

For more information about clinical trials or to order additional copies, call the National Cancer Institute's Cancer Information Service toll-free at 1-800-4-CANCER (1-800-422-6237).



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U.S. DEPARTMENT
OF HEALTH AND
HUMAN SERVICES
National Institutes
of Health

National Cancer Institute

Clinical Trials at NIH
in Bethesda, Maryland



- What is a clinical trial?
- How do I know if I can participate?
- How can I find a trial that's right for me?
- How can I get more information?





Working Toward a Cure

The National Cancer Institute

Founded by Congress in 1937, the National Cancer Institute leads a national effort to eliminate the suffering and death due to cancer. Through basic and clinical biomedical research and training, NCI conducts and supports research that will lead to a future in which we can prevent cancer before it starts, identify cancers that do develop at the earliest stage, eliminate cancers through innovative treatment interventions, and biologically control those cancers that we cannot eliminate so they become manageable, chronic diseases.

As part of its clinical research program, NCI enrolls thousands of people from around the country in over 150 clinical trials at the NIH Clinical Center. These trials, conducted at the Warren G. Magnuson and Mark O. Hatfield Centers in Bethesda, Maryland, are open to people regardless of where they live.

In addition to clinical trials taking place at the campus of the National Institutes of Health in Bethesda, Maryland, the National Cancer Institute sponsors clinical trials at designated cancer centers throughout the country. These constitute the majority of National Cancer Institute-sponsored clinical trials. This booklet includes only information about clinical trials taking place at the Bethesda campus. For information about National Cancer Institute clinical trials taking place at other locations across the nation, call 1-800-4-CANCER.

Treatments Used in Clinical Trials

This list does not include all available types of treatments. Talk to your doctor about treatment options that may be right for you.

Angiogenesis inhibitors

Drugs that block the development of new blood vessels, a process known as anti-angiogenesis, in an effort to stop the tumor from growing and spreading to other parts of the body

Bone marrow transplantation and peripheral blood stem cell transplantation

Procedures to replace bone marrow and/or stem cells destroyed by high doses of anticancer drugs or radiation treatments

Chemotherapy

Treatment with anticancer drugs, usually given orally, topically, intravenously, or by perfusion

Gene therapy

An experimental treatment that changes a gene to try to improve the body's natural ability to fight disease or to make cancer cells more sensitive to other kinds of therapy

(Cont.)

Clinical Trials

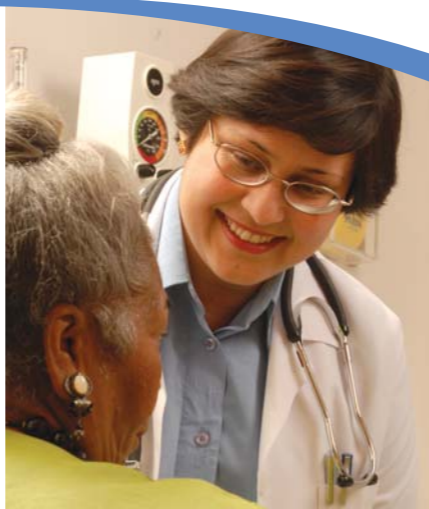
Today and Tomorrow

Clinical trials, also called clinical studies, evaluate investigational methods of treating, diagnosing, and preventing cancer. These investigational methods include approaches to surgery or radiation therapy as well as gene therapy, vaccine therapy, experimental drugs, or various combinations of these treatments.

Clinical trials are among the final stages of a long and careful process of cancer research. Only those treatments that show promising results in tests done in the laboratory are used in clinical trials involving people.

There is no guarantee that the investigational approach will produce good results, but if it is effective, trial participants may be among the first to benefit. You will receive detailed information about the trial and should join a trial only after you understand both the possible risks and benefits. Everyone who joins a clinical trial at the National Cancer Institute is cared for by a team of appropriate experts.

For more information, visit the National Cancer Institute Clinical Trials at NIH Web site at <http://bethesdaclinicaltrials.cancer.gov> or call 1-888-NCI-1937.



