URGENT:
Improving Pediatric Trials in Antibacterial Drug Development
No Sick Child Left Behind

Agenda of the Multi-Stakeholder Expert Meeting held Tuesday, April 5, 2016

Sheraton Silver Spring Hotel
8777 Georgia Avenue
Silver Spring, MD 20910

CTTI MISSION: To identify and promote practices that will increase the quality and efficiency of clinical trials

MEETING OBJECTIVES:

- Present findings
- Identify remaining gaps that may require further exploration
- Present and obtain feedback on draft considerations to improve the successful conduct and execution of pediatric antibacterial drug trials
- Develop initial consensus on the mechanisms for improving the conduct and execution of pediatric trials of antibacterial drugs

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7:15 AM **Registration and Breakfast** *(Provided)*

8:00 AM **Welcoming Remarks**

8:00 Introduction to the Clinical Trials Transformation Initiative and the ABDD Program
Pamela Tenaerts, Clinical Trials Transformation Initiative (CTTI)

8:15 Opening Remarks, Housekeeping
Jamie Roberts, Clinical Trials Transformation Initiative (CTTI)

8:30AM **Session I: The Challenge**

Facilitator: John Bradley, Rady Children's Hospital / UCSD
Session I Topics:

- Progress in antibacterial drug development: Perspectives from the FDA
- Mechanisms intended to foster pediatric drug development (BPCA/PREA)
- Infrastructure and networks supporting clinical trials for pediatric populations

8:30 Addressing the Challenges of Antibacterial Drug Development
Edward Cox, Food and Drug Administration, CDER

8:45 PREA & BPCA: The Details
Lynne Yao, Food and Drug Administration, CDER

9:00 Public/Private Partnerships to Support Pediatric Trials
Edward Connor, Clinical Research Alliance

9:15 Opportunities: Pediatric Trial Networks
Brian Smith, Duke University Medical Center, Duke Clinical Research Institute (DCRI)

9:30 Open Discussion

10:00 AM **Break** *(Refreshments Provided)*

10:15AM **Session II: The Landscape**

Facilitator: Gary Noel, Johnson and Johnson
Session II Objectives:

- Present and discuss findings from the AACT database review of Pediatric Trials of Antimicrobials
- Present and discuss findings from the FDA review of PREA and BPCA submissions
- Present and discuss US and global approaches to pediatric clinical trials

10:15 Quantifying Pediatric AB Trials in Clinical Trials.Gov
Joshua Thaden, Duke University School of Medicine

10:30 Quantifying BPCA and PREA Submissions
John Farley; Food and Drug Administration, CDER

10:45 US and Global Initiatives for Pediatric Trials in Antibacterials
Pamela Tenaerts, CTTI; Hasan Jafri, MedImmune; Mike Sharland, St. George's University Hospital

11:00 Open Discussion

11:30 **Working Lunch** *(Provided)*

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12:00 PM **Session III: The Findings**

Facilitator: Rosemary Tiernan, Food and Drug Administration, CDER
Session III Objectives:

- Present and discuss findings from interviews with parents
- Present and discuss findings from surveys of providers and investigators
- Present and discuss findings from interviews with industry personnel

12:00 Parent and Caregiver Perspectives
Diane Bloom, InFocus Research

12:15 Investigator Perspectives
Amy Corneli, Duke Clinical Research Institute

12:30 Community Provider Perspectives
Rachel Greenberg, Duke University School of Medicine

12:45 Industry Perspectives
Gary Noel, Johnson and Johnson

1:00 Open Discussion

1:30 **Break** *(Refreshments Provided)*

1:45 PM **Session IV: Presentation of Considerations and Breakouts**

Facilitator: Christopher Wheeler, Food and Drug Administration, CDER
Session IV Objectives:

- Present and discuss considerations for communicating with parents
- Present considerations for conducting studies for neonatal infections
- Present and discuss considerations for improving trial design and development

1:45 Communicating with Parents: Approaches to Informed Consent
Breck Gamel, Cincinnati Children's Hospital & Cystic Fibrosis Foundation

2:00 Considerations for Conducting Studies in Neonates
Brian Smith; Duke University Medical Center, DCRI

2:15 Improving Trial Design: Meeting the Needs of Investigators
John Bradley; Rady Children's Hospital, UCSD

2:30 Open Discussion

2:45 Intro and Move to Breakout Sessions

3:00PM **Session V: Breakout Sessions**

Breakout 1: Addressing challenges in neonatal infection studies
Facilitator: Brian Smith; Duke University Medical Center, DCRI

Breakout 2: Addressing challenges in informed consent for children
Facilitator: Rosemary Tiernan, Food and Drug Administration, CDER

Breakout 3: Making pediatric antibacterial drug trials more feasible & efficient
Facilitator: Pamela Tenaerts, CTTI

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4:15 PM	**Session VI: Breakout Session Reports**
4:15	**Report-Out 1:** Addressing challenges in neonatal infection studies
4:25	**Report-Out 2:** Addressing challenges in informed consent for children
4:35	**Report-Out 3:** Making pediatric antibacterial drug trials more feasible & efficient
4:45 PM	**Meeting Wrap Up**
4:45	**Highlights, Next Steps, Adjourn** *Jamie Roberts, CTTI; Sumathi Nambiar, Food and Drug Administration, CDER*