

A campaign to increase vaccine confidence while reinforcing basic prevention measures



Vaccine Confidence

Content last reviewed: December 20, 2022

Clinical Trials and the Latino Community

- Many of the COVID-19 clinical trials are still recruiting volunteers.
- Latino individuals are twice as likely to be hospitalized for COVID-19 than are non-Hispanic White individuals.
- Including the Latino community in COVID-19 clinical trials is essential. Help researchers develop vaccines and treatments that are **safe and effective for all of us**.
- Find out more about volunteering for clinical trials at combatCOVID.hhs.gov.



Vaccine Safety Through Clinical Trials

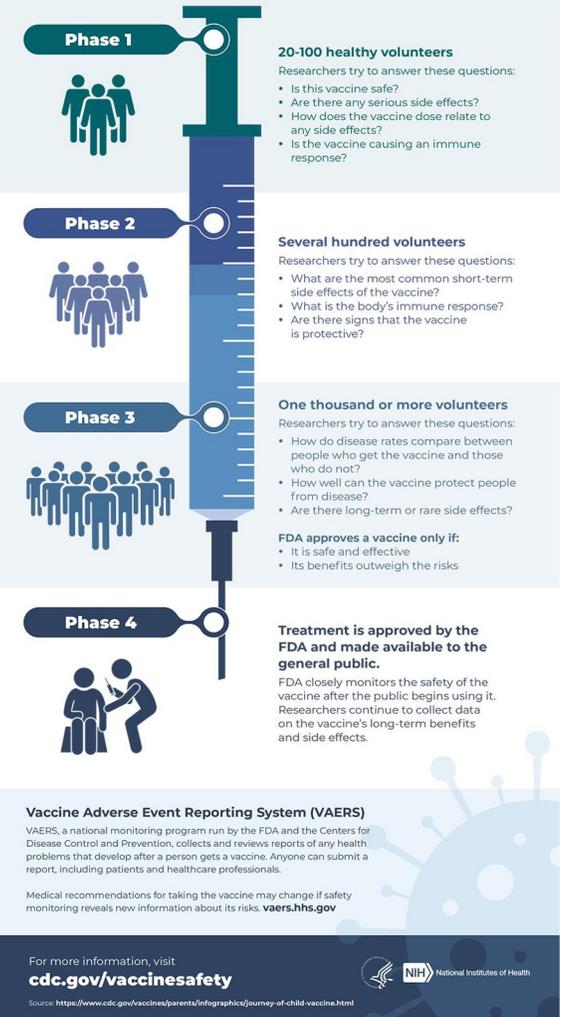
- FDA sets rules for four phases of clinical research, so researchers can learn about the effects of new therapies while keeping volunteers safe. This applies to COVID-19 vaccines.
- Each phase of a clinical trial helps researchers answer several questions, including:
 - **Phase I** — Is this vaccine safe?
 - **Phase II** — What are the most common short-term side effects of the vaccine?
 - **Phase III** — How well can the vaccine protect people from the disease?
 - **Phase IV** — Treatment is approved and made available to the general public.
- Typically, these phases run consecutively, meaning Phase II doesn't start until Phase I is complete. Mass production doesn't start until Phase III is complete.

Learn more about vaccine development on the National Institutes of Health [website](#).

The Journey of a Vaccine

How a new vaccine is developed, approved, and manufactured

The U.S. Food and Drug Administration (FDA) sets rules for the four phases of clinical research so that researchers can learn about the effects of new therapies while keeping volunteers safe. This includes trials of new vaccines to protect against infection; researchers always test vaccines with adults first.



Authorization and Approval Process for COVID-19 Vaccines

- Due to the emergency nature of the COVID-19 pandemic, the FDA has provided emergency use authorizations (EUA) to multiple COVID-19 vaccines.
- Through an EUA, the FDA can authorize a vaccine for immediate use in an emergency **while still ensuring that the same safety measures are being followed** as in any vaccine development process:
 - In the case of the COVID-19 clinical trials, larger trials than usual were run. There have been over 30,000 participants in each Phase III trials.
 - After a Phase III trial is complete for a specific vaccine, the FDA reviews the data and determines whether the vaccines are safe and effective.
 - The FDA has authorized multiple COVID-19 vaccines, with Phase III clinical trials underway for other vaccines.
- The FDA has fully approved the following vaccines after thoroughly evaluating additional data on their safety and effectiveness and inspecting where and how they're made:
 - The Pfizer-BioNTech COVID vaccine for people ages 12 and older.
 - The Moderna COVID vaccine for people ages 18 and older.



