OVERVIEW

As research subjects, children have special needs because of their vulnerabilities and developmental differences as compared to adults. Differences exist in the physiology, pathology, pharmacokinetics and pharmacodynamics between children and adults. These differences give credence to the fact that clinical trial data from the adult population cannot be extrapolated for use of medicines in the pediatric population.

There is much debate about the conduct of clinical trials in the pediatric population. Much of the debate is focused on how to balance the need for appropriately investigated medicines for children with the many ethical, practical, and regulatory issues that conducting clinical trials in the pediatric population involves. This program will explore these issues in the light of recent legislation and industry best practices.

TARGET AUDIENCE

This program will benefit
- Clinical investigators in academia and industry
- Investigative site personnel
- Regulatory Affairs personnel involved in clinical safety and pharmacovigilance
- Those interested in health policy
- Those involved in clinical research and development

PROGRAM COMMITTEE

CHRISTOPHER-PAUL MILNE, DVM, MPH, JD
Assistant Director
Tufts Center for the Study of Drug Development
Tufts University

M. RENEE SIMAR, PhD
Vice President, INC Pediatrics, INC Research

KLAUS ROSE, MD, MS
Head Pediatrics, Clinical Development and Medical Affairs
Novartis Pharma AG
Global Head Pediatrics
CD&MA, SWITZERLAND

TOPICS

- Overview of pediatric studies initiative in US
- Overview of pediatric studies initiative in EU
- Best Pharmaceuticals for Children Act
- Pediatric Research Equity Act
- Recruitment and retention challenges
- Children vs. adults in clinical trials
- Safety concerns
- Update on ethical issues

Tabletop Exhibit Opportunity

Contact Erin Gilliland, Exhibits Associate
Phone +1-215-442-6149 Fax +1-215-442-6199 email Erin.Gilliland@diahome.org
Accreditation and Credit Designation
The Drug Information Association is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. The Drug Information Association designates this educational activity for a maximum of 11 category 1 credits toward the AMA Physician’s Recognition Award. Each physician should claim only those credits that he/she actually spent in the activity.

If you would like to receive a statement of credit, you must attend the program and return the credit request and evaluation forms to the DIA. Statements of credit will be issued within 30 days of receipt of these forms.

Disclosure Policy: It is Drug Information Association policy that all faculty participating in continuing education activities must disclose to the program audience (1) any real or apparent conflicts of interest related to the content of their presentation and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosure will be included in the course materials.

Learning Objectives: At the conclusion of this meeting, participants should be able to:

- Explain the regulations and guidelines governing pediatric clinical research
- Describe the ethical, practical, and regulatory issues impacting pediatric clinical research
- Determine suitable designs for pediatric clinical trials
- Discuss the problems that can be encountered in clinical research
- Devise solutions to conducting appropriate trials for the pediatric population

Monday • October 24
6:00-8:00 PM
Registration

Tuesday • October 25
7:00-8:00 AM
Registration and Continental Breakfast

8:00-8:15 AM
Welcome and Opening Remarks
Christopher-Paul Milne, DVM, MPH, JD
Assistant Director
Tufts University MS Center for the Study of Drug Development

This session will commence with an overview of the status of the pediatric studies initiative in the US as we approach the time for public debate over its reauthorization. The current status and outline of the pediatric studies initiative in Europe will also be presented. In addition, speakers from NIH, FDA and industry will discuss the practical aspects of submitting requests to conduct pediatric studies under both the off-patent and on-patent programs of the Best Pharmaceuticals for Children Act (BPCA), as well as complying with the so-called “pediatric rule” as codified under the Pediatric Research Equity Act (PREA).

