

Vaccine Research

Vaccine research is a rigorous process that can take decades!

- First, scientists **learn more** about an **infectious disease** and begin **testing ideas** for **new vaccines** in a **laboratory**.
- Next, the **trial vaccine** is tested on small animals, like mice. This lets scientists see how **safe** and **effective** the trial vaccine is.
- Then, if a trial vaccine is **safe** and **effective in animals**, it will be tested **very carefully** in people through at least **3 Clinical Trial Phases**.
- Before a trial vaccine can be tested in people through clinical trial phases, the **U.S. Food & Drug Administration (FDA)** must **approve** the research.
 - The research approval depends on the **results** of both the **laboratory research** and **testing in animals** to check **how** the trial vaccine **works** and how **safe** it is.



Clinical Trial Phases

Before the FDA can approve a vaccine, there are at least 3 Clinical Trial Phases:

Phase 1: 20-100 healthy participants get the trial vaccine. Researchers look for

- the **best** vaccine **dose**
- the vaccine **safety**
- the **immune system response**

Phase 2: Hundreds of participants of **varying health statuses** and from **diverse populations** get the trial vaccine. Researchers learn more about

- the **side effects**
- the **effectiveness** in **producing** an **immune response**

Phase 3: Thousands of participants get the trial vaccine to

- **confirm** the Phase 1 and Phase 2 **results**
- compare the **safety** and **effectiveness** of the **trial vaccine** to a **placebo** or **already licensed vaccine**

Phase 4 (After FDA Approval):

Thousands of participants get the **now FDA approved** vaccine for

- **continuous monitoring** of the vaccine's **long-term safety** & **effectiveness** in **diverse populations**



What is a Vaccine Clinical Trial?

Vaccine Clinical Trials are research studies on the **safety** and **protective effects** of a new vaccine.

These trials are one of the **most important** steps before a vaccine can be approved for general use!



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Important Clinical Trial Vocabulary

- **Institutional Review Board (IRB):** Protects the rights of participants.
 - The IRB regularly reviews and monitors human research to ensure it is safe and ethical.
- **Informed Consent Form (ICF):** A written explanation of the trial to help a potential participant decide if they will choose to participate.
 - The ICF includes information on study procedures, the study schedule, and any benefits/risks of participating in the study.
- **Inclusion Criteria:** requirements a person must meet or have to participate in the study.
- **Exclusion Criteria:** requirements a person cannot meet or have to participate in the study.
- **Randomization:** The process of randomly assigning participants to different study groups. It's like a coin flip.
- **Sponsor:** The organization who starts, funds, and monitors the study.
- **Placebo:** An inactive product or comparator (already approved) vaccine that looks the same as and is given the same way as the trial vaccine.
- **Masking/Blinding:** A method by which study teams and/or participants do not know which study vaccine was given. This is done to reduce bias in the trial.
 - Can be a trial vaccine, placebo, or comparator vaccine.
 - **Open Label Study:** Both the study team & participants know exactly what vaccine is being given.
 - **Single-blind:** Only the study team knows what vaccine is being given.
 - The participant is considered to be blinded, since they do not know which vaccine was given.
 - **Double-blind:** Neither the on-site study team nor the participant know.
 - An off-site unblinded study team knows and keeps track of which vaccine was given to the participant.



What do I have to do in a Vaccine Clinical Trial?

- First, a study team member will carefully explain the study information, timeline, and requirements in detail.
- Next, you will review an informed consent form (ICF). If you agree to participate, you will sign the ICF. **Participating in a study is voluntary!**
- During the trial, you may be asked to
 - Go to regular study visits in the clinic.
 - Provide blood or other samples.
 - Complete a short diary after vaccination to keep track of any potential symptoms.
- Generally, you will be paid for your time spent participating in the trial!

Fun Facts

- According to National Geographic & the U.S. Library of Congress, vaccines are one of the top 10 most important inventions in the world!
- According to the World Health Organization (WHO), vaccines prevent 3.5 to 5 million deaths a year!