

IMMUNIZE. PREVENT WHAT'S PREVENTABLE

Simplifying Vaccine Science



THE
IMMUNIZATION
PARTNERSHIP

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THE IMMUNIZATION PARTNERSHIP

Vision

A community protected from vaccine preventable diseases

Mission

To eradicate vaccine-preventable diseases by educating the community, advocating for evidence-based public policy, and supporting immunization best practices



ACKNOWLEDGEMENTS

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DISCLOSURE AND DISCLAIMER

- The speakers and planning committee have disclosed no conflicts of interest
- This presentation is for educational use only and does not constitute medical or legal advice



AGENDA

Vaccine History

Vaccine Development

COVID-19 Vaccines Overview

Ingredients & Technology

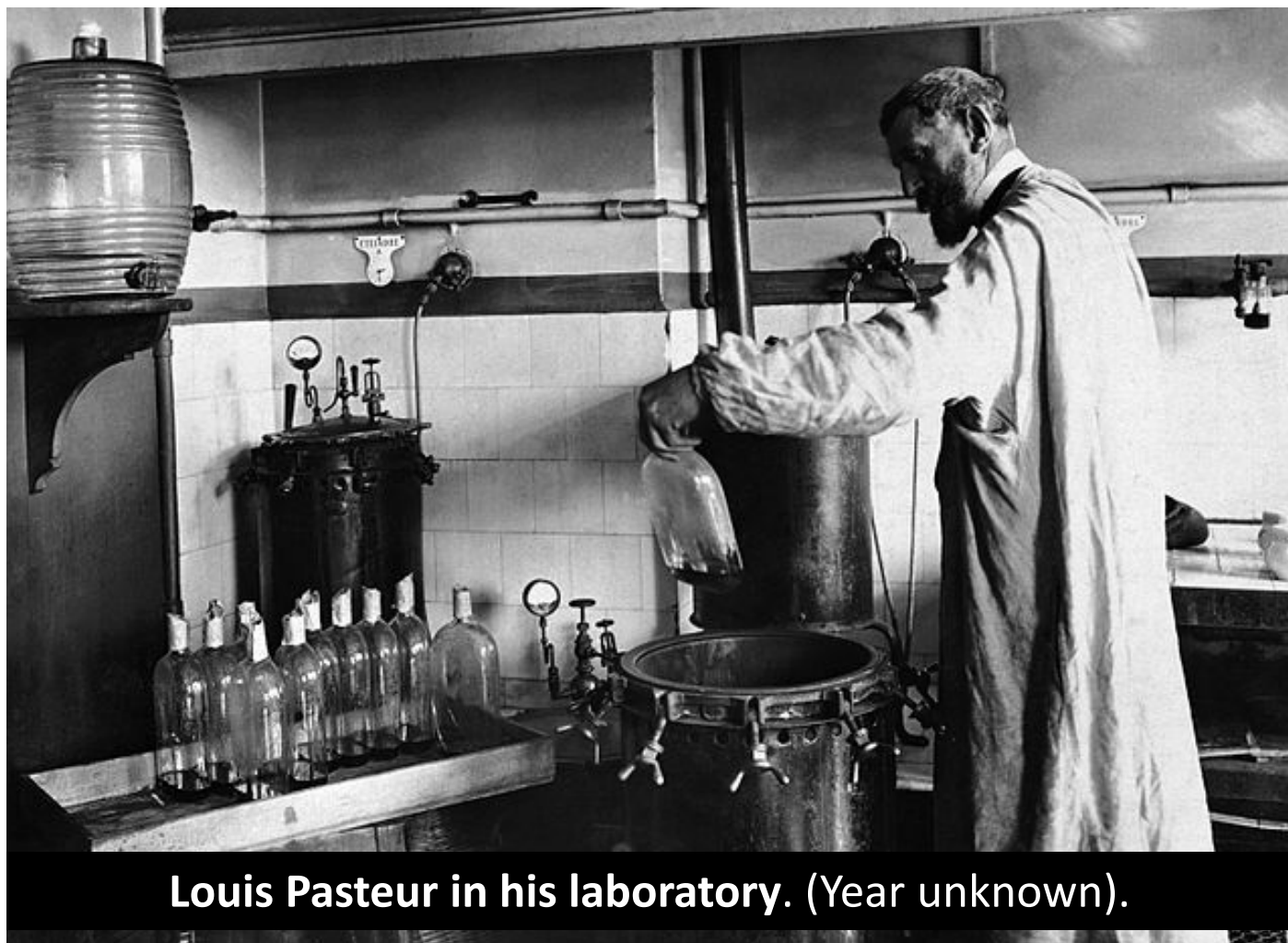
COVID-19 Vaccine Expectations

Helpful Resources



Vaccine History

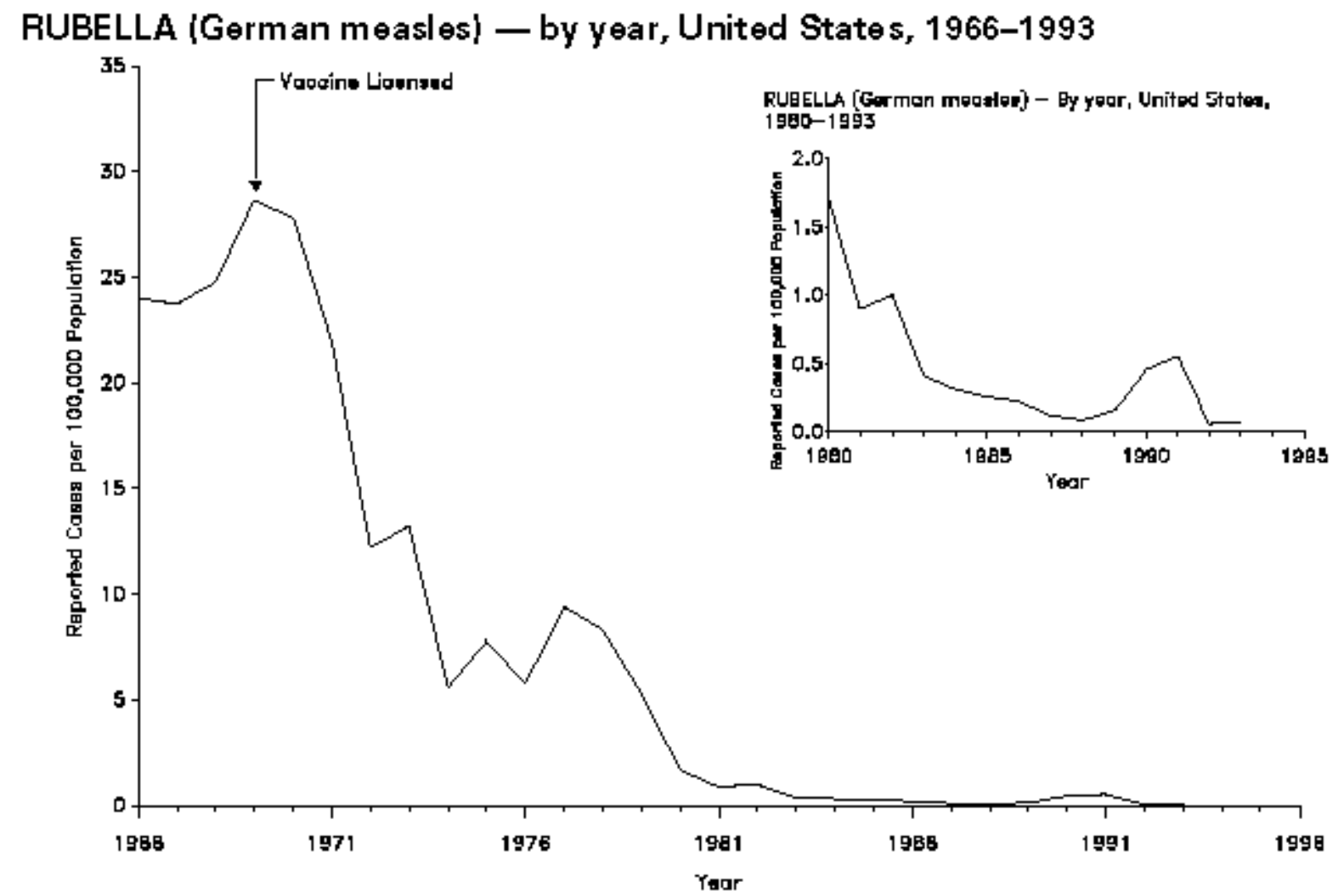




Louis Pasteur in his laboratory. (Year unknown).



UK immunization advocacy poster on Diphtheria, 1960.



Decline of Rubella cases in the US, 1966 – 1993.



Child receiving polio vaccine in Sweden, 1957.

