

A PATIENT'S GUIDE

To Cancer Clinical Trials



ST PETER'S HEALTH
PARTNERS

Cancer Care



When you or someone you love has been diagnosed with cancer, it is sure to be a difficult and overwhelming time in your life. As a newly diagnosed cancer patient, you will have many questions especially about what treatment options are available. One option you may wish to explore for treating your type of cancer is participation in a clinical trial.

Scientific and medical professionals are constantly examining new and more effective ways to treat disease. Clinical trials are often the culmination of several scientific studies targeting better ways to treat diseases like cancer.

Ultimately, clinical trials can offer the most cutting-edge form of treatment available for many types of cancers.

This booklet is designed to provide general information about clinical trials for cancer patients. There are also additional resources available to you in case you would like to find out more about these special studies and what might be available to you. We encourage you to use the information from this booklet as you consult with your physician to determine if a clinical trial is right for you.

What Are Clinical Trials?

Clinical trials are carefully designed and controlled studies in which patients volunteer to participate in the testing of new drugs, new combinations of drugs or procedures to prevent, detect, diagnose or treat disease. These research studies are necessary in the development of promising new treatments for serious diseases like cancer. Patients are asked to enroll in clinical trials based on their diagnosis, disease status and co-morbidities. Often clinical trials are the best option for many patients.

There are five different types of clinical trials:.

Type of Trial	Purpose
Treatment Trials	Test experimental treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.
Prevention Trials	Research better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These approaches may include medicines, vaccines, vitamins, minerals, or lifestyle changes.
Diagnostic Trials	Find better tests or procedures for diagnosing a particular disease or condition.
Screening Trials	Test the best way to detect certain diseases or health conditions.
Quality of Life Trials (Supportive Care Trials)	Explore ways to improve comfort and quality of life for individuals with a chronic illness.

Cancer-related clinical trials are designed to answer questions about new ways to:

- Treat cancer.
- Find and diagnose cancer.
- Prevent cancer.
- Manage symptoms of cancer or side effects from its treatment.

How Are Clinical Trials Conducted?

Clinical trials are conducted in a series of steps called phases. A treatment will become standard after completing four clinical trial phases. The earliest phases make sure that the treatment is safe. Later phases demonstrate whether the trial treatment is more effective than the standard treatment.

Phases of Cancer Clinical Trials

The trials at each phase have a different purpose and are designed to help researchers answer different questions.

- **Phase 1:** To find a safe dose, to decide how the new treatment should be given and to see how the new treatment affects the human body.
- **Phase 2:** To determine if the new treatment has an effect on a certain cancer and to see how the new treatment affects the human body.
- **Phase 3:** To compare the new treatment (or new use of treatment) with the current standard treatment.
- **Phase 4:** To further assess the long-term safety and effectiveness of a new treatment.

Guidelines for Clinical Trials

The guidelines that clinical trials follow clearly state which patients will be eligible to participate in the study and the treatment plan based on each individual's health status. Every trial has a person in charge, usually a doctor, who is called the principal investigator. The principal investigator prepares a plan for the study, called a protocol, which is like a roadmap for conducting a clinical trial.

The protocol explains what the trial will do, how the study will be carried out and why each part of the study is necessary. It includes information about:

- The reason for conducting the study
- Who can participate in the study
- How many people are needed for the study
- Any medications the patients will take, the dose and how often
- Any medical tests the patients will have and how often
- What information will be gathered on each patient

Randomization

Randomization is a process used in some clinical trials to prevent bias. Bias is defined as “preference or inclination, especially one that inhibits impartial judgment.” Randomization helps to ensure that unknown factors do not affect trial results. Randomization is used in some phase 2 and all phase 3 trials. These trials are called randomized clinical trials.

If you participate in such a trial, you will be assigned at random to either an investigational group or a control group. Your assignment will be determined by a computer program or table of random numbers. The control group receives the most widely accepted treatment (standard treatment) for your cancer. The investigational group receives the new treatment being tested.



Who Can Participate in a Clinical Trial?

Consideration to participate in a clinical trial should first be discussed with your physician to determine whether you meet the specific criteria set forth by the trial protocol. Criteria are used to identify appropriate participants with the highest safety standards and practices in mind.

Based on the questions the research is trying to answer, each clinical trial protocol clearly states criteria to identify whether or not a patient can participate in the trial. Common criteria for entering a trial:

- Having a certain type or stage of cancer
- Having received a certain kind of therapy in the past
- Being in a certain age group

This type of criteria helps to ensure that people in the trial are as similar to one another as possible. This way doctors can be sure that the results are due to the treatment being studied and not other factors. These criteria also help to ensure the safety of the participants involved along with accurate and meaningful study results.

What Protections Are in Place for Patients?

