Very few people are aware of the process of discovery and development of drugs. Well, here is a brief introduction to the process of drug development although the process itself takes years.

A new drug is first tested in animals. If animal studies reveal adequate efficacy and reasonable safety, then it is subjected to further testing in human beings. However, a drug cannot be used directly in a population just on the basis of successful animal studies because results of animal studies cannot be extrapolated in totality in human beings due to differences in anatomy, physiology and biochemistry. This is one of the most important differences between modern medicine and traditional systems of medicines.

**Phases of Clinical Trial**

Clinical trials are mainly divided into four phases. Phases I–III are pre-marketing studies and phase IV is the post marketing study. The clinical trial is a teamwork and includes doctors, clinical pharmacologists, paraclinical staff, health care professionals and social workers.

The team screens volunteers for participation and owns the total responsibility for the safety of trial participants. The trial is started after approval of regulatory authorities and depends on the protocol approved by regulatory authorities.

**Phase I:** In the first phase, evaluation of the new drug is performed on a small number (20-25) healthy volunteers. If the drug is expected to have significant toxicity (as in case of anticancer drugs or anti-HIV drugs), the volunteers with particular disease are taken rather than healthy volunteers.

**Phase II:** In phase II, the drug is studied for the first time in patients with the target disease to determine its efficacy. These trials are divided into EARLY and LATE phases.

In Early phase, a small number of patients (20-200) are studied in detail to observe the potential therapeutic benefits and side effects. In Late phase, trials are conducted on a larger number of patients (50-300) to ensure safety and efficacy of the new drug in a specific disease.

Data of Phase II is compared with that of standard drug (in market) used for the same disease.

**Phase III (Confirmatory trial):** These are large-scale randomized control trials in patients (250-1000 plus) to further establish safety and efficacy.

Phase III trials are conducted by a large number of clinicians at different centres. It may take an average of five years to be completed. At the end of this trial statistical analysis is performed. And then, NEW DRUG APPLICATION is filed to drug control authorities after satisfactory completion of Phase III trials.

**Phase IV (Post Marketing Study):** Once approval is obtained to market the drug, Phase IV of the trials begins. It is the post-licensing phase-field trial.

Phase IV has no fixed duration as it is the surveillance phase during the post-marketing clinical use of the drug. This is based on reporting by all physicians. The performance of the drug is monitored for several years, immediately after marketing, to discover relatively rare side effects (e.g., congenital effects) or previously unknown drug interactions or even a previously unknown therapeutic use detected by a chance discovery.

Clinical trials are the safest way to find efficacious treatment. With increasing globalization many multinational companies are trying to conduct clinical trials in developing countries like India to reduce their cost-related inputs. This can provide new career opportunities to those interested in this field but it also raises concerns regarding safety issues of participants.