

Journey of a Vaccine

Before a new vaccine is ever given to people, extensive lab testing is done that can take several years. Once testing in people begins, it can take several more years before clinical studies are complete and the vaccine is licensed.

How a new vaccine is developed, approved and manufactured.

The Food and Drug Administration (FDA) sets rules for the three phases of clinical trials to ensure the safety of the volunteers. Researchers test vaccines with adults first.

PHASE 1



20-100 Healthy Volunteers

- Is this vaccine safe?
- Does this vaccine seem to work?
- Are there any serious side effects?
- How is the size of the dose related to side effects?

PHASE 2



Several Hundred Volunteers

- What are the most common short-term side effects?
- How are the volunteers' immune systems responding to the vaccine?

PHASE 3

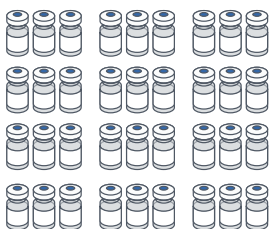


Hundreds or Thousands of Volunteers

- How do people who get the vaccine and people who do not get the vaccine compare?
- Is the vaccine safe?
- Is the vaccine effective?
- What are the most common side effects?

The FDA licenses a vaccine only if it's safe, effective and the benefits outweigh the risks.

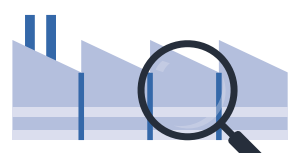
Vaccines are made in batches called lots.



Manufacturers must test all lots to make sure they are safe, pure and potent. The lots can only be released once FDA reviews their safety and quality.



The FDA inspects manufacturing facilities regularly to ensure quality and safety.



How a vaccine is added to the U.S. Recommended Immunization Schedule

1. ACIP

Advisory Committee on Immunization Practices

Medical + Public Health Experts

Medical and public health experts make up the ACIP. They carefully review data and clinical trials, and continually monitor a vaccine's safety and effectiveness. When making recommendations, they consider the following:

- How safe is the vaccine and how well does it work for specific age groups?
- How serious is the disease that the vaccine is preventing?
- How many children would get the disease if there was no vaccine?

2. CDC

Centers for Disease Control and Prevention

Recommendations are reviewed and approved by the CDC director.

3. Immunization Schedule

Officially added to the U.S. Childhood Immunization Schedule.

The United States currently has the safest vaccine supply in history. These vaccines keep children, families and communities protected from serious diseases.

How a vaccine's safety continues to be monitored

FDA + CDC

Food and Drug Administration + Centers for Disease Control and Prevention

Using a system of checks and balances (below), the FDA and CDC closely monitor a vaccine's safety after the public begins using it.

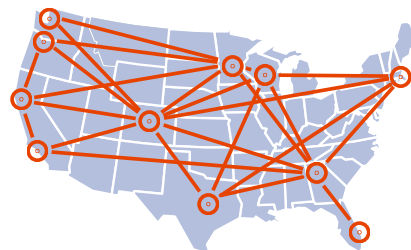
VAERS Reporting System

Vaccine Adverse Event Reporting System

Anyone can submit a report, including parents, patients and healthcare professionals.

Vaccine Safety Monitoring

Scientists use these two networks of healthcare organizations to actively monitor vaccine safety. Collectively, these organizations can analyze healthcare information from over 200 million people.



VSD = 24 million
Vaccine Safety Datalink

PRISM = 190 million
Post-Licensure Rapid
Immunization Safety
Monitoring

CISA Project

Clinical Immunization Safety Assessment Project

A collaboration between the CDC and seven medical research centers.

- **Vaccine safety experts** assist U.S. healthcare providers with complex vaccine safety questions about their patients.
- **CISA** conducts clinical research studies to better understand vaccine safety and identify prevention strategies for adverse events following immunization.

Recommendations May Change

Vaccine recommendations may change if safety monitoring reveals new information on vaccine risks (like a new serious side effect).