



## ClinicalTrials.gov - Clinical Trial Phases

### Question: What are clinical trial phases?

#### Answer:

- Clinical trials of experimental drugs proceed through four phases:
  - In **Phase I** clinical trials, researchers test a new drug or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.
  - In **Phase II** clinical trials, the study drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.
  - In **Phase III** studies, the study drug or treatment is given usually to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.
  - **Phase IV** studies are done after the drug or treatment has been marketed. These studies continue testing the study drug or treatment to collect information about its effect in various populations and any side effects associated with long-term use.

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