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!
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!