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Application of PBPK Models in Personalized Healthcare

Randhir Singh Dahiya*

Department of Pharmacy, Maharishi Markandeshwar College of Pharmacy, MM University, Mullana, Haryana, India

Personalized Healthcare is known as customization of healthcare, where medical decisions, and/or products are being tailored to the individual patient need with focus on special population based on different physiological and disease conditions. Personalized healthcare is a paradigm that exists more in conceptual terms than in reality, with only a few marketed drug–test companion products and not very many actual clinical practices set up to personalize healthcare in the way that supporters have intended. In the past decades the main challenge is to manage the expectations of the medical community and the public at large that have already been set by speculation, and promises, to benefit the special populations, which includes pediatric, pregnancy, geriatric, and/or diseased conditions. These classes of populations were generally kept away from drug research to avoid potential harm, whereas the ratio of off-label prescription in these populations is high, ignoring lack of information. In recent years there is renewed surge of interests in the applications of Physiological based Pharmacokinetic Modeling and Simulations (PBPK M&S) by pharmaceutical industry and regulatory agencies. This research is focused on the application of Physiological based Pharmacokinetic Modeling and Simulations in personalized healthcare with emphasize on (1) pediatric populations (2) pregnant population, (3) population with special disease conditions including geriatric.

While the use of medications in these special populations is very common, efforts continue to focus on safe and efficacious dosing regimen along with information allowing patients and their physicians to make informed decisions about treatment on case-by-case basis. Thus, the drug use in special population is often not well justified due to lack of relevant studies. Recent regulatory guidelines from both the Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have mandated the drug developers to provide pediatric information for new drugs unless a waiver or deferral is accepted. A major challenge in drug development, with focus on special population, is determination of a safe and effective dose for each patient with specific age, physiology and diseased condition. The age, physiology and diseased condition of target population and the elimination pathway were the guidelines for choosing an appropriate modeling approach.

In the past decade, modeling and simulation approach along with physiologically based pharmacokinetics (PBPK) has become a powerful tool for designing and influence clinical trials and supporting regulatory interactions and approval, considering different challenges that are addressed with regard to clinical evidence. Ideally, whole-body PBPK models are used to simultaneously evaluate parameters that are systems-based and drug formulation-based and adjust for different physiological changes among special population on case-by-case basis. Different minimal PBPK models along with full PBPK model and mammillary model have been developed, with varying degree of success. Most importantly, minimal PBPK modeling provides a sensible modeling approach when fitting ONLY plasma (or blood) data but yielding physiologically-relevant PK parameters.

Consequently different methods in building pediatric and Pregnancy Pharmacokinetics (PK) models, using PBPK approach to address various safety and efficacy issues, related to sub-class of population are of utmost importance. The incorporation of known changes in physiology for example changes in renal, hepatic, gastrointestinal and cardiovascular physiology, along with the impact of transporter ontogeny on drug disposition among these special population, to predict the Absorption, Distribution, Metabolism, Excretion (ADME) and Pharmacokinetic (PK) processes of different drugs can revolutionize the safety and efficacy of pharmacotherapy.

***Corresponding author:** Randhir Singh Dahiya, Department of Pharmacy, Maharishi Markandeshwar College of Pharmacy, MM University, Mullana, Haryana, India, Tel: 09896029234; E-mail: randhirsingh.dahiya@gmail.com

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