

volunteering for a clinical trial



:: about this pamphlet

This pamphlet provides an overview of the clinical trials process and answers frequently asked questions that many potential volunteers have about participating in a study. When considering volunteering for a clinical trial, it is important to make an informed decision.

:: **what is a clinical trial?**

A clinical trial is a research study in which volunteers receive investigational treatments under the supervision of a physician and other research professionals. These treatments are developed by pharmaceutical and biotechnology companies who select qualified physicians, also known as investigators, to conduct clinical trials to determine the benefits of investigational drugs.

Clinical trials are usually conducted in three phases (I, II, III). Only a small number of people participate in phase I trials while the later phases involve a larger number of volunteers.

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:: who can participate in a clinical trial?

All clinical trials have guidelines about who can participate. Before joining a clinical trial, a volunteer must qualify for the study. The factors that allow volunteers to participate in a clinical trial are called "inclusion criteria" and the factors that disallow volunteers from participating are called "exclusion criteria." These criteria can include age, gender, the type and stage of a disease, previous treatment history, and other medical conditions.

Some research studies seek participants with specific illnesses or conditions to be studied in a clinical trial, while others require healthy participants. It is important to note that inclusion and exclusion criteria are used to identify appropriate participants, promote participants' safety, and ensure that researchers learn the information they need.

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:: **how does a clinical trial work?**

In a clinical trial, a volunteer is usually assigned a specific study group. Volunteers in one study group may receive an investigational treatment or study drug while other volunteers may receive a placebo or a treatment already available.

A placebo is an inactive product used to assess the experimental treatment's effectiveness. The participant, physician, and research staff may not know which volunteer receives a placebo and which receives the active treatment. Not knowing which participants are receiving the active treatment allows the physician and research staff to objectively observe the volunteers during the study. Regardless of which treatment volunteers receive, however, the level of medical attention and care that each receives is the same.

:: **what can volunteers expect if they choose to participate?**

In some studies, participants receive a physical examination and their medical histories are reviewed by either the study physician or a research staff member once they are enrolled in the study. The volunteers' health will continue to be monitored during and after the trial. A detailed description of what's expected of volunteers will be outlined in consent forms along with specific clinical trial information.

:: what are the benefits and risks of joining a trial?

Volunteers in a clinical trial participate in the development of medical therapies that may offer better treatments and even cures for life-threatening and chronic diseases. However, there are risks involved.

Possible benefits for volunteers:

- Play an active role in their health care.
- Gain access to research treatments before they are widely available.
- Obtain medical care at health care facilities during the trial.
- Help others by contributing to medical research.

Possible risks for volunteers:

- There may be unpleasant, serious, or even life-threatening side effects to experimental treatment.
- The experimental treatment may not be effective.
- The protocol may require more time and attention than a non-protocol treatment, including trips to the study site, more treatments, hospital stays, or complex dosage requirements.

Please note: volunteers may withdraw from a study at any time for any reason.

:: **does information remain confidential and private?**

Access to personal information is usually available to the investigator and research team conducting the clinical trial. In some circumstances, the IRB overseeing the research and the sponsor or contract research organization coordinating the trial will also have access to personal information. This is explained more specifically in the consent form that participating volunteers are asked to sign. As a clinical trial progresses, researchers report the results of the trial at scientific meetings, to medical journals, and to various government agencies.

:: **what happens after the trial?**

After a study phase is complete, the data is collected to determine the drug's effectiveness, if it is safe, and if there are any side effects. Depending on the results, researchers then determine whether to stop testing or move to the next phase of study. After phase III of a study is complete, researchers decide if the results are medically important and may submit them to journals for peer-review. Data then may be submitted to the Food and Drug Administration (FDA) for approval.

If a drug is approved, pharmaceutical companies may continue to conduct studies that compare the new drug—in terms of its safety, effectiveness, and cost—to other drugs already on the market or assess a drug's long-term effectiveness and its impact on the quality of a person's life.

:: **about CenterWatch**

Founded in 1994, CenterWatch is a trusted source and global destination for clinical trials information for both professionals and patients. We provide proprietary data and information analysis on clinical trials through a variety of newsletters, books, databases, and information services used by pharmaceutical and biotechnology companies, contract research organizations (CROs), site management organizations (SMOs), and investigative sites involved in the management and conduct of clinical trials.

As a pioneer in publishing clinical trials information, CenterWatch was the first Internet site to publish detailed information about active clinical trials that could be accessed by patients and their advocates. Today, with more than 80,000 listings, we have the largest database of clinical trials actively seeking patients on the Internet. For a comprehensive listing and detailed information about our publications and services, please visit our web site at www.centerwatch.com.