

With the facts, we can all make informed decisions about our health.

A Discussion Guide Around the Safety and Speed of the COVID-19 Vaccines:

- It may seem that the vaccines were developed with unusual speed, but in fact there are years and even decades of research that went into developing the COVID-19 vaccines.
- Researchers got a head start on developing a vaccine because the virus that causes COVID-19 is similar to other viruses that have been around for a while.
- This includes Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS), which you may have heard about years ago.
- The speed at which the vaccines were developed reflects the priority the best medical and scientific experts put on finding the best way to combat the virus. These are not politicians, but people who dedicate their life to public health and protecting the safety of people.
- It is also important to know that the COVID-19 vaccines did not skip any of the clinical trial steps that all other vaccines or drugs seeking approval from the Food and Drug Administration (FDA) must go through.
- Another reason why COVID-19 vaccines were developed relatively quickly was that in some cases, developers could run Phase 1 and Phase 2 trials simultaneously, saving time without ever compromising safety.
- Clinical trials in the United States must go through multiple phases:
 - Phase 1 includes 20 – 100 health volunteers;
 - Phase 2 includes *several* hundred volunteers; and
 - Phase 3 includes over a *thousand* volunteers.
- The FDA can only authorize or approve a vaccine—including for “Emergency Use Authorization”—after looking at all of the results *after* Phase 3.
- For the COVID-19 vaccines, the FDA required that at least 30,000 volunteers were included in Phase 3 of the clinical trials.
- Even after a vaccine is approved, researchers continue to monitor and collect data on a vaccine’s long-term benefits and side effects.
- The federal government allowed the vaccine makers to start manufacturing the most promising vaccines to begin while the studies were ongoing. When the vaccines were authorized, they were immediately available. If they had not received approval, they would not have been made available.
- The public health success story that resulted in COVID-19 vaccines happened because of decades of research and an extraordinary global effort that began in January 2020 when the whole genetic code of the virus was published for every scientist in the world to see.
- Incredible investment and collaboration from the nation’s best scientists and medical health experts also helped to speed up the development process without sacrificing safety.
- The vaccines are safe, effective and our greatest protection against the virus, including severe outcomes like hospitalization, intubation and even death.

- We hope the information you learned today can help you feel confident about making the decision to get vaccinated – so you can protect yourself, your loved ones and your community against this dangerous virus.

It's OK to have questions, and that's why we want to make sure you have the information you need to get good answers.

Frequently Asked Questions:

Question: How was the vaccine developed so quickly?

Answer: The speed at which the vaccines were developed is a reflection of the priority the scientific community and the world put on finding a way to combat the virus.

There are many factors that combined to allow the COVID-19 vaccines to be developed quickly and safely:

- Researchers got a head start on developing a vaccine because the virus that causes COVID-19 is similar to other existing viruses that have been studied extensively in the past decade.
- Research about the new virus was shared almost immediately with scientists all over the world, which allowed work to begin on a vaccine right away.
- Some researchers were able to run [phase one and two trials at the same time](#).
- The studies on COVID-19 included a larger number of people than other recent vaccine trials, meaning there were a larger number of people in the trials over a shorter period of time.
- The federal government allowed manufacturing of the most promising vaccines to begin while the studies were ongoing. That means that when they were authorized they could be offered to the public almost immediately.
- It's important to note that all vaccine developers are required to go through each stage of the development process and meet all safety and efficacy (how well something works) standards. Learn about the many steps in the typical [vaccine testing and approval process](#).

Question: Are the COVID-19 vaccines safe and effective?

Answer: Yes, all of the COVID-19 vaccines authorized for emergency use in the United States are safe, effective and your greatest protection against the virus.

All of the vaccines available are extremely effective at preventing severe illness, hospitalization and death from COVID-19. All of our State and federal medical experts agree and strongly encourage all eligible individuals to get their COVID-19 vaccine as soon as possible.

