

Clinical Trials

by: Jack Kavanagh

We have all heard of clinical trials, and possibly a few of you have actually participated in one. Often pharmaceutical companies will announce that a drug they have developed is “now in clinical trials.” Just what does this mean?

Pharmaceutical companies with new drugs are required to furnish evidence to the Food and Drug Administration that the drug is safe and effective for the illness targeted before they can market it to the general public. They do this by means of a series of clinical trials. All participants are volunteers, and often have the illness that the drug is targeting. Typically, there are four phases to a complete clinical trial of a drug.

Phase I: If a drug shows some promise during animal or laboratory testing, it is a candidate for clinical trials. Phase I trials are designed primarily to test the safety of the drug in humans. Various dosages are used, and side effects are monitored carefully. These tests usually have a very small number of participants.

Phase II: If the drug can be used in humans without devastating side effects, it will move to Phase II trial. There are many more participants, and the prime objective is to determine the effectiveness of the drug. Safe dosages are determined, and side effects are observed and recorded.

Phase III: Assuming Phase II results are good, the drug will move into Phase III trials. This last phase, prior to approval, involves a larger numbers of participants. This phase is conducted to confirm that the drug is safe to put on the market, and to finalize dosages and identify other possible side effects.

Phase IV: After a drug has been approved by the FDA and is on the market, there may be an additional follow-up survey to rate its effectiveness and to uncover any unexpected side effects.

Clinical trials vary in length and number of participants. They may be stopped at any phase if effectiveness is not demonstrated, or if side effects are too severe. Although they may seem long and tedious at times, they are done to safeguard the general public.