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

- Jian Wang, PhD
  Associate Director for Regulatory Science
  Office of Drug Evaluation IV
  Office of New Drugs

- Jill Morgan, PharmD, BCPS, BCPPS
  Professor and Chair
  Department of Pharmacy Practice and Science
  University of Maryland School of Pharmacy

AGENDA:

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<th>TIME</th>
<th>ACTIVITY</th>
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<tr>
<td>8:00-8:35 a.m.</td>
<td><strong>INTRODUCTION</strong></td>
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<td><strong>WELCOME / PEDIATRIC DRUG DEVELOPMENT</strong></td>
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<td>Gilbert J. Burckart, PharmD</td>
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<td>Office of Clinical Pharmacology</td>
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<td>Food and Drug Administration</td>
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<td>8:35-8:55 a.m.</td>
<td><strong>DEVELOPMENTAL PHARMACOKINETICS</strong></td>
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<td>John van den Anker, MD, PhD</td>
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<td>Pediatric Clinical Pharmacology</td>
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<td>Children's National Medical Center</td>
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<td>8:55-9:15 a.m.</td>
<td><strong>DEVELOPMENTAL PHARMACODYNAMICS</strong></td>
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<td>Greg Kearns, PharmD, PhD</td>
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<td>President</td>
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<td>Arkansas Children’s Research Institute</td>
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<td>9:15-9:35 a.m.</td>
<td><strong>MODELING AND SIMULATION USING PEDIATRIC ONTOGENY INFORMATION</strong></td>
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<td>Stefan Willmann, PhD</td>
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<td>Clinical Pharmacometrics</td>
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<td>Research &amp; Development</td>
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9:35-10:00 a.m.  
**DRUG METABOLISM AND TRANSPORTER FUNCTION**

**ONTGENY AND PHASE II METABOLISM OF DRUGS**  
**Stephan Schmidt, PhD**  
Associate Professor  
Center for Pharmacometrics and Systems Pharmacology  
University of Florida

10:00-10:20 a.m.  
**BREAK**

10:20-10:45 a.m.  
**ONTGENY OF PHASE I METABOLISM OF DRUGS**  
**Steve Leeder, PharmD, PhD**  
Marion Merrell Dow Endowed Chair in Pediatric Precision Therapeutics  
Mercy Children’s Hospital

10:45-11:10 a.m.  
**ONTGENY OF DRUG TRANSPORTER FUNCTION**  
**Shiew Mei Huang, PhD**  
Deputy Directory, Office of Clinical Pharmacology  
Center for Drug Evaluation and Research  
Food and Drug Administration

11:10 a.m. - Noon  
**MODERATED PANEL DISCUSSION**  
**Moderators:** Drs. Burckart and Morgan  
**Panelists:** Drs. van den Anker, Kearns, Huang, Leeder, Willmann, Edress Darsey (Pfizer), and Sander Vinks (University of Cincinnati)

Noon – 1 p.m.  
**LUNCH**

1:00-1:25 p.m.  
**RENEAL FUNCTION, PHARMACOGENOMICS ONTOGENY**  
**ONTGENY OF RENAL FUNCTION AND RENAL DRUG ELIMINATION**  
**Jian Wang, PhD**  
Associate Director, Regulatory Science  
Office of Drug Evaluation IV  
Office of New Drugs  
Food and Drug Administration

1:25-1:50 p.m.  
**ONTGENY AND APPLICATION OF PHARMACOGENOMICS TO PEDIATRICS**  
**Dionna Green, MD**  
Deputy Director, Office of Pediatric Therapeutics  
Commissioner’s Office  
Food and Drug Administration  
**APPLICATIONS TO PEDIATRIC DRUG DEVELOPMENT**

1:50-2:20 p.m.  
**APPLICATION OF ONTOGENY WITHIN MIDD FOR PEDIATRICS**  
**Hao Zhu, PhD**  
Deputy Director, Division of Pharmacometrics  
Office of Clinical Pharmacology  
Center for Drug Evaluation  
Food and Drug Administration

2:20-2:40 p.m.  
**BREAK**
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)