[Learn more](#) about EUAs.

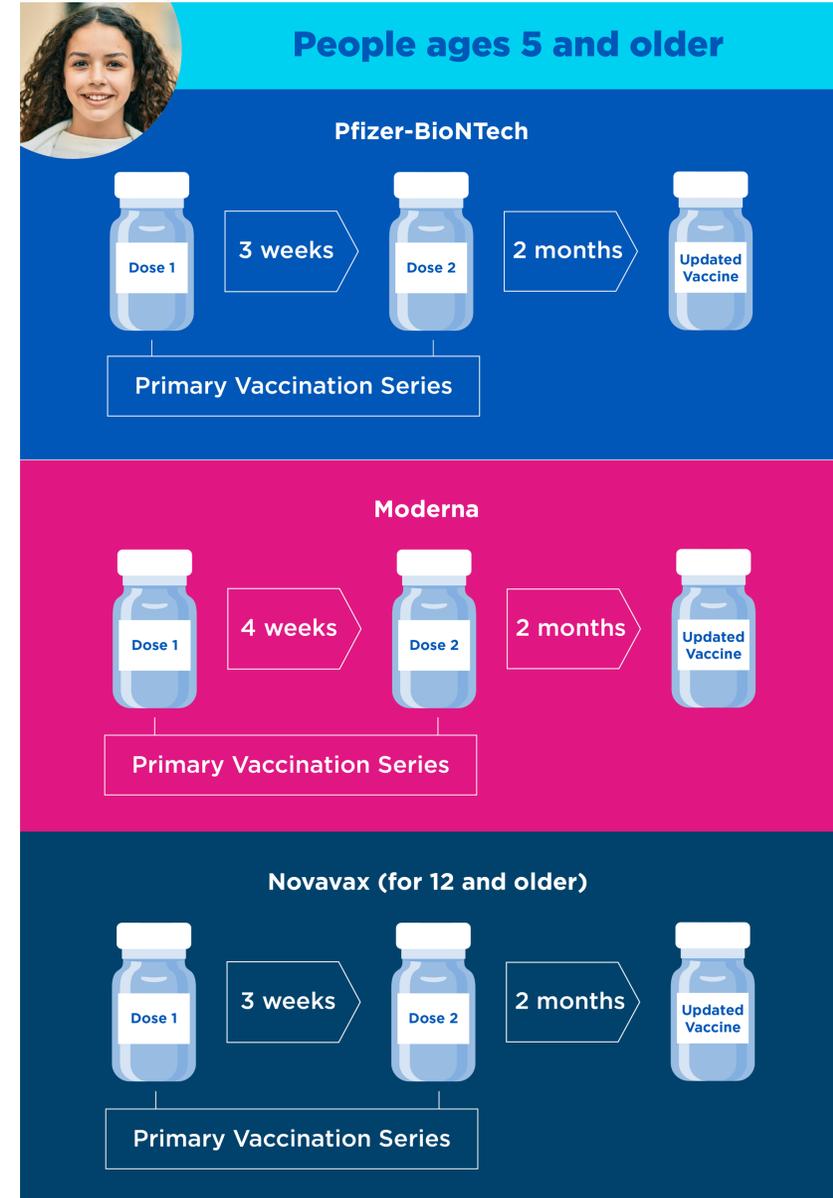
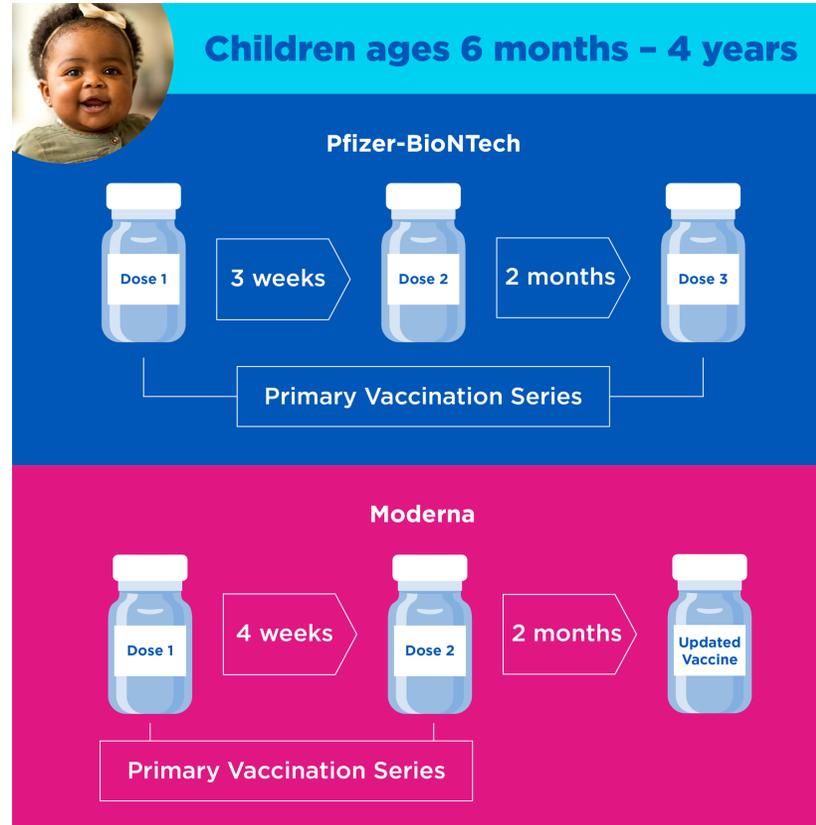
Currently Available COVID-19 Vaccines

