

THE UNIVERSITY OF MARYLAND CENTER OF EXCELLENCE IN REGULATORY SCIENCE AND INNOVATION, IN COLLABORATION WITH THE U.S. FOOD AND DRUG ADMINISTRATION, PRESENTS:

# PEDIATRIC ONTOGENY: READY FOR INCORPORATION INTO MODELING IN PEDIATRIC DRUG DEVELOPMENT?



University of Maryland School of Pharmacy

May 16, 2019

Bethesda, MD

# CONFERENCE AGENDA

THURSDAY, MAY 16, 2019

## MODERATORS:

- **Gilbert J. Burckart, PharmD**  
Associate Director for Pediatrics  
Office of Clinical Pharmacology  
Food and Drug Administration
- **Jill Morgan, PharmD, BCPS, BCPPS**  
Professor and Chair  
Department of Pharmacy Practice and Science  
University of Maryland School of Pharmacy
- **Jian Wang, PhD**  
Associate Director for Regulatory Science  
Office of Drug Evaluation IV  
Office of New Drugs

## AGENDA:

TIME	ACTIVITY
	<b>INTRODUCTION</b>
8:00-8:35 a.m.	<b>WELCOME / PEDIATRIC DRUG DEVELOPMENT</b> <b>Gilbert J. Burckart, PharmD</b> Associate Director for Pediatrics Office of Clinical Pharmacology Food and Drug Administration
8:35-8:55 a.m.	<b>DEVELOPMENTAL PHARMACOKINETICS</b> <b>John van den Anker, MD, PhD</b> Pediatric Clinical Pharmacology Children's National Medical Center
8:55-9:15 a.m.	<b>DEVELOPMENTAL PHARMACODYNAMICS</b> <b>Greg Kearns, PharmD, PhD</b> President Arkansas Children's Research Institute
9:15-9:35 a.m.	<b>MODELING AND SIMULATION USING PEDIATRIC ONTOGENY INFORMATION</b> <b>Stefan Willmann, PhD</b> Clinical Pharmacometrics Research & Development Bayer

9:35-10:00 a.m.	<b>DRUG METABOLISM AND TRANSPORTER FUNCTION</b>  <b>ONTOGENY AND PHASE II METABOLISM OF DRUGS</b> <b>Stephan Schmidt, PhD</b> Associate Professor Center for Pharmacometrics and Systems Pharmacology University of Florida
10:00-10:20 a.m.	<b>BREAK</b>
10:20-10:45 a.m.	<b>ONTOGENY OF PHASE I METABOLISM OF DRUGS</b> <b>Steve Leeder, PharmD, PhD</b> Marion Merrell Dow Endowed Chair in Pediatric Precision Therapeutics Mercy Children's Hospital
10:45-11:10 a.m.	<b>ONTOGENY OF DRUG TRANSPORTER FUNCTION</b> <b>Shiew Mei Huang, PhD</b> Deputy Directory, Office of Clinical Pharmacology Center for Drug Evaluation and Research Food and Drug Administration
11:10 a.m. - Noon	<b>MODERATED PANEL DISCUSSION</b> <b>Moderators:</b> Drs. Burckart and Morgan  <b>Panelists:</b> Drs. van den Anker, Kearns, Huang, Leeder, Willmann, Edress Darsey (Pfizer), and Sander Vinks (University of Cincinnati)
Noon – 1 p.m.	<b>LUNCH</b>
1:00-1:25 p.m.	<b>RENAL FUNCTION, PHARMACOGENOMICS ONTOGENY</b>  <b>ONTOGENY OF RENAL FUNCTION AND RENAL DRUG ELIMINATION</b> <b>Jian Wang, PhD</b> Associate Director, Regulatory Science Office of Drug Evaluation IV Office of New Drugs Food and Drug Administration
1:25-1:50 p.m.	<b>ONTOGENY AND APPLICATION OF PHARMACOGENOMICS TO PEDIATRICS</b> <b>Dionna Green, MD</b> Deputy Director, Office of Pediatric Therapeutics Commissioner's Office Food and Drug Administration
1:50-2:20 p.m.	<b>APPLICATIONS TO PEDIATRIC DRUG DEVELOPMENT</b>  <b>APPLICATION OF ONTOGENY WITHIN MIDD FOR PEDIATRICS</b> <b>Hao Zhu, PhD</b> Deputy Director, Division of Pharmacometrics Office of Clinical Pharmacology Center for Drug Evaluation Food and Drug Administration
2:20-2:40 p.m.	<b>BREAK</b>

2:40-3:10 p.m.

**INDUSTRY PERSPECTIVE ON UTILIZING MIDD FOR PEDIATRIC STUDIES  
REQUIRING INTEGRATION OF ONTOGENY**

**Solange Corriol Rohou, MD, PhD**

Chair, ICHE11 M&S Subcommittee

Senior Director, Global Regulatory Affairs & Policy, Europe

AstraZeneca Global Medicines Development

3:10-4:00 p.m.

**MODERATED PANEL DISCUSSION**

**Moderators:** Drs. Burckart and Jian Wang

**Panelists:** George Giacoia (NIH); Issam Zineh (FDA); Hao Zhu (FDA);  
Solange Corriol Rohou (AstraZeneca); Stephan Schmidt; Linh Van  
(Novartis); Dionna Green (FDA)

4:00-4:15 p.m.

**PEDIATRIC ONTOGENY AND MODELING AND SIMULATION: REMAINING  
QUESTIONS**

**Gilbert J. Burckart, PharmD**

Associate Director for Pediatrics

Office of Clinical Pharmacology

Food and Drug Administration

**THANKS TO PROGRAM COMMITTEE MEMBERS:**

- Gil Burckart (FDA)
- Jian Wang (FDA)
- Jill Morgan (University of Maryland)
- John van den Anker (Children's National, Washington D.C.)
- Andre Dallmann (Bayer)
- Dionna Green (FDA)
- Sander Vinks (University of Cincinnati)
- George Giacoia (NIH)