

What You Need to Know to Make Informed Decisions About Cancer Clinical Trials

What are clinical trials?

Clinical trials are human research studies that test new therapies to prevent or cure diseases such as cancer. The purpose of a clinical trial is to prove that a new therapy is better than the existing ***standard of care***. The standard of care is the treatment that is considered to be the most effective therapy that is currently available. A new therapy cannot be tested in a clinical trial until it has shown promising results in many prior laboratory tests on samples taken from the human body, such as cells, tissue, blood or urine. These samples are called ***biospecimens***.

Why are clinical trials important?

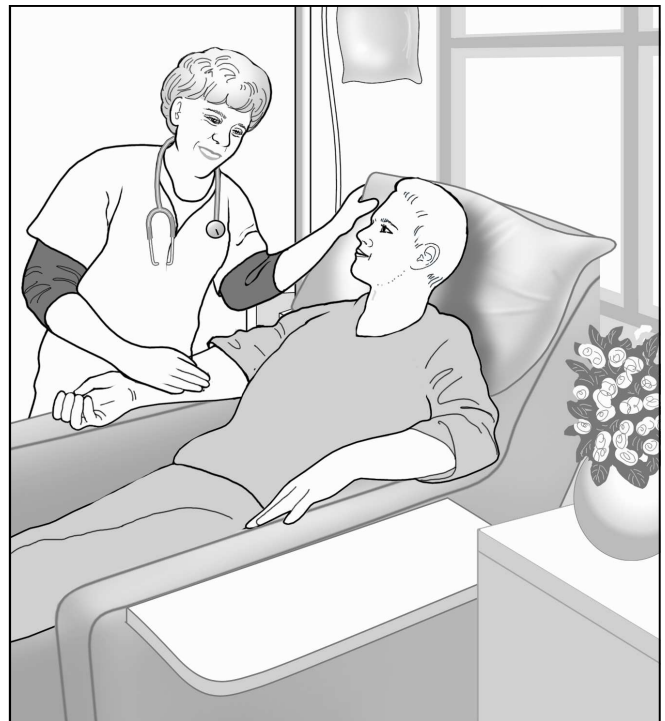
Clinical trials make progress in preventing and curing diseases possible. Every medical advance is the result of a series of studies that end with a clinical trial. Doctors conduct clinical trials to determine whether the therapy they are testing is safer and more effective than the current standard of care. The Food and Drug Administration approves a new therapy only after its safety and effectiveness have been demonstrated in a clinical trial.

Why do people participate in clinical trials?

People take part in clinical trials for many reasons. If they know that the standard of care is not necessarily a cure, they may want to see if a new therapy will better control their disease. Others say that even if they don't see a short-term benefit, they like being able to contribute to long-term progress.

How safe are clinical trials?

Clinical trials cannot be launched until many prior tests have shown promising results with regard to safety and effectiveness of a new therapy. Protective laws and institutional regulatory and scientific review boards exist for the sole purpose of ensuring people's safety and privacy in clinical trials. Clinical trial team members are involved because they are committed to patients and to curing and preventing cancer. In clinical trials, a patient's well-being is the top priority.



What are clinical trial “phases”?

The process of testing a new therapy starts with laboratory tests on tumor cells and biospecimens obtained during surgery and banked for cancer research. If a new therapy shows promising results, it moves into clinical trials, where it passes through carefully monitored progressive phases.

Phase I is the first step in testing a new therapy in people. Phase I studies have a very small number of participants. The purpose of a Phase I trial is to find:

- the correct amount or dose of the prescribed therapy
- how often to give each dose,
- the lowest dose that will be effective in fighting cancer cells, and what side effects may occur.

Phase II trials continue to test the safety and effectiveness of an investigational therapy, but in a larger population.

- Phase II trials can be randomized, which means patients are randomly selected to receive either the standard of care or the investigational therapy.
- Randomized trials are sometimes “blinded,” which means that neither the doctor nor the patient know who is getting the standard of care versus the investigational therapy.

Phase III trials enroll very large numbers of patients. The purpose of phase III trials is to:

- Compare the investigational therapy to the standard of care,
- Confirm how well the treatment works in a large number of people who have the disease.
- Look for possible side effects and clarify the risks and benefits to ensure the therapy is being used safely.

In clinical trials, you will never receive anything less than the standard of care for your cancer.

Types of Clinical Trials

- **Prevention trials** look for new ways to reduce the risk of cancer in people who have never had it or to prevent a recurrence in a person who was successfully treated.
- **Treatment trials** test new therapies that may include one or more drugs, surgical or radiation approaches, or innovative medical devices.
- **Screening trials** seek ways to detect cancer earlier for better treatment outcomes.
- **Diagnostic trials** look for better tools, tests, or procedures to diagnose cancer.
- **Quality-of-life trials** focus on how you feel during treatment as well as how complementary therapies such as meditation, yoga, and nutrition affect health and well-being. Quality-of-life studies are important in helping to ensure that new treatments not only arrest cancer, but also enhance comfort and well-being.

