


Clinical Trials: Exploring Disease And Its Treatment



What are clinical trials?

There are different kinds of clinical trials, which are also known as research studies. Most commonly, a clinical trial tests investigational drugs, devices, or procedures to see if they work and are safe for the condition being studied. Some clinical trials use investigational products and procedures that have not yet received approval by the Food and Drug Administration (FDA), while others may have FDA-approval, but not for the use, dose, or method being studied.

Other kinds of clinical trials include observational trials, which look to uncover patterns related to disease progression and possible cause-effect relationships. Observational trials may lay the foundation for studies that test investigational products or procedures.

Why are clinical trials important?

Information collected from clinical trials is presented to the FDA. The FDA is then able to determine whether the investigational product (e.g., drug, device, procedure) should be approved for use by the general public. Almost all prescription medications available today have gone through a series of clinical trials. Because of clinical studies, we now understand hundreds of diseases and have developed effective therapies to treat them.

Who sponsors clinical trials?

Pharmaceutical companies, federal health agencies, medical foundations, medical centers, and universities sponsor most clinical trials; however, independent physicians may also sponsor clinical trials.

What are the phases of clinical trials?

As part of the clinical trial process, investigational products go through a series of tests. These tests are broken down into "phases" and are outlined below:

Pre-Clinical Trials: Before a product can be tested in humans, a series of tests are performed in test tubes and with animals.

Phase I Trials: These studies are the first to test investigational products in people. A Phase I trial usually includes a small number of participants and will help determine how the investigational product works and any side effects associated with increasing doses or other variable. These studies may include healthy participants and/or patients with a specific medical condition.

Phase II Trials: These studies evaluate the safety and effectiveness of the investigational product in people with the medical condition for which the product is being studied.

Phase III Trials: These studies are performed after the results from previous studies suggest the investigational product may be safe and effective. Phase III studies usually

include a large number of study patients in order to collect additional information on effectiveness, side effects, and risk-benefit relationships.

Phase IV Trials: These studies are performed on products that have FDA approval. Generally, these studies collect additional information on the best possible use of the product being tested.

Who can participate in clinical trials?

In order to take part in clinical trials, individuals must meet study-specific criteria. Requirements vary greatly by study, but may include age restrictions, medical history requirements, stage of disease, and numerous other criteria.

Is a research subject's study participation and medical information kept confidential?

A participant in a clinical trial is referred to as a research subject. Maintaining a subject's confidentiality is taken seriously during and after a clinical trial. Outside of the research team, a research subject's name may not be disclosed without the subject's permission unless the subject gives permission or is required by law. Generally, the sponsor, FDA, and the IRB have access to the study subject's study-related medical records. To help ensure confidentiality, once enrolled in a trial volunteers are assigned a subject number. This number and subject initials identify participants during the study.

Subject confidentiality is maintained in the same manner when the results of a clinical trial are reported to government agencies and in scientific meetings and medical journals.

What are the potential benefits of participating in a clinical trial?

People participate in clinical trials for various reasons, including health, financial, and personal needs. Volunteers who participate in clinical trials may contribute to improving medical science, which may help others in the future. While there is no guarantee of benefit from taking part, some benefits **may** include:

- Possible effective investigational treatment, relieving symptoms better than previous therapy and/or with fewer side effects
- Receipt of investigational study medication and other related care [at no charge]
- Access to study-related treatment that is otherwise unavailable
- Monitoring of medical condition and possible side effects related to the investigational treatment
- Financial compensation
- Knowledge that participation may help others in the future

When deciding whether to take part, you should carefully consider both the risks and benefits to study participation.

What are the potential risks to participating in a clinical trial?

Like most medical options, participation in clinical trials has risk. Although every effort is made to determine risks during pre-clinical and early clinical studies, there may be side effects and other health risks that are yet unknown. Some risks and downsides to study participation may include:

- Experiencing side effects to investigational treatments or study procedures
- Ineffective study treatment
- Chance of receiving a placebo (inactive substance)
- Not having a choice in study treatments
- Being asked to withdraw from current treatment before starting the trial
- Inconvenience of frequent study visits or other study procedures

The reasonably foreseeable risks of the study are listed in the study-specific informed consent form (described later in this piece).

What is informed consent?

Before agreeing to participate in a clinical trial, individuals are given an informed consent form that provides information about the study. The informed consent includes:

- An explanation of the study purpose
- Study participant activities
- Duration of the study
- Frequency and length of the required study visits
- Risks and benefits associated with the study treatment

Participation in a clinical trial is completely voluntary. All questions about the study should be answered to the subject's satisfaction before signing the informed consent. Subjects have the right to refuse participation or to withdraw their consent at any time during the study without penalty.

Throughout the trial, participants will be provided with any new information that may affect their decision to continue with the study. In addition, the study physician may withdraw a subject at any time, without the subject's consent, if it becomes evident the treatment is not in the subject's best interest.

Are research subjects required to pay for participation in a clinical trial?

Study medication as well as study-related tests and procedures are usually provided [at no charge] to study participants. It is important to ask the research staff to explain exactly what charges, if any, may be the responsibility of the study participant. Tests and procedures that are part of a subject's routine health care may or may not be covered by the subject's health insurance plan.

What protection does a subject have as a participant in a clinical trial?

Clinical trials are governed by ethical and legal codes. In 1981, the FDA required all federally regulated clinical trials be reviewed and approved by an Institutional Review Board (IRB). An IRB is a committee of volunteers including experts and lay people such as doctors, scientists, clergy, and other community members. Their primary goals are to help protect the rights of research subjects, to evaluate whether the potential benefits of study participation outweigh the risks, and to help ensure subjects are not coerced into participating in a clinical trial.

Subjects may call the IRB with questions about their rights as a research participant. The name and telephone number of the IRB reviewing the clinical trial is included in the informed consent form.

What questions should you ask before deciding to participate in a clinical trial?

- Why is the clinical trial being conducted?
- What type of investigational treatment is being studied?
- What are the known side effects of the study treatment?
- How often, when, and how does the study treatment have to be taken?
- Can I continue my current medications?
- What medications do I need to avoid?
- Should I avoid alcohol, specific foods, or other agents?
- What procedures are involved during the study?
- What effects should I expect from these procedures?
- What other treatment options are available to me, and what advantages or disadvantages could I expect from them?
- How long is the study?
- How often and when will I be expected to come in for visits?
- How long will each visit last?
- When should I call the doctor?
- Who do I contact in case of an emergency?

- Will I be responsible for the cost of any of the visits, mediations, or procedures performed during the trial?
- Will my own physician be notified about my participation in the trial?
- How will my study participation affect my daily life?

For information about clinical trials currently available, please contact:

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