Phases of Clinical Trials

Participants

Challenges of Recruiting Participants
Many drugs and treatments tested are meant to treat a certain disease, so only those with that disease can participate. Some studies require people with a combination of uncommon disease characteristics. Finally, many qualified people may decline to participate, especially if there is no benefit to themselves.

Who are participants?
Researchers recruit consenting volunteers to serve as test subjects in clinical trials.

Rewards of Participation
Participants are often paid and have access to medical treatment that is not available to anyone else.

Phase I

Test Group Size
Around 20 – 80 test subjects.

Test Objectives
To analyze the safety of the tested product/procedure and determine its side effects.

Phase II

Test Group Size
Around 100 – 300 test subjects.

Test Objectives
To determine the effectiveness of the product/procedure and further evaluate its safety.

Phase III

Test Group Size
Around 300 – 3,000 or more.

Test Objectives
To confirm the effectiveness of the new drug or treatment, monitor its side effects, and compare it to standard or equivalent treatments.

Regulatory Submissions
After a drug or treatment passes Phase III of clinical trials, researchers submit detailed documentation to the FDA describing the methods and results of human and animal studies, manufacturing procedures, formulation details, and shelf life. This is called a regulatory submission, and if the FDA reviews it and approves the drug or treatment, the sponsor is given permission to begin marketing it.

Phase IV

Size and Duration
Phase IV evaluates a large group over a long time.

Information Sought
Phase IV is meant to discover the risks, benefits, and optimal use of the drug or treatment, as well as whether any unexpected side effects will occur in a small percentage of individuals.