Learning about Clinical Trials

What Is a Clinical Trial?

A clinical trial is a type of study that wants to see if a new drug or treatment therapy is safe and effective. The goal of a clinical trial is to find new and better ways to prevent, detect, or treat diseases.¹

Before giving a new drug or treatment to patients, researchers need to make sure that this drug is safe and effective to use.³ Researchers use clinical trials to learn different things:

- To see if a given drug is helpful in treating a specific disease.
- To see if a new therapy is better than an existing one.
- To compare two different drugs or treatments to see if one is better in treating a disease than the other.
- To see how a new therapy works in different amounts.







Clinical trials may look at new drugs, medical practices, devices, like a blood pressure monitor or pacemaker, or changes to participant's behavior, such as sleep or diet.³ Not all clinical trials test new drugs or treatments. Some clinical trials want to know about diseases and their effects on health.

A clinical trial has four phases, or stages. Each phase has a different goal and a different number of people in it. Each phase builds onto the one before it to make sure the treatment is safe and effective before it is given to the public. The four phases are:

- **Phase I:** Phase I trials are the first test of the treatment. In this phase, researchers work with small groups of people (anywhere from 20-80 people).^{3,4}
- **Phase II:** In Phase II trials, researchers test to make sure the treatment is safe and effective in a larger group of people (anywhere from 100-300 people).^{3,4}
- **Phase III:** In Phase III trials, researchers test the treatment in an even larger group of people (up to 3000 people).³
- **Phase IV:** Phase IV trials are done after the new treatment is approved for the public. Researchers continue to monitor how well the drug or treatment works over a long period of time and to see if there are any side effects related to the drug or treatment.⁴

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Why Be a Part of a Clinical Trial?

People decide to be in clinical trials to help move cures for diseases forward. People who already have diseases or conditions may hope that being in a clinical trial will help find an effective new treatment for their disease.^{2,4} Healthy people who join clinical trials may just want to be part of the effort to help others and give to research.^{2,4} Researchers take the information from each trial to create new and better treatments for illnesses.⁴

Where Do Clinical Trials Happen?

Clinical trials are done in different places depending on who leads the study. A clinical trial might take place in a hospital, university, doctor's office, or community clinic.⁵

How Long Do Clinical Trials Last?

The length of a trial depends on what is being studied. Those who are a part of the study are told how long the trial will last before they are part of it.⁵

What Are the Different Types of Clinical Trials?

There are six main types of clinical trials. Each of these have a different aim or goal³:

- Prevention trials look to prevent diseases with new medicines, vaccines, or behavior changes.
- Screening trials test new ways to find diseases.
- Diagnostic trials study ways to predict or diagnose diseases.
- Treatment trials test new medical treatments, drugs, or surgical procedures for diseases.
- Behavioral trials look for ways to encourage changes in how people act.
- Quality of life trials look for ways to improve the quality of life for people who have long-term illnesses or medical conditions.

Resources on Clinical Trials

- National Library of Medicine's Clinical Trials Search: <u>www.clinicaltrials.gov</u>
- U.S Food and Drug Administration: <u>www.fda.gov</u>
- National Cancer Institute at the National Institutes of Health: <u>https://www.cancer.gov/about-cancer/treatment/clinical-trials</u>
- American Cancer Society's Clinical Trial Matching Service: <u>www.cancer.org/clinicaltrials</u>
- BreastCancerTrials.Org: <u>www.breastcancertrials.org</u>
- Centerwatch: <u>www.centerwatch.org</u>
- Cancer Support Community: <u>www.cancersupportcommunity.org/clinicaltrials</u>
- Trialcheck: <u>www.cancertrialshelp.org/cancer-trial-search</u>

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