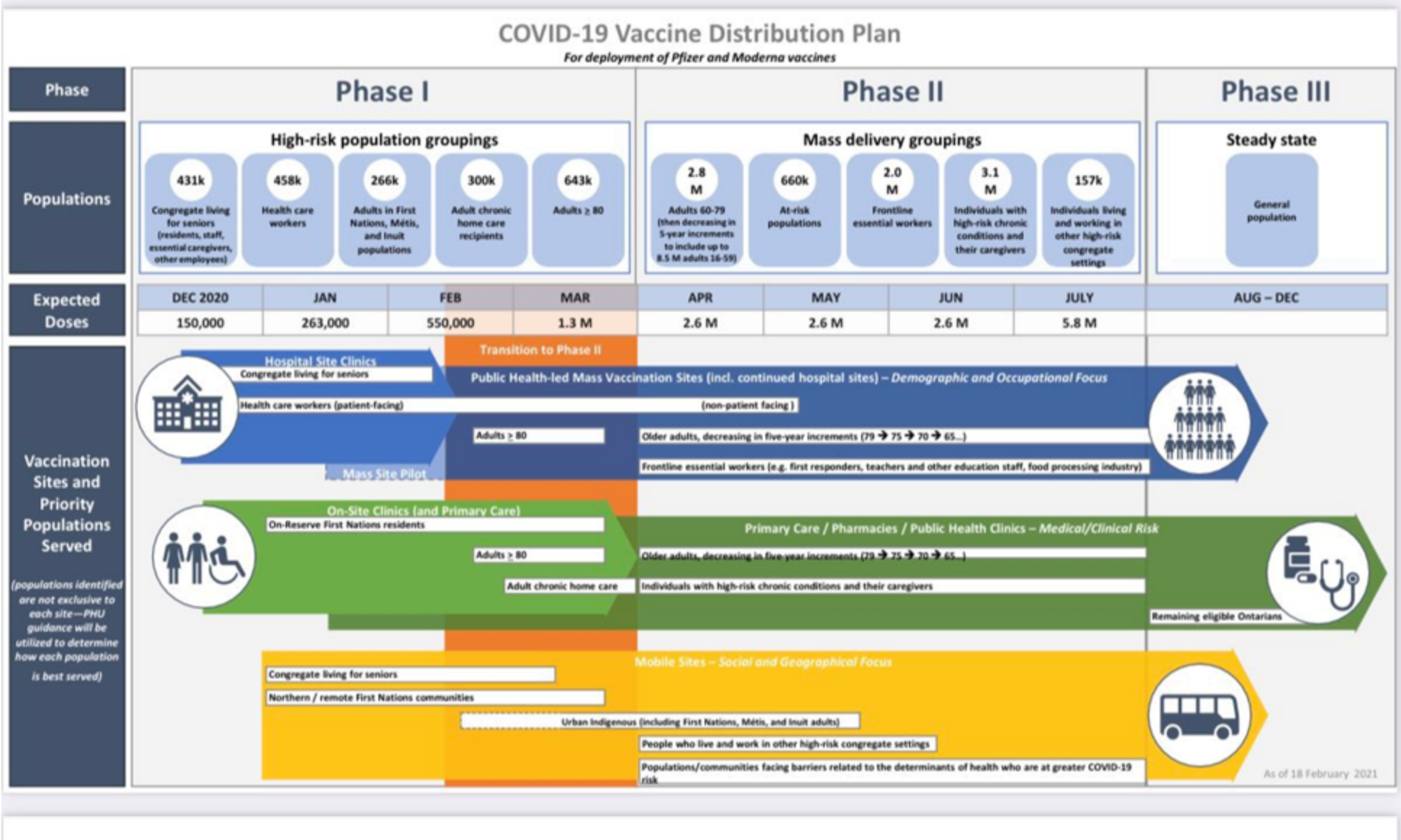
NACI Prioritization Plan (Feb 15)

