# CLINICAL TRIALS

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EMPOWER • NAVIGATE • ACTIVATE
FOR CLINICAL TRIALS
A collaboration of WomenHeart and The Mended Hearts, Inc.

# FREQUENTLY ASKED QUESTIONS

## About Clinical Trials

Clinical trials are research studies that test whether new treatments are safe and how well they work. These trials help find the best ways to prevent, diagnose, and treat diseases. Since people must volunteer for these studies to test safety and effectiveness, clinical trials are carefully planned and require approval before they can begin.

## 1 Why should I join a clinical trial?

Joining a clinical trial has many benefits:

- **Standard Care:** You get the recommended care for your condition.
- **New Treatments:** You might get new treatments that aren't available to everyone yet.
- **Extra Monitoring:** You are watched closely during the study, which can make you feel safer.
- **Learn More:** You learn more about your condition and how to take care of it.
- **Help Others:** You help discover new treatments that can help many people, including your loved ones.

Clinical trials help find new treatments, improve medical care, and give the best care to everyone in the study.

## 2 How do clinical trials work?

Every clinical trial is different, but here are some common steps and key points:

- **Principal Investigator (PI):** A PI oversees the trial to ensure it follows the plan.
- **Trial Coordinator:** This person connects with you most often during the trial.

**Informed Consent:** When you join, you receive detailed information about the study. This includes an "informed consent" process to ensure you understand the trial's details, potential risks, benefits, and your rights. You can leave the trial at any time, even after signing the consent form.

**Randomization:** Participants are often put into different groups randomly. One group gets the treatment being studied, and another gets a placebo (something that looks like the treatment, but isn't). This method helps researchers compare treatments fairly.

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## 3 Where can I find out about clinical trials?

To find out about clinical trials you might be eligible for, you can ask your doctor, local medical center, medical university, or look at online databases like ClinicalTrials.gov. Patient advocacy groups can also share information about trials specific to your condition. It's important to talk to your doctor about whether a clinical trial is a good option for you. To learn more about a specific trial, you can contact the trial coordinator.

## 4 How do I find and get to a trial location?

Trial locations are usually at hospitals, universities, or research centers. Your doctor can help you find a trial site, and some trials may offer help with transportation or compensation for your time. Note that the trial site may be in a different place from where you usually get care.

## 5 Once enrolled, why is it important to stay in the clinical trial?

Staying in a clinical trial gives you access to new treatments that may not be available to others yet. Staying enrolled helps make sure the data collected is accurate and helps researchers make valid conclusions. Your information is very important, so try to stay in the trial if possible. If you have any questions or concerns, you can contact the trial coordinator.

## 6 How can I get the results of the clinical trial I am in? What if the treatment is not approved?

After a clinical trial ends, researchers analyze the data and publish the results. Participants usually get a summary of the findings. If the treatment isn't approved, it might mean the trial didn't show it was safe or effective, or that more information is needed. It doesn't necessarily mean the treatment isn't good. The trial coordinator can tell you about any next steps, and your doctor can help you decide the best treatment after the trial.

**ENACT: Empower, Navigate, Activate for Clinical Trials** is an initiative to boost awareness and participation in cardiovascular clinical trials, especially among underrepresented groups like people of color and women. Funded by Cytokinetics, this project is a collaboration between The Mended Hearts, Inc. and WomenHeart, providing education, support, and empowerment to patients with the goal of reducing barriers and improving experiences in clinical research.

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