ASCO® answers

Cancer Clinical Trials

What is a clinical trial?

A clinical trial is a research study that people volunteer to take part in. Clinical trials help doctors find better treatments for cancer and other diseases. Most new ways of finding, preventing, and treating cancer were discovered in clinical trials.

You might want to take part in a clinical trial for a specific reason or several reasons. Your health care team might recommend one. Or you might want to try a treatment that is not yet available to everyone, help other people with cancer, help find ways to prevent cancer, or help doctors get better at finding cancer.

What do doctors study in clinical trials?

Doctors and researchers are always looking for new ways to prevent, diagnose, treat, and cure cancer. There are many aspects of treatment studied in clinical trials: new drugs, new surgical methods, different ways to deliver radiation therapy, and more. Some new cancer treatments are personalized based on the genes in a tumor. This is called "precision medicine" and is being studied a lot in clinical trials.

Doctors and researchers also do clinical trials to help improve the quality of life for people living with cancer by looking for better ways to relieve symptoms and side effects.

Are clinical trials safe for patients?

The safety of patients enrolled in clinical trials is very important. The U.S. government and other governments around the world have strict rules to protect patients. The clinical trial doctors and staff must follow these rules. However, most cancer clinical trials include experimental drugs, which means they are not yet proven to be safe or effective. Early scientific evidence may suggest that these drugs are safe, but a goal of clinical trials is to collect more data to be sure that treatments are safe enough to be approved by the U.S. Food and Drug Administration (FDA) for use by all patients.

Before you decide to join a clinical trial, the staff will talk with you about the possible risks and benefits. They will tell you about any possible costs and side effects and answer your questions.

Will I get real medicine or a "sugar pill"?

A "sugar pill," or placebo, is something that looks like the medicine or treatment that doctors are studying. However, it does not contain any real medicine. Using a placebo tells researchers if the study treatment works, because the study treatment is compared to no treatment at all.

If cancer clinical trials use placebos, they use them carefully. A placebo will never be used to replace treatments that are used to treat or cure cancer. This is because people with cancer need treatment for their serious disease. So, if you do not get the treatment doctors are learning about, you will probably get the usual treatment. For example, if doctors are learning about a new drug, you will probably get that or the drug you would usually get if you weren't participating in the study.

Will I be paid for taking part?

That depends on the clinical trial. Some clinical trials pay for your travel, such as gasoline or bus tickets. Others pay a small amount of cash. Most do not pay anything but will cover the costs of care that you would receive if you were not in the study. Talk with the research team ahead of time about the financial aspects of a clinical trial you are interested in.

Will my health insurance pay for the clinical trial?

Probably. The U.S. law requires insurance companies to pay for regular medical care in a clinical trial, but some tests and procedures may not be completely covered. Ask the clinical trial staff and your insurance company what your insurance will pay for the clinical trial.

Can children take part in clinical trials?

Yes. Most children with cancer take part in clinical trials, and most children with cancer are treated in clinical trials. Many children taking part has made children's cancer treatment more effective than in the past.

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.

Do I have to stay in a clinical trial if I don't like it?

No. Taking part in a clinical trial is your choice. You may leave at any time. Your health care team will keep taking care of you, even if you leave the study. Being in a clinical trial is a personal choice.

If you leave a clinical trial, you will still get good medical care. You and your health care team will decide which treatments are best.

How do I find a clinical trial?

First, learn what clinical trials are available for people with your type of cancer or treatment. Ask your health care team if they know about any clinical trials. You can also check the website of your local hospital. Or visit www.clinicaltrials.gov or www.cancer.net to find open clinical trials.

Questions to ask your health care team

Your health care team can help you learn more about clinical trials. It can be helpful to bring someone along to your appointments to take notes. The list below has some questions you might want to ask.

- Do you know about any clinical trials I could take part in?
- Will you keep taking care of me if I take part in a clinical trial?
- How can I learn more about my clinical trial options?
- What are my other treatment options, including regular care (no clinical trial)?

Questions to ask the clinical trial staff

You can ask the clinical trial staff any questions before you decide to take part in a specific study. Below are some questions you can ask.

- What do doctors hope to learn in this clinical trial?
- What is the treatment being studied?
- Who is the sponsor for this clinical trial?
- Who reviewed and approved this clinical trial?
- What will I need to do if I take part?
- What are my risks and benefits in this clinical trial? How are they different from the risks and benefits of regular treatment?
- Where will the clinical trial be? Do I need to stay overnight at the hospital?
- Will it cost me anything to take part?
- If I have a question or problem, who should I call?

You can find more questions at www.cancer.net/clinicaltrials. For a digital list of questions, download Cancer.Net's free mobile app at www.cancer.net/app.

Words to Know

Caregiver: Someone who helps with your medical care, daily activities, or both.

Consent: Also called "informed consent." The process of learning about a clinical trial, asking questions, and deciding if you want to take part. The study staff tell you what doctors want to learn, your rights, and how you will be kept safe. Before participating in a clinical trial, you will be asked to sign an informed consent form that describes what will happen in the clinical trial.

Dose: The amount of medicine you use at each time.

Exclusion criteria: The rules for who cannot take part in a clinical trial. For example, a clinical trial might only need volunteers who are 65 or older.

Inclusion criteria: The rules for who can take part in a clinical trial. For example, the study may only include those with a specific type of cancer.

Medicine calendar: A calendar that shows when you take each dose of medicine. You, your nurse, or your caregiver might write on the calendar. It might also be available on a computer or your phone.

Review board: A group of doctors and experts who read the clinical trial's plan before it starts. They help make sure it is safe for volunteers. Also called an "institutional review board."

Routine costs: Costs your insurer would cover even if you were not in a trial. These may include office visits, lab tests, or services or procedures you need while in the trial.

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