Vaccine Development



STAGES OF VACCINE DEVELOPMENT

Exploratory Stage



Pre-Clinical Stage



Phase 1 Clinical Trials



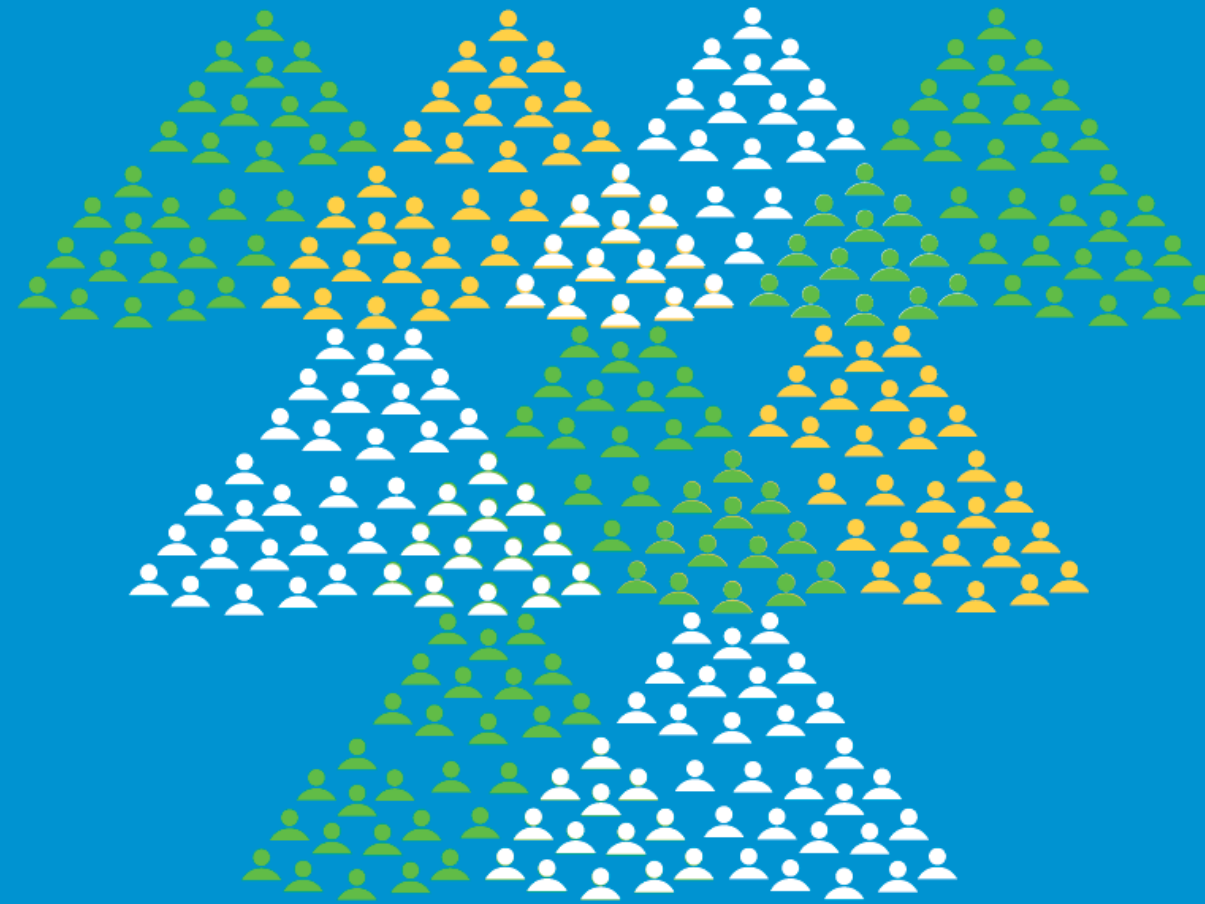
Phase 2 Clinical Trials



Review & Licensure



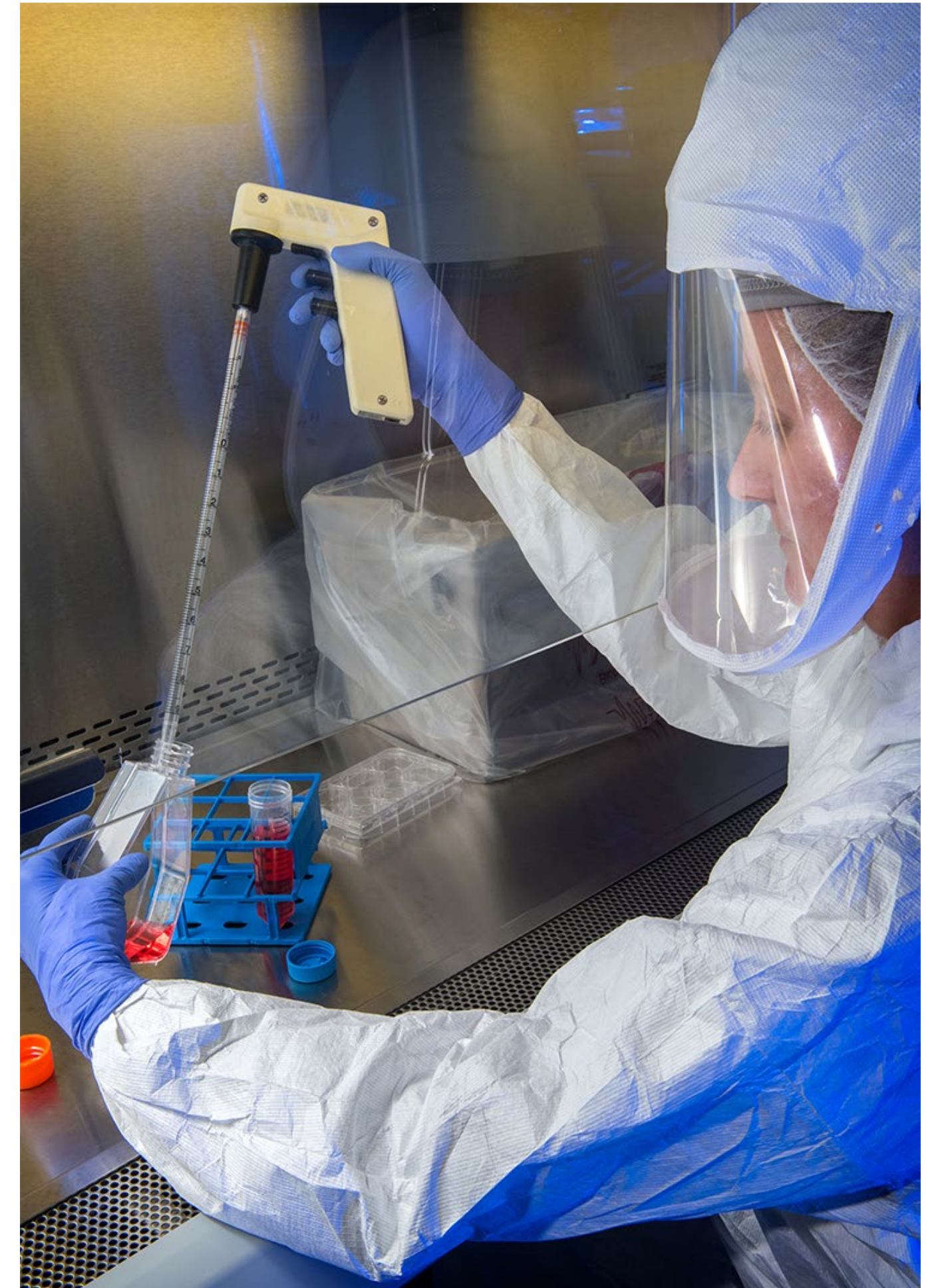
Phase 3 Clinical Trials





Exploratory Stage

- **Basic laboratory science**
- Researchers try to **identify antigens** that may help to prevent or treat a disease (either a virus or bacteria)
- **Test their ideas** to find a vaccine candidate
- **2 – 4 years** (but may take longer)





