# What are the phases of clinical trials?

New drugs are first discovered and tested in the lab. After this "preclinical" work, the phases of development include:

## BEFORE PHASE 1:

- For children and adolescents, the investigational drugs generally have already been tried in adult patients

## PHASE 1:

- Many Phase 1 studies involve healthy volunteers while others may involve people who have a specific illness where no known therapy exists
- Find out whether the drug is safe to continue studying
- Identify side effects
- Determine appropriate doses

## PHASE II:

- Studies involve patients with the specific condition/diagnosis
- Start testing whether the medication works in the patients with the disease of interest
- Continue monitoring for side effects
- Get information that goes into designing a larger Phase III trial including the selection of the most effective dose

## PHASE III:

- Confirmation of how well the drug works in treating patients at the selected dose
- Some Phase III trials may compare the new drug to existing medicines for the same condition
- Continue monitoring for side effects
- Once complete, FDA approval can be requested to make the new medicine available to the public

## PHASE IV:

- Roughly 25 to 30 percent of medications move on to Phase IV
- At this stage, the drug is already approved for patient use
- Research continues to keep gathering information on its long-term effects and safety

Please visit **www.nih.gov/health-information/nih-clinical-research-trials-you** for more information on clinical trials.

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# Understanding CLINICAL TRIALS

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Clinical trials are studies that collect data to determine if a new drug is safe and effective. Clinical trials are essential research practices for advancing science, enhancing medical knowledge and improving patient care.

## Why join a clinical trial?

People's involvement in clinical trials helps researchers uncover better ways to treat, prevent, diagnose and understand different diseases and medical conditions. People take part in clinical trials for many reasons. For example, you could advance understanding of a disease and help others like yourself. You may also receive a new research treatment before it becomes widely available.

Clinical trials can also have risks. For example, the investigational medication may not help you or it could have side effects. In some Phase III studies, it's possible you may receive a placebo instead of the study medication. A placebo is a pill or substance with no active ingredients and is not expected to have any real medical effect. You would be made aware of this possibility before starting a research trial.

You should speak to your doctor to learn about the risks and benefits of a clinical trial before making the decision to participate.

## What is involved in my participation in a clinical trial?

Each clinical trial is different and follows a plan known as a protocol. The protocol is carefully designed, usually reviewed and approved by the U.S. Food and Drug Administration (FDA) and other relevant government agencies outside the U.S., and includes:

- The goal of the trial
- Who is eligible to take part in the trial
- Protections against risks to participants
- Details about the tests, procedures and treatments
- How often you are to visit the clinic or hospital
- How long the study is expected to last
- What information will be gathered

Before you decide whether to participate in a clinical trial, you will be given an **informed consent form,** which provides key information about the study and the drug under investigation. Members of the research team at your doctor's office should explain what will happen during the trial and walk you through the informed consent, which you will be asked to sign should you decide to participate in the trial.

While participating in a clinical trial, it is important to follow the schedule and instructions provided by the research team. It is also important to remember that taking part in a clinical trial is voluntary and you can decide to leave the study at any time.

## How long do clinical trials last?

The length of each clinical trial is different. The informed consent document will explain how long the trial is expected to last, how often you will need to go in for appointments, and what to expect at each appointment.

## How do I find a clinical trial?

A conversation with your doctor is the best place to start. There are also several websites that contain information about clinical trials, including the National Institutes of Health and **Clinicaltrials.gov.**

## Are there costs associated with taking part in a clinical trial?

Study-related medication and medical care administered under the protocol as part of the trial are free of charge.

## Will I find out the results after the trial is over?

After a trial is complete, you can ask the research team members at your doctor's office if the study results have been or will be presented at a scientific meeting, published in a scientific journal, or otherwise disclosed by the study sponsor. Patient advocacy groups can also be a good resource for finding out the latest information on clinical trials, including the results of a recent trial.

Please also visit **www.nih.gov** for more information on clinical trials.

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