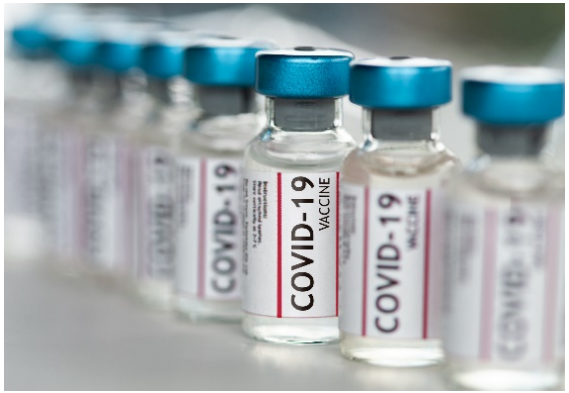
COVID-19 vaccines, mRNA Vaccine Technology, and Vaccine Safety Monitoring

Healthcare personnel: A priority for COVID-19 vaccination

- On the front lines and at risk of exposure
- Can potentially transmit the virus that causes COVID-19 to patients, their families, and their communities
- Can positively influence vaccination decisions of peers, patients, friends, and family
- *Healthcare personnel* = paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials – not exclusive to medical personnel, includes administration, support staff, etc.

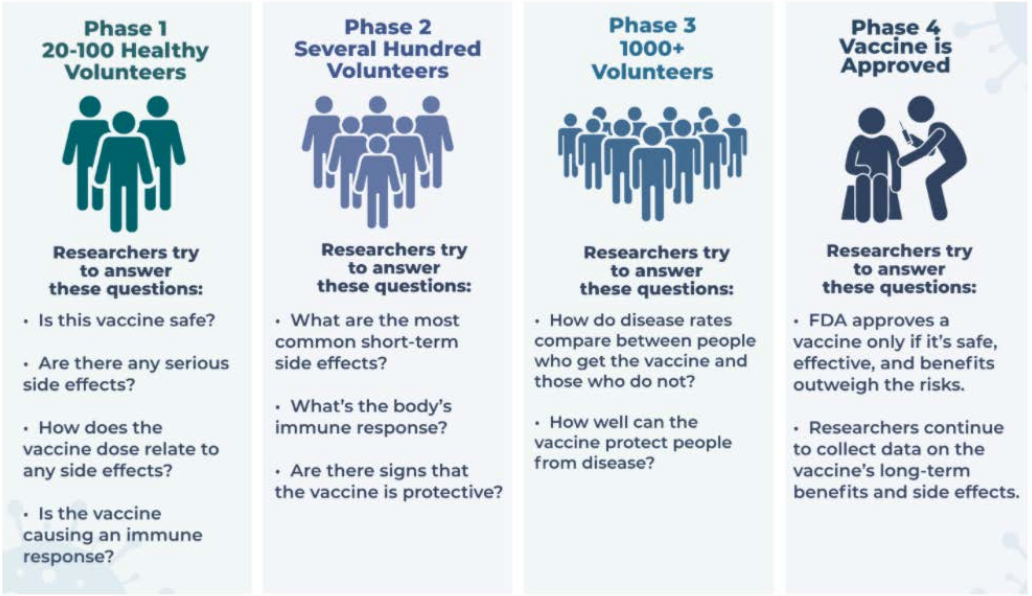
COVID-19 vaccines under development

- The federal government is funding and coordinating the development of multiple vaccine candidates, several of which are in large-scale (Phase 3) trials.
- COVID-19 vaccines are being held to the **same safety standards** as all other vaccines.



Phases of clinical trials

- There are four phases of clinical trials



Source: https://covid19community.nih.gov/resources/understanding-clinical-trials

COVID-19 vaccines expected to receive FDA Emergency Use Authorizations

- Two vaccines are expected to receive FDA Emergency Use Authorizations (EUAs):
  - **Pfizer/BioNTech (BNT162b2)** – 95% effective (manufacturer data)
  - **Moderna (mRNA-1273)** – 94.5% effective (manufacturer data)
- Both are mRNA vaccines with a 2-dose schedule.
- Duration of protection is not yet known.
- Both vaccines were tested in diverse adult populations, including older adults and communities of color.
- For the latest information about authorized vaccines, visit www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines.

Sources: https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-conclude-phase-3-study-covid-19-vaccine
https://investors.modernatx.com/news-releases/news-release-details/modernas-covid-19-vaccine-candidate-meets-its-primary-efficacy

COVID-19 vaccine trials by the numbers

As of November 30, 2020

Pfizer/BioNTech

- **43,931** enrolled
- **150** clinical sites
  - 39 U.S. states
- Racial/ethnic distribution
  - **13%** - Hispanic
  - **10%** - African American
  - **6%** - Asian
  - **1%** - Native American
- **45%** ages 56-85

Moderna

- **30,000** enrolled
- **89** clinical sites
  - 32 U.S. states
- Racial/ethnic distribution
  - **63%** - White
  - **20%** - Hispanic
  - **10%** - African American/Black
  - **4%** - Asian
  - **3%** - All others
- **64%** ages 45 and older
  - 39% ages 45-64
  - 25% ages 65+

Sources: https://www.pfizer.com/science/coronavirus/vaccine; https://www.modernatx.com/cove-study
For more information, visit www.clinicaltrials.gov

What are messenger RNA (mRNA) vaccines?

