# Developing Safe and Effective Vaccines

In the United States, vaccines are safe and effective because of the rigorous process they must complete. Vaccines are carefully tested and closely monitored by many health experts and organizations, from the first round of testing, to when a vaccine is available to the public, and beyond. Following years of rigorous research, here are the typical phases a vaccine must complete before it's ready for use.

## General Process for Creating Safe and Effective Vaccines

1. **Researchers study the vaccine's safety and efficacy in a lab environment.** As needed, researchers adjust the vaccine to make it more effective in the real world.

2. **Researchers submit a request to the U.S. Food and Drug Administration (FDA) to test the vaccine in humans in a clinical trial.** If approved by the FDA, researchers evaluate the vaccine's safety, efficacy, risks, and side effects in a series of trials that create cumulative findings on safety and effectiveness.

3. Once the vaccine passes its clinical trials, **the FDA closely inspects the proposed vaccine manufacturing facility.** The manufacturer is also required to produce large batches of the vaccine, which are tested by the FDA to ensure vaccine consistency.

4. **The company planning to distribute the vaccine provides the FDA with important data and information** from the testing phases, manufacturing facility, and processes for prescribing and administering the vaccine.

5. **The vaccine is reviewed by two committees of health experts:** the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) and the Advisory Committee on Immunization Practices (ACIP). ACIP develops recommendations for using the vaccine, which must be approved by the CDC Director in order to become official public health guidance.

6. After the vaccine is released to the public, **the CDC and FDA continue to monitor its development process, manufacturing facility, and overall safety and effectiveness.** Learn more about how the CDC and FDA continuously monitor vaccine safety.

### Why are some vaccines developed in less time?

Some vaccines go through the standard development and testing phases on a shorter than usual timeline. These vaccines can be developed quickly because of decades of previous vaccine research, global collaborations, and overlapping development and testing phases. For example, to develop the COVID-19 vaccine, leading medical experts in the United States and global pharmaceutical companies shared their research. Every study, and every phase of every trial, was carefully reviewed and approved by a safety board at the FDA. Every vaccine development process is transparent and rigorous throughout, with continual oversight and expert approval.

### How is the monitoring process different for vaccines that require frequent updates?

Some viruses, like the flu, change rapidly. These changes mean people need to update their defenses against the virus more often than for other viruses.

Year-round, there are more than 100 labs worldwide that monitor flu viruses and send samples to the World Health Organization (WHO). The WHO then uses the lab data to make recommendations about what the year's flu vaccine needs to include to be most effective. Based on the WHO's recommendations, the FDA makes the final decision about what flu vaccine will be available in the United States every fall.

## Why This Process Matters

The CDC, FDA, and other health experts require a rigorous vaccine testing process because it ensures that people receive the most benefit from vaccines in the safest manner. Vaccines are the best way to protect yourself against preventable, serious diseases that once routinely harmed or killed people in the United States. Here are just a few successes of some essential vaccines.

| VACCINE | IMPACT |
|---|---|
| Polio | At its peak in the mid-20th century, poliovirus killed or paralyzed more than 500,000 people every year. The polio vaccine has since eradicated polio in the Americas and the Western Pacific and brought down cases worldwide by more than 99%. |
| Chickenpox | In the early 1990s, more than 13,000 people were hospitalized with chickenpox per year in the U.S., mostly children. Today, there are fewer than 1,400 chickenpox hospitalizations per year in the U.S. |
| Measles, Mumps, and Rubella (MMR) | During the rubella epidemic of 1964–1965, 12.5 million people in the United States were diagnosed with rubella. Today, fewer than 10 people are diagnosed with rubella in the U.S. each year. |

## Stay Up-To-Date On Your Vaccines

Stay protected this fall and winter virus season by using the CDC's pharmacy lookup tool to find vaccine providers near you. In addition, talk with a healthcare professional or local pharmacist who can answer your vaccine questions, provide more information about the vaccine development process, and ensure you are up-to-date on all essential vaccinations.