



X-Plain *Clinical Trials*

Reference Summary

Introduction

A clinical trial is a research study done to evaluate new treatments in people.

Carefully conducted clinical trials are the fastest way to find new treatments that work in people.

You may be interested in or asked to consider participating in a clinical trial.

This reference summary will help explain clinical trials and help answer some of the most common questions.

What Is A Clinical Trial?

A clinical trial is a research study conducted to evaluate new treatments in people.

Each study is designed to learn about a potential treatment and its effects on people.

Before a new treatment is tried in people, it is carefully studied in the laboratory. The treatments with the most promising laboratory results are moved into clinical trials.

Clinical trials help us find out if a promising new treatment is safe and effective. During a trial, more and more information is gained about a new treatment, its risks, and how well it may or may not work.



Why Are Clinical Trials Important?

Researchers use clinical trials to help find new and better treatments.

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New treatments must prove to be safe and effective before they can be made widely available.

Carefully conducted clinical trials are the fastest way to find new and better treatments that work in people.

Why Should You Be Interested In A Clinical Trial?

People volunteer to take part in clinical trials for many reasons. First is the hope that by participating in a trial, they will benefit in some way.

There is always a chance that a new treatment will be disappointing. However, based on laboratory results, the researchers have reason to believe that the new treatment will be as good as, or better than, current treatments.

Participants in clinical trials may be the first to benefit from a new treatment.

Often people volunteer because they want to contribute to a research effort that may help others.

How Are Clinical Trials Conducted?

Every clinical trial is designed to answer a set of research questions.

The doctors who conduct a clinical trial follow a study plan called a “protocol.” This spells out what will be done and why. Studies are carefully designed to safeguard the health of the participants as well as to answer specific research questions.

Some clinical trials test one new treatment in one group of participants. Other trials compare two or more groups. Researchers make sure that participants in different groups are similar in certain ways, such as the nature and stage of their disease.

Which treatment each trial participant in a group receives is often decided by a process called “randomization.” It's like tossing a coin, only it's done by a computer. The researchers do not know which treatment is better. From what is known at the time, any one of the treatments chosen could be of benefit to the participant.

One of the groups may receive standard treatment and the other group the new treatment. The group receiving the standard treatment is called the “control” group.

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Sometimes, no standard treatment yet exists. In drug studies of such cases, one group might receive a new drug and the control group, none. But no one is placed in a control group without treatment if there is any known treatment that would benefit the participant.



The control group is followed as often and as carefully as the treatment group.

If there is firm evidence that one method is better than the others in a study, the trial is stopped and the participants in the trial are offered the benefit of the new treatment.

People should consider taking part in a study only after they understand both the possible risks and benefits.

Informed Consent

Informed consent is a process of learning key facts about a clinical trial before deciding whether or not to volunteer for the study.

First, the doctors and nurses involved in the trial explain the details of the study.

Then you are given an informed consent form to read and consider carefully. If you agree to take part, you can sign the form. Of course, you may also refuse.

If you participate in a clinical trial, you will continue to receive any new information about the study that may affect your willingness to stay in the trial. Signing a consent form does not bind you to the study. You can still leave at any time.

If you have questions at any time about any part of the study, be sure to ask your doctors or other members of the research team.

What Protection Do You Have As A Participant In A Clinical Trial?

The ethical and legal codes that govern medical practice apply to clinical trials. In addition, most clinical research is federally regulated with built-in safeguards to protect participants.

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Any well-run clinical trial, is reviewed for patient safety, and scientific merit by the research institution. Every study should provide for monitoring the data and the safety of patients on an ongoing basis.

As a clinical trial progresses, researchers report the results of the trial at scientific meetings, to medical journals, and to various government agencies. Individual participants' names will remain secret and will not be mentioned in these reports.



How To Find Trials Using *ClinicalTrials.gov*

For more information about clinical trials, talk to your doctor and visit the

ClinicalTrials.gov website at <http://clinicaltrials.gov>

ClinicalTrials.gov provides patients, families, and members of the public easy access to information about the location of clinical trials, their design and purpose, criteria for participation and links to further information about the disease and treatments under study.

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