

Abstract Vinks - PMDA-Keio symposium , December 8, 2015

**Title: Modeling and Simulation in Pediatric Drug Development: Application of Pharmacometrics to Define the Right Dose for Children.**

During the past decades significant progress has been made in development of age appropriate drug therapies for children. The application of modeling and simulation and pharmacometrics and the extrapolation of efficacy findings from adults to the pediatric population have streamlined the development process especially for studies in older children. However, focus on developmental changes in neonates and infants and developing a paradigm for conducting pharmacodynamic studies in children remain important unmet needs.

Learning objectives:

- Appreciate developmental pharmacology principles that are uniquely applicable to children, and which could be applied to the development and testing of drugs and biologics in children;
- Describe examples of the application of clinical trial simulation in designing informative pediatric trials;
- Understand the need for developmental pharmacodynamics paradigm and the potential of modeling and simulation to generate age-appropriate information.