

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	<p>Welcome and Opening Remarks</p> <p>Peter Stein, MD Director, Office of New Drugs, CDER, FDA</p> <p>Christopher Joneckis, PhD Associate Director of Review Management, CBER, FDA</p>
8:30-10:00	<p>Session 1: PBPK 360: The State of the Science</p> <p>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.</p> <p>Moderator:</p> <p>Issam Zineh, PharmD, MPH, FCP, FCCP Director, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA</p>

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

	<p>PBPK Co-Lead, Division of Pharmacometrics, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA</p> <p>Liang Zhao, PhD Director of the Division of Quantitative Methods and Modeling, Office of Research and Standards, Office of Generic Drugs, CDER, FDA</p> <p>Q and A</p>
Noon-1:00	Lunch
1:00-2:30	<p>Session 3: PBPK Case Studies</p> <p>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.</p> <p><u>Moderator:</u></p> <p>Shiew Mei Huang, PhD Deputy Director, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA</p> <p><u>Speakers:</u></p> <p>Xinyuan Zhang, PhD PBPK Co-Lead, Division of Pharmacometrics, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA</p> <p>Nina Isoherranen, PhD Professor and Milo Gibaldi Endowed Chair, Department of Pharmaceutics, School of Pharmacy, University of Washington</p> <p>Jan Snoeys, PhD Director & Research Fellow Drug Metabolism and Pharmacokinetics, Janssen R&D</p> <p>Q and A</p>
2:30-3:00	BREAK
3:00-4:30	<p>Session 4: Panel on Knowledge Gaps in PBPK</p> <p>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.</p>

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