

# The Safety of Vaccines

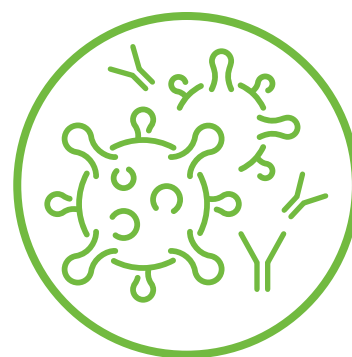
The U.S. Food and Drug Administration (FDA) ensures the safety, effectiveness and availability of vaccines for the United States. The FDA sets rules for three phases of clinical trials. Vaccines are tested with adults first.



## PHASE 1 – SAFETY

*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 dose related to any side effects?



## PHASE 2 – EFFECTIVENESS

*Several hundred volunteers*

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



## PHASE 3 – SAFETY AND EFFECTIVENESS

*Hundreds or thousands of volunteers*

- How do people who receive the vaccine compare with people who get a placebo?
- Is the vaccine safe?
- Is it effective?
- What are the most common side effects?



## CONTINUED MONITORING

The FDA and the Centers for Disease Control and Prevention closely monitor vaccine safety after the public begins receiving the vaccine.

## FDA licenses the vaccine only if:

- It's safe and effective
- Benefits outweigh risks



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HEALTHCARE

Sources: U.S. Federal Drug Administration, the Centers for Disease Control and Prevention