

COVID-19 Vaccine Development and Monitoring

The COVID-19 vaccines are safe and effective. Decades of research for other vaccines helped scientists develop the COVID-19 vaccines quickly. Researchers then tested the vaccines carefully in studies called clinical trials, without skipping any safety checks. Each vaccine goes through several phases of clinical trials.

Clinical trials are closely monitored by the U.S. Food and Drug Administration (FDA) and a safety monitoring board, an independent group that helps check for participant safety as well as accuracy and completeness of the information collected. Safety monitoring boards can recommend pausing or stopping a study if they have safety concerns.



Vaccine Development

- Scientists study the virus or bacteria they want to protect against with a vaccine.
- Vaccines are created and tested in labs and animals.
- If a vaccine appears to be safe and create an immune response, it may move to Phase One clinical trials.

1 Phase One Clinical Trials → 2 Phase Two Clinical Trials → 3 Phase Three Clinical Trials

- The vaccine is tested in a small group of about **20 to 100 people**.
- Researchers check if the vaccine:
 - ✓ Is safe
 - ✓ Creates an immune response
 - ✓ Causes side effects
- If the vaccine shows to be safe and create an immune response, it moves to the next phase.

- The vaccine is tested in **several hundred people** of different ages, physical health, and race and ethnicity.
- Researchers check:
 - ✓ If the vaccine causes any serious side effects
 - ✓ How participants' immune systems respond to the vaccine
 - ✓ If different doses are safer or more effective
- If the vaccine shows to be safe and creates a strong immune response in the people who get it, it moves to the next phase.

- The vaccine is tested in **thousands of people**.
- Some participants get the vaccine and others get a placebo (a harmless substance without active ingredients).
- Researchers check:
 - ✓ How participants who got the vaccine and participants who got the placebo compare (for example, how many people in each group get the disease the vaccine is designed to protect against)
 - ✓ If the vaccine is safe and effective



Vaccine Authorization or Approval

The manufacturer can submit the vaccine to the FDA for emergency use authorization (EUA) or approval (licensure).

In an emergency, such as the COVID-19 pandemic, the FDA can grant vaccines an EUA. An EUA allows a vaccine to be used to prevent life-threatening illness, if there are no other vaccines or medicines available. All vaccines granted an EUA must go through the same clinical trials as approved vaccines. The FDA only grants vaccines an EUA if the data shows the known and possible benefits of getting vaccinated outweigh the known and possible risks. Manufacturers granted an EUA are expected to apply for licensure once they have followed the study participants for a longer time.



Continued Monitoring

Safety studies continue even after vaccines are authorized or approved and in use. The studies can look for very rare adverse events. If a link is found between a possible side effect and a vaccine, public health officials determine if the benefits of the vaccine outweigh the risks. Sometimes, changes to vaccine recommendations are needed.

The Advisory Committee on Immunization Practices, a group of medical and public health experts, use vaccine safety and effectiveness data to make or change vaccine recommendations, as needed. Some systems used to monitor vaccine safety include:

- ✓ **Vaccine Adverse Event Reporting System (VAERS)**, the U.S.'s early warning system that collects reports of possible health problems after vaccination. If a possible problem is found, the FDA and Centers for Disease Control and Prevention (CDC) will look into it.
- ✓ **Vaccine Safety Datalink**, a network of eight managed care organizations across the U.S. with more than 24 million people. It is used to see if possible side effects found using VAERS are actually caused by a vaccine.
- ✓ **Post-Licensure Rapid Immunization Safety Monitoring**, which can check information from health plans and immunization registries to find and check out rare health events.
- ✓ **Clinical Immunization Safety Assessment Project** conducts studies to learn about vaccine safety and helps health care providers who have vaccine safety questions about specific patients.

The federal government is taking extra steps with the COVID-19 vaccines to monitor them. For example, the CDC's v-safe tool provides information on side effects from people who have been vaccinated. Millions of people have registered with v-safe and provided information about their vaccination experience.