Pediatric Drug Development: Use of Exposure Matching and Exposure-Response for Extrapolation of Efficacy in Pediatric Product Development

Mark your calendars for Pediatric Drug Development: Use of Exposure Matching and Exposure-Response for Extrapolation of Efficacy in Pediatric Product Development, a workshop sponsored by the University of Maryland Center for Excellence in Regulatory Science and Innovation and the Food and Drug Administration (FDA).

Pharmacists and pharmaceutical researchers from industry, academia, and regulatory agencies are invited to attend Pediatric Drug Development: Use of Exposure Matching and Exposure-Response for Extrapolation of Efficacy in Pediatric Product Development on Thursday, January 22, 2015, 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.

This one-day workshop will examine current practices and applications of pediatric exposure matching and pediatric exposure-response analyses from a variety of perspectives, with special attention to recommendations for application of these practices in drug development.

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

Please provide the following information:

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Name

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Address

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Phone

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Email

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Title and Company/School/Agency

Please indicate highest degree obtained:

☐ High School ☐ Bachelor’s Degree ☐ Master’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)
January 22, 2015

8:30-8:40 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

8:40-9:10 a.m.  
Pediatric Extrapolation: Using Exposure As A Surrogate for Efficacy  
Robert “Skip” Nelson, MD, PhD  
Senior Pediatric Ethicist and Lead Medical Officer  
Office of Pediatric Therapeutics  
Office of the Commissioner  
Food and Drug Administration

9:10-9:30 a.m.  
FDA Perspective: Exposure-Response Assessments and Applications to Drug Development in the FDA  
Kevin Krudys, PhD  
Pharmacometrics Reviewer  
Office of Clinical Pharmacology  
Food and Drug Administration

9:30-9:45 a.m.  
What Constitutes A Meaningful Endpoint for Establishing Exposure-Response Similarity Between Adults and Pediatric Patients?  
Issam Zineh, PharmD  
Director  
Office of Clinical Pharmacology  
Food and Drug Administration

9:45-10:00 a.m.  
Case Examples: Exposure-response to Support Extrapolation of Efficacy of IBD for Children  
Kerry Jo Lee, MD  
Pediatric Gastroenterologist, Gastroenterology and Inborn Errors Products  
Office of New Drugs  
Food and Drug Administration

10:00-10:20 a.m.  
Assessing Quality and Quantity of Data to Establish Exposure-Response Similarity Between Adults and Pediatric Patients: PEACE Initiative  
Angela Men, MD, PhD  
Neurology Team Leader  
Food and Drug Administration

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10:20-10:45 a.m.
Break

10:45-11:00 a.m.
Case Examples: Extrapolation of Efficacy for JIA in Children
Satjit Brar, PharmD, PhD
Team Leader, Clinical Pharmacology
Food and Drug Administration

11:00-11:15 a.m.
Dealing with Uncertainty of Extrapolation Assumptions
Tarek Leil, PhD
Head, Quantitative Clinical Pharmacology Group
Bristol-Myers Squibb

11:15 a.m.-12:30 p.m.
Panel Discussion/Public Q&A
Moderators: Vikram Sinha and Gilbert Burckart

Panel Members: Dianne Murphy, Marc Gastonguay, Tarek Leil, John Pellock, Ron Portman, and Lynne Yao

12:30-1:30 p.m.
Lunch

1:30-1:45 p.m.
Experience in FDA Submissions with Matching Pediatric Drug Exposure to Adult Drug Exposure
Lily Mulugeta, PharmD
Pediatric Clinical Pharmacologist
Office of Clinical Pharmacology
Food and Drug Administration

1:45-2:00 p.m.
Case Examples: Extrapolation of Efficacy of GERD in Children
Insook Kim, PhD
Clinical Pharmacology Reviewer
Food and Drug Administration

2:00-2:15 p.m.
The Pediatric Trials Network: Experience with Matching Drug Exposure in Infants and Neonates to Adult Drug Exposure
Daniel Gonzalez, PharmD, PhD
Assistant Professor
Department of Pharmacotherapy and Experimental Therapeutics
University of North Carolina Eshelman School of Pharmacy

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2:15-2:40 p.m.  
Methods for Determining Similarity of Exposures Between Adult and Pediatric Patients and Trial: Design Considerations  
Marc R. Gastonguay, PhD  
President & Chief Executive Officer  
Metrum Research Institute

2:40-3:00 p.m.  
When Does Exposure Matching Require Additional Consideration?  
Jeff Barrett, PhD  
Vice President, Interdisciplinary Pharmacometrics Program  
Sanofi

3:00-3:15 p.m.  
Break

3:15-4:00 p.m.  
Panel Discussion/Public Q&A  
Moderators: Lily Mulugeta and Jeff Barrett

Panel Members: Shirley Seo, Skip Nelson, Andrew Mulberg, Kimberly Bergman, Daniel Gonzalez, Catherine Sherwin, and Marc Gastonguay

4:00-4:15 p.m.  
Closing Remarks and Next Steps  
Issam Zineh, PharmD  
Director  
Office of Clinical Pharmacology  
Food and Drug Administration

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