

FDA/CRCG Workshop: Advances in PBPK Modeling and its Regulatory Utility for Oral Drug Product Development

- **Session 3: PBPK Modeling to Support Bioavailability and Bioequivalence Assessment in Pediatric Populations**
- **Why is modeling of BA and BE important for drug development in pediatric patients?**
 - BE studies on new drugs are only conducted in healthy adult subjects due to ethical considerations
 - Generic drug formulations approved for pediatric patients are not tested in pediatric patients

Therefore

- (1) the effects of ontogeny (e.g. pH, membrane transporters, surface area) are not considered;
- (2) the effects of excipients/solvents may be very different in pediatric patients, and
- (3) the concurrent administration of other drugs (e.g. pH modifiers) and food may be very different in pediatric patients.

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- Presenter 1:** **Lanyan (Lucy) Fang, PhD** Deputy Director, DQMM, ORS, OGD, FDA
Regulatory Applications and Research of Absorption Modeling for Pediatric Products
- Presenter 2:** **Gaohua Lu, PhD** Senior Director, Head of PBPK, Bristol Myers Squibb
Is Pediatric Absorption Modeling Ready for BE Assessment?
- Presenter 3:** **Kazuko Sagawa, PhD** Research Fellow, Pfizer Global Research and Development
PBPK Absorption Modeling and Virtual Bioequivalence Assessment to Support a Pediatric Formulation Regulatory

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Session 3: PBPK Modeling to Support Bioavailability and Bioequivalence Assessment in Pediatric Populations

- *Moderators:*
 - Gilbert Burckart, PharmD**
Associate Director for Pediatrics, OCP, OTS, FDA
 - Rebeka Jereb, PhD**
Senior Scientist Clinical Innovations, Lek, a Sandoz company
- *Panelists:*
 - Siva Vaithiyalingam, PhD**
Sr. Vice President of Regulatory Affairs, Cipla LTD
 - Jianghong Fan, PhD**
Senior Staff Fellow, DPM, OCP, OTS, FDA
 - Lanyan (Lucy) Fang, PhD**
Deputy Director, DQMM, ORS, OGD, FDA
 - Nikoletta Fotaki, MSc, PhD, FAAPS**
Professor of Biopharmaceutics, CTI, University of Bath
 - Gaohua Lu, PhD**
Senior Director, Head of PBPK, Bristol Myers Squibb
 - Viera Lukacova, PhD**
Chief Scientist, Simulations Plus, Inc.
 - Nikunj Kumar Patel, PhD**
Senior Director of PBPK Consultancy, Certera Inc
 - Kazuko Sagawa, PhD**
Research Fellow, Pfizer Global Research and Development