PATIENT EDUCATION MATERIALS
English version

What is a clinical trial?

A clinical trial is a research program conducted with patients to evaluate a new medical treatment, drug, or device. The purpose of clinical trials is to find new and improved methods of treating, preventing, screening for, and diagnosing different diseases. Clinical trials make it possible to apply the latest scientific and technological advances to patient care.

During a clinical trial, doctors use the best available treatment as a standard to evaluate new treatments. The new treatments are hoped to be at least as effective as (or possibly more effective than) current treatments.

New treatment options are first researched in the laboratory, where they are carefully studied in the test tube and in laboratory animals. Only the treatments most likely to work are further evaluated in a small group of humans prior to applying them in a larger clinical trial.

What are the different phases of a clinical trial?

Phase I clinical trial

A new research treatment is given to a small number of participants and emphasizes safety. The researchers determine the best way to give the new treatment, find out the drug's most frequent and serious side effects, and how much of it can be given safely.

Phase II clinical trial

Determine the effect of a research treatment on the particular disease or condition being evaluated.

Phase III clinical trial

Compare the new treatment with the standard treatment and study different populations and different dosages and combinations of drugs.

Phase IV clinical trial

Apply the new treatment to general patient care, for example, a new drug that was found effective in a clinical trial may be used together with other effective drugs to treat the particular disease or condition in a select group of patients.

What are the advantages of participating in a clinical trial?

- You may receive a new treatment before it is widely available to the public.
- You can provide researchers with the information they need to continue developing new procedures and introducing new treatment methods.
- Your treatment costs may be decreased, because many of the tests and doctor visits that are directly related to the clinical trial are paid for by the company or agency sponsoring the study. Be sure to discuss your treatment costs with the physicians and nurses conducting the clinical trial.

Could any problems arise from participating in a clinical trial?

This will depend on the type of treatment and the patient's condition. Because the drug or device being studied is new, all the risks and side effects of the treatment are not known at the beginning of the clinical trial, and in some cases may not be known until the trial is long completed. Since this is the case, there may be unknown side effects, as well as hoped-for benefits. It is important to note that most treatments, as well as the disease or condition itself, have potentially unpleasant effects.

Patients will be informed of any known side effects they could experience, as well as any side effects that occur or become known while they are participating in the trial.

How could my treatment be different If I participated in a clinical trial?

You may receive more examinations and tests than are usually given for your particular condition. The purpose of these tests is to follow your progress and collect study data. Of course, tests can carry certain benefits and risks or discomforts of their own. Although they can be inconvenient, these tests can assure extra observation. Depending on the type of clinical trial, you may be asked to stop or change the medication(s) you are currently taking. You may also be asked to change your diet or any activities that could affect the outcome of the trial.

Some clinical trials are double-blind, placebo-controlled. This means that the clinical trial participants may receive the real drug or an inactive substance that looks exactly like the drug (called a placebo). Neither the participant nor the researcher will know which drug they are receiving. This is done to make certain that the real drug is effective.

Clinical trial participants are willing volunteers. Even though patients may be asked by their doctors to take part in a clinical trial, it is up to the patient to make the final decision, or to pull out of the trial if they want to.

What is informed consent?

Informed consent means that as a patient, you are given all available information so you can understand what is involved in a specific clinical trial. The doctors and nurses conducting the trial will explain the treatment to you, including its possible benefits and risks.

You will be given an informed consent form to read and consider carefully. Before signing, be sure you find out as much as possible about the clinical trial, including what risks you may face. Ask the researchers to explain parts of the form or the trial that are not clear.

You are free to decide whether or not you want to take part in the trial. If you decide to participate, you will sign the consent form. If you do not want to participate in the trial, you may refuse. If you choose not to participate in the trial, your care will not be affected in any way.

Your signature on the informed consent form does not bind you to the study. Even if you sign the form, you are free to leave the trial at any time to receive other available treatments.

The informed consent process is ongoing. After you agree to participate in a clinical trial, you will continue to receive any new information about your treatment that may affect your willingness to stay in the trial.

Who can participate in a clinical trial?

Every clinical trial is designed to meet a specific set of research criteria. Each study enrolls patients with certain conditions and symptoms. If you fit the guidelines for a trial, you may be able to participate. In some instances, you may be required to undergo certain tests to confirm your acceptability as a candidate.

What is it like to participate in a clinical trial?

All patients face a new world of medical terms and procedures. Fears and myths of being experimented upon or being a guinea pig are common concerns of patients who are thinking about participating in a clinical trial.

Even though there are always going to be fears of the unknown, understanding what is involved in a clinical trial before agreeing to participate can relieve some of your anxieties.

Important things to know:

- The personal information gathered about you during the clinical trial will remain confidential and will not be reported with your name attached.
- If at any time throughout the trial you or your physician feel it is in your best interest to exit the trial and use other known treatments, you will be free to do so. This will not in any way affect your future treatment.

- Clinical trial participants typically receive their care in the same places that the standard treatments are given in a clinic or doctor's office.
- Clinical trial participants are watched closely, and information about you will be carefully recorded and reviewed.

Important questions to ask

It is the responsibility of the drug developer to provide you with all available information about the clinical trial and if you are thinking about taking part in a clinical trial, find out as much as possible about the study before you decide to participate.

Here are some important questions to ask:

- What is the purpose of the clinical trial?
- What kinds of tests and treatments does the clinical trial involve, and how are these tests given?
- What is likely to happen in my case with, or without, this new research treatment? (Are there standard treatment options for my case, and how does the study compare with them?)
- How could the clinical trial affect my daily life?
- What side effects can I expect from the clinical trial? (Note: There can also be side effects from standard treatments and unpleasant effects from the disease itself.)
- How long will the clinical trial last?
- Will the clinical trial require extra time on my part?
- Will I have to be hospitalized? If so, how often and for how long?
- If I agree to withdraw from the clinical trial, will my care be affected? Will I need to change physicians?

Courtesy of Cromos Pharma.