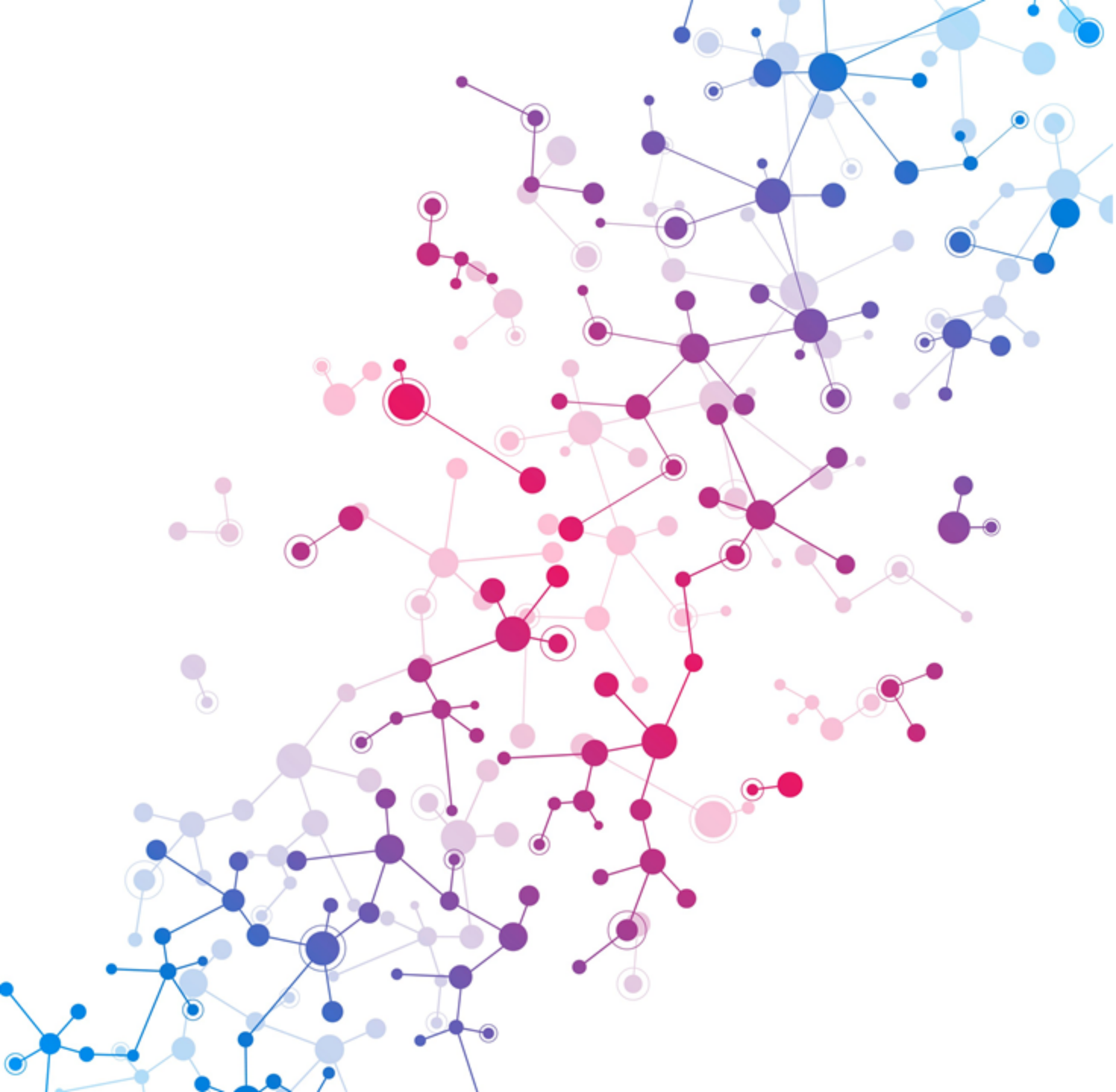


¹ Key populations in Stages 2 and 3, recommended since the previous NACI guidance on Stage 1, are listed in order of priority. Examples listed within key populations are suggestions that are not listed in order of priority.
² Key populations are not mutually exclusive and may overlap. Sequencing and sub-prioritization may differ between jurisdictions based on differences in local epidemiology and logistical contexts.
³ Having direct close physical contact with the public.

⁴ The adult primarily responsible for taking care of a family member or loved one who cannot care for themselves.
⁵ IPC = infection prevention and control measures.
⁶ Based on the systematic assessment of ethics, equity, feasibility and acceptability using an evidence-informed framework, available at: <https://doi.org/10.1016/j.vaccine.2020.05.051>

