

Advancing Pediatric Platform Trials: Streamlining Development, Maximizing Impact

Workshop agenda

Major Depressive Disorder (MDD) – Room Location: West Wing

Day 1: Tuesday, October 29, 2024

Time	Topic	Speaker
8:00 – 8:30 AM	Breakfast (on-site)	
8:30 – 8:45 AM Room Location: Art Gallery	Welcome	Lisa Koppelman The Multi-Regional Clinical Trials Center of Brigham & Women's Hospital and Harvard
8:45 – 9:45 AM Room Location: Art Gallery	Keynote Address: Platform Trials for Children: History, Common Goals, and a Path Forward	Dr. Danny Benjamin Duke University
9:45 – 10:45 AM Room Location: Art Gallery	Keynote Address: Intellectual Property Considerations in Platform Trials	Dr. Melissa Rones Ropes & Gray
10:45 – 11:00 AM	Coffee/tea break	
11:00 AM – 12:00 PM Room Location: Art Gallery	Panel Discussion and Q&A Multi-stakeholder Perspectives for the Design and Implementation of Pediatric Platform Trials	Dr. Barbara Bierer (Moderator) The Multi-Regional Clinical Trials Center of Brigham & Women's Hospital and Harvard Dr. Danny Benjamin Duke University



		Dr. Suzie McCune PPD Clinical Research Business of Thermo Fisher Scientific Dr. Melissa Rones Ropes & Gray
12:00 – 1:00 PM	Lunch (on-site)	
MDD Breakout Sessions: Disease-area experts will discuss study design, operational considerations, & legal implications of implementing pediatric platform trials.		
1:00 – 1:30 PM Room Location: West Wing	MDD Breakout Session 1 <i>(inclusive of afternoon beverage break)</i> Study Design How can we design a pediatric MDD platform trial to increase the probability of a positive trial? <i>*The designated person will moderate the discussion of each question/topic area. Other than any introductory comments, there will not be any formal presentations to allow sufficient time for discussion among the attendees.</i>	1. Dr. Robert “Skip” Nelson Johnson & Johnson <i>Extrapolation</i>
1:30 – 2:00 PM Room Location: West Wing		2. Dr. Robert Findling Virginia Commonwealth University School of Medicine <i>Dosing</i>
2:00 – 2:30 PM Room Location: West Wing		3. Dr. Manpreet Kaur Singh University of California-Davis <i>Placebo Response</i>
2:30 – 3:00 PM Room Location: West Wing		4. Dr. Margaret Grabb National Institute of Mental Health <i>Biomarkers/Measure</i>
3:00 – 3:30 PM Room Location: West Wing		5. Dr. Melissa DelBello University of Cincinnati College of Medicine <i>Monotherapy and/or “add-on” treatments</i>
3:30 – 4:00 PM Room Location: West Wing		6. Dr. Christoph Correll Zucker School of Medicine & Charité University <i>Study Design Challenges</i>



4:00 - 4:30 PM Room Location: West Wing		7. Drs. Robert "Skip" Nelson and Manpreet Kaur Singh Johnson & Johnson and University of California-Davis <i>Summary and Preparation for Day 2</i>
5:30 PM	Group Dinner (<u>Mission Dupont</u>)	

Day 2: Wednesday, October 30, 2024

Time	Topic	Speaker
7:30 – 8:00 AM	Breakfast (on-site)	
8:00 – 9:00 AM Room Location: Art Gallery	Keynote Address: Designing a platform trial for depression: Experience from EU-PEARL	Prof. Dr. Stefan Gold Charité – Universitätsmedizin Berlin
MDR-TB Breakout Sessions: Disease-area experts will discuss study design, operational considerations, & legal implications of implementing pediatric platform trials.		
9:00 – 10:45 AM Room Location: West Wing	MDD Breakout Session 2 Panel & Group Discussions on Planning and Executing a Pediatric MDD Trial Platform Discussion Topics: - Establishing platform trial networks	Moderator Dr. Robert "Skip" Nelson Johnson and Johnson Panelists 1. Dr. Christoph Correll Zucker School of Medicine & Charité University 2. Dr. Melissa DelBello University of Cincinnati College of Medicine 3. Dr. Willie Earley Intra-Cellular Therapies



	- Sponsorship of a platform trial - Implementation of a high-quality and cost-effective platform trial	4. Dr. Robert Findling Virginia Commonwealth University School of Medicine 5. Dr. Margaret Grabb National Institute of Mental Health 6. Dr. Susan McCune PPD Clinical Research Business of Thermo Fisher Scientific 7. Dr. Gahan Pandina Janssen Research and Development 8. Dr. Adelaide Robb Children’s National Hospital
10:45 – 11:00 AM	Break	
All Attendees Reconvene in the Main Room Room Location: Art Gallery		
11:00 AM – 12:30 PM Room Location: Art Gallery	Breakout Session Report Outs Thematic learnings from breakout sessions, which include identified issues, causation, barriers, and identified solutions	Co-leads & Breakout Groups
12:45 – 1:30 PM	Lunch (on-site)	
1:30 – 2:15 PM Room Location: Art Gallery	Group Discussion (All Attendees) Part 1: Commonalities and Differences Across Disease Areas	Co-leads



2:15 – 3:15 PM Room Location: Art Gallery	Group Discussion (Cont.) (All Attendees) Part 2: Next Steps & Synthesis	Dr. Barbara Bierer (<i>Moderator</i>) The Multi-Regional Clinical Trials Center of Brigham & Women's Hospital and Harvard
3:15 – 3:30 PM Room Location: Art Gallery	Closing Remarks	Dr. Barbara Bierer The Multi-Regional Clinical Trials Center of Brigham & Women's Hospital and Harvard

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