2nd Annual Pediatric Pharmacology Conference

Leveraging PKPD Studies, Modeling and Simulation Techniques to Enhance Pediatric Drug Development

January 26-27, 2012
Philadelphia, PA

Conference Chairperson:
Barry Mangum PharmD FCP
Associate Professor Clinical Pharmacology
Duke University Medical Center
Director, Clinical Pharmacology
Duke Clinical Research Institute

Attending this Premier marcus evans Conference will Enable You to:

• Address current challenges in pediatric pharmacology with Pfizer
• Optimize modeling and simulation techniques by AstraZeneca
• Enhance the use of adult data for pediatric patients from Astellas
• Evaluate PKPD and population PK studies with Johnson and Johnson
• Examine the ethical challenges of working with neonates, infants, and adolescents by Cephalon

Who Should Attend:
marcus evans invites Heads, Vice Presidents, Directors with responsibilities or involvement in the following areas:
• Clinical Pharmacology
• Pharmacology
• PKPD
• Modeling and Simulation
• Pharmacometrics
• Medical Affairs

Featured Speakers Include:
Jeffrey Skolink MD
Senior Director, Clinical Development
AstraZeneca

George McCormick
Vice President, Drug Safety & Disposition
Cephalon, Inc

Gary Pasternack
Chief Executive Officer
Asklepiion Pharmaceuticals

Thomas McCauley
Director, Clinical Pharmacology & Pharmacokinetics
Shire Pharmaceuticals HGT

Margaret Wooddell PhD MPH MBA
Director, Clinical Development
Kyowa Hakko Kirin Pharma, Inc

Karen Thompson PhD
Distinguished Senior Investigator
Merck Research Labs

Sharon Ripp PhD
Senior Principal Scientist
Pharmacokinetics, Dynamics & Development
Pfizer Global Research & Development

Ernest A. Kopecky PhD MBA
Head, Pain Group, Clinical Development
Endo Pharmaceuticals Inc
Fellow, Division of Clinical Pharmacology/Toxicology
Hospital For Sick Children

Gina Pastino
Associate Director, Clinical Pharmacology & Translational Medicine
Eisai Medical Research

Mike Roy PhD
Modeler
Astellas Pharma

Zexun Zhou
Associate Director, Clinical Pharmacology & Pharmacometrics
Bristol-Myers Squibb

Martha Gonzales
Senior Clinical Pharmacology Scientist
Johnson & Johnson

Albert John Allen MD PhD
Senior Medical Director
Eli Lilly

Michael Reed PharmD FCCP FCP
Director
Rebecca D. Considine Research Institute
Professor of Pediatrics
Northeast Ohio Medical University

Edmund V. Capparelli PharmD
Clinical Professor Pediatric Pharmacology & Drug Discovery
University of California, San Diego

Shawn Spencer
Group Leader, Clinical Pharmacology
NIH Clinical Center, National Cancer Institute at Frederick

“Optimizing pediatric pharmacology to achieve safe and ethical drug development through PKPD studies.”

If an organization has a pediatric drug approved, they can receive a six-month extension on the patent for the drug in both pediatrics and the general population.
Day One | January 26, 2012

8:00 Registration and Morning Coffee

8:30 Chairman’s Opening Address
Barry Mangum PharmD FCP, Associate Professor Clinical Pharmacology
Duke University Medical Center
Director, Clinical Pharmacology
Duke Clinical Research Institute

1:15 Evaluating the Long Term Effects of Drugs in Pediatrics
- Understanding the changes in enzymes in a relatively short period of time
- Addressing the issues of long term drug safety in children
- Separating events associated with normal development from actual safety signals
- Examining case studies where a long term drug has been used by children
Gary Pasternack, Chief Executive Officer
Asklepios Pharmaceuticals

2:00 Addressing Common Challenges in Pediatric Labeling
- Analyzing how organizations have gone about receiving the clearance for pediatric labeling from beginning to end
- Creating effective collaboration between the modelling and development functions to achieve pediatric labeling
- Assessing how to go about attaining a label change for a drug
Michael Reed PharmD FCCP FCP, Director
Rebecca D. Considine Research Institute
Professor of Pediatrics
Northeast Ohio Medical University

2:45 Networking Break

3:15 Examining Population PK Studies in Pediatrics
- Addressing body size adjustments of patients during the development of PKPD models
- Analyzing the design and validation of limited sampling strategies
- Integrating historical priors in data analysis and trial simulation
- Clarifying allometric size adjustments with empiric approaches based on body weight or body surface area
- Determining the best sites in which to draw from during a POPPK study
Thomas McCauley, Director, Clinical Pharmacology & Pharmacokinetics
Shire Pharmaceuticals HGT

3:45 Evaluating the Common Challenges of PKPD Studies in Pediatric Oncology
- Using topoisomerase I inhibitors in early clinical PK studies
- Designing clinical PKPD studies of targeted drug therapy
- Comparing results from adult and pediatric phase I studies for the topoisomerase I inhibitors
- Understanding how to overcome challenges in resources an infrastructure in PKPD assessments for pediatric oncology
Martha Gonzales,
Senior Clinical Pharmacology Scientist,
Johnson & Johnson

4:45 Closing Remarks of the Chair & End of Day One

WHY YOU SHOULD ATTEND:

This marcus evans event will address the practical issues in pediatric pharmacology. Organizations must be able to prove, before using population trials with children, that the drug will have a positive affect with the dosage given or be very close to doing so. This requires a number of modeling simulations of which there are many. The FDA and the EMA are requiring it in order for the drug to go to population trials.

