Human Clinical Trials

**Introduction:** Human clinical trials are an important component of the biomedical research process and are most often used in developing prescription drugs. Even after a promising new drug has undergone extensive laboratory research and testing, scientists still need actual human data from controlled studies to answer two key questions: Is the drug biologically active in humans? And, is it safe in humans?

There are three major phases of clinical trials that begin after a pharmaceutical firm files an Investigational New Drug (IND) application with the Food and Drug Administration (FDA). In the IND, a pharmaceutical firm shows the results of laboratory testing and explains how the drug is made.

In **Phase I** clinical trials, researchers determine a drug’s interaction with the human system, including how it is absorbed, distributed, metabolized and excreted, and the likely duration of its therapeutic effect. This phase involves a small number of healthy volunteers and takes approximately one year.

**Phase II** trials use controlled tests that help determine a drug’s effectiveness. These studies involve 100 to 300 volunteer patients. Simultaneous animal and human tests are also conducted at this stage as researchers continue to assess the safety of the drug. This phase takes approximately two years.

**Phase III** trials are conducted to confirm the results of earlier efficacy tests and further identify any adverse reactions. Clinical testing at this point is extensive, involving 1,000 to 3,000 volunteer patients in medical clinics and hospitals. This phase takes approximately three years.

After human clinical trials are completed, firms file a New Drug Application (NDA) with the FDA. The NDA is a comprehensive statement of the information on: drug structure, the scientific rationale and purpose of the drug therapy, pre-clinical animal and other laboratory study results, all human clinical testing results, drug formulation and production details and the company’s proposed labeling. This takes approximately 2.5 years to complete.

Currently, it takes approximately 12 years from initiation of animal and other laboratory studies through all phases of clinical trials and submission of data to the FDA for approval: For each new medicine approved, the cost is hundreds of millions of dollars.