

CLINICAL TRIALS

What Are Clinical Trials?

Clinical trials are medical research studies that find ways to more effectively prevent, diagnose or treat diseases in humans. Clinical trials measure the safety and effectiveness of new medications or new uses of existing medications, medical devices, or tests and procedures for diagnosing illnesses.

Phases of Clinical Trials

Clinical trials are done in phases. There are four phases in which experimental medications, devices or tests are conducted. Phase 1 includes 20 to 80 people. Phase 2 includes 100 to 300 people. Phase 3 includes 1,000 to 3,000 people. Each phase is designed to test for safety, side effects, and effectiveness.

If the experimental treatment works well in a Phase 3 trial, researchers can apply to the U.S. Food and Drug Administration (FDA) to ask for permission to make the treatment available to the public. After approval, Phase 4 begins in which researchers collect information they have about the experimental treatment's long-term safety and effectiveness after the drug is approved.

Clinical Trial Participation

The decision to participate in a clinical trial should involve talking to your doctor, your family and caregivers, the clinical trial team and sometimes your insurance company to see if it is an option for you. Another important person to talk with is the clinical trial coordinator, whose role includes providing important information to the people who take part in these studies.

Every clinical trial has guidelines and requirements about who can participate, depending on the goals of each trial.

Clinical Trial Benefits

Potential benefits of participating in a clinical trial include:

- Access to new research treatments
- Access to specialists and/or expert care
- Contributing to medical research that can help others

Clinical Trial Risks

Potential risks of participating in a clinical trial include:

- Serious side effects
- Unsuccessful treatment outcome
- Inability to participate in other trials

To learn more about clinical trials, scan the QR code below. For a complete list of all of our free resources, please visit: liverfoundation.org/resource-center.

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For questions about liver wellness and disease, or for emotional support to patients at the point of crisis and information on local resources including physician referrals, please contact our Helpline at 1-800-465-4837.