Overview of Pediatric Studies Initiative in US
Christopher-Paul Milne, DVM, MPH, JD
Assistant Director
Tufts University MS Center for the Study of Drug Development

Overview of Pediatric Studies Initiative in Europe
Klaus Rose, MD, MS
Head Pediatrics, Clinical Development and Medical Affairs
Novartis Pharma AG

BPCA Part I: Practical Aspects of Submitting Applications to NIH under BPCA
Anne Zajicek, MD, PharmD
Pediatric Medical Officer
Obstetric and Pediatric Pharmacology Branch,
Center for Research for Mothers and Children,
National Institute of Child Health and Human Development,
National Institutes of Health

10:00-10:15 AM
Refreshment Break

Overview of Pediatric Studies Initiative in Europe
Klaus Rose, MD, MS
Head Pediatrics, Clinical Development and Medical Affairs
Novartis Pharma AG

BPCA Part I: Practical Aspects of Submitting Applications to NIH under BPCA
Anne Zajicek, MD, PharmD
Pediatric Medical Officer
Obstetric and Pediatric Pharmacology Branch,
Center for Research for Mothers and Children,
National Institute of Child Health and Human Development,
National Institutes of Health

10:00-10:15 AM
Refreshment Break
10:15 AM - 12:00 PM  SESSION I CONT’D

**PEDIATRIC DRUG STUDY INITIATIVES IN THE US AND EUROPE: UPDATE AND REGULATORY PRIMER**

**BPCA PART II: PRACTICAL ASPECTS OF PEDIATRIC EXCLUSIVITY**
Chin Koerner  
Executive Director, DRA  
NOVARTIS PHARMACEUTICAL CORPORATION

**LINKAGES AND DIFFERENCES BETWEEN BPCA AND PREA**
Mary Dianne Murphy, MD  
Director, Office of Pediatric Therapeutics OC  
FDA

11:45-1:00 PM  LUNCHEON

1:00-2:30 PM  SESSION II

**PEDIATRIC CLINICAL TRIAL EXECUTION: CHALLENGES AND STRATEGIES FOR SUCCESS**

**CHAIRPERSON**
Renee Simar, PhD  
Vice President, INC Pediatrics  
INC RESEARCH

Pediatric product development has grown considerably in recent years, yet the best means to satisfy regulatory requirements remains elusive. It involves translating ethical principles into practical considerations unique to children and their families. Trial design and execution must consider the perspectives of industry, investigators and pediatric patients. This session will discuss strategies for “doable” designs, enrollment challenges, and protocol safeguards.

**SPONSOR AND INVESTIGATOR EXPECTATION FOR SUCCESSFUL IMPLEMENTATION**
Barry Mangum, PharmD  
Associate Clinical Professor Clinical Pharmacology  
DUKE UNIVERSITY MEDICAL CENTER, DUKE CLINICAL RESEARCH INSTITUTE

**RECRUITMENT AND RETENTION CHALLENGES: ISSUES FOR LONG-TERM SAFETY TRIALS OR COMPLEX MEDICAL CONDITIONS**
Renee Simar, PhD  
Vice President, INC Pediatrics  
INC RESEARCH

2:30-2:45 PM  REFRESHMENT BREAK

2:45-4:15 PM  SESSION II CONT’D

**PEDIATRIC CLINICAL TRIAL EXECUTION: CHALLENGES AND STRATEGIES FOR SUCCESS**

**CHILDREN VS. ADULT IN CTs: EXTRAPOLATION, ADOLESCENT GAP AND JOINT TRIALS**
Jon B. Bruss, MD, MPH, MBA, FAAP  
Chief Medical Officer  
PEDIAMED PHARMACEUTICALS-The Pediatrics Company

**OVERVIEW OF SAFETY REVIEWS MANDATED BY BPCA**
Rosemary Johann-Liang, MD, FAAP  
Deputy Director Division of Drug Risk Evaluation  
CDER, FDA