Pre-Clinical Stage

- Before a vaccine can be tested in humans, safety and efficacy tests are done using:
 - Tissue cultures
 - Cell cultures
 - Animals (mice, monkeys)
- Helps researchers **understand the immune response** created by the vaccine



- **1 - 2 years** (but may take longer)

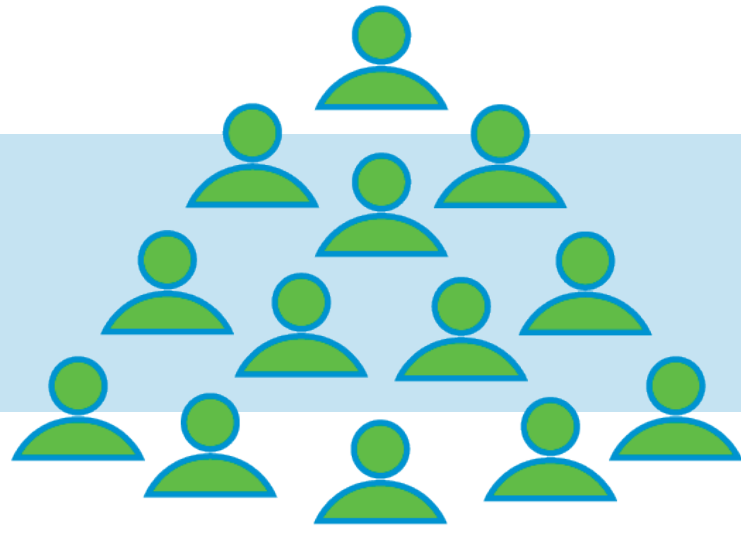


Placebo-Controlled Vaccine Trials

(Phase 1 Clinical Trials, Phase 2 Clinical Trials and Phase 3 Clinical Trials)

- Clinical trials for vaccines are configured to include both a **control group** and an **experimental group** – this is essential for comparison.
- **Control group receives a placebo** (often a vaccine that is already approved or saline solution) and the **experimental group receives the vaccine being tested**.
- The **control and experimental groups are made up of similar participants** (age, race, health status, sex) so researchers can compare and determine the true effects of the vaccine.
- Studies are **randomized** and **double-blinded** (meaning neither researchers of participants know which group they are in) **to avoid bias**.

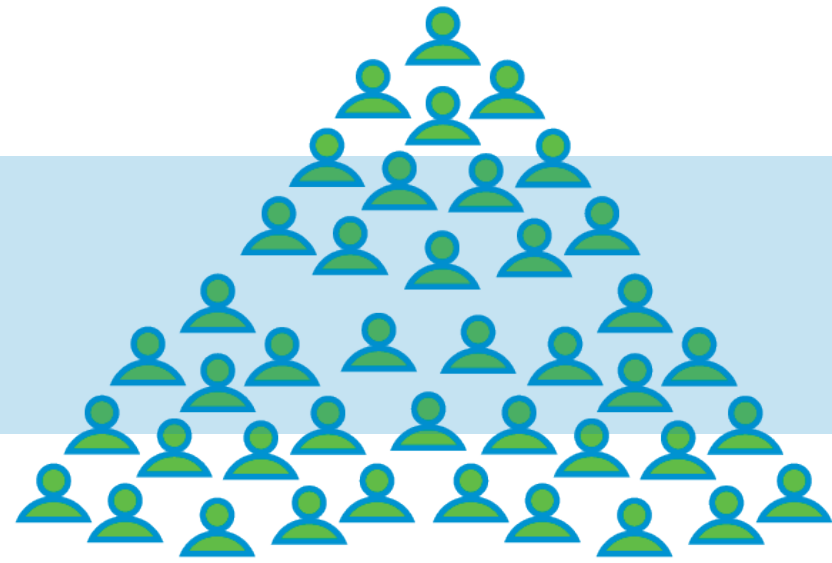




Phase 1 Clinical Trials

- Begin **testing** the vaccine in **healthy adults**
- Studies start small with **20 – 100 participants**
- Focused on answering 2 questions:
 1. Is the vaccine **safe**?
 2. Is the vaccine **effective**? (does it generate the expected immune response)
- **1 – 2 years**

