How Vaccines Are Made and Monitored

Research and Development

Prior to human clinical trials, new vaccines undergo **extensive lab testing**, often for several years.

After 10–15 years of lab research and promising results, the U.S. Food and Drug Administration (FDA) requires three phases of clinical trials before vaccines can be approved.

A small group of healthy volunteers takes the vaccine to assess that the vaccine is safe in humans.

1–10 Years

A larger group takes the vaccine to assess how it triggers individuals' immune response.

2–3 Years

An even larger group of thousands takes the vaccine so scientists can determine whether it is more effective than current vaccines or standard of care.

2–4 Years

The FDA will only license a new vaccine if it is:

☑ Safe ☑ Effective ☑ Benefits Outweigh Risks

After approval...

Recommendation Process

- The Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) is a group of independent medical and public health experts responsible for recommending how new vaccines should be used and who should take them.
- ACIP follows a transparent process, including written and oral public comment and public meetings, to develop vaccine recommendations based on data from clinical trials, studies, and insights from other expert groups.
- After the ACIP offers a recommendation, the CDC Director reviews and decides whether to formally issue a new recommendation. This enables insurance coverage and patient access to the vaccine.
- An ACIP recommendation does not mean a vaccine is required or mandated.

Safety Monitoring

Vaccine safety monitoring doesn't stop once a new vaccine is approved. The United States has one of the most robust vaccine safety monitoring systems in the world.

- The FDA regularly examines vaccine manufacturing facilities and inspects every batch of vaccines produced.
- Under the guidance of the FDA, manufacturers conduct Phase IV trials to confirm its long-term safety and effectiveness in real world settings.

- The Vaccine Adverse Event Reporting System (VAERS) allows anyone to report a reaction they or their patients experience.
- The Vaccine Safety Datalink (VSD) and Post-Licensure Rapid Immunization Safety Monitoring (PRISM) networks review data from millions of people to identify potential safety issues.
- The Clinical Immunization Safety Assessment (CISA) Project is a nationwide network of vaccine safety experts who conduct studies on vaccine adverse events and advise healthcare providers about complex vaccine safety questions.

- If new safety risks or side effects are identified during the ongoing safety monitoring, the FDA and/or CDC can update their guidance at any time.

Bio Biotechnology Innovation Organization