Pharmacology

Pharmacology is a branch of medicine, biology and pharmaceutical sciences concerned with drug or medication action, where a drug may be defined as any artificial, natural, or endogenous molecule which exerts a biochemical or physiological effect on the cell, tissue, organ, or organism.

Modern pharmacologists use techniques from genetics, molecular biology, biochemistry, and other advanced tools to transform information about molecular mechanisms and targets into therapies directed against disease, defects or pathogens, and create methods for preventive care, diagnostics, and ultimately personalized medicine.

Pharmacokinetics vs. Pharmacodynamics

The main difference between pharmacokinetics and pharmacodynamics is that pharmacokinetics (PK) is defined as the movement of drugs through the body, whereas pharmacodynamics (PD) is defined as the body's biological response to drugs.

In other words, PK describes a drug's absorption, distribution, metabolism, and excretion (also known as ADME) and PD describes how biological processes in the body respond to or are impacted by a drug. Put in the simplest terms, pharmacokinetics is what the body does to the drug and pharmacodynamics is what the drug does to the body.

While PK describes a drug's *exposure* by characterizing its ADME properties and bioavailability as a function of time, PD describes a drug's *response* in terms of biochemical or molecular interactions. PK/PD together can be thought of as an *exposure/response* relationship.

Understanding the exposure-response relationship (PK/PD) is key to the development and approval of every drug. PK and PD data contribute to about 25% of what is in a drug package insert or drug label. Strategic planning of the overall drug development program and an intelligent pharmacokinetic study design can accelerate the development process to help ensure safety and efficacy endpoints are achievable.

The Importance of Pharmacokinetic and Pharmacodynamic Analyses

PK and PD analyses are important because they help us understand how drugs behave in the body and how the body reacts to drugs, respectively. Drug developers use insights gained from PK and PD analyses to design better clinical studies (i.e., what dose to use or how different drugs interact with each other in the body). Clinicians use the information from PK and PD analyses (as presented in the drug label or package insert) to treat different types of patients (e.g., patients with and without renal impairment or elderly versus younger patients).

PK and PD analyses can be used to determine a number of important drug development parameters related to clinical study design. PK and PD analyses can be used to:

- **Characterize drug exposure**: With the exception of drugs delivered intravenously, only a fraction of a drug's dose is absorbed and pharmacologically active. Quantifying the rate and magnitude of exposure to a drug is critical for determining how best to guide its use in the clinic.
- **Determine an appropriate dose for a clinical study**: PK and PK/PD modeling can help predict dosing requirements early in the development process (i.e., dose justification), making the first dose-range finding studies informative and consequential.
- **Assess changes in dose requirements**: Assessing and predicting the effect of dosing changes is important early in the development process to provide insights into designing better clinical studies.
- **Estimate the rate of elimination and absorption**: Knowing how quickly a drug is absorbed and eliminated can help make decisions regarding formulation design and dosing regimens.
- **Assess relative bioavailability/bioequivalence**: Comparing the extent of a new formulation's absorption to an existing formulation can often help demonstrate therapeutic advantages.
- **Characterize intra- and inter-subject variability**: High variability can quickly derail clinical development programs. Understanding how a drug's PK and PD change within and between individuals can help design clinical trials in ways that reduce variability and make the results more robust.
- **Understand concentration-effect relationships**: The concentration-effect relationship is the cornerstone of pharmacodynamics. Identifying the variables that affect this relationship is critical for a successful development program.
- **Establish safety margins and efficacy characteristics**: Successful drugs have clearly defined therapeutic windows. PK/PD modeling can help determine dosing thresholds. *Sola dosis facit venenum… "The dose makes the poison."*