

National Immunization Awareness Month

The Journey of Your Child's 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?

FDA licenses the vaccine only if:

- It's safe and effective
- Benefits outweigh 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.



FOR MORE INFORMATION, VISIT [HTTPS://WWW.FDA.GOV/CBER](https://www.fda.gov/cber)



Myth: Natural immunity is better than vaccine-acquired immunity.

Fact: In some cases, natural immunity — meaning actually catching a disease and getting sick— results in a stronger immunity to the disease than a vaccination. However, the dangers of this approach far outweigh the relative benefits.

Myth: Vaccines can infect my child with the disease it's trying to prevent.

Fact: Vaccines can cause mild symptoms resembling those of the disease they are protecting against. A common misconception is that these symptoms signal infection. In fact, in the small percentage where symptoms do occur, the vaccine recipients are experiencing a body's immune response to the vaccine, not the disease itself.