

Understanding Clinical Trial Phases

Every new cancer treatment must go through a series of clinical trial phases before it can become widely available to patients. Each phase is designed to answer different research questions about a treatment's safety, effectiveness, and long-term outcomes.

Depending on your diagnosis, treatment history, and eligibility, you may qualify to participate in a Phase I, Phase II, Phase III, or Phase IV clinical trial. Your physician and our research team will help determine whether a clinical trial may be appropriate for your individual care.

Phase I Trials

Advancing New Treatments Safely

Interested in early-phase research?

The primary goal of a Phase I clinical trial is to determine the safest dose of a new treatment that patients can receive while minimizing harmful side effects. Researchers also evaluate the best way to administer the treatment, such as by mouth or intravenously (through a vein).

Although researchers carefully observe whether the treatment shows activity against cancer, the primary purpose of a Phase I study is to establish safety – not to determine how well the treatment fights cancer.

Who May Participate?

Phase I trials typically enroll **15 to 30 participants**. These studies often include patients whose cancer has not responded to standard treatments or who have exhausted other available treatment options.

How Phase I Studies Work

Patients are usually enrolled in small groups called **cohorts**, often consisting of three participants.

The first cohort receives a low dose of the investigational treatment. If researchers determine that the dose is safe, the next cohort receives a slightly higher dose. This process continues until researchers identify either unacceptable side effects or the optimal dose for future studies.

If a treatment demonstrates an acceptable safety profile during Phase I, it may advance to a Phase II clinical trial.

Phase II Trials

Evaluating How Well a Treatment Works

The primary goal of a Phase II clinical trial is to determine how effectively a new treatment works against a specific type of cancer while continuing to monitor patient safety.

Phase II studies typically enroll **fewer than 100 patients**. Participants may have previously received chemotherapy, immunotherapy, surgery, radiation therapy, or other cancer treatments and still require additional treatment options.

Because more patients participate than in Phase I studies, researchers continue monitoring for side effects, including those that may not have appeared during earlier testing.

If the treatment demonstrates promising results and an acceptable safety profile, it may move forward into a Phase III clinical trial.

Phase III Trials

Comparing New Treatments to Today's Standard of Care

Phase III clinical trials compare a new treatment with the current standard treatment to determine whether the investigational therapy is better than, equivalent to, or less effective than existing care.

These studies often include **hundreds or even thousands of patients** across multiple hospitals, cancer centers, and countries.

Clinical Trial Groups

In many Phase III studies, participants are randomly assigned to one of two or more treatment groups (called **study arms**).

In a study with two treatment arms:

- **Control Group:** Receives the current standard treatment.
- **Investigational Group:** Receives the new treatment being studied.

Regardless of the group assignment, every participant receives appropriate medical care. Patients either receive today's best standard treatment or a treatment researchers believe may be as effective – or potentially more effective – than the current standard.

Understanding Randomization

Randomization is the process of assigning participants to treatment groups by chance.

Randomization helps eliminate bias and ensures researchers can accurately compare treatment outcomes. Neither the patient nor the physician chooses which treatment group a participant joins.

Single-Blind vs. Double-Blind Studies

Single-Blind Study

Patients do not know whether they are receiving the investigational treatment or the standard treatment.

Double-Blind Study

Neither patients nor researchers know which treatment each participant receives during the study.

However, treatment assignments are securely recorded and can be revealed immediately if medically necessary.

FDA Approval

Before a new drug or treatment becomes widely available, researchers submit years of clinical trial data to the U.S. Food and Drug Administration (FDA).

The FDA carefully reviews the evidence to determine whether a treatment is safe and effective for patient use. If approved, the treatment becomes available to patients and, in many cases, may become the new standard of care.

Phase IV Trials

Monitoring Long-Term Safety and Effectiveness

Phase IV clinical trials take place after a treatment has received FDA approval.

These studies help researchers better understand how safe and effective an approved treatment remains over time by monitoring larger patient populations during routine clinical use.

Researchers continue evaluating long-term outcomes, rare side effects, and how treatments perform in different patient populations. If significant safety concerns are identified, additional warnings may be issued or the treatment may be removed from the market.

Questions About Clinical Trials?

Every patient's situation is unique.

If you're interested in learning whether a clinical trial may be right for you, our research team is here to answer your questions and help you understand your options.

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