

FEATURE STORY

Before Treatment: Understanding Clinical Trials

What you need to know to decide if a clinical trial is right for you

Clinical trials provide data that may prove a new, experimental treatment is better than the standard therapy. They offer a source of hope if you have few options or if you're seeking treatments with the potential to be more beneficial than the standard treatment, one with fewer toxicities or one that is more convenient, such as oral medication or shorter treatment times. You may also be motivated to join a clinical trial to further cancer research and help future cancer patients.

Although an increasing number of investigational cancer drugs are being approved by the Food and Drug Administration each year, the process of drug testing and approval is still lengthy and complex. Most clinical research of a new drug progresses in an orderly series of steps, called phases.

Phase I trials enroll a small number of patients and evaluate how a new treatment should be given (for example, if a new drug is best taken orally or injected into the bloodstream or muscle), how often it should be administered, and the most effective dose with the fewest and least severe side effects. Most patients who enter phase I trials have limited therapeutic options or do not improve with standard therapies. The primary goals of phase I trials are studying side effects and establishing a safe dosage.

Phase II trials continue to test the safety of a treatment, and also begin to evaluate how well it works. These trials are usually limited to a specific cancer that showed benefit with the treatment in earlier trials.

Phase III studies either test an experimental drug, combination of drugs, regimen of radiation therapy, or surgical procedure in comparison with the current standard. Enrollment is often in the thousands across multiple locations, and the treatment is more likely to be effective. Typically, a participant is randomly assigned to the standard treatment or the new treatment (called randomization). Those patients who are not randomized to the experimental treatment will receive the best standard treatment available.

View Illustration: From the Laboratory to the Clinic

Before enrolling in a clinical trial, you must sign an informed consent document that states you understand the purpose of the research, risks, benefits, other treatment options, and your rights as a patient. The informed consent process also provides an ongoing, open line of communication between you and the researchers to ask questions. Keep a copy of the informed consent document with your medical records. No informed consent document can ask you to waive your legal rights or release the trial's research team, trial sponsor, drug manufacturer, or institution from liability for negligence.

You are allowed time to discuss the informed consent documents with family, friends, or your physicians, and to ask follow-up questions of the research team. As the trial progresses, the research team will continue to provide information and updates. It is important for you to understand that because the treatment is experimental, the outcomes and side effects are not always foreseeable, although any predicted risks should be explained to you in detail beforehand.

Discuss the costs associated with the trial with the research team and ask what would be covered by insurance. In most trials, the therapy under investigation is provided at no cost to the trial participant. Routine costs, such as hospital stays, outpatient appointments, and tests accrued during a trial, are often covered by insurance or Medicare if the trial meets certain criteria.

Contact your insurance provider and discuss your policy coverage. Although insurers will not usually cover "experimental" treatments, recently passed legislation in several states requires insurance companies to cover routine medical care during a clinical trial. If an insurance company refuses coverage, appeal before the study begins.

You should also consider the cost of travel and lodging, especially if the trial extends over several weeks or months and frequent trips are needed. Some institutions and nonprofit organizations can help with certain expenses for travel and housing (see [Toolbox](#)).