- Carry genetic material that teaches our cells how to make a harmless piece of "spike protein," which is found on the surface of the SARS-CoV-2 virus.
  - Genetic material from the vaccine is destroyed by our cells once copies of the spike protein are made and it is no longer needed.
- Cells display this piece of spike protein on their surface, and an immune response is triggered inside our bodies. This produces antibodies to protect us from getting infected if the SARS-CoV-2 virus enters our bodies.
- Do not affect our DNA; mRNA does not enter the cell nucleus.
- Cannot give someone COVID-19.
- Use technology that is new but not unknown. mRNA vaccines have been studied for influenza, Zika, rabies, and cytomegalovirus (CMV).

Sources: College of Physicians of Philadelphia. What is an mRNA vaccine? https://historyofvaccines.blog/2020/07/29/what-is-an-mrna-vaccine/
JAMA. COVID-19 and mRNA Vaccines—First Large Test for a New Approach. https://jamanetwork.com/journals/jama/fullarticle/2770485

About these COVID-19 mRNA vaccines

- These mRNA vaccines are expected to produce side effects after vaccination, especially after the 2nd dose.
  - Side effects may include:
    - Fever
    - Headache
    - Muscle aches

- No significant safety concerns were identified in the clinical trials.
- At least 8 weeks of safety data were gathered in the trials. It is unusual for side effects to appear more than 8 weeks after vaccination.

Source: https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19/clinical-considerations.html

Safety of COVID-19 vaccines is a top priority

- COVID-19 vaccines are being held to the same safety standards as all vaccines.
- FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) reviews applications for EUAs.
- The Advisory Committee on Immunization Practices (ACIP) considers safety and efficacy data before recommending use.
- VRBPAC and ACIP are independent committees composed of scientific and clinical experts.
- FDA and CDC monitor vaccine safety and side effects once vaccines are in use.

Robust vaccine safety monitoring systems exist

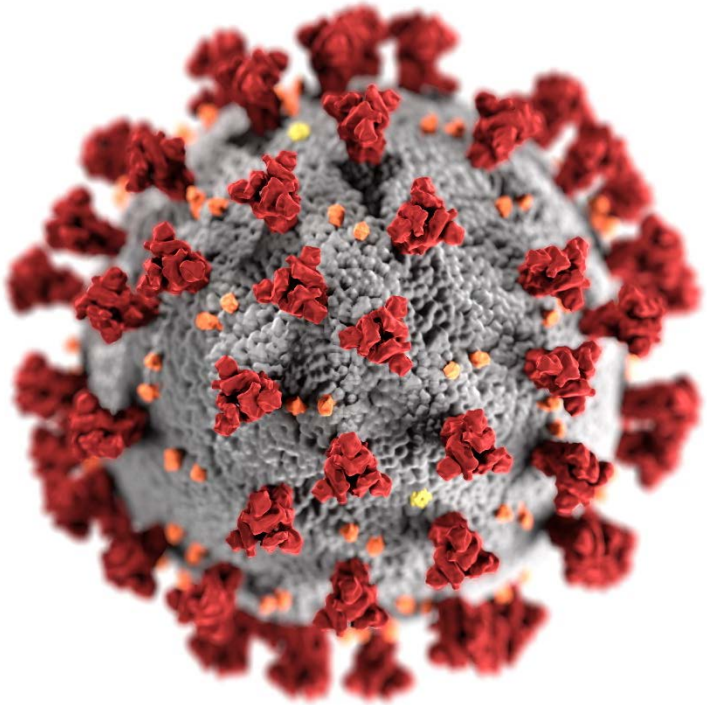
- **Existing** systems and data sources are used to monitor safety of vaccines post-authorization and post-licensure, such as:
  - Vaccine Adverse Event Reporting System (VAERS)
  - Vaccine Safety Datalink (VSD)
  - Clinical Immunization Safety Assessment (CISA)
  - Biologics Effectiveness and Safety System (BEST)

- **New** systems have been developed to monitor COVID-19 vaccine safety, such as **v-safe:**
  - Active surveillance that uses text messaging to initiate web-based survey monitoring.
  - Will provide telephone follow up to anyone who reports medically significant adverse events.

How was the vaccine development timeline accelerated while ensuring safety?

- Researchers used existing clinical trial networks to begin conducting COVID-19 vaccine trials.
- Manufacturing was started while the clinical trials were still underway. Normally, manufacturing doesn't begin until after completion of the trials.
- mRNA vaccines are faster to produce than traditional vaccines.
- FDA and CDC are prioritizing review, authorization, and recommendation of COVID-19 vaccines.

*For more information, visit the COVID-19 Prevention Network: www.coronaviruspreventionnetwork.org/about-covpn



For more information, contact CDC
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TTY: 1-888-232-6348 www.cdc.gov

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