Phase 1 Clinical Pharmacology Studies

Clinical pharmacology is the scientific discipline that deals with the relationship between drugs and humans. Clinical pharmacology is a clinical development science in pharmaceutical research, and it connects the laboratory research with the clinical practice in order to bring promising drug therapies to the market. Clinical pharmacology studies are one of the most interesting clinical studies conducted during the clinical development of any new pharmaceutical product. Depending upon the pharmacological or therapeutic class of the product, these studies mainly involves different kinds of phase 1 studies.

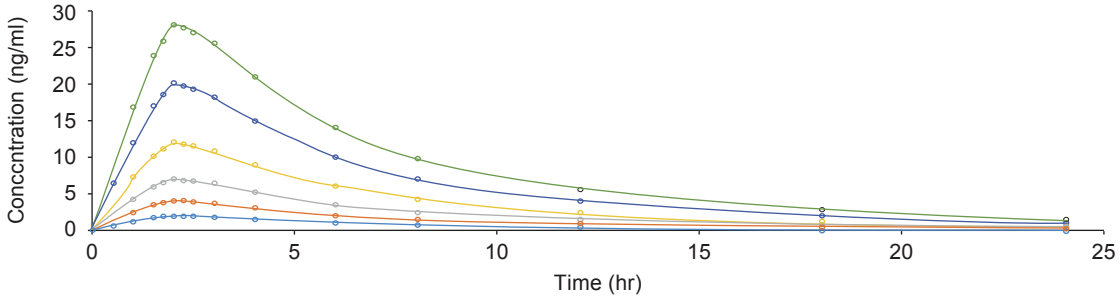
Clinical Pharmacology

These clinical pharmacology studies are very specialized studies and are conducted with specific objectives to understand safety, tolerability, pharmacokinetics and / or pharmacodynamics of the drug. Not only designing of such studies, but conducting, analysing and interpreting results of such studies are challenging. Designing such studies requires understanding of basic and clinical pharmacology as well as understanding of feasibility of conducting the studies. Conducting such studies requires knowledge and clinical skills. Bioanalytical knowledge and skills are required for bioanalysis in order to estimate the drug and / or metabolites of interest. Knowledge of pharmacokinetics, pharmacodynamics and biostatistics is required for data analysis and interpretation.

Clinical:

Bioanalytical:

Pharmacokinetics:



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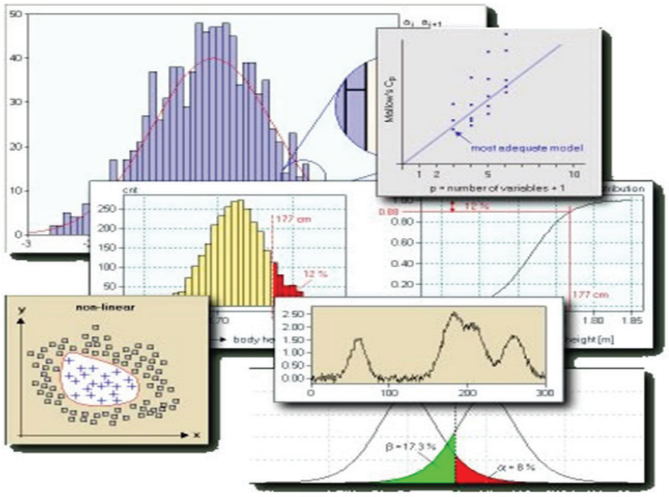
Pharmacodynamics:

Statistics:



Early phase clinical pharmacology studies are mainly proof of mechanism (POM) studies and are normally done within phase I clinical development program in healthy volunteers. These studies are designed to show that a new medicine reaches its target organ(s), interacts with its molecular target and affects the biology of the target as intended. Phase 1 clinical pharmacology studies are mainly early phase exploratory studies conducted with following objectives.

- To find Maximum Tolerated Dose (MTD) in human
- To study adverse effects
- To study pharmacokinetics
- If possible, to study pharmacodynamics

First-in-human (FIH) clinical studies are part of the exploratory phase of drug development and represent a significant milestone in the clinical development of new medicines. FIH Studies in which the new compound is first studied in cohorts of healthy volunteers or patients with single increasing dose are called SAD studies. The objectives of SAD studies are to study safety, tolerability and pharmacokinetic of the investigational product administered in single dose. Studies in which the new compound is administered in cohorts of healthy volunteers or patients in multiple administrations with increasing multiple dose are called MAD studies. The objectives of MAD studies are to study safety, tolerability and pharmacokinetic of the investigational product administered in multiple doses. Objectives of such dose escalation studies is to find maximum tolerated dose (MTD), to check tolerability upto certain dose and / or to find the recommended phase 2 dose (RP2D).