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About Clinical Trials [1]

This section has been reviewed and approved by the [Cancer.Net Editorial Board](#) [2], 12/2015

Clinical trials are research studies that involve volunteers. Doctors use the studies to advance science. Many clinical trials study new cancer treatments, but they can also be used to study the following:

- Combining existing treatments
- Using radiation therapy or surgery
- Easing symptoms and side effects during treatment
- Managing the long-term side effects that can happen after treatment
- Preventing cancer

Why clinical trials matter

Clinical trials are the way to make progress in preventing and treating cancer. Clinical trials must be done before new drugs are approved by U.S. Food and Drug Administration (FDA). They also must be done before new surgical or radiation therapy methods are regularly included with cancer treatment. People with cancer are often offered the option of treatment in a clinical trial.

In a clinical trial, patients can be assured of receiving excellent treatment with the possibility of receiving additional new treatments that could help them. Their participation also helps contribute to improved treatments for future patients.

Clinical trials may include hundreds or even thousands of people. That means it can take a long time to get results. This process is also ongoing. As doctors learn and study new information, they add new care standards or replace old ones. Clinical trials are the only accepted way scientists can find out if new treatments work better than standard ones.

Although clinical trials offer great hope, less than 5% of adults with cancer join one. Not having volunteers slows down therapy advances. However, more than 60% of children with cancer get treatment through a clinical trial. Around three-quarters of children with cancer survive long term, compared with half of adults. Doctors link the higher survival rate for children, in part, to the enrollment of patients in cancer clinical trials over many years. Read [stories about why patients choose to be in clinical trials](#) [3].

Clinical trials and placebos

Some clinical trials, called placebo-controlled clinical trials compare a new treatment with a placebo. A placebo is a drug or treatment that is inactive. Doctors don't use them a lot in cancer clinical trials. When placebos are used, they are usually combined with standard treatment. This ensures that neither the patient nor the doctor knows which patients are receiving the treatment being studied. Additionally, placebos are sometime used:

- When there's no standard treatment available
- With treatment to manage symptoms and side effects of the cancer, called [palliative care](#) [4]

The research team will tell people when a placebo is part of a study. Find out more about [placebos in cancer clinical trials](#) [5].

Clinical trials set-up

All clinical trials have requirements for who can join. Researchers call those requirements inclusion and exclusion criteria. Examples of the criteria are a person's:

- Age
- Disease type

- Medical history
- Current health
- Previous treatments

Inclusion criteria help make sure that people in a clinical trial are medically similar. For example, the criteria may want each person to have the same kind of cancer or the same stage of disease. If people have too many medical differences, the doctors will have trouble understanding the results.

Exclusion criteria help keep people safe. Take, for example, people with a severe heart condition or kidney failure. Some cancer treatments are unsafe for them so they can't join certain clinical trials. Researchers don't use exclusion criteria to reject people personally. The criteria protect people from potential harm. The criteria also help researchers learn more from each study.

Clinical trials also follow a set of rules called a protocol. A protocol describes:

- Inclusion and exclusion criteria
- The schedule of tests, procedures, medications, and doses
- The length of the study
- How groups will be compared, for example, the percent of patients whose tumor gets smaller

While a person is in a clinical trial, the research team monitors his or her health. The team also monitors the person for a time after the treatment is over. That lets the team learn about the safety of the treatment and how well it works. The [research team](#) [6] includes:

- Doctors
- Nurses
- Social workers

- Other health care professionals

The team will:

- Answer questions about the trial and get a patient's written informed consent
- Check a person's health at the beginning of the clinical trial
- Give participation instructions
- Watch the person closely during the clinical trial
- Stay in touch with the person after the study

People in clinical trials should follow their team's instructions and stay in touch with its members. They should also tell the research team if they have any side effects or other concerns. That way, the patient can be confident their care is a priority and the clinical trial will be as successful as possible.

Clinical trial sponsorship

Many organizations sponsor clinical trials, including:

- Government agencies, such as the National Institutes of Health (NIH), including the National Cancer Institute (NCI)
- Pharmaceutical companies
- Individual doctors
- Health care centers, such as health maintenance organizations (HMOs)
- Organizations that develop medical devices or equipment
- Nonprofit advocacy organizations

Clinical trials can take place in:

- Hospitals
- Universities
- Doctor's offices
- Community clinics

One effective way to run clinical trials is through an NCI-funded cooperative group. Cooperative groups are large networks of doctors and other health care professionals. The groups can be from many different centers. Together, they develop and coordinate clinical trials. The clinical trials sponsored by cooperative groups can enroll more people than a clinical trial at a single hospital. Also, the cooperation makes it easier for people from different parts of the country to join a clinical trial. [Find an NCI cancer center or cooperative group](#) [7].

More Information

[ASCO Answers Fact Sheet: Clinical Trials \(PDF\)](#) [8]

[Finding a Clinical Trial](#) [9]

Cancer.Net Video: [What are Clinical Trials, with Richard Goldberg, MD](#) [10]

Cancer.Net Video: [Types of Cancer Clinical Trials, with Louis Weiner, MD](#) [11]

Cancer.Net Video: [Clinical Trials and Safety with Eric Singer, MD, MA](#) [12]

[PRE-ACT: Preparatory Education About Clinical Trials](#) [13]

Additional Resources

National Cancer Institute: [Clinical Trials](#) [14]

ClinicalTrials.gov: [Learn About Clinical Studies](#) [15]

[Center for Information and Study on Clinical Research Participation](#) [16]

Links

- [1] <http://www.cancer.net/navigating-cancer-care/how-cancer-treated/clinical-trials/about-clinical-trials>
- [2] <http://www.cancer.net/about-us>
- [3] <http://www.cancerprogress.net/stories>
- [4] <http://www.cancer.net/node/25282>
- [5] <http://www.cancer.net/node/24390>
- [6] <http://www.cancer.net/node/24957>
- [7] <http://www.cancer.net/publications-and-resources/support-and-resource-links/general-cancer-organizations-and-resources/cancer-centers-coop-groups>
- [8] http://www.cancer.net/sites/cancer.net/files/asco_answers_clinical_trials.pdf
- [9] <http://www.cancer.net/node/24878>
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