- The COVID-19 vaccines are held to the **same rigorous safety and effectiveness standards** as all other types of vaccines in the United States.
- Each vaccine had three rounds of clinical trials **with tens of thousands of participants** with a diverse range of race, age and other demographics.
- After vaccine is authorized, multiple **safety systems** at the FDA and the CDC constantly monitor for adverse events. If an adverse event is found, it is immediately investigated to determine if it poses a true health issue and public recommendations are made if necessary.

Question: Should the public have confidence in the process for a COVID-19 vaccine to get authorized or approved?

Answer: Absolutely. All the vaccines we use each day, from the flu to tetanus shots, have followed a similarly rigorous scientific approval process.

The FDA and the CDC have a long history in evaluating the safety and effectiveness of vaccines before they are authorized or approved for use by members of the public. It's important to note that there is transparency during every step of the way. When key committees at the FDA and CDC meet to consider authorizing or approving a drug, or recommending a drug, these meetings are open to the public and available online via live webcast. Similarly, applications by drug companies for FDA authorization or approval, as well as underlying clinical trial data, are also publicly available.

In New York State, an independent Clinical Advisory Task Force was formed to provide an additional layer of review before recommending New Yorkers get a COVID-19 vaccine or vaccine booster. The Clinical Advisory Task Force is comprised of leading scientists, doctors and health experts. Our best, most dedicated federal and state health experts and medical scientists agree that the vaccine is safe, effective and our greatest protection against this dangerous virus.

Question: Are there any fully approved vaccines for COVID-19?

Answer: Yes. The Pfizer-BioNTech vaccine is fully approved by the FDA.

On August 23, 2021, the FDA announced the full approval of the Pfizer-BioNTech vaccine for the prevention of COVID-19 disease in individuals aged 16 and older. The FDA-licensed vaccine will be marketed under the name Comirnaty, but nothing about its ingredients have changed. The Pfizer-BioNTech vaccine is authorized for emergency use for individuals ages 12 through 15. The Moderna and Janssen/Johnson & Johnson COVID-19 vaccines are also authorized for emergency use.

Question: Is the approval or authorization of COVID-19 vaccines a political process?

Answer: No. The FDA and CDC approval processes are designed to be immune to the influence of partisan politics.

It's understandable that people may question whether or not politics impact decisions made about the COVID-19 vaccines because of the involvement of federal agencies. However, all New Yorkers should know that the FDA, CDC and New York State's health experts, including the Clinical Advisory Task Force, are not political. They are only focused on the public health and safety of the vaccines.

While the FDA and CDC are both federal agencies, they have established processes for evaluating potential drug and vaccine candidates that are protected from political interference. All vaccines authorized or approved by the FDA *must* meet the agency's high standards for approval or for emergency use authorization. There have been many instances throughout the pandemic during which guidelines proposed by the FDA or the CDC have been opposed by presidential administrations. This demonstrates the independence of these agencies and their strict commitment to public health and scientific integrity. Finally, meetings of key advisory committees at the FDA and CDC are open to the public, and documents and data are made publicly available so that there is transparency and accountability throughout the process.

Question: What are the risks of *not* getting vaccinated?

Answer: The vaccines are extremely effective at preventing serious illness, including hospitalization and death, from COVID-19. Not being vaccinated against COVID-19 puts you at greater risk of these severe outcomes.

Another risk of not being vaccinated is the increased likelihood of passing on the virus to others, including family members and people who may have other medical conditions.

- Hundreds of thousands of Americans have died due to COVID-19. Many more have been hospitalized.
- Even people who recover from COVID-19 may suffer from long-term symptoms that can be serious and affect your quality of life.
- According to the CDC, 97% of pregnant people hospitalized for COVID-19 were unvaccinated.
- Getting vaccinated is—and continues to be—the best way to prevent against these serious outcomes.

Question: Is it better to get natural immunity to COVID-19, rather than immunity from a vaccine?

Answer: No! While you may have some short-term immunity after recovering from COVID-19, we don't yet know how long this protection lasts.

Vaccination is the best protection, and it is safe. People who get COVID-19 can have serious illnesses, and some have debilitating symptoms that persist for months. Sometimes this is called "Long Covid."