

CLINICAL TRIAL PHASES, PROTOCOLS & PATIENT SAFETY

Phases of a clinical trial are the building blocks developed to help researchers learn the benefits and risks of new treatments while assuring the safety of the participants. Beginning with a pre-clinical study, a clinical trial may be launched. This trial designed to answer certain questions about a drug or treatment and if it is successful it will advance from phase I to phase IV. When the US Food and Drug Administration (FDA) gives permission to test a drug or treatment on a population, researchers are required to follow strict [regulations and guidelines](#) and establish rules and terms unique to each trial, they are known as protocols.

Protocols include what drugs and dosages are used, schedules for testing and/or procedures, how long the trial will last and what researchers hope to learn. A clinical trial from start-to-finish can take months or years. Protocols are set to ensure that a clinical trial is as safe as possible throughout the entire process. Additionally, a clinical trial is monitored by scientific experts, an Institutional Review Board and Data & Safety Monitoring Boards.

CLINICAL TRIAL PHASES

Pre-clinical or laboratory studies tests human or animal cancer cell growth

Pre-clinical studies help determine the effect of a new treatment using cells in a test tube or petri dish. Animal studies may be used to also determine the reaction in a living creature. To advance to a clinical trial tested on people, the FDA must give permission.

Phase 0 trials explore testing a new drug in small doses with frequent testing

Phase 0 tests fewer people with smaller doses to determine how a drug acts in the human body and how human cancer cells respond. The study may require additional gathering of data such as biopsies, scans and blood samples. This phase may be more beneficial to future patients rather than those participating.

Phase I trials begin testing safe dosages on patients

Phase I of a clinical trial tests a new drug or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range and identify side effects.

Phase II trials determine whether a treatment is working

Phase II focuses on whether the drug or treatment works in people who have specific cancers, diseases or conditions. Participants receiving the new drug or treatment may be compared with similar participants receiving a different drug or treatment.

Phase III trials compare whether a new treatment is better than current treatments

Phase III studies a large group of people to confirm effectiveness, monitor side effects, compare to commonly used drugs or treatments and collect information that will allow the drug or treatment to be used safely.

Phase IV trials explores what is still unknown after the treatment is approved for the public

Phase IV studies are conducted after a drug or treatment has been approved by the FDA for the general public. These studies provide more information on side effects, the long-term risks and benefits and how well the treatment works on a larger population.