- Vaccines currently available for use against COVID-19 were tested on diverse adult populations, including older adults and communities of color.



Get the [latest information](#) on the COVID-19 vaccines.

How many vaccine doses do I need for the best protection?



How many vaccine doses do I need for the best protection?

- **For males ages 12–39:** You may benefit from waiting longer between the 1st and 2nd doses of your primary vaccination series. Talk to your health care or vaccine provider.
- **For vaccinated people:** Updated vaccines are available to help protect against Omicron.
- Get your updated vaccine now if your last dose was before September 2022 (October 2022 for kids 6 months – 11 years).
- Otherwise, wait until 2 months after you complete your primary vaccination series to get your updated vaccine dose.
- Completing your primary vaccination series means you got your first 2 doses of the Pfizer-BioNTech, Moderna, or Novavax vaccine, or your 1 dose of Johnson & Johnson’s Janssen vaccine.
- If you recently had COVID, you should wait 3 months from when you got sick to get your updated vaccine.
- Children 6 months – 4 years who got all 3 doses of the Pfizer-BioNTech primary vaccination series don’t need an updated vaccine at this time.
- **For people with [compromised immune systems](#):** Because you’re less able to fight infections, you may need more than these recommended doses. Talk to your health care provider.

COVID-19 Vaccines Are Safe and Effective

The vaccines are safe.

- Scientists carefully evaluated the COVID-19 vaccines to ensure that they met rigorous safety standards before they were made available to the public.
- Very strict systems are in place to monitor [vaccine safety](#) and side effects after the vaccines are in use.

The vaccines are effective.

- People who get all recommended doses of their COVID vaccine are well protected against severe illness, hospitalization, and death from COVID, including from the highly contagious Omicron variant.

More on Vaccine Safety

Safety is the top priority

The FDA and CDC have the highest standards when it comes to ensuring the safety and effectiveness of vaccines. Their process includes the following procedures:

Scientists must first test vaccines extensively in medical studies to ensure they are safe and effective.

Before the FDA authorizes a vaccine for use among the public, it ensures its safety by independently:

- Reviewing the data from the medical studies, and
- Inspecting the manufacturing facilities.