4:15-5:00 PM  QUESTION AND ANSWER PANEL

**WEDNESDAY • OCTOBER 26**

7:00-8:00 AM  REGISTRATION AND CONTINENTAL BREAKFAST

8:00-8:15 AM  OPENING REMARKS, SUMMARY OF DAY ONE AND PREVIEW OF DAY TWO

8:15-9:45 AM  SESSION III

**HOW WILL EU PEDIATRIC LEGISLATION STIMULATE PEDIATRIC RESEARCH?**

**CHAIRPERSON**
Klaus Rose, MD, MS  
Head Pediatrics, Clinical Development and Medical Affairs  
NOVARTIS PHARMA AG

It will take several years before drugs that are now in early development will require pediatric trials. For most of today’s modern drugs a significant amount of pediatric data has already been generated due to the US legislation. This includes data on dosing, PK/PD, new indications, safety & efficacy, and pediatric formulations. Significant clinical questions remain that require additional pediatric research on existing medicines. This debate has in Europe only just initiated. As the planned pediatric EMEA structures do not yet exist, it is now time to prepare suitable ways for communication, guidance, and preliminary commitments between health authorities, industry and clinicians. Effective stimulation of pediatric clinical research in Europe also requires a concerted, broad public awareness.
PEDIATRIC RESEARCH IN A GLOBAL ENVIRONMENT
Klaus Rose, MD, MS
Head Pediatrics, Clinical Development and Medical Affairs
Novartis Pharma AG

US WORKING IN EU SYSTEMS
Speaker invited

9:45-10:00 AM  REFRESHMENT BREAK

10:00-11:30 AM  SESSION III CONT’D
HOW WILL EU PEDIATRIC LEGISLATION STIMULATE PEDIATRIC RESEARCH?
UPDATE ON ETHICAL ISSUES
Speaker invited

Statements made by speakers are their own opinion and not necessarily that of the organization they represent, or that of the Drug Information Association.
Speakers and agenda are subject to change without notice. Recording of any DIA tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA.

TRAVEL AND HOTEL  The most convenient airport is Ronald Reagan National Airport and attendees should make airline reservations as early as possible to ensure availability. The Washington Marriott Hotel is holding a block of rooms at the reduced rate below until October 3, 2005, or until block is filled, for the DIA meeting attendees.

Single $209  Double $209
Please contact the Washington Marriott Hotel by telephone at +1-800-228-9290 or +1-202-872-1500 or by fax at +1-202-872-1424 and mention the DIA meeting. The hotel is located at 1221 22nd Street NW, Washington, DC 20037, USA.

GROUP DISCOUNTS*  Register 3 individuals from the same company and receive complimentary registration for a 4th! All 4 individuals must register and prepay at the same time – no exceptions. DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred. Group registration is not available online and does not apply to the already-discounted fees for government or charitable nonprofit/academia.

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Participants with Disabilities: DIA meeting facilities and overnight accommodations are accessible to persons with disabilities. Services will be made available to sensory-impaired persons attending the meeting if requested at least 15 days prior to meeting. Contact the DIA office to indicate your needs.

DRUG INFORMATION ASSOCIATION  http://www.diahome.org

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US Airways  US Airways’ Group and Meeting Reservations staff can assist you in obtaining flight, fare and availability information toll-free at +1-877-874-7687. Be sure to refer to Gold File Number 22633254.
Ethical, Practical and Regulatory Issues in Pediatric Clinical Trials

Meeting ID #05036
Washington Marriott Hotel, Washington, DC, USA
OCTOBER 25-26, 2005

Register online or fax this page to +1-215-442-6199

CONTACT & TABLETOP EXHIBIT INFORMATION
Attendees may visit the tabletop exhibits during the meeting and receptions.
Meeting information: Contact Jolene McNeil at the DIA office by telephone +1-215-293-5810, fax +1-215-442-6199 or email Jolene.McNeil@diahome.org.
Tabletop exhibit information: Contact Erin Gilliland, Exhibits Associate, at the DIA office by telephone +1-215-442-6149, fax +1-215-442-6199 or email Erin.Gilliland@diahome.org. For tabletop exhibit space, please check the box below.
☐ To receive a tabletop exhibit application, please check.

GROUP DISCOUNTS (not available online or on already discounted fees)
Register 3 individuals from the same company and receive complimentary registration for a 4th! All 4 individuals must register and prepay at the same time. See page 5 for complete details.

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