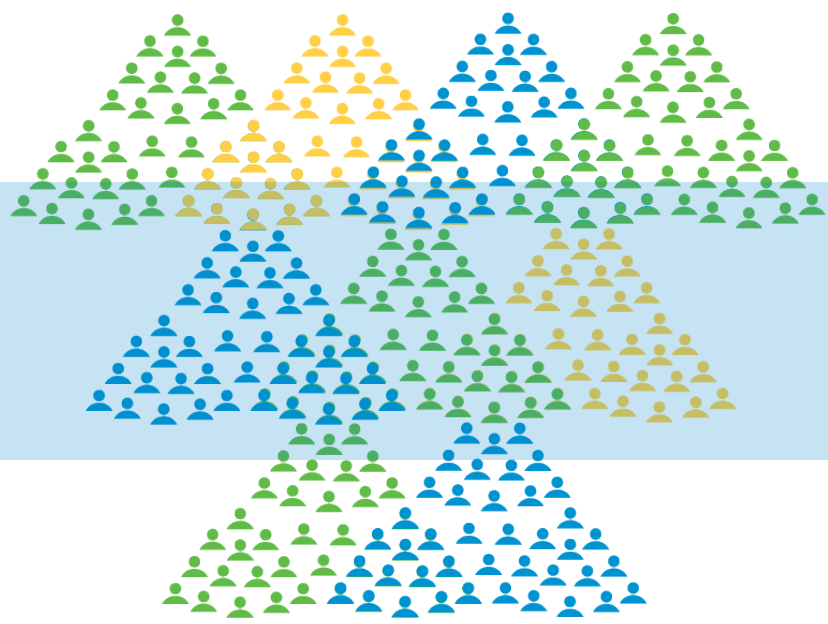




Phase 2 Clinical Trials

- Phase 2 includes **more study participants (several 100)** – those with **different health statuses, demographic backgrounds, and at risk for acquiring disease** are included.
- Participants may receive the vaccine (of **varying doses**) or a **placebo** as part of **randomized-controlled studies**.
- Focused on vaccine **safety among diverse populations, short-term side effects**, and understanding the vaccine's **immune response**, including **dosing**.
- **2+ years**





Phase 3 Clinical Trials

- Phase 3 **includes hundreds of thousands of people** – **experimental group** (receive the vaccine) and **control** group (receive a placebo).
- The study is **double-blinded** (for researchers AND participants)
- Goal is to **assess vaccine safety in a large group** of people and identify common side effects and any **rare side effects**.
- **Vaccine efficacy** is tested – does the vaccine **prevent disease**, does it **prevent infection**, does it lead to **production of antibodies**?
- **Can last several years**





Review & Licensure

- After successful Phase 3 trials, a vaccine developer submits a **Biologics License Application** to the FDA for review
- FDA reviews the data from a vaccine's clinical trials to determine whether the vaccine has been shown to be both safe and effective.
- **Manufacturing processes** are also reviewed to **ensure vaccine quality and consistency**
- **FDA will approve** (license) the vaccine for use in the United States if the **benefits and of the vaccine outweigh any risks.**



COVID-19 Vaccines

Overview





moderna



- EUA approval:
Dec. 11,
2020

- 2 doses

- EUA approval:
Dec. 18,
2020

- 2 doses

- EUA approval:
Feb. 11,
2021

- 1 dose



Factors of Vaccine Development Speed

1. Global public health threat - #1 priority

- Unprecedented number of vaccine candidates / public and private funding
- Included "Operation Warp Speed"

2. Decades of research informed work for COVID-19 vaccines:

- Other coronaviruses (**SARS** and **MERS**)
- Previous vaccine research using **mRNA technology** for other viruses such as **Zika**, **rabies**, and **influenza**



Ingredients & Technology



What's in the Pfizer/BioNTech Vaccine?

- **mRNA** – Provides instructions for our body on how to make a viral protein that triggers an immune response.
- **Lipids (fats)** – Protect the mRNA & helps mRNA slide inside of the cell
- **Salts** – Help balance acidity in the body
- **Sugar (sucrose)** – Helps molecules maintain their shape during freezing



Pfizer/BioNTech Vaccine Ingredients

Active Ingredient	<ul style="list-style-type: none">• mRNA coding for a form of the spike protein of SARS-CoV-2
Lipids (fats)	<ul style="list-style-type: none">• (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)• 2[(polyethylene glycol)-2000]- N,N-ditetradecylacetamide• 1,2-distearoyl-sn-glycero-3-phosphocholine• cholesterol
Salts	<ul style="list-style-type: none">• potassium chloride• monobasic potassium phosphate• sodium chloride• dibasic sodium phosphate dihydrate
Other	<ul style="list-style-type: none">• sucrose

Image adapted from: <https://www.nebraskamed.com/COVID/you-asked-we-answered-are-covid-19-vaccine-ingredients-public>



What's in the Moderna Vaccine?

- **mRNA** – Provides instructions for our body on how to make a viral protein that triggers an immune response.
- **Lipids (fats)** – Protect the mRNA & helps mRNA slide inside of the cell
- **Acids, Acid Stabilizers, & Salts** – work together to maintain the stability of the vaccine after production
- **Sugar (sucrose)** – Helps molecules maintain their shape during freezing



Moderna Vaccine Ingredients

Active Ingredient	<ul style="list-style-type: none">• mRNA coding for a form of the spike protein of SARS-CoV-2
Lipids (fats)	<ul style="list-style-type: none">• SM-102• polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG]• cholesterol• 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]
Salts	<ul style="list-style-type: none">• sodium chloride• trisodium citrate dehydrate• Citric acid monohydrate
Other	<ul style="list-style-type: none">• tromethamine• tromethamine hydrochloride• acetic acid• sucrose

Image adapted from: <https://www.nebraskamed.com/COVID/you-asked-we-answered-are-covid-19-vaccine-ingredients-public>

