

Application of Model Informed Pediatric Extrapolation in Drug Development

Christine Xu

Sanofi

E-mail: Christine.Xu@sanofi.com

Abstract: Under the regulatory guidance, the pediatric extrapolation concept has been built on evidence of similarities or differences in the disease and the clinical response across the source (e.g. adult) and target populations (e.g. children). Drug development in pediatric patients is challenging. There are many gaps in knowledge need to be investigated under the extrapolation concept and require more innovative approach. The quantitative methods help to establish the relationship between dose, drug exposure, pharmacodynamic effects and clinical responses as well as the understanding of disease. In this session, speaker will demonstrate impacts of model informed extrapolation approaches with a few examples: 1) population pharmacokinetic simulations to support dose selection and optimize the experimental study designs in pediatric population; 2) physiologically-based pharmacokinetic model to extrapolate to a special population and drug-drug interactions; and 3) quantitative systems pharmacology model to integrate knowledge and extrapolate beyond collected data. The applications are varied from more empirical approaches to the integrated computational modeling of biological systems/pharmacologic systems and demonstrate the utility of these quantitative approaches in pediatric drug development.