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Commentary

Preclinical Drug Development

Krishna Tanneru*

Department of Biotechnology, Osmania University, Hyderabad, India

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Address for Correspondence
Department of Biotechnology, Osmania University, Hyderabad, India

E-mail:
krishna.tanneru009@gmail.com

Preclinical drug development incorporates the activities that link to the discovery of drug in the laboratory to human clinical trials. Before the clinical trials, tests and treatments are assessed in the research of preclinical. Preclinical research is not done with the persons. Preclinical studies also designed to identify the lead candidate from many hits; to develop the best procedure for new drug scale-up; to select the best formulation; to determine the route, frequency, and duration of exposure; and support the intended clinical trial design ultimately. The specifics of each preclinical development package may vary, but all have few common features.

The process of drug development is divided into three main steps: discovery, preclinical development, and clinical trial. From discovery to preclinical development continuum and results of preliminary pharmacology and toxicology testing are often contribute to lead candidate. The limit between preclinical development and clinical trial is defined by the filing the IND (Investigational New Drug).

Once lead candidate is identified, typical preclinical development program consists of six major efforts: manufacture of drug substance (DS)/active pharmaceutical ingredient (API); preformulation and formulation (dosage design); analytical and bioanalytical methods development and validation; metabolism and pharmacokinetics; toxicology, both safety and genetic toxicology and possibly safety pharmacology; and good manufacturing practice (GMP) manufacture and documentation of drug product for use in clinical trials.

Drug development through IND submission requires effective communication and execution team with diverse skills. The progressive transition of drug candidate from early to late preclinical stages is critical. To understand the intended clinical plan for a drug candidate and anticipate potential problems team members need to execute effective preclinical approach. The TPP provides a framework for defining the desired features of the new DP, known or suspected risks and liabilities, and metrics of success.

Despite of the careful planning, drug candidates will fail. Reasons for failure include poor solubility, life threatening or other undesirable side effects, poor bio-distribution by the proposed clinical route of administration, prohibitive scale-up and manufacturing costs, market competition, and poor efficacy in the preclinical trials.

The project can do is clear 'Go/No-Go' criteria and design a strategy focused on preclinical identification of main issues to clear out problematic drug candidates in the process. Preclinical drug development is often called as 'Valley of Death,' where good ideas die through the flaws of design, lack of expertise (specialization), and insufficient funds. The effective navigation path of preclinical development is essential for the pharmaceutical industry and also for the society.

The details of the preclinical development may vary, but have few common features. Rodent and non-rodent mammalian models are used in the pharmacokinetic profile and also for the general safety in identifying the toxicity patterns.

For drugs to treat Alzheimer's disease or other brain, the ability of a drug to cross the blood brain barrier related targeted diseases, are the key issue. Toxicology and safety studies are used to identify the potential target organs for adverse effects and define the Therapeutic Index to set the starting doses in the clinical trials phase.