University of Maryland Center of Excellence in Regulatory Science and Innovation

Science that speeds health innovation

Innovative Approaches to Pediatric Drug Development and Pediatric Medical Countermeasures: A Role for Physiologically-Based PK?

Mark your calendars for **Innovative Approaches to Pediatric Drug Development and Pediatric Medical Countermeasures: A Role for Physiologically-Based PK?**, a conference sponsored by the University of Maryland Center of Excellence in Regulatory Science and Innovation and the Food and Drug Administration (FDA), in collaboration with the America College of Clinical Pharmacology.

Understanding drug disposition and elimination in pediatric populations, especially neonates and infants, is a challenging problem that requires a clear understanding of the dynamic interplay between pediatric growth and development, maturation of processes involved in drug metabolism and elimination, disease effects, and intrinsic properties of the drug. Physiologically-based pharmacokinetic (PBPK) modeling provides a platform that could account for these processes to predict pharmacokinetic properties and assist with devising pediatric development strategies.

Join scientists from industry, academia, and regulatory agencies on **Monday, May 5, 2014**, from 8:30 a.m. to 5:00 p.m. at the Food and Drug Administration's (FDA) White Oak Campus, located at 10903 New Hampshire Avenue in Silver Spring, MD, as they share their experiences and discuss best practices for PBPK in pediatric drug development and pediatric medical countermeasures.

For more information, please visit www.pharmacy.umaryland.edu/pediatricPBPK.

Registering by mail? Please detach this form and submit it to the address below. All participants can also register online at www.pharmacy.umaryland.edu/pediatricPBPK.

Innovative Approaches to Pediatric Drug Development and Pediatric Medical Countermeasures: A Role for Physiologically-Based PK?

University of Maryland School of Pharmacy
Attn: Sharese Essien
20 Penn Street
HSF II, Room 503B
Baltimore, MD 21201

Make all checks payable to the **University of Maryland, Baltimore Foundation**.

Please provide the following information:

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☐ Bachelor's Degree ☐ Doctorate

Please indicate which category best describes you:

☐ Faculty, Staff, Student from the University of Maryland, Baltimore or College Park Campus (FREE)
☐ M-CERSI Industrial Consortia Member (FREE)
☐ Federal Government Employee (FREE)
☐ Other Participant ($50.00)

CONFERENCE AGENDA

May 5, 2014

8:30-8:45 a.m.
Opening Remarks: Opportunities and Challenges in Pediatric Drug Development and Regulatory Science
Gil Burckart, PharmD
Associate Director for Pediatrics
Office of Clinical Pharmacology
Food and Drug Administration

8:45-9:15 a.m.
Modeling and Simulation in Pediatric Patients: Top-Down, Bottom-Up, and What It All Means Clinically
Sander Vinks, PharmD, PhD
Director, Division of Clinical Pharmacology
Professor of Pediatrics
University of Cincinnati

9:15-9:45 a.m.
PBPK in Pediatric Drug Development: Prior FDA Experience
Vikram Sinha, PhD
Director, Division of Pharmacometrics
Food and Drug Administration

9:45-10:15 a.m.
EMA Experience with Pediatric PBPK
Ine Skottheim Rusten, PhD
Scientific Officer
European Medicines Agency

10:15-10:30 a.m.
Break

10:30-11:00 a.m.
A Workflow Example of PBPK Modeling to Support Pediatric Research and Development
Jeff Barrett, PhD
Vice President, Interdisciplinary Pharmacometrics Program
Sanofi

11:00-11:30 a.m.
Use of PBPK in Drug Development and Application to the Pediatric Setting
Jörg Lippert, PhD
Global Head, Clinical Pharmacometrics
Bayer

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May 5, 2014

11:30-12:00 p.m.
Practical Application of PBPK in Neonates and Infants, Including Case Studies
Neil Parrott, PhD
M&S Scientist
Roche Pharmaceuticals

12:00-1:00 p.m.
Lunch

1:00-1:30 p.m.
Managing Pediatric Poisons: How Important Are Accurate Dose Recommendations?
Kevin Watt, MD
Assistant Professor of Pediatrics
Duke University School of Medicine

1:30-2:30 p.m.
Panel Discussion #1: Special Considerations and Utility of PBPK for Pediatric MCM
Moderator: Dionna Green

- Dionna Green -- Introduction (15 minutes)
- Jiang Liu -- Case Presentation (10 minutes)
- Panel Discussion (35 minutes) with Panelists:
  - Suzie McCune, MD (Deputy Director, OTS)
  - Ping Zhao, PhD, (PBPK Lead, OCP)
  - Kim Bergman, PhD (Antiviral Team Leader, OCP)
  - Jiang Liu, PhD (Pharmacometrics Reviewer, OCP)
  - Karen Davis-Bruno, PhD (Nonclinical Team Leader, OND)
  - Jorg Lippert, PhD, Bayer Pharmaceuticals
  - Jeffrey Fisher, PhD, Research Toxicologist, NCTR, FDA

2:30-2:45 p.m.
Break

2:45-3:45 p.m.
Panel Discussion #2: Modeling and Simulation in Neonates and Infants
Moderators: Sander Vinks and Tom Dowling

- Jian Wang -- FDA Experience with Neonatal Trials (10 minutes)
- Panel Discussion (50 minutes) with Panelists:
  - Suzie McCune, MD (Deputy Director, OTS)
  - Jian Wang, PhD, Senior Reviewer, Pediatric Clin Pharm Staff
  - Yaning Wang, PhD, Deputy Director, Division of Pharmacometrics
  - Kevin Watt, MD, Duke University School of Medicine
  - Neil Parrott, PhD, Roche Pharmaceuticals
  - Jeff Barrett, PhD, Sanofi
  - Ine Skottheim Rusten, PhD, Norwegian Medicines Agency

3:45-4:00 p.m.
Closing Remarks
Issam Zineh, PharmD, MPH, FCP, FCCP
Director, Office of Clinical Pharmacology
Food and Drug Administration