Development of Best Practices in Physiologically Based Pharmacokinetic Modeling to Support Clinical Pharmacology Regulatory Decision-Making

November 18th, 2019

FDA White Oak Campus Great Room

8:00 AM to 5:00 PM

Workshop Chairs

Yuching Yang, PhD, FDA

Xinyuan Zhang, PhD, FDA

Lauren Milligan, PhD, FDA

AGENDA

8:00-8:30	**Welcome and Opening Remarks** **Peter Stein, MD** Director, Office of New Drugs, CDER, FDA **Christopher Joneckis, PhD** Associate Director of Review Management, CBER, FDA
8:30-10:00	**Session 1: PBPK 360: The State of the Science** **This session will focus on the state of the science of PBPK from three points of view (FDA, academia, and industry) and highlight enabling factors for the PBPK approach.** **Moderator:** **Issam Zineh, PharmD, MPH, FCP, FCCP** Director, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA

	Speakers: **Don Mager, PharmD, PhD** Professor and Vice Chair of Pharmaceutical Sciences, University at Buffalo, SUNY **Steve Hall, PhD** Department of Drug Disposition, Eli Lilly **Yaning Wang. PhD** Director, Division of Pharmacometrics, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA **Q and A**
10:00-10:30	**Break**
10:30-Noon	**Session 2: Panel Discussion on the FDA's Regulatory Framework for Evidentiary Criteria for PBPK** **FDA stakeholders and audience members have the opportunity to react to the Agency's PBPK white paper and express current thinking and practices.** **Moderator:** **Ping Zhao, PhD** Senior Program Officer, Integrated Development-Quantitative Sciences, Bill & Melinda Gates Foundation **Speaker:** **Colleen Kuemmel, PhD** Staff Fellow, Immediate Office, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA **Panelists:** **Sue Cole, BSc** Expert Pharmacokinetics Assessor and Head of the Pharmacokinetics Group, Medicines and Healthcare products Regulatory Agency **Tina Morrison, PhD** Deputy Director, Division of Applied Mechanics, Office of Science and Engineering Laboratories, CDRH, FDA **Million Tegenge, RPh, PhD** Pharmacologist, Office of Biostatistics & Epidemiology, CBER, FDA **Yuching Yang, PhD**

	PBPK Co-Lead, Division of Pharmacometrics, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA **Liang Zhao, PhD** Director of the Division of Quantitative Methods and Modeling, Office of Research and Standards, Office of Generic Drugs, CDER, FDA **Q and A**
Noon-1:00	**Lunch**
1:00-2:30	**Session 3: PBPK Case Studies** **These real-life examples will highlight the need to understand the contextual factors and technical considerations involved in the use of PBPK for a particular application and will generate ideas on what we need to see for successful development and verification of models.** **Moderator:** **Shiew Mei Huang, PhD** Deputy Director, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA **Speakers:** **Xinyuan Zhang, PhD** PBPK Co-Lead, Division of Pharmacometrics, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA **Nina Isoherranen, PhD** Professor and Milo Gibaldi Endowed Chair, Department of Pharmaceutics, School of Pharmacy, University of Washington **Jan Snoeys, PhD** Director & Research Fellow Drug Metabolism and Pharmacokinetics, Janssen R&D **Q and A**
2:30-3:00	**BREAK**
3:00-4:30	**Session 4: Panel on Knowledge Gaps in PBPK** **What are the most pressing and high-impact scientific and technical challenges in the application of PBPK? What biological and physiological challenges need to be addressed to allow the application of PBPK to specific populations? Panelists will identify common themes, challenges, and strategies to move the science of PBPK forward.**

	<u>Moderator and Speaker:</u> **Steve Hall, PhD** Department of Drug Disposition, Eli Lilly **<u>Panelists:</u>** **Iain Gardner, PhD** Head of Translational DMPK Science, Simcyp **Grace Fraczkiewicz, BS, MSc** Team Leader, Simulation Studies, Simulations Plus, Inc. **Paul Seo, PhD** Director, Division of Biopharmaceutics, Office of New Drug Products, Office of Pharmaceutical Quality, CDER, FDA **Marc Gastonguay, PhD** CEO, Metrum Research Group **Tycho Heimbach, PhD** Director, PK Sciences, PBPK and Biopharmaceutics, Novartis Institutes for Biomedical Research **Q and A**
4:30-4:45	**Meeting Summary and Closing Remarks** **Issam Zineh, PharmD, MPH, FCP, FCCP** Director, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA
5:00	**Meeting adjourns**