

Commonly Asked Questions About Clinical Trials

What is a clinical trial?

A clinical trial is a research study in healthy volunteers or patients that helps to determine whether a new drug or device is safe and/or effective. Each study is designed to answer scientific questions and tries to find better ways to screen, diagnose, prevent, or treat a disease or condition.

What happens during a clinical trial?

- Each study has a protocol, or action plan, that maps out the procedures of the study – what will be done, by whom, when and why. The protocol also explains who is eligible to participate in a trial and what is expected of each person. If you are eligible to join the trial, a team of doctors and nurses will manage your care. Trials are held at hospitals and research centers around the country and are categorized in four phases. Phase 1 trials determine the proper dosing, or amount of drug to be given to a patient, and predominant side effects.
- Phase 2 trials gather data on a treatment's safety and benefits.
- Phase 3 trials test the treatment's effectiveness, monitor side effects and often compare the new product to an existing treatment to determine which is better.
- Phase 4 trials are conducted after a treatment has been approved by a regulatory health authority, for example, the United States Food & Drug Administration (FDA) and CHMP in Europe. During this phase, researchers study the long-term risks, benefits, and optimal use of the therapy.

Why are clinical trials needed?

Without clinical trials, new treatments for diseases and conditions would not be discovered. Some clinical trials help to determine if a new treatment is safe and can improve the health of patients. Other trials compare a new therapy to an existing one to find out which is better at treating or preventing a disease.

Who sponsors clinical trials?

Usually clinical trials are sponsored by drug manufacturers and/or government agencies. In addition, organizations or individuals, such as doctors, medical institutions, foundations and advocacy groups sponsor research studies.

Should I consider taking part in a clinical trial?

Clinical trials are not right for everyone. Before signing up, you should learn as much as possible about the trial that interests you. Then discuss your options with your doctor. Before starting any trial, you should understand what will happen during the study, what is expected of you, the type of care you will receive and the costs that you may have to cover. You will be asked to read and sign an informed consent form that details exactly what will happen during the study and what the risks may be.

I was just diagnosed. Should I go into a trial now, or try other treatment first?

You should discuss your options with your doctor, as there may already be approved therapies to treat your condition. It's important to evaluate all of your options before starting any treatment.

What are the benefits of participating in a clinical trial?

Participation in a clinical trial gives you access to cutting-edge, potentially life-saving and life-enhancing treatments, as well as medical care from a team of researchers, doctors, and nurses. Your participation contributes to the advancement of medicine and helps others who share your condition.

What are the risks?

The risks depend on the type of treatment being studied and the health of the patient. For some people, there could be unpleasant, even serious, side effects. Often these side effects are temporary and end when the treatment stops. There are both known and unknown risks with any clinical trial. Be sure you understand the known risks before you join any study.

Isn't it dangerous to take an experimental drug?

Whilst most clinical trials involve some risk, researchers must follow strict scientific guidelines and ethical and legal codes to ensure that you are protected. Studies need to be approved by an Independent Ethics Committee (IEC) or Institutional Review Board (IRB). This board – made up of scientists, doctors, and other people from the local community – reviews each study to see that it is designed to protect the patient and to ensure that the benefits of the study outweigh the risks. In addition, each trial must meet the Good Clinical Practice (GCP) standard. GCP is an ethical and scientific quality standard that ensures that the rights, safety and well being of study participants are protected.

What will the cost be?

Costs will vary depending on the study you choose to join. However, patients do not pay any money to participate in a clinical trial. In fact, under some circumstances they may even receive a small amount of money for joining the study. This payment usually depends on how much risk is involved and how much the trial may disrupt your everyday life. More commonly, trial participants will receive free of charge the drug being tested. They may receive medical tests and their medical care related to the trial at no cost. They may also receive payment to cover other expenses such as parking and travel. National health and private insurers often do not cover the costs related to a clinical trial. You will need to check with your health care provider to find out what, if any, costs will be covered.

Will I still get regular medical care?