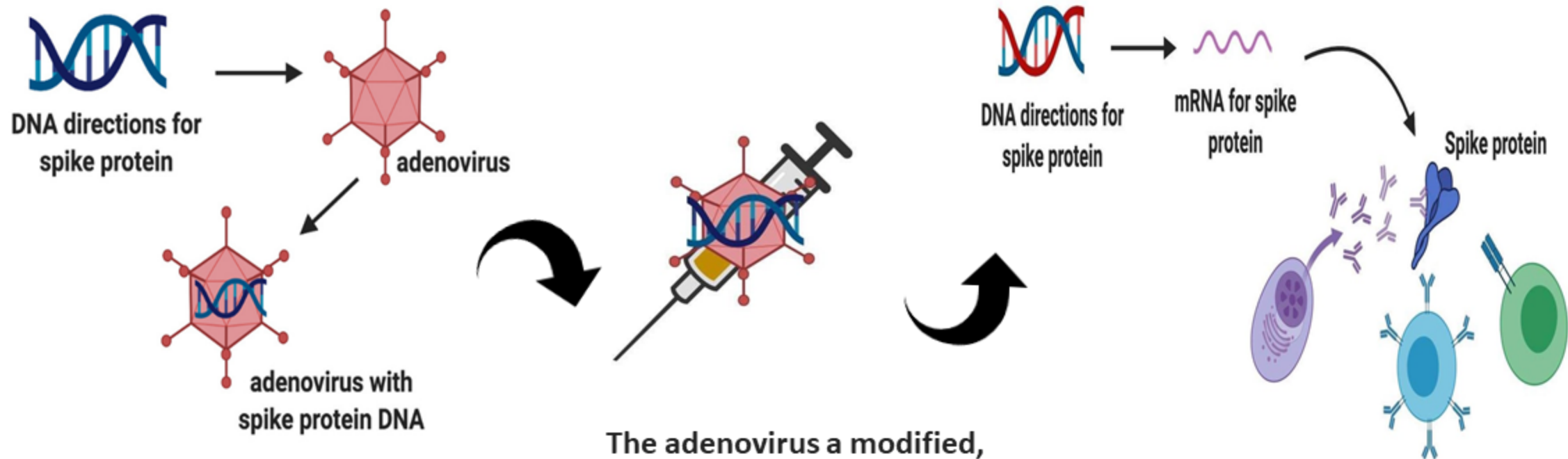
Ontario Distribution Plan (Feb 19)





Other Covid-19 Vaccine Types

Astrazeneca/J & J: How it works



The directions to make the spike protein that is found on the surface of SARS-CoV-2 is made into a DNA sequence inserted into another virus called an adenovirus.

The adenovirus a modified, weakened, non-replicating version of a common cold virus.

It does not cause any permanent changes to your DNA.

The adenovirus containing the DNA that codes for the spike protein is injected into the person. DNA is then made into mRNA, which then instructs the cell how to make the spike protein.

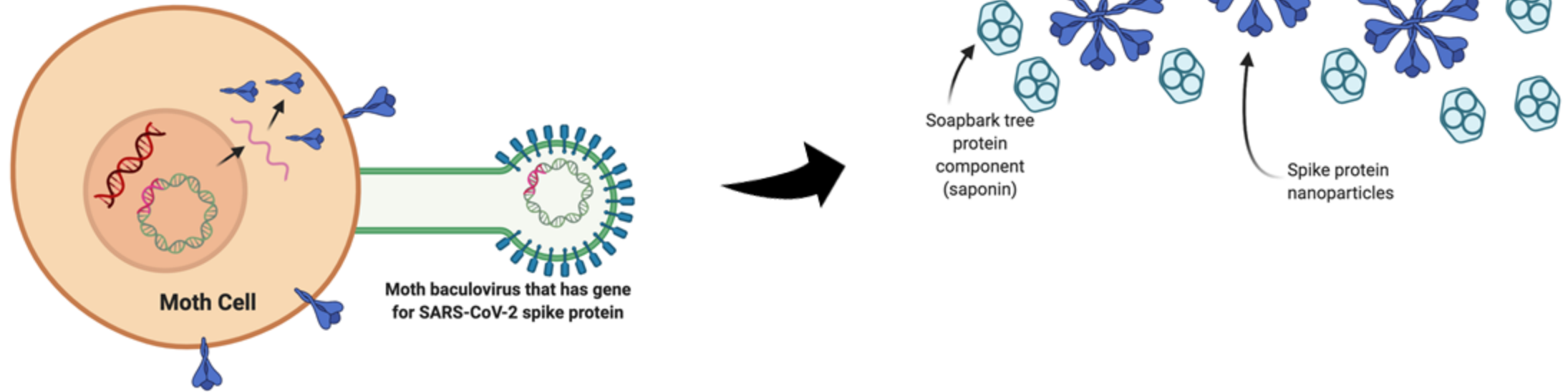
Astrazeneca/Oxford

- Adenovirus vector
- Two doses, 28 days apart
- 22,000+ participants
- 62% efficacy in the two full dose regimen
- 90% efficacy in a smaller subset that received half dose followed by full dose

Johnson & Johnson

- Adenovirus vector
- Single dose
- 43,000+ participants
- 72% effective in the US and 66% effective overall
- 85% effective in preventing severe illness

Novavax: How it works



Protein based
Two doses, 21 days apart
20,000+ participants