Centers for Disease Control and Prevention

COVID-19

Developing COVID-19 Vaccines

Updated Feb. 4, 2022

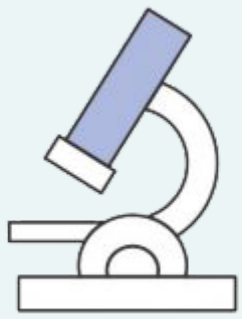
Overview

Bringing a new vaccine to the public involves many steps including vaccine development, clinical trials, U.S. Food and Drug Administration (FDA) authorization or approval, manufacturing, and distribution. Many different public organizations and private companies have worked together to make COVID-19 vaccines available to the public. While COVID-19 vaccines were developed rapidly, all steps have been taken to ensure their safety and effectiveness.

The Vaccine Process: From the Lab to You

Initial Development

New vaccines are first developed in laboratories. Scientists have been working for many years to develop vaccines against coronaviruses, such as those that cause severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS). SARS-CoV-2, the virus that causes COVID-19, is related to these other coronaviruses. The knowledge that was gained through past research on coronavirus vaccines helped speed up the initial development of the current COVID-19 vaccines.



Clinical Trials

After initial development, vaccines go through three phases of clinical trials to make sure they are safe and effective. For other vaccines routinely used in the United States, the three phases of clinical trials are performed one at a time. During the development of COVID-19 vaccines, these phases overlapped to speed up the process so the vaccines could be used as quickly as possible to control the pandemic. No trial phases have been skipped.

The clinical trials for COVID-19 vaccines have involved tens of thousands of volunteers of different ages, races, and ethnicities. Clinical trials for vaccines compare outcomes (such as how many people get sick) between people who are vaccinated and people who are not. Because COVID-19 continues to be widespread, the vaccine clinical trials have been conducted more quickly than if the disease were less common. Results from these trials have shown that COVID-19 vaccines are effective, especially against severe illness, hospitalization, and death.

The clinical trials showed no serious safety concerns within 8 weeks following vaccination. This is an important milestone, as it is unusual for adverse effects caused by vaccines to appear after this amount of time. Now that COVID-19 vaccines are available to the public, CDC and FDA continue to monitor their safety and alert the public about health problems that are reported after vaccination.

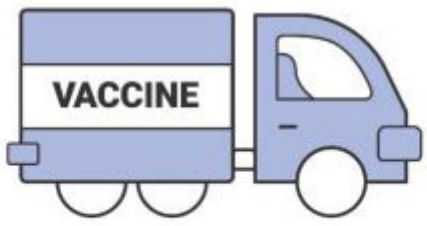
Authorization or Approval

Before vaccines are made available to people in real-world settings, FDA assesses the findings from clinical trials. Initially, they determined that three COVID-19 vaccines met FDA's safety and effectiveness standards and granted those vaccines Emergency Use Authorizations (EUAs). The EUAs allowed the vaccines to be quickly distributed for use while maintaining the same high safety standards required for all vaccines. Learn more in this video about EUAs.

FDA has now granted full approval for Pfizer-BioNTech (COMIRNATY) COVID-19 Vaccine for people ages 16 years and older and for Moderna (Spikevax) COVID-19 Vaccine for people ages 18 years and older. Before granting approval, FDA reviewed evidence that built on the data and information submitted to support the EUA. This included preclinical and clinical trial data and information, as well as details of the manufacturing process, vaccine testing results to ensure vaccine quality, and inspections of the sites where the vaccine is made. These vaccines were found to meet the high standards for safety, effectiveness, and manufacturing quality FDA requires of an approved product. Learn more about the process for FDA approval.

Manufacturing and Distribution

The U.S. government has invested substantial resources for both manufacturing and distribution of COVID-19 vaccines. This allowed manufacturing to begin when the vaccines were still in the third phase of clinical trials so that distribution could begin as soon as FDA authorized each vaccine.



Tracking Safety Using Vaccine Monitoring Systems

As vaccines are distributed outside of clinical trials, several monitoring systems continue to track them to ensure their safety. Hundreds of millions of people in the United States have received COVID-19 vaccines under the most intense safety monitoring in U.S. history. Some people have no side effects. Many people have reported common side effects after COVID-19 vaccination, like pain or swelling at the injection site, a headache, chills, or fever. These reactions are common and are normal signs that your body is building protection.

Reports of serious adverse events after vaccination are rare. CDC and FDA continue to closely monitor several reporting systems, like the Vaccine Adverse Event Reporting System (VAERS), Vaccine Safety Datalink (VSD), and v-safe, which help look for safety issues now that the vaccines are being given to patients in real-world settings across the country. CDC provides timely updates on selected serious adverse events reported after COVID-19 vaccination.

What This Means for You

COVID-19 vaccines have been rapidly developed and distributed to help fight the pandemic. During this process, all steps have been taken to ensure their safety and effectiveness. CDC recommends you get a COVID-19 vaccine as soon as you can to help protect yourself and others.

Related Pages

- Different COVID-19 Vaccines
- Possible Side Effects After Getting a COVID-19 Vaccine
- What to Do if You Had an Allergic Reaction After Getting a COVID-19 Vaccine
- V-safe after Vaccination Health Checker
- Understanding mRNA COVID-19 Vaccines

For Healthcare Professionals

- Quick Answers for Healthcare Professionals [217 KB, 2 Pages]
- Answering Your Questions About the New COVID-19 Vaccines [368 KB, 4 Pages]
- COVID-19 Vaccine Basics: What Healthcare Personnel Need to Know [1.32 MB, 23 Pages]
- COVID-19 Vaccination Communication Toolkit
- COVID-19 Vaccination: Clinical Resources for Each COVID-19 Vaccine

More Information

COVID-19, MERS & SARS

Vaccine Development Process: How Was Time Saved [779 KB, 1 Page]

FDA Approves First COVID-19 Vaccine

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