

## ***Pediatric Drug & Medical Device Development: Setting Specifications & Defining Expectations***

**February 26, 2009  
8:30 a.m. – 5:30 p.m.  
Natcher Conference Center  
45 Center Drive  
National Institutes of Health  
Bethesda, Maryland**

### **AGENDA**

#### **Morning Session (8:30 a.m. – Noon)**

**8:30 a.m.**

#### **Welcome and Introductions:**

Dr. Mary Purucker, NCRR and NIH Co-Chair, Pediatric Drugs and Devices Workgroup, CTSA Consortium Child Health Oversight Committee (CC-CHOC)

#### **Overview of CTSA Program as Framework for Expectations**

Dr. Anthony Hayward, Director, Division of Clinical Research Resources, NCRR, NIH

#### **Purpose, Vision and Expected Outcomes**

Dr. Carole Marcus, Professor of Pediatrics, Director of Sleep Center, Children's Hospital of Philadelphia; Co-Chair, Pediatric Drugs and Devices Workgroup, CC-CHOC; and Dr. Jennifer Li, Professor of Pediatrics, Division of Cardiology, Duke University Medical Center; and Co-Chair, Pediatric Drugs and Devices Workgroup, CC-CHOC  
**Dr. Carole Marcus** presenting

#### **Current Status of U.S. Pediatric Clinical Research Infrastructure**

Dr. Richard "Mort" Wasserman, University of Vermont and representing the American Academy of Pediatrics; and Dr. Anne Zajicek, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

#### **Introduction to Panel Format, Etiquette and Housekeeping Issues**

Dr. Mary Purucker

#### **BREAK (15 min.)**

**10:00 a.m.**

#### **Comments on Child Health Research**

Dr. Steven Hirschfeld, Associate Director for Clinical Research, NICHD and NIH Co-Chair, Pediatric Drugs and Devices Workgroup, CC-CHOC; and Dr. Duane Alexander, Director, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and member, Advisory Board, CTSA Program

**Panel 1. Pediatric Medical Product Development: EU Perspective**

Dr. Adriana Ceci, Consorzio per Valutazioni Biologiche e Farmacologiche, representing TEDDY NoE (<http://www.teddyoung.org/>)

Dr. Kalle Hoppu, University of Helsinki, representing FINPEDMED ([www.finpedmed.com](http://www.finpedmed.com))

Dr. Martin Offringa, University of Amsterdam, representing Medicines for Children Research Network (<http://www.mcrn.nl/>)

Drs. Monika Seibert-Grafe and Raunhild Butzer, University of Mainz, representing PAED-net (<http://www.paed-net.org/>)

Via teleconference.

**Panel 2. U.S. Regulatory Framework for Pharmaceutical Development**

Chair: Dr. Dianne Murphy, Director, FDA Office of Pediatric Therapeutics. Panel will discuss pediatric labeling, claims and exclusivity for pharmaceuticals, licensure for pediatric medical devices, orphan products designation, and human subject protection issues unique to children in therapeutics clinical trials.

Noon – 1:00 p.m.

**LUNCH (on your own)**

Afternoon Session: 1:00 – 5:30 p.m.

Each of the following panels will provide their perspective by describing their expectations of a partnership with a national child health clinical and translational infrastructure to develop pediatric products with specific recommendations for the infrastructure as well as comments on what collaborating partners may provide.

1:00 p.m.

**Panel 3: What do large Pharmaceutical Companies expect and what can they offer?**

Panel chaired by Dr. Mary Christian, Co-Chair, Pediatric Drug Development Committee, Bristol-Myers Squibb

**Panel 4: What do Biotechnology Companies expect and what can they offer?**

Panel chaired by Dr. Lawrence Grylack, PAREXEL Consulting

**Panel 5: What do Medical Device Manufacturers expect and what can they offer?**

Panel chaired by Dr. Robert Campbell, Children's Hospital of Philadelphia

**BREAK (15 min.)**

3:30 p.m.

**Panel 6. What do Advocacy and Patient/Parent Groups expect and what can they offer?**

Panel chaired by Ms. Ann Gettys, Children's Interstitial Lung Disease Foundation

**Panel 7. What do Nonprofit Organizations and Academic Investigators expect and what can they offer?**

Panel chaired by Dr. Andre Muelenaer, Jr., Carilion Biomedical Institute

**Summary of what has been learned: Important components identified by stakeholders to be incorporated into the process of pediatric product development. With discussion.**

Drs. Jennifer Li & Carole Marcus, Co-Chairs, CC-CHOC Pediatric Drugs and Devices Workgroup

**Wrap up & Next Steps**

Drs. Jennifer Li & Carole Marcus, Co-Chairs, CC-CHOC Pediatric Drugs and Devices Workgroup

**NOTE:** Following the Workshop, materials will be posted on the CTSA public website, [www.ctsaweb.org](http://www.ctsaweb.org), and on the CC-CHOC Pediatric Drug and Medical Device Development Workshop registration site, [www.seeuthere.com/pediatric](http://www.seeuthere.com/pediatric).