As a participant of a clinical trial, you would receive excellent medical care from a team of doctors, nurses, researchers, social workers, and other health professionals, who are on hand to manage your condition. The trial's protocol may require you to visit the study site more often to check in with your study doctor. Plus you may receive more tests and treatments than usual.

How will I know if a trial is right for me?

This is a decision best made by you and your doctor. Together you will need to evaluate the study options available to you, weigh the benefits and risks of each, and then choose the one that's right for you.

What if I get a placebo?

If you want to join a clinical trial to receive a certain medication, you may want to reconsider participating. As a rule, trials of drugs for cancer do not use a placebo but rather participants receive either an approved drug or the approved drug plus the drug being studied. Many trials for other conditions test a new drug against a placebo (sometimes called a sugar pill) that looks like the real medication but, in fact, does not contain the benefits of the real drug. In a "randomized" trial, researchers use a computer to randomly decide who will get the real drug and who will receive the placebo. In a "blinded" trial, neither the researchers nor you will know if you're receiving the real drug. The randomized system ensures the process is fair for everyone.

If I start a trial, do I have to stay in it?

No, you can leave the trial at any time for any reason. Even if you signed paperwork at the start of the trial, you may still leave the study if you choose.

Does my doctor have to participate (be one of the doctors involved in the trial) for me to be in a trial?

No, your doctor does not have to participate in the trial in order for you to join. Depending on the trial, trial researchers may provide you with care or they will want your regular doctor to care for you. Whether or not your doctor participates in the trial, you will need to see him or her for general medical care.

How do I find out if I'm eligible?

Each study's protocol has guidelines stating who can and cannot join the clinical trial. These guidelines, or eligibility criteria, apply to anyone who wants to sign up for the study. The criteria vary by study and could include your age, gender, medical history, current health status, and the particular type or stage of disease you may have. Before you join the trial, you will be asked to sign an informed consent form (see below). Then a doctor or nurse will assess your medical history, perform a physical exam and perform laboratory tests to determine whether you meet the eligibility criteria.

Is everyone with my disease eligible?

No, only people meeting the study's guidelines, or eligibility criteria, may join the study.

What if I'm not eligible?

If you are found to be ineligible, you should talk to your doctor to see if there is another clinical trial that may be right for you.

What would be required of me if I participate?

The doctor will first talk to you about "informed consent." Informed consent is a process by which you will learn the details of the trial – what is involved, the purpose of the study, the tests and procedures that will be used, and the risks and benefits. You will then be given a written consent form, which explains the study. If you agree to take part, you will be asked to sign the form. If there is something on the form you do not understand, ask questions. Study doctors and nurses are available to answer your questions and help you understand the risks and benefits of the trial. Even if you sign the consent form, you are free to leave the trial at any time for any reason.

How long will the study last?

The length of each study is different. If you are considering joining a trial, you will need to discuss the trial's protocol with your doctor. That document will provide you with information on how long the trial lasts and what is expected of you.

What happens at the end of the trial – will I still be able to receive the drug?

After you complete the study, you may or may not be able to continue receiving the drug. In some cases the treatment will not be made available to you again until it is government-approved. Once the trial ends, researchers analyse the data to understand the safety and effectiveness of the treatment. If the study is considered a pivotal one and the results are positive they will be submitted to the national health authority for approval. During the approval process some pharmaceutical companies choose to continue to make the drug available through a pre-approval access program.

How do I find a clinical trial?

There are several ways to locate clinical trials in your area. First, talk to your doctor. He or she will be able to access an up-to-date listing of clinical trials through a system, for example, this is called PDQ, which is sponsored by the National Cancer Institute in the United States. PDQ includes trials in the U.S. and Europe. You may also want to call patient advocacy groups and local university medical centers to find clinical trials. If you have Internet access, you may want to look into these helpful resources.

- www.CenterWatch.com
- www.Controlled-Trials.com
- www.CancerBackup.org.uk/Trials/Search