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  Congressional Ballroom
           Working Lunch

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, connect4children  
               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**  
*Grand Ballroom*

*Guest speakers: Lucas and Karla Kramer*

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**Day 2**

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*

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_If you need assistance or have any questions, please contact:_

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