

## Clinical Trials

This section has been reviewed and approved by the Cancer.Net Editorial Board, 10/2012



*Listen to the [Cancer.Net Podcast: What Are Clinical Trials?](#) [1]*



*Watch the [Cancer.Net Video: What are Clinical Trials?, with Richard Goldberg, MD](#) [3]*

Doctors and scientists are always looking for better ways to treat young adults with cancer. To make [scientific advances](#) [4], doctors design research studies involving people, called clinical trials. Clinical trials may be sponsored by government agencies, such as the National Cancer Institute (NCI), hospitals, pharmaceutical companies, or other health organizations.

Many clinical trials test new treatments to find out whether they are safe, effective, and possibly better than the current (standard) treatment. These types of studies evaluate new drugs, different combinations of existing treatments, new approaches to radiation therapy or surgery, and new methods of treatment.

Young adults who participate in clinical trials are often among the first to receive new treatments before they are widely available. However, there is no guarantee that the new treatment will be safe, effective, or better than a standard treatment.

There are also clinical trials that study new ways to ease symptoms and side effects during treatment and manage the late effects that may occur after treatment, as well as ongoing studies about ways to prevent the disease.

### Participating in a clinical trial

Currently, only about 2% of young adults with cancer participate in clinical trials. However, many oncologists are trying to make clinical trials more accessible by adjusting the age limits for some studies. Because the biology of cancers in young adults can differ from the same cancers in children or adults, it is important to consider participating in a clinical trial. Nearly every treatment that is available today is a result of a clinical trial.

As a first step, ask your doctor about clinical trial options. You may also search databases of cancer clinical trials [5] or check specific NCI-designated cancer centers and cooperative groups [6]. Cooperative groups are large networks of doctors and other health care professionals from many different institutions that develop and coordinate clinical trials with NCI funding.

If you have a type of cancer that is common in childhood?such as osteosarcoma, Ewing's sarcoma, medulloblastoma, and leukemia?you may consider enrolling in a clinical trial conducted by the Children's Oncology Group [7], which runs large clinical trials for children and teens with cancer.

Learn about personal experiences of people with cancer who have participated in clinical trials [8].

## **Safety**

Clinical trials follow a rigorous review and oversight process to protect participants. Medical professionals and other experts in the cancer research community review each clinical trial design to ensure that patients will be safe and will have their rights upheld.

In addition, research institutions are required to obtain informed consent [9] from every clinical trial participant. During the informed consent process, the doctor must talk about all of the treatment options so that you understand how the new treatment differs from the standard treatment. The doctor must also tell you about the risks of the new treatment, which may or may not be different from the risks of standard treatment. Finally, the doctor must explain what will be required of each patient in order to participate in the clinical trial, including the number of doctor visits, the number of tests, and the treatment schedule. It is also important to keep in mind that you may stop participating in a trial at any time. When you give informed consent, it means that you understand what will happen in the study and that you agree to participate.

Informed consent is not a one-time event; it is an ongoing process between you and your health care team that allows you to ask questions, discuss your concerns, and learn about any new information about the particular trial or therapy.

## **Phases**

Clinical trials are done in three phases, and each phase has a different goal.

**Phase I trial.** The goal is to prove that a new treatment may be safe to give to people by finding the appropriate dosage and identifying the possible side effects of the treatment. It involves about 10 to 20 people and lasts several months to a year.

**Phase II trial.** The goal is to find out more about the safety and effectiveness of the new treatment, evaluating how it works treating a specific type of cancer. It involves about 20 to 40 people and lasts about two years.

**Phase III trial.** The goal is to compare the new treatment with the current, standard treatment for the type of cancer in which it is being tested. After a successful phase III trial, an application is submitted to the U.S. Food and Drug Administration for approval to sell the new treatment

To learn more, [watch a video about the phases of a clinical trial](#) [10] and ask your doctor to explain the phase of the clinical trial you are considering and what it means for you.

## Costs

The costs of a clinical trial vary by state and depend on which costs the clinical trial sponsors and your insurance company covers. Some clinical trials offer payment, while others do not. In some programs, clinical trial sponsors will reimburse for expenses associated with participating in the research, such as transportation, childcare, meals, and accommodations.

Consider asking the clinical trial research team the following questions about costs:

- What costs can I expect if I choose to participate in this clinical trial?
- How do these costs compare to the costs of my other treatment options?
- Is my insurance likely to cover my expenses from this clinical trial? How can I find out what my insurance covers before the clinical trial begins?
- If I'm worried about [managing the costs related to my cancer care](#) [11], who can help me with these concerns?

Learn more about [questions to ask the clinical trial research team](#) [12].

## More Information

[Cancer in Young Adults](#) [13]

[Clinical Trials](#) [14]

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### Links:

[1] [http://www.cancer.net/sites/cancer.net/files/what\\_are\\_clinical\\_trials.mp3](http://www.cancer.net/sites/cancer.net/files/what_are_clinical_trials.mp3)

[2] <http://www.cancer.net/file/478>

[3] <http://www.cancer.net/node/27106>

[4] <http://www.cancerprogress.net/>

[5] <http://www.cancer.net/node/24878>

[6] <http://www.cancer.net/publications-and-resources/support-and-resource-links/general-cancer-organizations-and-resources/cancer-centers-coop-groups>

[7] <http://www.childrensoncologygroup.org/>

[8] <http://www.cancer.net/node/24873>

[9] <http://www.cancer.net/node/24386>

[10] <http://www.cancer.net/node/27091>

[11] <http://www.cancer.net/node/24865>

[12] <http://www.cancer.net/node/24881>

[13] <http://www.cancer.net/node/25117>

[14] <http://www.cancer.net/node/24863>