Weighing Risks vs. Benefits

Risks:

- Risks vary with each new therapy. Before anyone can be enrolled in a clinical trial, the study team discusses risks. Risks are explained on the study consent form, which is given to each patient who may be eligible for a clinical trial.
- Clinical trials usually require a greater time commitment than when receiving standard treatment.

Benefits:

- One benefit is having early access to new drugs, which can be costly and will usually be paid for by sponsors of the clinical trial.
- Participants receive close observation, which means you will know relatively quickly if the treatment is working or not.
- Participants are free to change their mind and drop out at any time after enrolling. They do not need to worry that a change of heart will affect the quality of their ongoing care.
- While participation may not bring a short-term benefit, many participants like knowing that they are contributing to longer-term advances in the standard of care.

How is my safety protected?

National laws, ***Institutional Review Boards*** (IRBs), scientific committees, and clinical research teams govern and monitor clinical trials for the sole purpose of ensuring safety. Clinical research teams must meet strict ethical guidelines to protect participants' safety and privacy.

What is expected of me on a trial?

Clinical trial participants are closely monitored and expected to adhere to the study schedule. Participants may also be asked to keep a drug diary, side effect log, and home medication log.

How do I get started?

- Tell your nurse or doctor that you are interested in knowing if there is a clinical trial for you.
- Your doctor will provide information regarding a clinical trial for which you may be eligible. He or she will explain treatment options as well as details of the clinical trial.
- After you have had time to think about joining a clinical trial and you have no further questions, you should feel ready to make an informed decision.
- After you make an informed decision about participating in a trial, you will be ready to sign the informed consent.
- The research coordinator will then order whatever tests are needed to determine your eligibility for the trial. All trials have different eligibility criteria.
- The doctor and research coordinator will review your test results and medical records.
- The trial sponsor will view the determination and confirm that you are eligible to participate. With the sponsor's acknowledgement, you will be ready to start the trial. If you do not meet the eligibility criteria, you will not be allowed to participate and will have the opportunity to discuss other treatment options with your doctor.

Will my insurance pay for a clinical trial?

The informed consent for the clinical trial will list specific items that the study sponsor pays for. It will also list the tests or procedures that may be necessary for receiving treatment in the clinical trial. These extra care costs are not always covered by health insurance. You may want to call your insurance company and verify coverage before deciding to enter a clinical trial. Only the research-related costs specifically mentioned in the consent form will be covered by the study sponsor. If the item is not listed in the consent form as a cost that the sponsor will pay, then you or your insurance company will be responsible for payment. If extra tests or procedures are required that exceed the usual standard of care, the study sponsor usually covers these costs.

What if I want to stop participating in the trial, or choose not to go on the trial?

You are encouraged to make an informed decision, and are free to change your mind at any time. Your decision will NOT have a negative impact on the quality of the care you receive at Moffitt Cancer Center. You should never feel pressured to enroll or remain in a trial if you have doubts or concerns. **Participation in a clinical trial is voluntary.**

Are there resources that can help me make an informed decision?

Yes. In addition to talking to your doctor, nurse, and clinical trial coordinator, you can find print and internet resources in the Patient Library & Welcome Center on the 2nd floor of the Muriel Rothman Clinic Building. Please ask one of the patient education representatives for help in finding and using resources to help you make an informed decision about participation in clinical trials.

Glossary

Biospecimens: Samples of human material, such as urine, blood, tissue, cells, and DNA that are stored and used for laboratory research.

Standard of care: A treatment currently in wide use and approved by the Food and Drug Administration, considered to be effective in the treatment of a specific disease or condition.

Institutional Review Boards (IRB): An IRB is a committee that takes responsibility for approving and reviewing research that involves people. The IRB is committed to protecting the rights and welfare of study participants. IRBs provide critical oversight of all clinical research to ensure scientific, ethical, and regulatory integrity.

Informed consent: The process of learning the key facts about a clinical trial before deciding whether or not to participate. Informed consent is an ongoing process where doctors and nurses involved in the trial provide information for participants.

Study/trial sponsor: The sponsor of a study is the company who is proposing a new treatment or device. The sponsor produces the drug or device, is the author of the study protocol, and pays for the study.

Glossary Sources

[Glossary of Clinical Trials Terms](#), ClinicalTrials.gov, U.S. National Institutes of Health.
National Cancer Institute: [Cancer.gov Dictionary](#).

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