

Advancing Pediatric Platform Trials: Streamlining Development, Maximizing Impact

Workshop agenda

Multi Drug-Resistant Tuberculosis (MDR-TB) Breakout Sessions – Room Location: Second Gallery

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)	
MDR-TB Breakout Sessions: Disease-area experts will discuss study design, operational considerations, & legal implications of implementing pediatric platform trials.		
1:00 – 2:10 PM Room Location: Second Gallery	MDR-TB Breakout Session 1 Introduction and Context Setting	Drs. Tony Garcia-Prats and Sumati Nambiar University of Wisconsin-Madison and Johnson & Johnson <i>Introductions, Ground Rules, and Day 1 Objectives</i> Dr. Tony Garcia-Prats University of Wisconsin-Madison <i>Current capacity, opportunities, and challenges with pediatric trials in MDR-TB</i> Dr. David Holtzman Bill & Melinda Gates Medical Research Institute <i>Lessons for a pediatric MDR-TB platform trial from PAN-TB</i> Q & A Discussion (All)
2:10 – 2:20 PM	Break	



2:20 – 4:30 PM Room Location: Second Gallery	MDR-TB Breakout Session 2 Focused Topic Discussions	Dr. Anneke Hesseling (Facilitator) Desmond Tutu TB Centre at Stellenbosch University <i>Scientific/trial design considerations</i> Dr. Patrick Jean-Philippe (Facilitator) National Institute of Allergy and Infectious Diseases (NIAID) <i>Trial site capacity and operational considerations</i> Dr. Martina Penazzato (Facilitator) World Health Organization (WHO) <i>Industry/TB drug developer considerations</i> Drs. Sumati Nambiar and Tony Garcia-Prats University of Madison-Wisconsin and Johnson & Johnson <i>Day 1 Summary and Closing</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 - 9:15 AM Room Location: Second Gallery	MDR-TB Breakout Session Recap of Day 1 and Day 2 Objectives	1. Drs. Tony Garcia-Prats and Sumati Nambiar University of Madison-Wisconsin and Johnson & Johnson
9:15 - 10:45 AM Room Location: Second Gallery	MDR-TB Breakout Session 3 Focused Topic Discussions (Cont'd)	1. Lindsay Mckenna (Facilitator) Treatment Action Group Community and Country Engagement 2. Drs. Sumati Nambiar and Tony Garcia-Prats (Facilitators) University of Madison-Wisconsin and Johnson & Johnson Follow-up discussions from Day 1, Next Steps 3. Prepare Report Out for Large Group
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

Workshop Sponsorship

Johnson & Johnson, AstraZeneca, and Sanofi have provided sponsorship grants towards this independent program. Sanofi is part of the Steering Committee of the MRCT Center. Johnson & Johnson and AstraZeneca are part of the Executive Committee.

