



University of Maryland Center of Excellence in Regulatory Science and Innovation
Science that speeds health innovation

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.



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/PedExposure.



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

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:

Name

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Please indicate highest degree obtained:

- | | |
|--|--|
| <input type="checkbox"/> High School | <input type="checkbox"/> Master's Degree |
| <input type="checkbox"/> Bachelor's Degree | <input type="checkbox"/> 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

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

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



CONFERENCE AGENDA

January 22, 2015

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



CONFERENCE AGENDA

January 22, 2015

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