

Frequently Asked Questions

What are the pros and cons of participating in a clinical study?

On the positive side, all clinical study patients receive quality medical care and may receive early access to experimental drugs that may prove beneficial in treating people with life-threatening conditions. You also help with the development of safer and better drugs for future generations.

Conversely, the new drug or treatment may not be any better and may be worse than standard care, or it may have undesirable side effects. Furthermore, you may incur costs that are not covered by your healthcare plan.

How do you find out about clinical studies?

Information on most clinical studies can be found by checking with your doctor or searching clinical study registries on sites such as www.clinicalresearch.com.

How do drugs get approved?

Regulatory authorities worldwide (such as the FDA in the U.S.) are charged with ensuring the safety and effectiveness of prescription drugs.

Before regulatory authorities give the drug manufacturer approval for marketing a given drug, two primary points are considered:

- whether the clinical studies provide substantial evidence that the drug is effective, and
- whether the drug is safe under the conditions outlined in labeling.

Ultimately, what the regulatory authority considers is whether the benefits of the drug outweigh its risks. For life-threatening diseases, there may be mechanisms that allow the approval process to be condensed so the treatment can be used and brought to market in an accelerated manner.

What questions should I ask before I agree to be in a clinical study?

You have the right to ask any number of questions of the clinical study doctors and sponsors prior to volunteering.

Some questions may include:

- **Has this drug been tested on humans before? If so, to what extent?**
- **What is the purpose of the drug?**
- **What are the perceived risks?**
- **Which company developed the drug?**
- **Will any invasive procedures be carried out?**
- **What is the samples type and how often will they be taken?**
- **How long does the study last?**

What does 'informed consent' mean?

Informed consent refers to the process by which volunteer patients discover the details of their clinical study. Patients must be provided with all facts about a study before giving consent to participate, including treatment details and possible risks and benefits. An informed consent form must be signed by patients prior to participation. The informed consent process continues throughout the clinical study.

How are clinical study patients protected?

Clinical study protocols are developed to ensure that patients are not put at undue risk. These protocols are carefully reviewed by a committee of experts and lay persons, called an Ethics Committee, before testing can start. As a volunteer, you have the right to refuse treatment at any point in the clinical study and leave at any time and for any reason. If doctors discover that the study treatment is harmful to you, you have the right to leave the trial and return to your doctor's care.

Who can participate in a clinical study?

Each clinical study has guidelines for patients based on specific factors, such as age, type of disease, medical history and current health. Depending on the study, sponsors may seek healthy individuals or those with the particular illness under study. Inclusion and exclusion criteria are used to determine which participants are chosen for the study.

Where are clinical studies conducted?

For phase I studies, the patients stay within the clinical unit throughout the study and generally are not allowed to leave the premises due to safety reasons. Some studies may be conducted at other medical facilities and may not require you to stay for the duration.

What happens in a clinical study?

In a clinical study, patients receive test treatments and doctors study how the treatment affects the patients. Some patients do not actually receive the test treatment, but instead receive a placebo or standard treatment as part of the "control" group. Patients' progress is followed closely by doctors.

Will my insurance or provider pay for the clinical study expenses?

Not always. Make a point to find out up front whether your health insurance or managed care provider will cover the costs of a given clinical study. Speak with one of the clinical study's doctors about cost issues before you volunteer as a participant.

Why should I consider getting involved in a clinical study?

There are many individual and personal reasons for participating. These include: appreciation for the benefits such involvement could have for future generations; assisting in the process that uncovers more successful medicines, which at times benefit serious or life-threatening conditions; drugs on trial today could go on to become the licensed drugs of tomorrow and benefit you or family members. Some study patients enjoy the social interaction or reward that comes from participating.

How safe are clinical studies?

Strict guidelines are followed and experts review the studies to ensure patients are not subjected to undue risk. However, all studies contain some form of risk.

How long do clinical studies last?

Phase I studies typically last between one and two weeks. In some studies, periodic visits are required, typically over longer periods. Phase II-IV studies can last several months to several years.

What happens at a clinical study screening?

At a study screening, you are provided with information about the study and a doctor takes your medical history. You may receive a health screening. If your health status matches the criteria for the study, you will be given the option to participate.

Visit www.clinicalresearch.com for more information.