ASCOanswers

Clinical Trials

What is a clinical trial?

A clinical trial is a research study that involves volunteers. Many clinical trials study new treatments. They may also study new ways of preventing cancer, diagnosing cancer, managing side effects, or improving a patient's quality of life. Clinical trials may offer a patient treatment options not otherwise available, access to high-quality care, and the chance to help other patients with cancer. Almost all medical advances related to the prevention and treatment of cancer are a result of clinical trials.

What are the phases of a clinical trial?

Research is completed in three phases. Phase I aims to show that the new treatment can be given safely to people. Phase II provides more information about the safety of the treatment and how well it works. Phase III tests the treatment in a large group of people to determine how it will be used, often comparing it with a standard treatment.

How is a patient safely monitored?

Patient safety is the highest priority in clinical trials. Before a clinical trial begins, it must be approved by an institutional review board (IRB) that ensures the clinical trial's protocol is ethical and that participant rights are protected. During the study, a data safety monitoring board (DSMB) protects patient safety by regularly reviewing the research data and making recommendations to stop, change, or continue the study. Several federal regulations also help ensure safety, requiring that participants be given written information on every aspect of the clinical trial. Participants are seen regularly by the research team—doctors, nurses, and other health care professionals—to monitor their health and determine the safety and effectiveness of the treatment being tested. It is also important to know that a participant can leave a study at any time for any personal or medical reason.

Is a clinical trial right for me?

It is important for a person with cancer to consider all treatment options, including clinical trials. Talk with your doctor to learn about current clinical trials and whether they may be appropriate for you. As with any treatment, you need to weigh the benefits of participating in a clinical trial against the potential risks. For some, a clinical trial may be the best treatment option available. For example, most children with cancer participate in clinical trials, and these studies have improved survival for children with cancer. Talking with people who have participated in a clinical trial may be helpful.

Several websites listed at www.cancer.net/clinicaltrials allow you to search for current clinical trials. All clinical trials have specific participation requirements that help keep patients safe and ensure researchers get the information needed to answer the study's questions.

ASCO ANSWERS is a collection of oncologist-approved patient education materials developed by the American Society of Clinical Oncology (ASCO) for people with cancer and their caregivers.

Questions to ask the doctor

Your doctor can help you understand more about clinical trials. Consider asking:

- What clinical trials are open to me?
- What happens during a clinical trial?
- What are the benefits and risks of participating in a clinical trial?
- Will you continue to be a part of my care during the clinical trial?
- Where can I learn more about clinical trials?

Questions to ask a clinical trial's research team

Before participating in a clinical trial, ask the research team for as much information as possible. Consider asking:

- What is the purpose of this clinical trial?
- What is the specific approach being studied?
- What other treatment options are available to me?
- Who or what organization is sponsoring the clinical trial?
- Who has reviewed and approved this clinical trial?
- What are my responsibilities during the clinical trial?
- What are the possible risks and benefits of participating in this clinical trial? How do they compare with the risks and benefits of the standard treatment?
- Where will the clinical trial take place? Will I need to stay in the hospital?
- Are there costs associated with my participation in this clinical trial?

Find additional questions at www.cancer.net/clinicaltrials.

To order more printed copies, please call 888-273-3508 or visit www.cancer.net/estore.

TERMS TO KNOW

Control group:
A select group of clinical trial participants to which others are compared

Data safety monitoring board:
An independent committee of doctors, medical ethicists, statisticians, and other health professionals that monitor an ongoing trial's research data

Institutional review board:
A committee of doctors, statisticians, community advocates, and others who ensure a clinical trial is safe and ethical

Inclusion/exclusion criteria:
Guidelines that determine if a person is eligible or ineligible to participate in a clinical trial

Informed consent:
The process by which participants learn about a clinical trial, including their rights, safety measures, and what is being tested

Investigational drug:
A new drug used in a clinical trial

Placebo:
An inactive drug or treatment (used only when there is no effective standard treatment or in addition to standard treatment)

Preclinical research:
Testing of new drugs or treatments in the laboratory before clinical trials

Protocol:
A set of rules describing the study

Standard treatment:
The current most effective treatment

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