

# CLINICAL TRIALS

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- *A clinical trial is a research study conducted in human beings with the goal of answering specific questions about new medicines, vaccines or diagnostic medical procedures. Clinical trials are used to determine whether new drugs, Vaccines, diagnostics are both safe and effective.*
- *Carefully conducted clinical trials are the fastest and safest way to find treatments that help people.*

*Carefully conducted clinical trials are performed in human volunteers to provide answers to questions such as:*

- *Does a treatment work?*
  - *Does it work better than other treatments?*
  - *Does it have side effects?*
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- *Before an experimental treatment can be tested in a clinical trial, it must have shown benefit in laboratory testing, animal research studies, or research in a small group of humans. Clinical trials are required to follow the same ethical and legal guidelines as standard medical practice to protect the safety of participants.*

## Clinical Trials Phases

*Clinical trials testing are divided into different stages, called phases. Each phase of the clinical trial has a different purpose.*

- **Phase 1:** *experimental treatment is given to a small group of people (20-80) for the first time to evaluate its safety, dosage range, and side effects.*
- **Phase 2:** *experimental treatment is given to a larger group of people (100-300) to evaluate its safety and effectiveness*
- **Phase 3:** *experimental treatment is given to large groups of people (1,000 –3,000) to confirm its effectiveness, monitor side effects, compare to current treatments.*

*If the experimental treatment works well in a Phase 3 trial, researchers can submit an application to the Food and Drug Administration (FDA) asking permission to make the treatment available to the public. The FDA approval process generally takes about a year. In some cases, research continues even after the FDA has approved a treatment. The FDA can ask researchers to conduct a Phase 4 trial.*

- **Phase 4:** *collect information on experimental treatment's long term safety and effectiveness*