

The clinical testing of new drugs is usually done in three initial phases by research sites carefully selected by the pharmaceutical company doing the research. It is only after this required testing has been completed that a drug is submitted to the FDA for approval.

Phase I studies are mainly concerned with determining the safety of a new drug. This first phase involves only a few healthy volunteers, usually from 20 to 80. This phase is designed to assess what occurs to the drug in the human body as well as examine the side effects that occur as dosage levels are increased.

While Phase I determines the primary safety of a new drug it's in Phase II that researchers begin to test its beneficial effects. This phase of testing may involve up to several hundred patients who have the health condition that the study drug is being developed to treat, and last from a few months to two years. Most phase II studies will have one group of patients who will receive the experimental drug, while a second "control" group receives a placebo. Usually in these studies neither the patients nor the researchers know who is getting the experimental drug. This "double blind" study is to prevent any subconscious influence the patient or the researchers might have on the results.

A phase III study involves large-scale testing in usually several thousand patients. The purpose of this phase is to develop a more comprehensive understanding of the study drug's effectiveness, benefits, and the range of possible adverse effects. Phase III studies can last several months to several years and is the final phase of testing before a drug can be submitted to the FDA for approval.

(To be continued)

To learn more about medical research and what studies are currently enrolling participants please visit the website of Horizons Clinical Research Center, LLC www.horizonscrc.com or call 303-399-4067.