INSTITUTE FOR ADVANCED CLINICAL TRIALS FOR CHILDREN

PEDIATRIC RESEARCH INNOVATION FORUM 2019

INCLUSION OF ADOLESCENTS IN ADULT CLINICAL TRIALS

Adolescents in Adult Clinical Trials: Implementing the Vision

Oct. 15-16, 2019
Pooks Hill Marriott – Bethesda, Md.

Purpose: The workshop will focus on bioethical, scientific and operational issues related to inclusion of adolescents in adult clinical trials that are designed to assess the efficacy and safety of investigational drugs. The goal of the workshop is to define the major gaps and develop recommendations to support implementation.

Format: Planning Committee and stakeholder representatives will develop a draft framework that will outline the landscape of the bioethical, scientific and operational issues related to inclusion of adolescents in adult clinical trials and provide a set of questions for each of three topic areas that panelists will address. Participants will use the discussions from Day 1 to refine the draft framework in working sessions on the morning of Day 2, and a revised framework will be presented and discussed in the afternoon.

Outcome: The outcome of this meeting will be a summary document with recommendations designed to assist in implementation of the vision for inclusion of adolescents in adult clinical trials.

Agenda

Day 1

11:30 am	**Registration open** **Working Lunch**	*Congressional Ballroom*
Noon-12:15 pm	**Goals, Objectives, Workshop Format** *Ed Connor, MD, MBE, I-ACT for Children*	
12:15-1:15 pm	**Background, Current Landscape & Gaps** *Christina Bucci-Rechtweg, MD, Novartis* *Carmen Moreno, MD, PhD, conect4children* *Lily (Yeruk) Mulugeta, PharmD, U.S. Food & Drug Administration* *Collin Hovinga, PharmD, I-ACT for Children*	

1:15-2:15 pm **Panel 1: Scientific, Trial Design & Analytical Issues & Potential Solutions**

Moderators: *Dionna Green, MD, U.S. Food & Drug Administration*
Margaret Gamalo, PhD, Eli Lilly

Panelists: *Holly Lindsay, MD, Texas Children's Hospital*
John Bradley, MD, Rady Children's Hospital
Tara Altepeter, MD, U.S. Food & Drug Administration
Pamela Zeitlin, MD, National Jewish Health
Bernd Meibohm, PhD, University of Tennessee
Lily (Yeruk) Mulugeta, PharmD, U.S. Food & Drug Administration
Wallace Crandall, MD, Eli Lilly
Tonya Winders, MBA, Allergy & Asthma Network

2:15-2:30 pm **Break**

2:30-3:30 pm **Panel 2: Bioethical Issues & Other Adolescent-Specific Factors**

Moderators: *Robert "Skip" Nelson, MD, PhD, Johnson & Johnson*
Donna Snyder, MD, U.S. Food & Drug Administration

Panelists: *Alison Bateman-House, MPH, PhD, New York University*
Melanie Bhatnagar, MD, U.S. Food & Drug Administration
Ross McKinney Jr., MD, American Association of Medical Colleges
Albert J. "AJ" Allen, MD, PhD, Eli Lilly
Kristin Stegenga, PhD, RN, Children's Mercy Hospital
Vivian Tsang, KidsCan Young Persons' Advisory Group
Laura Schanberg, MD, Duke University

3:30-4:45 pm **Panel 3: Operational Challenges, Lessons Learned & Proposed Solutions**

Moderators: *Thomas F. Miller, PhD, Bayer*
Gregory Reaman, MD, U.S. Food & Drug Administration

Panelists: *Lisa Imundo, MD, Columbia University*
Kathleen Neville, MD, Johnson & Johnson
Rohan Hazra, MD, National Institute of Child Health & Human Development
Mary Short, RN, MSN, Eli Lilly
Elaine Siegfried, MD, Saint Louis University
Suvankar Majumdar, MD, Children's National Medical Center
Lynne Yao, MD, U.S. Food & Drug Administration
Julie Block, National Eczema Association

4:45-5 pm	**Day 1 Summary** *Ron Portman, MD, Novartis*	
5-5:15 pm	**Working Group Assignments, Format & Objectives for Day 2** *Laura Gordon, I-ACT for Children*	
5:45 pm	**Moderators meet with Day 2 Rapporteurs**	*Congressional Ballroom*
6 pm	**Dinner** *Guest speakers: Lucas and Karla Kramer*	*Grand Ballroom*

<u>Day 2</u>

8-8:30 am	**Breakfast**	*Congressional Ballroom*
8:30 am-Noon	**Working Group Sessions**	*Congressional Ballroom, Annapolis & Chesapeake*
Noon-1 pm	**Working Lunch**	*Congressional Ballroom*
1-4 pm	**Presentation of Draft Framework and Recommendations** *Working Group moderators*	
4-4:30 pm	**Summary, Closing Remarks and Next Steps** *Ed Connor, MD, MBE, I-ACT for Children* *Ron Portman, MD, Novartis*	

If you need assistance or have any questions, please contact:

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