CLINICAL TRIALS RESULT IN PROVEN INNOVATIONS

WHO WE ARE

Mended Hearts® is the largest cardiovascular peer-to-peer support non-profit organization in the United States. Along with its program, Mended *Little* Hearts, Mended Hearts is the only organization in the nation that supports cardiovascular disease patients and their families throughout the entire lifespan of the patient.

Our volunteers inspire, educate, and provide hope to hundreds of thousands of patients and family members each year. We are a trusted source of patient and family education on living with heart disease.

The Mended Hearts, Inc.

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CLINICAL TRIALS

WHAT ARE CLINICAL TRIALS AND WHY DO THEY MATTER TO HEART PATIENTS?

LEADING THE WAY

Advancing Innovation Through Clinical Trial Education

The Mended Hearts, Inc.

WHAT?

A clinical trial is a way to test an **intervention**—a new drug, device (like a pacemaker), a new procedure, or even changes in behavior—to see what its impact is by following a research plan. The intervention also might be an existing drug, device or procedure used for a different disease or in a different way. In a clinical trial, researchers might be testing for safety and effectiveness of the intervention, or they may be testing to see what the benefits of the intervention might be and how it might improve lives. The intervention is often compared with a different intervention that already exists or with no intervention. Often, some trial participants are given a **placebo**, a harmless drug, device or procedure so participants don't know whether or not they are getting the intervention being tested. When people are given the intervention or no intervention (or a placebo) at random, this is called "**randomization**."

WHY?

There are many myths and misunderstandings about clinical trials that may prevent patients from asking about them and participating in them. Some believe that clinical trials are only for patients with no other options or that they are too risky—neither is true. In fact, almost all cures for diseases, including drugs and devices, to keep people who have diseases healthier were created through clinical trials.

Clinical trials are vital to finding new treatments and cures for chronic diseases, including heart disease and diabetes. They are also the most important way we can make sure new drugs or devices are safe and effective. As the main goal of most clinical trials it to improve the lives of people with diseases and to help them live longer, they are a significant benefit to the cardiovascular disease community.

WHO?

Someone called a principal investigator (PI) usually leads a clinical trial. This person is typically a doctor. Other healthcare professionals, like social workers, nurses, and other doctors, will often be part of the research team.

WHERE?

Clinical trials often take place in hospitals, clinics, doctors offices and universities, but they can take place in different locations.

WHY PARTICIPATE?

People have different reasons for participating in clinical trials, but some of the main reasons are:

- advancing science and helping others
- access to new medications and devices
- to play a more active role in their healthcare
- no options currently available for treatment of their disease
- to help bring new medications and devices to market

MORE INFORMATION CAN BE FOUND AT: CLINICALTRIALS.GOV

PARTICIPATION

In a recent study of 1081 patients:

95%
trial participation was worth it

90%
would do it again

65%
said their quality of life was improved

QUESTIONS TO ASK

- Can you tell me about any clinical trials that would be right for me?
- What is the purpose of the trial?
- Where does the trial take place?
- Who is leading the trial?
- What are my responsibilities if I participate?
- What are the risks and benefits of the trial?
- How long is the trial?
- Who can I talk to for more information?