Federal rules help ensure that clinical trials operate in an ethical manner. Your rights and safety are protected through:

- Informed consent, a process through which you learn the purpose, risks and benefits of a clinical trial before deciding whether or not to participate.
- Careful review and approval of the clinical trial protocol by two review panels, a scientific review panel and an institutional review board (IRB).
- Ongoing monitoring provided during the trial by the IRB,

Will My Insurance Cover the Costs?

Before you decide to participate in a clinical trial, you may want to speak with your health care provider and insurance company about the costs of any treatments or tests including medications, radiation and/or surgery that may be necessary.



How Do I Decide to Take Part in a Clinical Trial?

When you need treatment for cancer, clinical trials may be an option for you. Choosing to participate in a clinical trial is something only you, your loved ones and your doctors and nurses can decide together. You may want to discuss the following pros and cons with your health care providers and loved ones.

Possible Benefits of Clinical Trials

- Clinical trials offer high-quality cancer care. If you are in a randomized study and do not receive the new treatment being tested, you will receive the best known standard treatment. This may be as good as, or better than, the new approach.
- If a new treatment is proven to work and you are receiving it, you may be among the first to benefit.
- By looking at all of your treatment choices including clinical trials, you are taking an active role in a decision that affects your life.
- You have the chance to help others and improve cancer treatment.

Possible Drawbacks and Risks of Clinical Trials

- New treatments under study are not always better than, or even as good as, standard care.
- If you receive standard care instead of the new treatment being tested, it may not be as effective as the new approach.
- New treatments may have side effects that doctors do not expect or are worse than those of standard treatment.
- Even if a new treatment has benefits, it may not work for you. Even standard treatments, proven effective for many people, do not help everyone.
- Health insurance and managed care providers may not cover all patient care costs in a study. What they cover varies by plan and by study. To find out in advance what costs are likely to be covered, check with your insurance company and the billing staff at the hospital or doctor's office.

Questions to Ask

If you are thinking about taking part in a clinical trial, here are some questions that can help you decide:

About the trial

- Why is this trial being done?
- Why do the doctors who designed the trial believe that the treatment being studied may be better than the standard treatment?
- How long will I be in the trial?
- What kinds of tests and treatments are involved?
- What are the possible side effects or risks of the new treatment?
- What are the possible benefits?
- How will we know if the treatment is working?

Daily life

- How could the trial affect my daily life?
- How often will I have to come to the hospital or clinic?
- Will I have to travel long distances to take part?



Comparing choices

- What are my other treatment choices including standard treatments?
- How does the treatment I would receive in this trial compare with the other treatment choices?

Resources

If you would like more information about clinical trials, you may call:

- St. Peter's Hospital Cancer Care Center Research Department at (518) 525-6739
- The National Cancer Institute (NCI),
1-800-4-CANCER (1-800-422-6237)
or www.cancer.gov
- Clinical Trials.gov, www.clinicaltrials.gov
- The National Institutes of Health (NIH),
301-496-4000
or www.nih.gov
- The American Cancer Society (ACS),
1-800-227-2345
or www.cancer.org

A Patient-Focused Approach to Care

Our program is dedicated to providing comprehensive cancer care centered on the needs of our patients. Through innovative and up-to-date clinical research, we are positioned to offer our patients the best possible treatment options.

We provide advanced diagnostic testing, medical oncology, radiation therapy and multiple surgical specialties. Our expert team of physicians, surgeons, nurses, therapists, physicists, dosimetrists, administrators and support staff work together to meet the needs of our patients and their families.

Our program collaborates with The National Cancer Institute, pharmaceutical companies, medical institutions and other organizations to sponsor clinical trials. We are your partner in the fight against cancer.



MEDICAL ONCOLOGY AND HEMATOLOGY

St. Peter's Medical Oncology/Hematology

Operated by St. Peter's Hospital
317 S. Manning Blvd., Suite 220
Albany, NY 12208
(518) 525-6418

St. Peter's Medical Oncology/Hematology

Operated by St. Mary's Hospital
1 Tallow Wood Drive., Bldg. A
Clifton Park, NY 12065
(518) 268-5060

St. Peter's Medical Oncology/Hematology

Operated by St. Mary's Hospital
Hildegard Medicus Cancer Center
1300 Massachusetts Ave.
Troy, NY 12180
(518) 268-5060

RADIATION ONCOLOGY

St. Peter's Radiation Oncology

Operated by St. Peter's Hospital
317 S. Manning Blvd., Suite 100
Albany, NY 12208
(518) 525-1404

St. Peter's Radiation Oncology

Hildegard Medicus Cancer Center
2215 Burdett Ave.
Troy, NY 12180
(518) 271-3775

St. Peter's Hospital Cancer Care Center

St. Peter's Hospital
317 S. Manning Boulevard | Albany, New York 12208
(518) 525-1662



Hildegard Medicus Cancer Center

St. Mary's Hospital
1300 Massachusetts Avenue | Troy, New York 12180
(518) 268-5060

Samaritan Hospital
2215 Burdett Avenue | Troy, New York 12180
(518) 271-3775



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