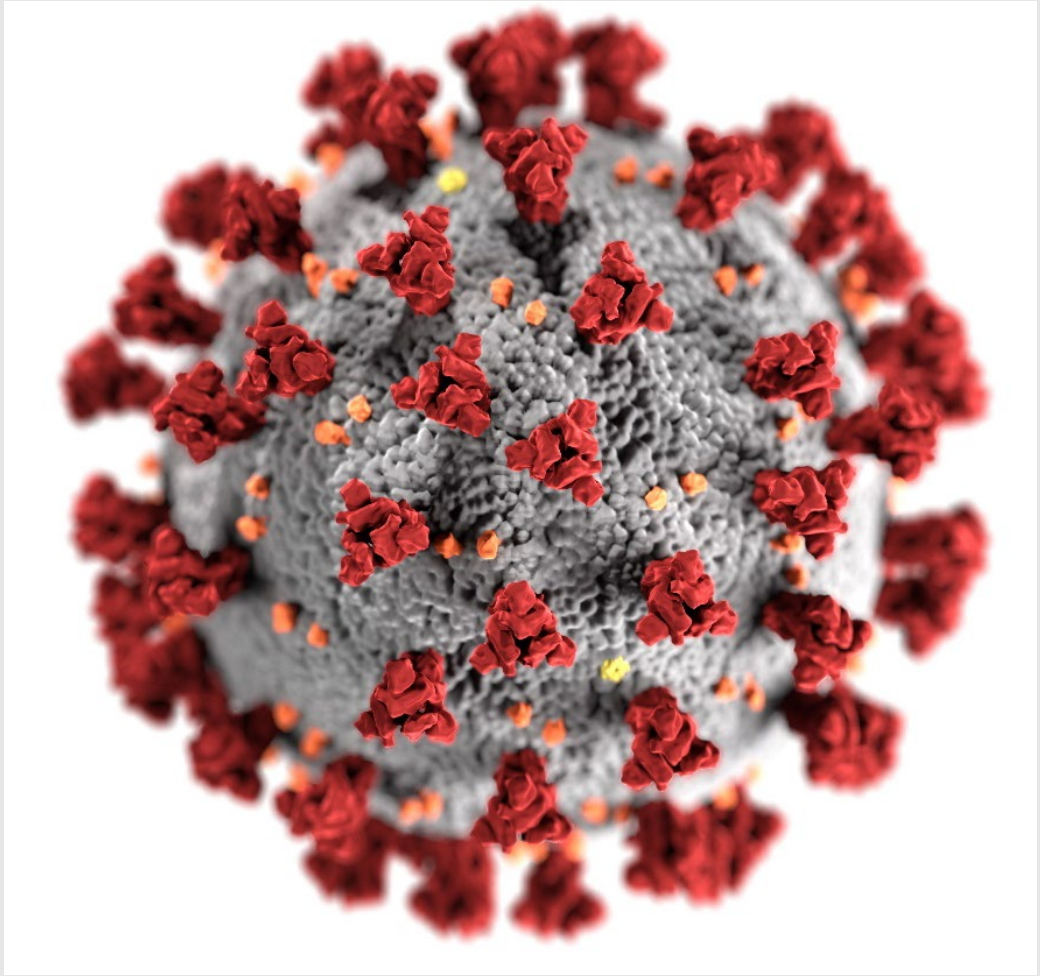


For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

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

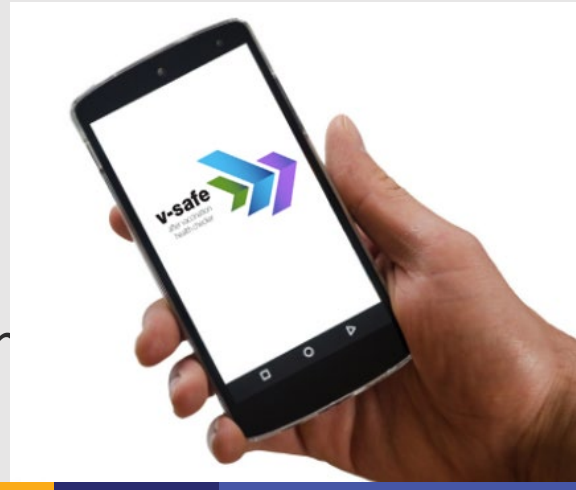
Safety of COVID-19 vaccines is a top priority

- 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 based survey monitoring.
  - Will provide telephone follow up to anyone who reports 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 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, visit the COVID-19 Prevention Network: www.coronaviruspreventionnetwork.org/about-covpn

COVID-19 vaccination will help protect you from COVID-19.

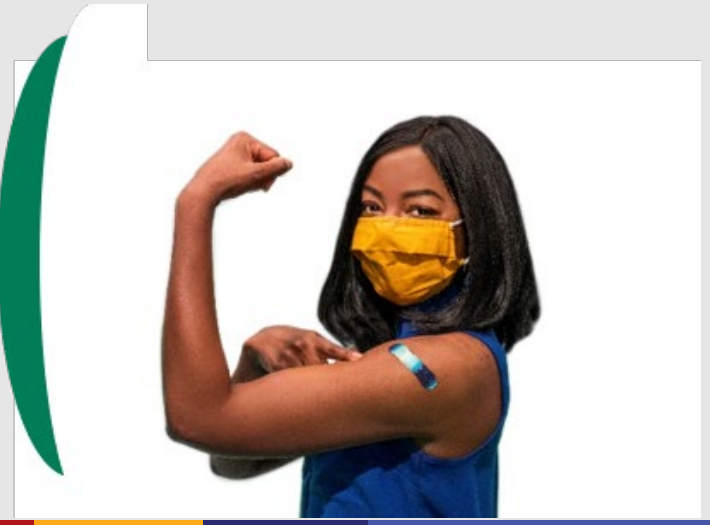
Getting a COVID-19 vaccine...

- Will help create an immune response in your body against the virus.
- May help keep you from getting severely ill, even if you do get COVID-19.

- Can protect your family, your coworkers, and patients.

COVID-19 vaccination is a safer way to build protection.

- Getting the virus that causes COVID-19 may offer some natural protection, known as immunity. But experts don’t know how long this protection lasts.
- The risk of severe illness and death from COVID-19 far outweighs any benefits of natural immunity.
- COVID-19 vaccination will help protect you by creating an antibody response without the risk of severe illness.



Vaccination is one measure to help stop the pandemic.

- While COVID-19 mRNA vaccines appear to be highly effective, additional preventive tools remain important to limit the spread of COVID-19.
- The combination of getting vaccinated and following CDC recommendations to protect yourself and others offers the best protection from COVID-19.
  - Cover your nose and mouth with a mask.
  - Avoid close contact. Maintain social distancing.
  - Clean and disinfect.
  - Wash your hands.