Hormone therapy

The removal, blockage, or addition of hormones to halt or limit cancer cell growth

Immunotherapy

Treatment to stimulate or restore the ability of the immune system to fight infection and disease

Radiation therapy

Treatment using X-rays, neutrons, and other sources of high-energy radiation to kill cancer cells and shrink tumors

Surgery

An operation to remove a cancerous growth

Targeted cancer therapies

The use of drugs that block the growth and spread of cancer by interfering with the growth and division of cancer cells

Vaccine

A substance or group of substances, usually given by injection, meant to cause the immune system to recognize and destroy cancer cells or microorganisms

Clinical Trial Phases

Most clinical trials are classified into one of five phases:

In phase 0 trials, investigational treatments that have shown promise in lab studies are given, for the first time, to a small group of patients (10 to 15). Small doses of the new agent are given over a short period to confirm that the treatment works safely in humans in the way predicted by earlier lab studies. If the agent was designed to reach a specific target in cancer cells, tests will be done to check on its success. Any side effects are carefully monitored.

In phase I trials, investigational treatments are tested in a small group of patients to decide what dose is safe, how the new agent should be given (by mouth, injection, etc.), and how often it should be given. Researchers also watch carefully for harmful side effects.

In phase II trials, researchers study the safety and effectiveness of an agent or intervention. These studies usually focus on a particular type of cancer and include fewer than 100 patients.

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Joining a Clinical Trial

Joining a clinical trial is a big decision. After discussing the idea with your family, you may wish to consult with your doctor or other medical professionals for help in narrowing down your options.

If you decide that a clinical trial is an option you want to pursue, it is important to understand that each trial has a screening process based on its own set of eligibility criteria. The purpose of the eligibility criteria is to make sure that usable data is captured for the trial and to protect the patient from unnecessary risks.

For step-by-step instructions on how you can find a clinical trial, including a description of the screening and referral process, please turn to pages 9-10.



Phase III trials compare an investigational treatment with a standard treatment and help researchers gain more information on safety, effectiveness, and side effects. Because more is known about a treatment at this phase of its development, phase III trials may include hundreds or thousands of patients.

Phase IV trials evaluate side effects that were not apparent in the phase III trial and are conducted after a treatment has been approved and is being marketed. Thousands of patients are enrolled in a phase IV trial.

For more information, visit the National Cancer Institute Clinical Trials at NIH Web site at <http://bethesdaclinicaltrials.cancer.gov> or call 1-888-NCI-1937.



NCI Clinical Trials

Clinical Trials Referral Office 1-888-NCI-1937

When you call our toll free number, an NCI information specialist will consider the preliminary information you provide, identify the trials that may be appropriate for your type of cancer, and explain how to take the next step if you are interested in participating. They will talk to you in language you can understand. You can expect personalized answers, and the information that you provide will be kept completely confidential.

Our information specialists receive calls from hundreds of people each month—many who have just been diagnosed with cancer, some who are already receiving treatment, and some who have a family member or friend with cancer. Physicians and other health professionals may also call to inquire about trials for their patients.

For more information, visit the National Cancer Institute Clinical Trials at NIH Web site at <http://bethesdaclinicaltrials.cancer.gov> or call 1-888-NCI-1937.



How You Can Find a Clinical Trial

at the Bethesda, Maryland campus of the National Cancer Institute

1 Call our toll free number or visit the NCI Clinical Trials at NIH Web site.

Call 1-888-NCI-1937 to reach our referral office. Based on the medical history you provide, the staff will identify clinical trials that might be options for you. With your permission, your information will be sent as a referral to the research team of each trial identified.

You may also visit the NCI Clinical Trials at NIH Web site at <http://bethesdatrials.cancer.gov>. At this Web site, you are able to search for clinical trials and find contact information for the appropriate research teams, so that you can contact the researchers directly.

2 Talk with members of appropriate research team(s).

If, when you call our toll free number, you are then referred to a trial, a member of that

trial's research team will contact you within a specified amount of time. That team member will provide you with information about the trial and will ask additional screening questions to further determine your eligibility.

3 Talk to your physician/health care professional.

We suggest that you review the information you receive about an appropriate clinical trial with your physician/health care professional. If you decide that you wish to participate in a trial, you or your physician/health care professional should contact the trial's research team to discuss your medical history and current health status.

4 Schedule a screening visit.

If you appear to meet eligibility requirements, you will be invited to NCI's

Bethesda campus for a screening visit.

A research nurse or investigator in charge of the trial will set up the visit for you.

Before the screening visit, you will receive a packet of information containing:

- Maps
- Travel and hotel information
- Instructions on what paperwork to bring (Generally, this includes copies of your medical and treatment summary, pathology reports and slides, and radiology reports.)

