COVID-19 Vaccine FAQ

VACCINE SAFETY & DEVELOPMENT

How are vaccines developed and tested?

The most commonly used vaccines have been around for decades, with millions of people receiving them safely every year. As with all medicines, every vaccine must go through **extensive and rigorous testing** to ensure it is safe before it can be introduced in a country.

An experimental vaccine is first tested in animals to evaluate its safety and potential to prevent disease. It is then tested in human clinical trials in three phases.

Phase I

- The vaccine is given to a small number of volunteers to assess its safety, confirm it generates an immune response, and determine the right dosage.

Phase II

- The vaccine is usually administered to hundreds of volunteers, who are closely monitored for any side effects, to further assess its ability to generate an immune response. Data is also collected whenever possible on disease outcomes, but usually not in large enough numbers to have a clear picture of the effect of the vaccine on disease. Participants in this phase have the same characteristics (such as age and sex) as the people for whom the vaccine is intended. Some volunteers receive the vaccine and others receive a placebo, which allows comparisons to be made and conclusions to be drawn.

Phase III

- The vaccine is given to thousands of volunteers. Half receive the investigational vaccine and the others receive a placebo, similar to phase 2. Data from both groups is carefully compared to see if the vaccine is safe and effective against the disease it is designed to protect against.

Once the results of the clinical trials are available, a series to steps is required, including reviews of efficacy, safety, and manufacturing for regulatory and public health policy approvals, before a vaccine may be introduced into a national immunization program.

How does an mRNA vaccine differ from previous vaccines?

mRNA vaccines are a new type of vaccine to protect against infectious diseases. To trigger an immune response, many vaccines put a weakened or inactivated germ into our bodies. mRNA vaccines instead **teach our cells** how to make a protein that triggers an immune response inside our bodies. That immune response, which produces antibodies, is what protects us from getting infected if the real virus enters our bodies.

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How is the research and development process being accelerated without compromising safety?

The CEOs of the following companies have made a **historic pledge** to the world, outlining a united commitment to uphold the integrity of the scientific process as they work towards potential regulatory filings and approvals of the first COVID-19 vaccines.

- AstraZeneca
- BioNTech
- GlaxoSmithKline
- Johnston & Johnston
- Merck
- Moderna
- Novavax
- Pfizer
- Sanofi

Currently, clinical trials are evaluating investigational COVID-19 vaccines in many thousands of study participants to generate scientific data regarding safety and efficacy. If FDA determines a vaccine meets required safety and effectiveness standards, FDA may permit the vaccine to be distributed and used in the United States under an Emergency Use Authorization (EUA) or licensure. Once FDA makes its determination, the Advisory Committee on Immunization Practices (ACIP) will review available data before making vaccine recommendations to CDC.

Once a COVID-19 vaccine is authorized or approved for use, CDC, FDA, and other federal partners will use multiple existing, robust systems and data sources to conduct ongoing safety monitoring.

Have Louisiana residents participated in the clinical trials?

The Pfizer/BioNTech and Moderna clinical trials for the vaccine included **patients from across Louisiana**. The evidence for the vaccine's safety comes in part from the people in our own community.

Pfizer/BioNTech Clinical Sites
- **Oschner Clinic Foundation** | New Orleans, LA
- **Benchmark Research** | Metairie, LA
- **LSUHSC-Shreveport** | Shreveport, LA

Moderna Clinical Sites
- **Benchmark Research** | Metairie, LA
- **Meridian Clinical Research** | Baton Rouge, LA

What are the side effects of the vaccine?

Details on the vaccines and their safety data have not been presented to the general public yet, but they will be once they receive **Emergency Use Authorizations (EUA)** from FDA.

It is anticipated that you may experience similar side effects of the flu vaccine, which are:

- Sore arm at the injection site
- Fever
- Fatigue
- Headache
- Joint Pain
- Muscle Aches

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GENERAL INFORMATION

Why is it important to get the COVID-19 vaccine?

Getting the vaccine has several benefits. The most important one being that we can safely establish **herd immunity**, so the population at large can be protected from the virus if a threshold of vaccination is reached. It's a tall order, as experts estimate that roughly 70% of people in the U.S. (200 million) need to be vaccinated to reach this level of protection for COVID-19 specifically. This is especially important for vulnerable, high-risk groups, like the elderly and immunocompromised.

You have the power to make a difference. Every person who gets vaccinated brings us closer to getting our lives back to normal.

Will the COVID-19 vaccine infect me with COVID-19?

No. None of the COVID-19 vaccines currently in development in the United States use the live virus that causes COVID-19. There are several different types of vaccines in development. However, the goal for each of them is to teach our immune systems how to recognize and fight the virus that causes COVID-19. Sometimes this process can cause symptoms, such as fever, but these symptoms are normal and are a sign that the body is building immunity.

Will the COVID-19 vaccines cause me to test positive on COVID-19 viral tests?

Vaccines currently in clinical trials in the United States **won't cause you to test positive** on viral tests, which are used to see if you have a current infection. If your body develops an immune response, which is the goal of vaccination, there is a possibility you may test positive on some antibody tests. Antibody tests indicate you had a previous infection and that you may have some level of protection against the virus. Experts are currently looking at how COVID-19 vaccination may affect antibody testing results.

If I've already gotten sick with COVID-19, do I still need to take the COVID-19 vaccine?

Due to the severe health risks associated with COVID-19 and the fact that re-infection with COVID-19 is possible, people **may be advised to get a COVID-19 vaccine** even if they have been sick with COVID-19 before.

At this time, experts do not know how long someone is protected from getting sick again after recovering from COVID-19. The immunity someone gains from having an infection, called natural immunity, varies from person to person. Some early evidence suggests natural immunity may not last very long.

We won't know how long immunity produced by vaccination lasts until we have a vaccine and more data on how well it works. Both natural immunity and vaccine-induced immunity are important aspects of COVID-19 that experts are trying to learn more about, and CDC will keep the public informed as new evidence becomes available.

Is the COVID-19 vaccine more effective than the flu vaccine?

Recent studies show that flu vaccination reduces the risk of flu illness between 40% and 60% among the overall population during seasons when most circulating flu viruses are well-matched to the flu vaccine. Current COVID-19 vaccine results are showing efficacy ratings above 90%, making the **COVID-19 vaccine more effective than the flu vaccine**.

REFERENCES

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- Centers for Disease Control and Prevention (CDC): https://www.cdc.gov/coronavirus/2019-nCoV/index.html
- Moderna: https://www.modernatx.com/
- Pfizer: https://www.pfizer.com/

Videos

- The Four Phases of Clinical Trials (Pfizer): https://www.pfizer.com/science/clinical-trials/guide-to-clinical-trials/phases
- Moderna Potential Vaccine Against COVID-19: https://youtu.be/qJIP91xjvsQ
- How Vaccines are Developed (U.S. Department of Health and Human Services): https://youtu.be/Z06JQhyZLUI