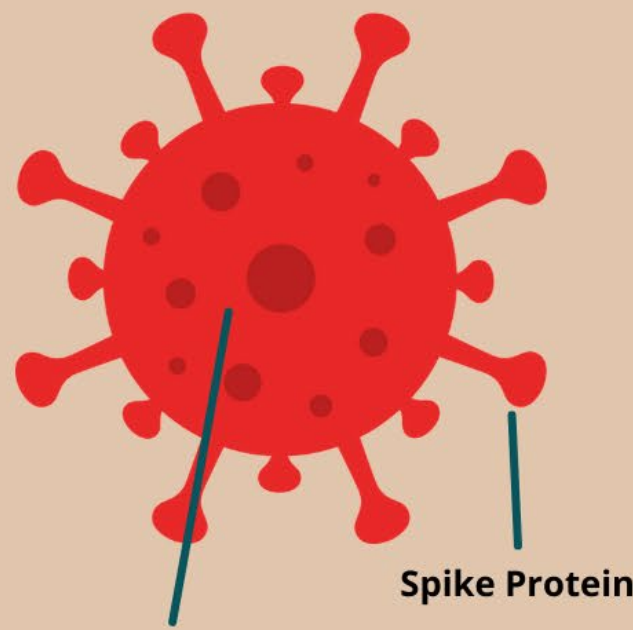


How mRNA Technology Works



VACCINE

messenger RNA (mRNA) from virus's genetic code is injected into patient.

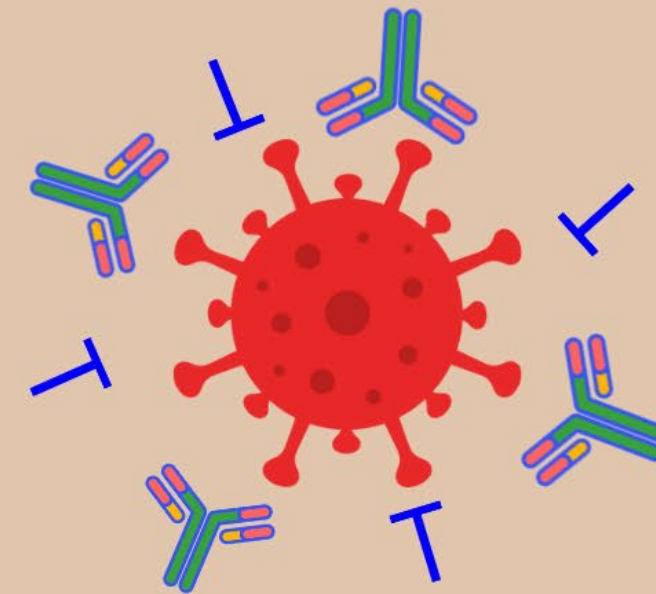


SARS-COV-2-Virus

Spike Protein

VIRUS

The mRNA instructs human cells to create part of the SARS-CoV-2 virus called the "spike" protein. The cell gets rid of the protein once it breaks down mRNA instructions.

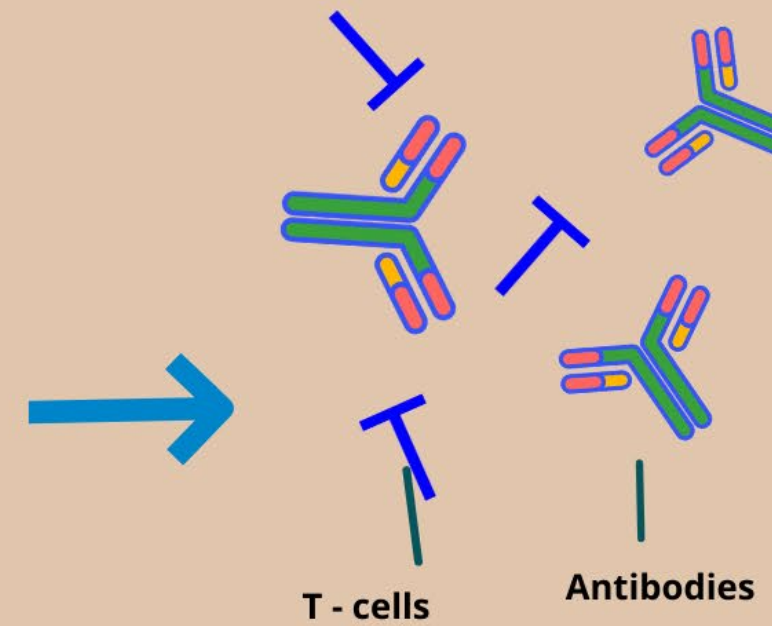


PRODUCE

The T-cells and antibodies will remember how to fight the virus, and protect you from getting sick if you are exposed in the future.

PROTECT

Our immune system reacts to the protein (because it doesn't belong) by producing antibodies and activating T-cells to destroy the spike proteins.



T - cells

Antibodies

Image adapted from:

https://www.michigan.gov/documents/coronavirus/2020_MDHHS_COVIDVaccine_Infograph_3.0_710373_7.pdf



What's in the J&J Vaccine?

- **Adenovirus vector** – is used as the vehicle to introduce the vaccine (virus cannot replicate)
- **Acid & acid stabilizers** – work together to maintain the stability of the vaccine after production
- **Salt** – help balance acidity in the body



J&J Pause & Ongoing Safety Monitoring

The CDC and FDA recommended a temporary pause of the J&J vaccine on April 13th following several reports of a **rare blood clot condition**, thrombosis with thrombocytopenia syndrome (TTS), 1-2 weeks following vaccination.

