

# Clinical Trials, What They Are and Why They Are So Important...

Clinical trials are research studies that test a medical, surgical, or behavioral intervention in people. These trials are the primary way that researchers determine if a new form of treatment or prevention, such as a new drug, diet, or medical device, is safe and effective in people.

## There are 4 Phases of Clinical Trials:

### Phase I Clinical Trial:

Doctors do a phase I clinical trial to learn if a new drug, treatment, or treatment combination is safe for people. They may have already tested it in laboratory animals. These trials usually last several months to a year. They usually have 10 – 30 volunteers. Doctors collect information on the dose or treatment, when and how often you take it, and any side effects.

### Phase II Clinical Trial:

A phase II clinical trial tells doctors more about how safe the treatment is and how well it works. A Phase II clinical trial lasts about 2 years. Volunteers sometimes receive different treatments. For example, a phase II trial could have 2 groups.

- Group 1 – People who receive the usual treatment for the condition. This is also called the standard treatment. It is the best treatment known.
- Group 2 – People who receive the usual treatment plus the new treatment doctors are studying.

Or a phase II clinical trial could have 3 groups. Volunteers in each group get a different dose of the treatment doctors are studying.

If the phase II clinical trial shows the treatment works and is as safe as the regular treatment, doctors can do a phase III trial.

Doctors use computers to randomly put volunteers into different groups. This ensures the researchers do not manipulate the study.

### Phase III Clinical Trial:

A phase III clinical trial tests a treatment that worked well for volunteers in a phase II clinical trial. Doctors use phase III to compare the new treatment with the standard treatment. They want to know if the new treatment is better, has fewer side effects, or both.

Phase III clinical trials can take many years and may have several thousand volunteers. These should include men, women, and people of different ages and ethnic groups. This helps doctors learn how the treatment works in different people.

If a phase III clinical trial shows the treatment works well, doctors might begin using it with people outside the clinical trial. For example, if they learn that a certain amount of exercise lowers your cancer risk, they publish a report. This shares the information with other doctors. If the researchers or sponsor learn a new medicine is safe and effective, they can ask the government to approve it for people to use. In the United States, they ask the Food and Drug Administration (FDA). The FDA looks at the results of the clinical trial's phases. They approve the treatment if the results meet their standards.

### **Phase IV Clinical Trial:**

Doctors can prescribe a drug for their patients after the FDA approves it. But the FDA may require the sponsor to keep studying that approved treatment. In these clinical trials, doctors may check if the treatment benefits people as much as it did earlier. These clinical trials are called phase IV clinical trials.

In a Phase IV clinical trial, doctors might study the drug or treatment in different doses, or with other drugs or treatments. They might study it in different people than earlier trial, for example, children or older adults. Doctors can also study how well a drug or treatment works overtime.

Drug makers may do phase IV clinical trials even if the FDA does not ask them to. They might do this to get FDA approval to use the drug in a new way.

Phase IV clinical trials can also check the safety of drugs or treatments being used now. They do this to make sure drug makers report any new or serious side effects. The FDA may take away a drug's approval if new research shows it is not as safe or effective as earlier testing showed. Doctors cannot prescribe it any longer if this happens.

### **Do I need to be in all the phases of a clinical trial?**

No. You can join any phase of a clinical trial if you qualify to join. For example, you may join a phase II clinical trial whether you were in phase I, or not.

You always have a choice to be in the clinical trial, and you may leave at any time.

