



# Ask Us About Clinical Trials

## Clinical Trials and You.

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Our specialists and researchers are at the forefront of their fields and are leading the way in developing new therapies and procedures for diagnosing and treating cancer patients. Clinical trials are the best way physicians have to translate exciting scientific developments into treatments that may be valuable to you.



**Sidney Kimmel  
Cancer Center™**

at Thomas Jefferson University

# Clinical Trials at Jefferson

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## Clinical Trials Advance Cancer Care

Years ago, little was known about the different types of each specific cancer (e.g., lung, breast) or about how the unique nature of each cancer type could affect treatment outcomes. Today, what we have learned from clinical trials has changed cancer treatment from a one-size-fits-all approach to a choice of more-tailored therapies which have made both longer survival and improved quality of life after treatment a reality for many men and women. These treatment breakthroughs never would have happened without thousands of men and women choosing to participate in clinical trials.

## What Are Clinical Trials?

A clinical trial is a type of research study that tests how well new medical approaches work in people.

*Depending on the goals of the trial, there are several different types:*

**Prevention Trials** look for improved ways to reduce the risk of cancer in people who have never had it or to prevent cancer from recurring (coming back).

**Screening Trials** test the best way to detect (find) cancer.

**Diagnostic Trials** are conducted to find better tests or procedures for diagnosing a particular cancer.

**Therapeutic Trials** look for new ways to treat cancer by studying:

- the effects of a new medicine, surgery or radiation treatment
- new combinations of existing medicines or therapies
- new treatment sequences (the order in which medicines or other treatments are given)
- new dosing schedules or methods (injection or mouth) by which the dose is given
- entirely new methods to deliver treatment, such as gene therapy or vaccines

**Quality-of-Life Trials** explore ways to improve comfort and the quality of life for people with cancer.

## Phases of Clinical Trials

Most clinical research involving the testing of a new drug progresses in an orderly series of steps called phases. This allows researchers to ask and answer questions in a way that results in reliable information about the risks and benefits seen with any drug.

- **Phase I trials:** These first studies in people evaluate how a new drug should be given (by mouth, injected into the blood, or injected into the muscle), how often, and what dose is safe. A phase I trial usually enrolls only a small number of patients.
- **Phase II trials:** A phase II trial continues to test the safety of the drug, and begins to evaluate how well the new drug works. Phase II studies usually focus on a particular type of cancer.
- **Phase III trials:** These studies test a new drug, a new combination of drugs, or a new surgical procedure in comparison to the current standard. A participant will usually be assigned to the standard group or the new group by chance (called randomization). Phase III trials often enroll large numbers of people and may be conducted at many doctors' offices, clinics and cancer centers nationwide.
- **Phase IV trials:** The purpose of phase IV trials is to evaluate the side effects, risks and benefits of a drug over a longer period of time and in a larger number of people than in a phase III clinical trial.



## Potential Benefits of Clinical Trials

- You may have access to new medicines, combinations of medicines or treatment methods that are not otherwise available to you.
- Your cancer treatment is closely monitored by both your clinical and research team members.
- If a new treatment works, you may benefit from it before it is generally available to others.
- Some trials give you access to medicines, complementary treatments or supportive therapies.

# “Ask Us” If One May Be Right For You

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## Am I Eligible for a Clinical Trial?

In planning a clinical trial, researchers decide on the “eligibility criteria” – the patient characteristics most appropriate for the study. These characteristics generally include how young or old a person must be to join, what type and stage of cancer that person has, what previous treatments they have undergone and other medical problems the person may have.

## What Rights and Protections Do I Have in a Clinical Trial?

Clinical trials are reviewed at a national level and again locally. Each hospital or cancer center has an Institutional Review Board (IRB). It is the job of the IRB to review clinical trials and make sure they are run in a safe and fair manner. Our IRB has many different members, including doctors, nurses, patient advocates, patients and people from the community.

Before you join a clinical trial, a healthcare provider or other qualified person will explain who the trial is for and what will happen. You can ask any questions you have about the trial. You will also be given a consent form to sign.

## The consent form gives you:

- Detailed information about the clinical trial.
- What to expect during the trial.
- The expected end date of the trial.
- The possible side effects from the treatment and more.

*Not taking part in a clinical trial is your choice. Clinical trials are voluntary. As part of this process, you will discuss with your doctor, other healthcare team members and your family all of the treatment options available to you. This will help you decide if participating in a clinical trial is right for you.*



# Key Terms to Know

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## **Clinical Trial**

A type of research study that tests how well new medical approaches work in people.

## **Informed Consent**

A process in which patients are given important information, including possible risks and benefits, about a medical procedure or treatment to help them decide if they want to be treated, tested or take part in the trial.

## **Institutional Review Board (IRB)**

Group of medical providers and community members that evaluates and approves studies for safety before they begin and while they are going on.

## **Protocol**

The plan that describes what will happen in the trial and how it will be conducted.

## **Phase**

Clinical trials that test new drugs, methods or other treatments proceed through phases or steps: Phase I, Phase II, Phase III and Phase IV trials.

## **Randomized Study**

Clinical trial in which patients are assigned by chance to different arms, or branches, of the study.

## **Principle Investigator**

Researcher in charge of a clinical trial

## **Research Coordinator**

Link between participant, doctor and the clinical trial, providing information and answering questions. Collects and reports data throughout the trial.

# Ask Us About Clinical Trials

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**The following are just a few questions to ask us.**

- What clinical trials are available to me?
- What is the purpose of the clinical trial?
- What treatment under study in the trial will be added to the standard treatment I receive?
- What tests and treatments are done as part of the clinical trial?
- What are the potential benefits to me (and possible side effects or risks) of each trial?
- Where will I go for treatment, how often, and for how long?
- Are the study costs covered by my insurance or by the trial sponsors?
- How long will the clinical trial last?
- How long do I have to decide before joining the clinical trial?
- Will I find out about the results of the trial?

To find out if there is a clinical trial available that might be right for you, ask your healthcare providers, visit our website, or contact the Sidney Kimmel Cancer Center Clinical Research Management Office at **215-955-1661**.

[Jefferson.edu/ClinicalTrials](https://www.jefferson.edu/ClinicalTrials)

The **Sidney Kimmel Cancer Center at Thomas Jefferson University** is a National Cancer Institute (NCI)-designated cancer center. We have earned this recognition for excellence through innovative basic science and clinical research programs that have been developed to provide patients access to leading-edge clinical care. Clinical trials are an important option in the cancer care we provide.



A Cancer Center Designated by the  
National Cancer Institute