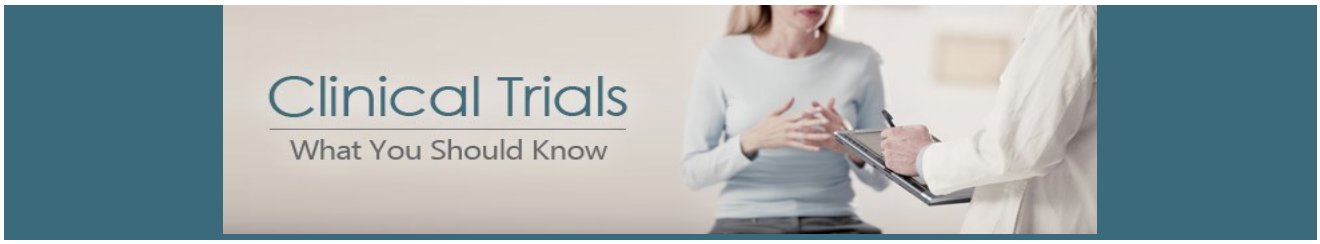

A Clinical Trial is a study of new drugs, combinations of drugs (some already FDA approved for other purposes) and/or treatments to see how well they work - especially when compared with current standard of care treatment. Each trial has a **protocol** which explains what the trial will do, how the trial will be conducted, location of the study, eligibility criteria, and how and when the participants will be evaluated.

An independent committee of physicians (**Institutional Review Board**), statisticians and members of the community must approve and monitor the protocol. They make sure that the risks are small and are worth the potential benefits. Also, many trials are supervised by a Data and Safety Monitoring Committee made up of experts in the trial's field. Congress has passed laws to protect study participants and rules are enforced by the Federal Government. Also, the **informed consent** process, whereby patients are told before joining a trial what to expect and all the things that might happen, helps protect patients. This process is where the patient has the opportunity to ask their questions about the trial. If, after hearing all this information, the patients decide to join the trial, they will sign the informed consent form. It is not a contract and they can leave the trial at any time.

Sponsors of clinical trials include such groups as physicians, single institutions, organizations like the National Cancer Institute, government agencies like the Department of Veterans Affairs, and biopharmaceutical manufacturers.

Clinical trials are done to gather information for many purposes. The purpose of the trial defines how it will be conducted. The different **types** of trials are: Treatment (new treatments, drugs, therapies); Prevention (ways to prevent diseases); Diagnostic (better tests to diagnose diseases); Screening (best way to detect diseases); Quality of Life (ways to improve quality of life).

Clinical trials are designed in **phases** (1-4) to test the new treatments being proposed. As results are obtained, the trial moves to the next phase. They are: Phase 1 (to determine how the drug or treatment will be administered); Phase 2 (to determine its effectiveness); Phase 3 (to determine if one treatment is better than another); Phase 4 (to monitor long-term safety and effectiveness). As a drug or treatment advances in each phase of a clinical trial the number of institutions, or facilities, offering the trial increases. Major medical centers across the nation participate in Phase 2, 3 and 4 trials.

The FDA (Food and Drug Administration) requires all new drugs or treatments complete multiple years of testing before approving them. All current drugs have been through Clinical Trial testing at some point to achieve the standard of care label from the FDA.

Each clinical trial has ***eligibility criteria,*** which are requirements that patients must meet before they can participate. Eligibility criteria might include information about: age and gender; previous treatments that you must, or must not, have had; length of time since you last received treatment; results of certain laboratory tests; medicines that you are taking; other medical conditions; previous history of any other autoimmune diseases; other conditions that are specific to each clinical trial

Many insurance policies do not provide coverage for clinical trials that are considered Experimental and/or Investigational. Some policies may cover trials in certain stages - for example, coverage for Phase 3 or Phase 4 trials. Health plans may specify specific criteria a trial must meet to be covered. So check the pertinent language in your insurance policy to determine coverage if any and discuss insurance coverage with the study coordinator.

Clinical trials can offer patients a chance to participate in cutting edge treatments, before they are available to the general public. Other benefits— participants play a more active role in their own health care, are provided medical care and more frequent health check-ups and have the chance to help others in the future. On the other hand, participants need to consider having serious side effects, not being in the treatment group but in the control group (receiving a placebo) and time needed and distance to travel to be in the trial.

To find on-going trials go to clinicaltrials.gov. If you find a clinical trial you might qualify for, talk to your doctor, or contact the clinical trial's principal investigator or research nurse.

Edited for brevity from "A Practical Guide to Clinical Trials" from the Patient Advocate Foundation