There is also a need to understand how to get viable samples from pediatric patients. As there is a growing understanding that children are not simply “little humans” we are beginning to understand that in order for a drug to work efficiently, effectively, and safely; we must see what effect drugs have on these under-developed molecules.
Day Two | January 27, 2012

8:00 Registration and Morning Coffee

8:25 Chairman’s Opening Address

Barry Mangum PharmD, Associate Professor Clinical Pharmacology
Duke University Medical Center
Director, Clinical Pharmacology
Duke Clinical Research Institute

8:30 Utilizing Modeling and Simulation for Optimization of Sampling Times in Pediatric Trials
- Evaluating the need for limited versus intensive sampling in the pediatric population
- Understanding available methods for optimizing limited sampling strategies
- Exploring lessons learned from a limited sampling clinical trial in adult and pediatric patients
Shawn Spencer, Group Leader, Clinical Pharmacology
NIH Clinical Center, National Cancer Institute at Frederick

9:15 Interactive Panel Discussion
Implementing New Technologies to Ensure Safety of Pediatric Patients
- Understanding what new biomarkers are available and how you can use them in your organization
- Responding to changes in clinical chemistry or hematology consistent in both animals and humans
- Comprehending the use of mitochondrial toxicology
- Utilizing animal models of disease instead of healthy animals to better understand how the drug will work with a disease

10:00 Networking Break

EXPLORING MODELING AND SIMULATION

10:30 Clinical Development - Taking Modeling and Simulation Data and Moving it Forward
- Comprehending the requirements for a pediatric clinical program for submission (FDA, EMA) with respect to clinical pharmacology data
- Obtaining expertise in modeling and simulation to inform clinical pharmacology program for submission
- Leveraging modeling expertise and “translating” into the clinical development program
- Reviewing lessons learned from real-life submissions of pediatric clinical pharmacology (modeled) data
Jeffrey Skolink MD, Senior Director, Clinical Development
AstraZeneca

11:15 Enhancing the Use of Adult Data and Changing it to Work for Children
- Utilizing modeling and simulation techniques to adapt adult data into data that will work in children to best determine the dose selection
- Examining techniques to assist in determining the probability of a successful trial
- Uncovering the dose-exposure-response similarity between adult and pediatric populations
- Understanding the altered body composition and physiology in children when compared to adults
Mike Roy PhD, Modeler
Astellas Pharma

12:00 Luncheon

Assessing The Modeling and Simulation in the Selection of Dose
ges
- Addressing techniques to get the dosage right the first time
- Providing information on a dose-response relationship, including a toxic dose and a no observed adverse effect level (NOAEL)
- Reviewing and understanding of the effects of volume, concentration, formulation, and the site of administration
- Use of physiologically based pharmacokinetic-pharmacodynamic modeling to dose selection and study design
Gina Pastino, Associate Director, Clinical Pharmacology & Translational Medicine
Eisai Medical Research

1:45 Evaluating Issues and Challenges in Pediatric Formulation Development
- Analyzing the requirements for pediatric formulations
- Examining the types of pediatric dosage forms and relevance to different age ranges
- Assessing the challenges in developing appropriate formulations for children
- Improving the use of formulations and extem poraneous preparations
Karen Thompson PhD, Distinguished Senior Investigator
Merck Research Labs

3:00 Utilizing Meta-Analysis to Improve Pediatric Drug Development
- Analyzing how to use modeling and simulation before creating novel study designs
- Demonstrating how systematic reviews and meta-analyses can inform clinical and health policy decisions
- Identifying fundamental components of a systematic review and meta-analysis
- Evaluating the quality of systematic review and meta-analysis
Margaret Wooddell PhD MPH MBA, Director, Clinical Development
Kyowa Hakko Kirin Pharma, Inc

3:45 A Single Unified Adult and Pediatric Population Pharmacokinetic Model Describing Drug Exposure in Both Adult and Pediatric Patients
- Comprehending the unique questions surrounding PK sample size in children
- Understanding how modeling and simulation play a role in concluding what the appropriate sample size should be
- Analyzing difference cases where modeling and simulation had a hand in the conclusion of what a adequate sample size was in pediatric drug development
Zexun Zhou, Associate Director, Clinical Pharmacology & Pharmacometrics, Bristol-Myers Squibb

4:30 Implementing Modeling and Simulation for Pediatric Investigational Plans
- Utilizing allometric scaling from adult pharmacokinetics when it is rational to do so
- Incorporating of known and/or expected maturation affects on disposition
- Bridging the gap between known and unknown data
- Understanding the impact of limited resolution
Albert John Allen MD PhD, Senior Medical Director
Eli Lilly

5:15 Closing Remarks of the Chair & Close of Conference

More Registration Details, Click Here

MARKETING INFO
For more information regarding sponsorship, speaking or attending this conference please contact, David Drey, +1 312 540 3000 ext 6583.

PRODUCER INFO
I would like to thank everyone who has assisted with the research and organization of the event, particularly the speakers for their support and commitment. Nicole Wilsey
Conference Producer, nicolew@marcusevansch.com.