

How are Vaccines Tested?

Before a new vaccine is ever given to people, a lot of testing is done in a laboratory.

The next step is to test the vaccine in people in clinical trials. There are three phases of clinical trials to make sure a vaccine is safe and effective:

- During Phase I clinical trials, small groups of people get the vaccine. Phase I clinical trials are used to determine if the vaccine is generally safe, if it works, if there are any serious side effects, and what the best dose of the vaccine may be.
- In Phase II clinical trials, scientists give the vaccine to a larger group of people, including people who have characteristics (such as age and physical health) similar to those for whom the new vaccine is intended. Phase II clinical trials are used to study short-term side effects and how people's immune systems respond to the vaccine.
- In Phase III clinical trials, scientists give the vaccine to thousands of people to determine if the vaccine is safe and effective. In particular, Phase III trials determine how people who get the vaccine compare with people who do not get the vaccine.

Once the U.S. Food and Drug Administration (FDA) approves a vaccine for use, the FDA continues to monitor the vaccine and its manufacturing process to make sure that it remains safe.

The United States has an extensive vaccine monitoring system, where patients, health care professionals, vaccine companies, and health insurance companies report side effects and other data to gather and analyze information on the vaccine's safety.