The screening visit is very much like a consultation visit with a medical specialist. During the visit, you may be asked to have several common diagnostic tests such as blood tests, a chest X-ray, and an EKG.

You will also have a chance to:

- Meet and speak with the physicians, nurses, and social workers who make up the research team

When you have decided that a clinical trial is an option you want to consider, follow these steps to see if there is a trial that is right for you.

- Learn about the risks and benefits of the trial you are considering
- Ask questions about any aspect of the trial

The purpose of the screening visit is to determine if you are a candidate for a particular trial. You are not expected to make a decision about participation at the time of this visit.

5 Decide whether to enroll.

If you are eligible to join a trial, you will want to consider the following.

- Possible risks and benefits
- How the trial will affect your everyday life (For example, inpatient trials require you to stay at the NIH Clinical Center for a few days or longer. Outpatient trials allow you to receive treatment and go home the same day.)

- How the trial may contribute to the overall improvement of cancer treatment for generations to come

If you decide to participate, you will be asked to sign a consent document that describes, among other things:

- The trial's treatment schedule
- Possible benefits and side effects

Signing a consent document does not mean that you sign away any personal rights or protections. It simply means that you have read the document and understand the purpose and elements of a trial, and that you are participating voluntarily.

You may withdraw from the trial at any time. If you choose to leave the trial, you will have the opportunity to discuss other treatment options or any concerns with the clinical trial team.

To find out more about clinical trials at the Bethesda campus of the National Cancer Institute, call 1-888-NCI-1937 (1-888-624-1937) Monday through Friday, 9:00 a.m. to 5:00 p.m., Eastern Time.

For more information, visit the National Cancer Institute Clinical Trials at NIH Web site at <http://bethesdatrials.cancer.gov> or call 1-888-NCI-1937.



Cancer Resources

from the National Cancer Institute

Clinical Trials Referral Office • 1-888-NCI-1937

The National Cancer Institute can help you identify appropriate clinical trials taking place at the National Cancer Institute in Bethesda, Maryland. You can be referred directly to the research teams that conduct clinical trials for a particular type and stage of cancer.

National Cancer Institute Clinical Trials at NIH <http://bethesdatrials.cancer.gov>

The NCI Clinical Trials at NIH Web site helps the general public and health care professionals identify cancer clinical trials taking place at the National Cancer Institute in Bethesda, Maryland. This easy-to-use Web site lets you search and print information about these ongoing clinical trials. You can also learn more about how to enroll in a trial, read Frequently Asked Questions (FAQs), download educational materials, and link to additional resources.

Cancer Information Service

1-800-4-CANCER • TTY: 1-800-332-8615 • www.cancer.gov

The Cancer Information Service provides accurate, up-to-date cancer information. You can request information on clinical trials sponsored by the National Cancer Institute and some trials conducted by independent investigators at hospitals and medical centers in the United States and Europe. You can also receive brochures on specific types of cancer and other cancer-related topics.

National Cancer Institute • www.cancer.gov

The National Cancer Institute's Web site provides links to information and resources for researchers, health professionals, and the general public. The Clinical Trials section of this site enables you to search for trials currently underway throughout the United States.

For general information about clinical trials, you can request a copy of the booklet "Taking Part in Cancer Treatment Studies: What You Need to Know" by contacting any of the resources on this page. You can also access this and other NCI publications online by visiting <http://www.cancer.gov/clinicaltrials> and clicking on "NCI Publications" in the "Quick Links" box.

What are the costs?

There is no charge for medical care received at the National Institutes of Health (NIH) Clinical Center. You will be responsible for travel costs for your initial screening visits. In most cases, once you are enrolled in a trial, the National Cancer Institute (NCI) will pay the transportation costs for all subsequent trial-related visits for persons who do not live in the local area. In addition, you will receive a small per diem for food and lodging expenses if you are being treated as an outpatient.

It will be important to maintain your current insurance plan to cover all medical care that is provided away from the NIH Clinical Center.

Where is the National Cancer Institute?

The National Cancer Institute is located just outside of Washington, D.C., on the campus of the National Institutes of Health in Bethesda, Maryland. If traveling by car, you will find the campus just south of Cedar Lane between Rockville Pike and Old Georgetown Road. If you join a trial, almost all of your care will be provided in the Clinical Center (located in Building 10). Patient parking is located under the Clinical Center. If traveling by public transportation, you should take the Red Line Metro to the Medical Center stop.