- As of June 21, 2021 , **36 cases of TTS (submitted to VAERS)** have occurred among the more than 12 million doses of the J&J in the United States. All cases occurred among women between 18 – 59 years.
- Pause was lifted on April 23rd after review of all available data showed that the J&J/Janssen COVID-19 Vaccine's known and **potential benefits outweigh its known and potential risks.**
- Women 50 and younger should be aware of this rare but adverse event risk.



J&J Vaccine Ingredients

Active Ingredient	<ul style="list-style-type: none">• Recombinant, replication-incompetent adenovirus type 26 expressing the SARS-CoV-2 spike protein
Salts	<ul style="list-style-type: none">• potassium chloride• monobasic potassium phosphate• sodium chloride• dibasic sodium phosphate dihydrate
Other	<ul style="list-style-type: none">• ethanol• polysorbate-80• acetic acid• Sucrose

Image adapted from: <https://www.nebraskamed.com/COVID/you-asked-we-answered-are-covid-19-vaccine-ingredients-public>

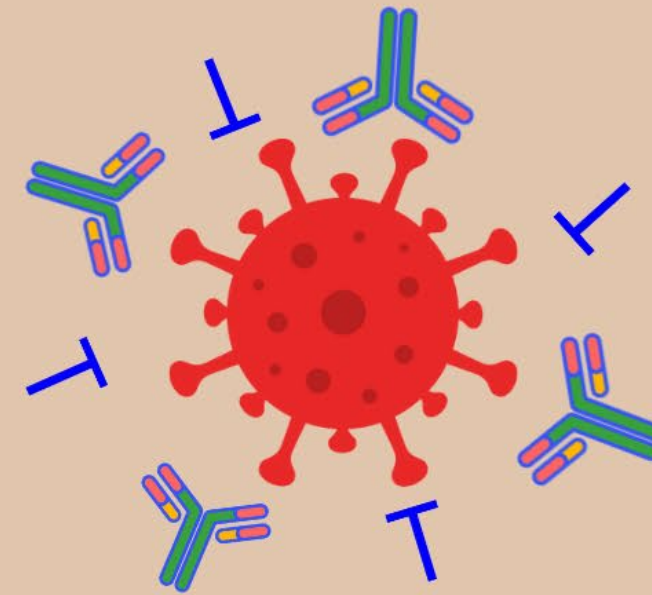


How AdVac® Technology Works



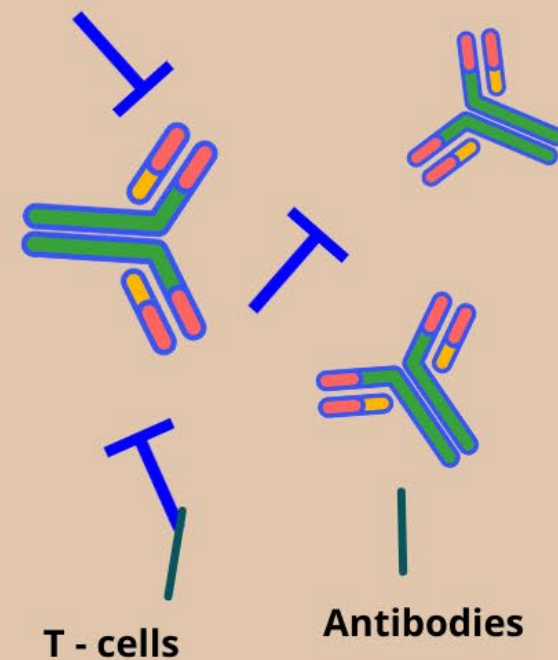
VACCINE

An adenovirus vector (a carrier) from an antigen's genetic code, used to mimic the virus, is injected into the patient.



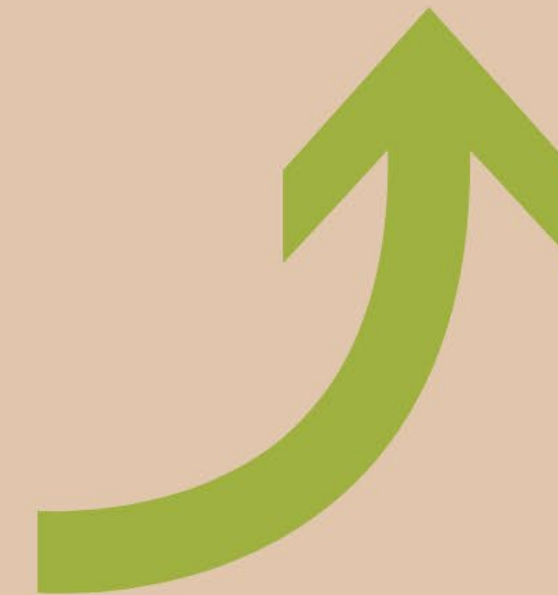
PRODUCE

The T-cells and antibodies will remember how to fight the virus, and protect you from getting sick if you are exposed in the future.



PROTECT

Our immune system reacts to the antigen (because it doesn't belong) by producing antibodies and activating T-cells.



What's the latest on the Novavax Vaccine?

