

Advancing Pediatric Platform Trials: Streamlining Development, Maximizing Impact

Workshop agenda

Hematologic Oncology Breakout Sessions – Room Location: Chancellory

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)	
Oncology Breakout Sessions: Disease-area experts will discuss study design, operational considerations, & legal implications of implementing pediatric platform trials.		
1:00 – 2:00 PM Room Location: Chancellory	Oncology Breakout Session 1 Why we are here and what we (hope) to accomplish?	Dr. Adam Levy (<i>Facilitator</i>) Bristol Myers Squibb (BMS): <i>What is better, faster, most cost effective for each stakeholder and are advantages clear to all?</i> Dr. Dominik Karres European Medicines Agency (EMA): <i>Agreement on shared meeting objectives and platform trial value proposition; discussion of GLO-B-NHL</i> Dr. Martha Donoghue US Food and Drug Administration (FDA): <i>Regulatory perspective and examples of EMA-FDA collaboration</i>
2:00 – 3:00 PM Room Location: Chancellory	Oncology Breakout Session 2 Reflecting on the major feasibility challenges, what is key towards success	Dr. Andy Kolb (<i>Facilitator</i>) Leukemia & Lymphoma Society (LLS) <i>Barriers to international trials and those utilizing existing infrastructure. Other limitations?</i>



		2. Dr. Douglas Hawkins Seattle Children's & University of Washington <i>Rare populations of rare diseases require tempered expectations and highly coordinated, collaborative effort</i> 3. Dr. Wendy London Boston Children's Hospital/Harvard Medical School <i>Trial design challenges and possible solutions</i> 4. Dr. Amy Rosenfeld AstraZeneca <i>Industry perspective on feasibility challenges and steps toward success</i>
3:00 – 3:15 PM	Break	
3:15 – 4:30 PM Room Location: Chancellory	Oncology Breakout Session 3 Examples of past/current platform trials: Looking ahead, what can be part of the solution?	1. Dr. Pamela Kearns (Facilitator) ITCC and University of Birmingham <i>Features of a successful platform; how successful have these examples been at achieving our shared objectives; identification of gaps</i> 2. Dr. Todd Cooper Seattle Children's <i>PedAL</i> 3. Dr. Douglas Hawkins Seattle Children's & University of Washington <i>Pediatric Match</i>



		4. Dr. Adam Levy BMS <i>Pharma perspective on participation in platform trials with academic sponsors/participation</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
Oncology 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: Chancellory	Oncology Breakout Session 4 Day 1 Breakout Session Recaps Multi-stakeholder perspectives for concrete next steps	1. Dr. Dominik Karres (<i>Facilitator</i>) European Medicines Agency (EMA) 2. Dr. Adam Levy Bristol Myers Squibb (BMS): 3. Dr. Andy Kolb Leukemia & Lymphoma Society (LLS) 4. Dr. Pamela Kearns ITCC and University of Birmingham
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.

