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Understanding the Importance of Clinical Pharmacology in Drug Development

Lohith Khan*

Department of Pharmacy, University of Rajshahi, Bangladesh

INTRODUCTION

Clinical pharmacology is a translational scientific field that seeks to understand the effects and behaviour of drugs in humans by combining knowledge of human pharmacology. Clinical pharmacology research is fundamental to understanding how drugs are processed in our bodies and how they affect human physiology. Clinical pharmacology also helps us understand the relationship between drug doses and their effects, variability in response to drugs and treatments, reasons for side effects in some patients, and ways to minimize side effects. Understanding these aspects of the action (pharmacodynamics) and disposition (pharmacokinetics) helps you achieve safe, effective and optimal treatment outcomes for your patients. Clinical pharmacology is essential for developing safe and effective medicines/therapeutics and obtaining regulatory approval. One of the most common mistakes in drug development is underutilizing clinical pharmacology. Appropriate use of clinical pharmacology data can serve as a roadmap for an entire clinical development program, saving valuable time and resources.

DESCRIPTION

Clinical pharmacology studies should examine the absorption, distribution, metabolism, and excretion (ADME) properties of a drug, its pharmacodynamics, including desired and undesired effects, and intrinsic factors (age, sex, weight, racial/ethnic affiliation, genetics, etc.) and extrinsic factors (food exposure, drug interactions). Drug development involves sequential, planned trials, including the initial preclinical stage, followed by human clinical trials. Clinical pharmacologists help determine which clinical trials to conduct throughout the drug development process. Depending on the drug, additional clinical pharmacology studies may be required, or some studies may be avoided using existing data and modeling tools. In recent years, Model Informed Drug Development (MIDD) has become an essential tool for optimizing the entire drug development process in clinical pharmacology. The use of MIDD is beneficial as it helps drive optimal decision-making for drug developers by leveraging all available data for drug candidates from *in vitro*, preclinical, and clinical studies. Various types of modeling tools, such as exposure-based models, biological models, and statistical models, ultimately help predict the probability of success of new drug candidates. MIDD helps streamline and accelerate the drug development process by facilitating more informed decision-making and reducing or eliminating the need for additional research. Drug developers use MIDD strategies to optimize and reduce the number of patients enrolled in studies, helping to select appropriate doses, durations and patient populations, thereby increasing the likelihood of study success. By applying the knowledge gained through MIDD-based approaches, we can better understand the relationship between drug concentrations in the body and their pharmacological responses.

CONCLUSION

The MIDD approach can also provide insight into specific unstudied subpopulations or scenarios that can help bridge efficacy and safety in such cases. An important application of MIDD is in the development of pediatric medicines, particularly in determining adult doses, exposures, and efficacy in pediatric populations, based on a comprehensive understanding of disease pathology, drug pharmacology, and response to treatment is to inform sex extrapolation. The role of clinical pharmacology is paramount in rational and efficient drug development. A thorough understanding of clinical pharmacology principles, guidelines, and tools is critical to successful regulatory approval of a drug.

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Corresponding author Lohith Khan, Department of Pharmacy, University of Rajshahi, Bangladesh, E-mail: Khanlohi1212@gmail.com

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CONFLICT OF INTEREST

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