- 96% efficacy against the original coronavirus strain in the UK
- 89% efficacy against B.1.1.7 variant
- 49% efficacy against B.1.351 variant (South Africa trial)
- Company working on an a version tailored to B.1.351 variant
- Results of Phase 3 trials (30,000 participants): 90.4% efficacy in preventing symptomatic COVID-19

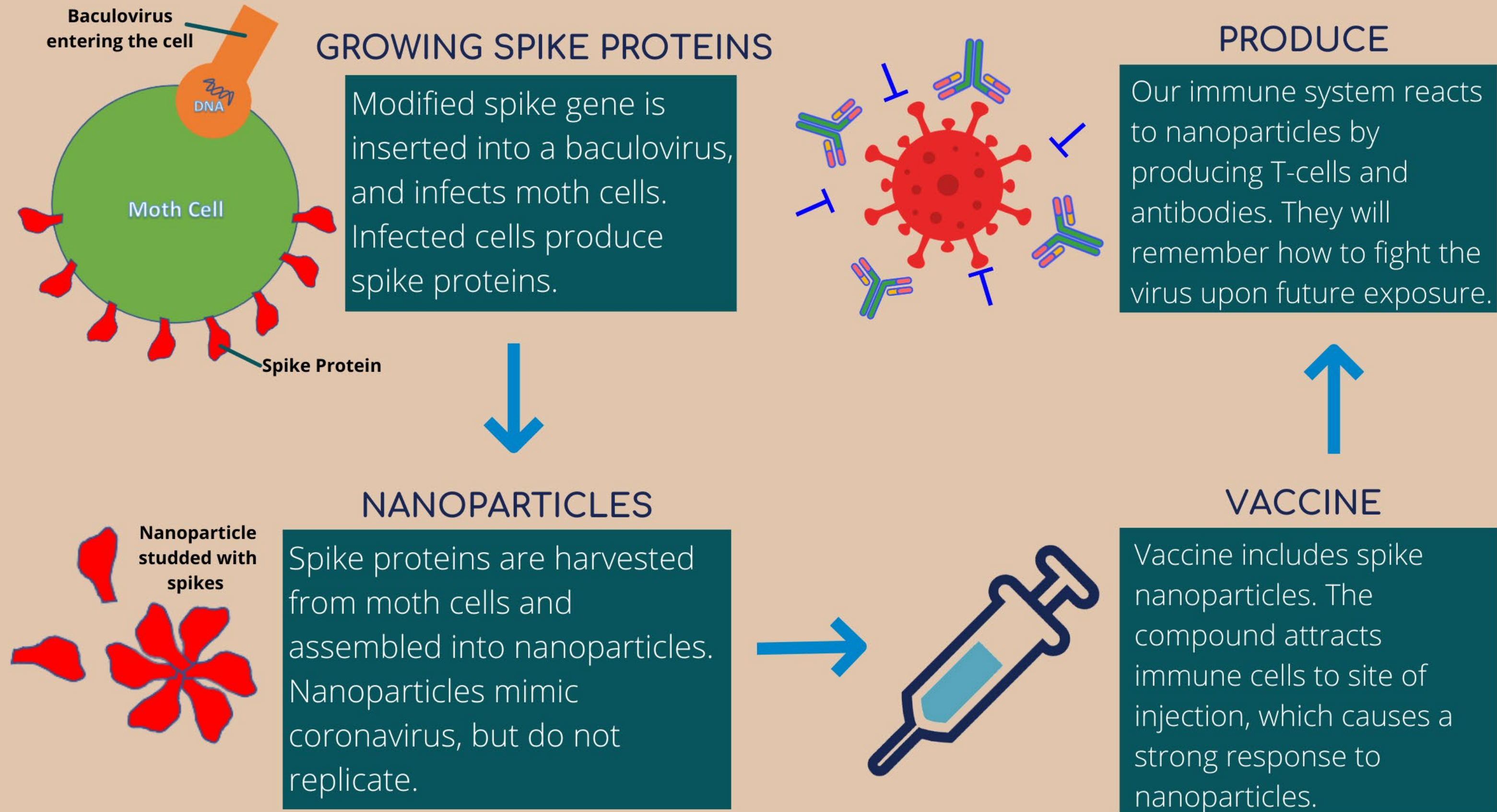


Novavax Vaccine Details

- Protein-based vaccine
- Includes harmless proteins of the virus that causes COVID-19
- 2 doses, one month apart
- Storage: basic refrigeration



How Protein-Based Technology Works



COVID-19 Vaccine Expectations



Common Side Effects

On the arm where you got the shot:



- Pain
- Redness
- Swelling

Throughout the rest of your body:



- Tiredness
- Headache
- Muscle pain
- Chills
- Fever
- Nausea



Tips for Pain or Discomfort

To reduce pain and discomfort where you got the shot



- Apply a clean, cool, wet washcloth over the area.
- Use or exercise your arm.

To reduce discomfort from fever



- Drink plenty of fluids.
- Dress lightly.



Things to Remember

- Considered fully vaccinated
 - 2 weeks after second shot for Pfizer & Moderna
 - 2 weeks after single-dose J&J
- Once fully vaccinated, you may be able to do things that had to stop because of pandemic
- Keep taking precautions after being fully vaccinated



Helpful Resources



- CDC, Understanding How COVID-19 Vaccines Work.
<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/how-they-work.html>
- PubChem, World's largest collection of freely accessible chemical information. <https://pubchem.ncbi.nlm.nih.gov/>
- Children's Hospital of Philadelphia, Vaccine Science.
<https://www.chop.edu/centers-programs/vaccine-education-center/vaccine-science>
- World Health Organization, Science in 5.
<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/media-resources/science-in-5>



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27. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html>

THANK YOU!



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If you have any questions about this presentation please email Ashley Beale at abeale@immunizeUSA.org or Rachel Walker at rwalker@immunizeUSA.org