Even after a vaccine has been authorized, the FDA and CDC closely monitor vaccine administration to identify even rare side effects or reactions.

The FDA and CDC closely review any reports of side effects or reactions and share these facts with the public.

SAFETY MONITORING IN ACTION

The extremely rare cases of blood clotting and Guillain-Barré Syndrome following Johnson & Johnson's Janssen vaccine and heart inflammation following Pfizer-BioNTech's and Moderna's vaccines—a very small number of cases out of millions of vaccinations—show that the FDA and CDC's vaccine safety monitoring systems work and catch even the rarest reactions.

Thorough investigations have confirmed that all three FDA-authorized vaccines are safe and effective. However, CDC [recommends](#) most people get the Pfizer-BioNTech, Moderna, or Novavax vaccine.

The monitoring systems ensure that doctors are notified to watch for signs of serious reactions, no matter how rare, and are aware of proper courses of treatment.

How COVID-19 Vaccines Work

- COVID-19 vaccines help your body develop immunity to the virus that causes COVID-19 without you having to get the illness.
- Different types of vaccines work in different ways, but all types of vaccines teach your body how to fight the virus in the future and build immunity.
- Sometimes after getting the vaccine, you may experience side effects, such as a fever. This is normal and a sign that your body is building protection against the disease.



Benefits of Receiving a COVID-19 Vaccine

- COVID-19 vaccines help your body build defenses (immunity) to prevent you from getting the disease. If you do get COVID-19, though, the vaccines will help prevent you from getting seriously ill.
- Getting vaccinated can also help protect people around you, particularly people at increased risk for severe illness from COVID-19.
- It's important to understand that infection doesn't necessarily lead to illness. If you're up to date with your COVID vaccines and the virus manages to enter your body and begins to multiply—that is, infect you—your immune system will be prepared to quickly recognize the virus and will work to keep it from doing real harm. That's why most people who get infected with COVID-19 despite being vaccinated—so-called breakthrough cases—have no symptoms (asymptomatic) or only mild-to-moderate illness.



Side Effects of COVID-19 Vaccines

- The COVID-19 vaccines, like other vaccines, can have side effects, but are generally mild and go away in a few days.
- Some side effects include:
 - Pain and swelling in the area where the vaccine was administered
 - Headache, fever, feeling tired, or body aches
- More serious side effects can happen in people with severe allergic reaction to any ingredient in the vaccines. However, this is very rare.



Staying Up to Date with Your Vaccines

- You're best protected when you're [up to date with your COVID vaccines](#).
- To get the most protection from the vaccines, you need all the [recommended doses](#) for people your age.
- If you're 6 months or older and vaccinated, you should get an updated vaccine to help protect against Omicron.
 - Children 6 months – 4 years who got all 3 doses of the Pfizer-BioNTech primary vaccination series don't need an updated vaccine at this time.



According to CDC...

- To maximize protection from highly contagious variants and prevent possibly spreading COVID to others, both vaccinated and unvaccinated people should wear a well-fitting mask inside public places when the [COVID risk to your community is high](#).
- If you're at [higher risk of getting very sick from COVID](#), you can also protect yourself by:
 - Keeping at least 6 feet away from people who don't live with you.
 - Avoiding crowds and poorly ventilated spaces.
 - Washing your hands often with soap and water for at least 20 seconds or using hand sanitizer with at least 60% alcohol if you don't have soap and water.
- Vaccinated and unvaccinated people must still follow federal, state, local, tribal, and territorial laws, rules, and regulations. That includes public transportation, airport/airplane, local business, and workplace guidance.



According to CDC... (Cont.)

- People with compromised immune systems are less able to fight infections. If any of the following apply to you, you may need additional vaccine doses:

You have a moderate or severe primary immunodeficiency disorder, such as DiGeorge syndrome or Wiskott-Aldrich syndrome.

You have an advanced or untreated HIV infection.

You've ever had an organ transplant or had a stem cell transplant within the last 2 years.

