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About Clinical Trials " >

A clinical trial is a research study that is done to find out if a treatment can improve people's health. They are research studies intended to answer scientific questions to help understand whether an investigational treatment is both safe and effective for people with a particular disease or condition. A treatment can be a drug, medical device, medical procedure, or a change in a person's behavior such as diet or exercise.

People who take part in clinical trials are volunteers. They may also be called "participants" or "subjects." When people participate in clinical trials they help contribute to medical research that finds new or better treatments for people with illnesses and diseases. The results of every clinical trial are important because they give researchers more information about the risks and benefits of the treatments in the trial.

Because of participation from volunteers, clinical trials help:

- Develop potential new medicines
- Discover if certain medicines work better than others
- Find new users for already-approved medications

Clinical trials are the fastest and safest way to find treatments that help improve people's health.

Clinical trial execution

Developing a new treatment can take a long time, sometimes even more than a decade. This is to ensure the treatment has been properly tested and is effective and safe enough for the greater public.

What happens before a clinical trial starts?

Before a clinical trial can start, a research plan is created. The plan details what researchers will do in the study and is designed to safeguard the well-being of the participants and to help answer specific research questions.

The research plan is also called the “protocol”. The protocol describes:

- the length of the study
- the rules about who may or may not participate in the trial
- the schedule of tests, procedures, and treatments
- the information the researchers want to collect about the treatment

The protocol is usually reviewed by an independent group of scientists and other professionals. They help make sure that the study will be safe for people with the disease or condition. Once the protocol is approved, the clinical trial can begin and participants can join.

What happens during a clinical trial?

During a clinical trial, the participants receive treatments and have tests done according to the protocol.

Some trials compare a new treatment to a standard one that is already available. Other trials compare a treatment to a placebo. A placebo looks like a treatment but does not have any medicine in it. Some trials just look at a treatment without any comparisons.

Clinical trials can take place in a variety of locations, such as hospitals, universities, doctors' offices, or community clinics. Each location has a research team. The research team includes doctors, nurses, and other health care professionals.

The research team collects information from the participants during the trial to determine if the treatments are safe and effective. It can take months or even years to collect and review all the information.

What are the phases of clinical trials?

Clinical trials are broken down into smaller steps that are called “phases”. There are four phases of trials, ranging from 1 to 4, also written as phase I - IV. Each phase has a different purpose and helps researchers answer different questions. One phase cannot conclude until it meets all of its objectives.

Earlier phases determine the safety of a treatment and any potential side effects, while later stages examine

whether a new medicine is more effective than existing therapies:

- Phase I trials test an experimental drug, vaccine or device in a small group of participants (about 20-80 people) to evaluate safety, identify side effects and determine how the drug should be used or delivered. This phase can last several months.
- Phase II trials involve larger groups of participants than Phase I (about 100-300 people) and they are designed to assess whether an experimental treatment is safe and whether it works. This phase can last several years.
- Phase III trials are usually large studies (about 1000-3000 people) comparing the experimental drug or vaccine to a placebo or standard treatment, to evaluate whether the drug works and collect information to allow it to be used safely. The regulatory health authority, such as the U.S. Food and Drug Administration, will consider the results of clinical trials up to and including Phase III trials when determining whether to approve a new drug or vaccine.
- Phase IV trials are performed once a drug has reached the market, to provide additional information about the best use of the drug, its risks and its benefits.

Glossary of clinical trial terms

There are a lot of words and terms about clinical research that may be new to you. This section provides definitions for words and terms you may want to know.

Review Glossary
