What is a Clinical Trial?

Basic information about clinical trials

What are clinical trials, and why are they important?

Clinical trials are the best way to study new treatments or vaccines to find out if they work and learn how safe they are. If you have ever taken medicine or gotten a vaccine, then you have benefited from clinical trials. Trials can also test new medical devices, surgeries, physical therapies, or diets.

Trials try to answer specific health questions like:

- How safe is a treatment or vaccine?
- Does a treatment work?
- Does a treatment improve patients' quality of life?
- What is the best dose of a treatment?
- Does this treatment work better than existing treatments?

If clinical trials show that a new treatment works and is safe, then it can be approved to be used by the people who need it.

What are the risks and benefits of a trial?

Every clinical trial has different potential risks and benefits. The treatment in a trial may or may not help you, and you may have side effects. Trials take time and may have some costs. All participants help researchers learn more about how a treatment might affect the people who need it.

What happens in trials?

If you agree to participate in a clinical trial, you might receive a new treatment or a treatment that is already approved for public use.

Some trials use a placebo, which looks like a drug or vaccine but does not have any actual drug or vaccine in it. If participants have a condition that needs medical attention, they will not receive a placebo as their only treatment. Participants do not get to choose which treatment they get, and the treatment each participant gets is often decided randomly.

Participants may need to visit the trial site for tests, treatments, and for doctors to check their health. These visits may also happen through telemedicine, at participants' homes.

Before joining a trial

The trial staff makes sure you understand the trial information, including risks, and allows you to ask any questions. This process is called informed consent. If you agree to be in a trial, you may be "screened", which means the doctors will do tests to make sure you can join the trial.

During a trial

During a trial, you will receive treatment, which could be a drug, vaccine, medical device, placebo, or something else. The doctors will do tests, such as taking blood samples or doing scans. You may also need to fill out questionnaires about how you are feeling.

After a trial

After the trial, the doctors may do more tests and measurements to continue checking on your health. You may have follow-up visits, which may be able to happen over the phone.

Ask your doctor about how a trial may affect you. You may also want to talk with your family members, trusted friends, or members of your community.

Being in a trial is your choice

When you sign an informed consent form to participate in a trial, you are not signing your rights away. **Being in a trial is optional.** You can stop at any time and for any reason. The trial staff will help you do this safely.

How does clinical research work?

Researchers want to learn if a treatment can help a certain condition.

Phase 1 and 2 trials

Researchers include small groups of participants to learn how a treatment works and how safe it is. They also find what the best dose of treatment is.

If the treatment is safe, researchers can move to the next phase.

Phase 3 trials

Researchers include larger groups of participants to learn more about whether a treatment works and more about its safety.

If the treatment works and is safe, researchers can move to the next phase.

Approval

A treatment is approved for public use in treating a specific condition by a government agency, which means you may find it in pharmacies or doctors can prescribe it.

Phase 4 trials

Researchers study the treatment even after it is approved to learn more about its risks and benefits, as well as the best way to use it.

Researchers may start this process over with an approved treatment to learn if it can help people with a different condition, or to learn if it can be used in a different way.

If at any point in this process the researchers think that the treatment is unsafe or that the benefits do not outweigh the risks, they will stop the trial.

Who runs clinical trials?

The organization that runs a clinical trial is called a **sponsor**. This could be a drug company, biotechnology company, research institution, or individual doctors. The sponsor is responsible for planning, overseeing, and funding the trial.

Who participates in trials?

Patients

Most trials need patients with the condition the treatment is trying to help. There are also **observational studies** that only collect health data, which means that participants continue their regular health plan.

Healthy volunteers

Some trials ask for "healthy volunteers". These participants help researchers learn how a new treatment acts in the body before giving it to the people it might help.

Children (pediatric trials)

Pediatric trials study a treatment that is already approved for adults to find out if it can help children, or to find the right dose for children.

How are you protected if you participate?

Federal laws protect the safety of clinical trial participants. Clinical trials must:

- Follow laws and guidelines that make sure trials are ethical
- Include a process called informed consent to fully inform people about a trial before they can agree to be in it
- Be approved by an expert group called an institutional review board (IRB) that helps make sure the trial is as fair and as safe as possible
- Follow a carefully developed plan called a "protocol" that has been reviewed and approved by an IRB

How can you find more information?

CISCRP has resources to help you decide if joining a trial is right for you. Visit www.ciscrp.org/resources for brochures, videos, FAQs, and more.

- If you need help finding a trial, we recommend our "How to Find a Clinical Trial" brochure.
- If you already have a trial in mind, we recommend our "Should I Participate?" brochure, which helps you make the best choice for yourself and your family.
- For information on potential costs and reimbursements, see our "Costs and Payments" brochure.
- For other questions, visit ciscrp.org/faqs.

A panel of patients, professionals, and members of the public reviewed this educational brochure.

CISCRP is an independent non-profit organization dedicated to engaging the public and patients as partners in the clinical research process. CISCRP does not recruit patients for clinical trials and does not conduct clinical research. CISCRP is also known as the Center for Information and Study on Clinical Research Participation.
Visit www.CISCRP.org or call toll free 1-877-633-4376

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