How are clinical trials done?

Every clinical trial follows a plan that details what researchers will do in the study and is designed to safeguard the well-being of the participants and to help answer specific research questions.

Accordion:
What happens before a clinical trial starts?

Before a clinical trial can start, a research plan is created. The plan details what researchers will do in the study and is designed to safeguard the well-being of the participants and to help answer specific research questions.

The research plan is also called the "protocol". The protocol describes:

- the length of the study
- the rules about who may or may not participate in the trial
- the schedule of tests, procedures, and treatments
- the information the researchers want to collect about the treatment

The protocol is usually reviewed by an independent group of scientists and other professionals. They help make sure that the study will be safe for people with the disease or condition. Once the protocol is approved, the clinical trial can begin and participants can join.

What happens during a clinical trial?

During a clinical trial, the participants receive treatments and have tests done according to the protocol.

Some trials compare a new treatment to a standard one that is already available. Other trials compare a treatment to a placebo. A placebo looks like a treatment but does not have any medicine in it. Some trials just look at a treatment without any comparisons.

Clinical trials can take place in a variety of locations, such as hospitals, universities, doctors' offices, or community clinics. Each location has a research team. The research team includes doctors, nurses, and other health care professionals.

The research team collects information from the participants during the trial to determine if the
treatments are safe and effective. It can take months or even years to collect and review all the information.

What are the phases of clinical trials?

Clinical trials are done in steps that are called “phases”. There are 4 phases of trials. Each phase has a different purpose and helps researchers answer different questions:

- **Phase I** trials test an experimental drug, vaccine or device in a small group of people to evaluate safety, identify side effects and determine safe dosages.
- **Phase II** trials involve larger groups of people than Phase I and they are designed to assess whether an experimental treatment is safe and whether it works. This phase can last several years.
- **Phase III** trials are usually large studies comparing the experimental drug or vaccine to a placebo or standard treatment, to evaluate whether the drug works and collect information to allow it to be used safely.
- **Phase IV** trials are performed once a drug has reached the market, to provide additional information about the best use of the drug.

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