You're being treated with corticosteroids or other immunosuppressant medicines for such conditions as arthritis, asthma, or an autoimmune disease, such as lupus, sarcoidosis, inflammatory bowel disease, rheumatoid arthritis, and psoriasis.

You're being treated for cancer.



How to Answer Frequently Asked Questions About the Vaccines From Your Community



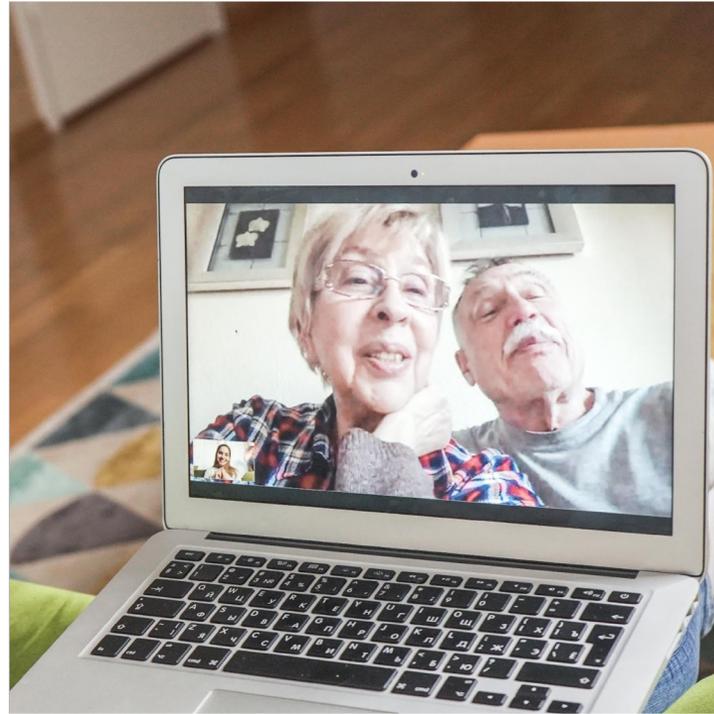
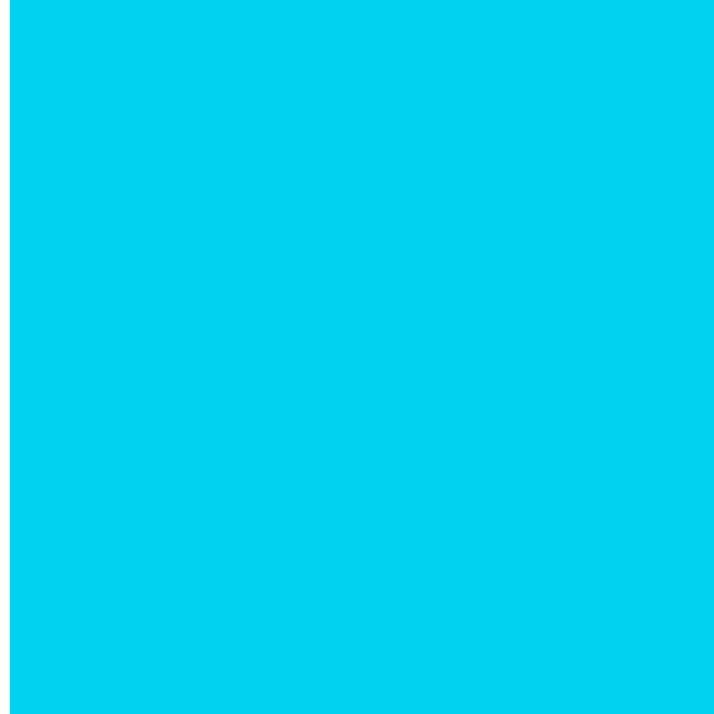
When Will the Vaccines Be Available to You?

