

CREATING A LIVING LEGACY

What are clinical trials?

A type of medical study to see if new drugs, devices, and treatments are safe and work in people.



Who is in charge of a clinical trial?

The people who lead a clinical trial are doctors or other people who work in medicine called investigators or principal (lead) investigators.



Why are clinical trials important?

Clinical trials lead to new treatments that help people live longer and healthier lives. Clinical trials also help us learn more about diseases and other health conditions.



Why should I participate?

The race and ethnicity of people that join clinical trials does not always match the race and ethnicity of people that most often have the diseases that are being studied in clinical trials. When there are not enough BIPOC (Black, Indigenous, People Of Color) people joining clinical trials, it is harder to see if the new treatments are safe and effective for these groups. People that join a clinical trial are also usually able to receive the newest treatments and high quality care.



How are clinical trials planned?

The person leading the trial has a detailed description of the plan and procedures for the trial called a protocol. This plan explains how the study will be performed and how the information will be used to decide whether the treatment is safe and works in people.



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What are the different types of clinical trials?

Clinical trials are categorized into four phases or types.

Phase 1:

Phase 1 trials are the first time the treatment is used by people. A small group of healthy people are given the drug to learn about side effects and dosing (how much of the treatment a person should take for it to work). Phase 2:

Phase 2 trials start after Phase 1 trials. The people that take part in these trials have the disease or condition that is being studied. Phase 2 studies see if the new treatment is safe and effective.

Phase 3:

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Phase 3 trials start after Phase 2 trials. These are often the last studies before the FDA decides whether a treatment should be available to everyone. In Phase 3 trials, the drug is given to a larger group of patients with the disease.

Phase 4:

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Phase 4 trials are sometimes called post-market studies and are performed after the drug is available to everyone to provide more information about the drug's safety and how well it works.

How to talk to your doctor about clinical trials?

Just ask! You can ask your doctor if there are any clinical trials in your area that you might be able to join. Your doctor might not be leading a clinical trial as an investigator but they may be able to help you get in contact with someone who is leading a trial or part of a study team.

How do I talk to my family about clinical trials?

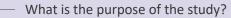
Joining a clinical trial is a big decision! Talking with family can help you make the decision on whether or not to take part in a study. **Here is some information you may want to talk about:**

- Why do you want to join a clinical trial?
- What are the benefits and risks?
- How will you know if the treatment is working?
- What does it cost?
- What happens if you take a placebo?

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Questions you may want to ask your doctor or study team include:



- ____ Who can join the study?
- How will I know that the treatment is working?
- Who will be in charge of my care?
- Has the drug, device, or treatment been tested before?
- What are the possible risks, side effects, and benefits that could happen if I joined the study?
 How might this clinical trial affect
- my daily life?
- Who will pay for my treatment?

