

MARG

Medical Associates Research Group, Inc.

8008 Frost Street, Suite 200
San Diego, CA 92123
Phone 858-277-5678
Fax 858-277-2317

Difference between Phase I, II, & III Trials

A clinical trial (or study) consists of three phases. Even before any of the phases begin, treatments are thoroughly tested in labs, sometimes on animals, in order to gather valuable information about the toxicity of the investigational treatments.

Phase I studies are done to identify the proper dosage ranges for which an investigational drug can be administered while monitoring and studying the method of absorption and possible toxicity of a new treatment. In Phase I studies, an investigational drug is tested for the first time in small numbers (usually between 20 and 100 subjects) on healthy volunteers. Volunteers are administered the study drug in a single dose to start, with dosages gradually increasing until minor side effects occur. This gives researchers valuable information on how the drug interacts with the body while also alerting them to the common side effects. Participants in Phase I studies are often confined for 24 hour periods at special overnight research centers where they are closely studied and monitored with frequent blood and urine tests.

MARG does not currently do any Phase I studies.

In Phase II studies, researchers begin to understand the safety and effectiveness of the investigational drug being tested. Phase II studies also deal with a relatively small number of subjects, usually between 100 and 300 patients that have the targeted disease or condition. Like Phase I studies, safety is the main goal of these trials. Phase II studies can often take between one and three years to complete and are geared towards adjusting treatment doses. Researchers are also looking to monitor common side effects and whether patients improve as a result of the drug. In Phase II studies subjects are randomized, or assigned to different groups. One of the groups receives the study drug while the other group, or control group, will receive the standard treatment or a placebo for part or possibly the duration of the study. Phase II studies are usually double-blinded, which means neither the patient nor the researchers know whether a patient is receiving the investigational drug or a placebo/standard treatment. Only about 1/3 of drugs that enter clinical testing complete the Phase II process.

Phase III studies provide the facts about an investigational drug through extensive testing of the safety, efficacy, and proper dosage levels in a large group of patients with a specific illness or disease. In a Phase III study the investigational drug may be tested on several thousand subjects over a two to five year span. In Phase III, the goal is to have practicing physicians evaluate the investigational drug and its positive and negative effects. Often times the Phase III research includes evaluating the safety and effectiveness of treatment on various subsets of patients such as men versus women, African American versus Caucasian, elderly versus young, etc. Many drugs tested in Phase III may already be approved by the FDA but are being evaluated against a placebo or the existing standard treatment for the particular illness or disease. Treatments that have reached Phase III have already passed toxicity testing and have proved to be at least somewhat effective. About 80% of drugs that enter Phase III will successfully complete it.