- Everyone ages 6 months and older in the United States should get a COVID-19 vaccine.
- You have three ways to find vaccines near you:

Go to [vaccines.gov](https://www.vaccines.gov)

Text your ZIP code to 438829

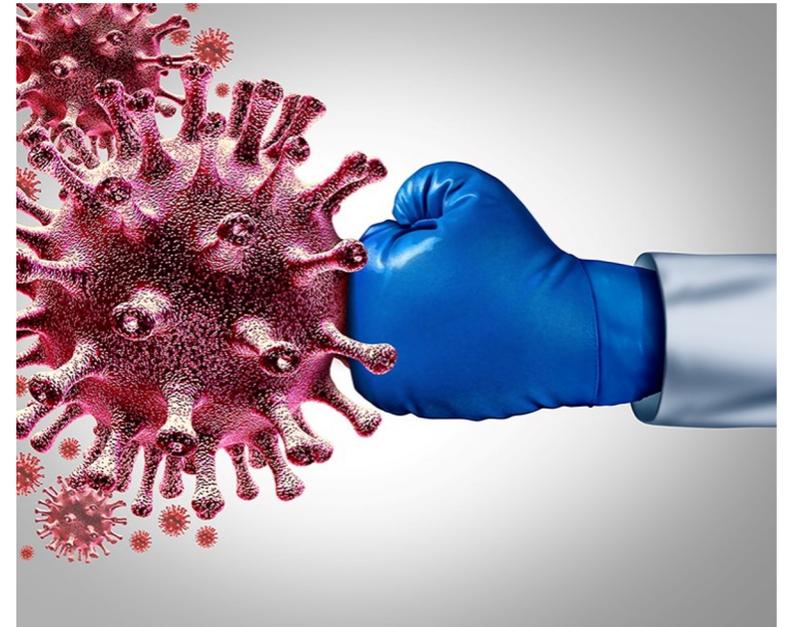
Call 1-800-232-0233



Can the COVID-19 Vaccines Give You COVID-19?

No. You can't get COVID-19 from the vaccines.

- None of the COVID-19 vaccines in use or in testing in the United States uses the live virus that causes COVID-19.



How Much Does a COVID-19 Vaccine Cost?

- COVID-19 vaccines are free for people who live in the United States, regardless of your immigration or health insurance status.
- Vaccine providers can be reimbursed by:
 - The patient's public or private insurance provider or,
 - For uninsured patients, by the Health Resources and Services Administration's Provider Relief Fund.
- No one can be denied a vaccine if you're unable to pay a vaccine administration fee.



Will Everyone Have Access to a COVID-19 Vaccine?

- Federal government partners fully support equal access to the COVID-19 vaccines and **vaccine distribution sites for everyone, including undocumented immigrants.**
 - It's a moral and public health imperative to ensure that all individuals residing in the United States have access to the vaccine.
 - All individuals, regardless of immigration status, should receive the COVID-19 vaccine once eligible under local distribution guidelines as soon as they can.
- Receiving a COVID-19 vaccine, as well as testing and treatment for COVID-19, doesn't negatively affect your immigration process or your family.
 - If you have questions about how to get a vaccine, then contact the nearest community clinic or your state health department.

Should People Who Have Gotten Sick With COVID-19 Get a Vaccine?

- Yes. You should get a COVID-19 vaccine even if [you've been sick with COVID-19 before.](#)
- Having COVID-19 may offer some protection or natural immunity against the virus, but scientists still don't know how long that protection lasts and how protected you are from the new variants.
- It's possible for a person who has had COVID-19 to be reinfected and have serious health complications, so [it's better to get vaccinated.](#)



Can You Stop Wearing a Face Mask After Receiving a Vaccine?

- To maximize protection from highly contagious variants and prevent possibly spreading COVID to others, both vaccinated and unvaccinated people should wear a well-fitting mask inside public places when the COVID risk to your community is high.
- If you're at [higher risk of getting very sick from COVID](#), you can also protect yourself by:
 - Keeping at least 6 feet away from people who don't live with you.
 - Avoiding crowds and poorly ventilated spaces.
 - Washing your hands often with soap and water for at least 20 seconds or using hand sanitizer with at least 60% alcohol if you don't have soap and water.
- Vaccinated and unvaccinated people must still follow federal, state, local, tribal, and territorial laws, rules, and regulations. That includes public transportation, airport/airplane, local business, and workplace guidance.



Thank you



Brought to you by the U.S. Department of Health and Human Services

