MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER OF BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

MRCT Center 2025 Annual Symposium

Wednesday, October 22, 2025

Ropes & Gray, Prudential Tower, 800 Boylston Street, Boston, MA 02199

7:45 – 8:15	**Breakfast & Registration**
8:15 – 8:30	**Welcoming Remarks** • Barbara Bierer, MRCT Center • Mark Barnes, Ropes & Gray and MRCT Center
8:30 – 9:30	**Keynote:** **John F. Crowley** President and CEO Biotechnology Innovation Organization (BIO)
9:30-10:45	**Panel 1** **Clinical Trial Reform: The need for change and progress** This panel will reflect on John Crowley's vision for clinical trial reform and priorities to improve access to innovative therapies. Perspectives from Industry, government, and the patient/participant community will contribute to the discussion. **Panelists** • Bridgette René McCullough, ACIRAH Health, Inc. • Ann Meeker-O'Connell, Novartis • Kevin Bugin, Amgen • Karen Hartman, Mayo Clinic **Moderators:** Barbara Bierer, MRCT Center & Mark Barnes, Ropes & Gray and MRCT Center

10:45-11:00	**Break**
11:00-11:30	**Meeting the Moment in an Evolving Research Environment** MRCT Center Executive Director Sarah White will reflect on the past year and the MRCT Center's steadfast commitment to advance ethical, actionable, and practical solutions for global clinical trials.
11:30-12:45	**Panel 2** **Rethinking Informed Consent with Artificial Intelligence: Opportunities and Challenges** This panel will focus specifically on how artificial intelligence (AI), including large language models (LLMs), could reshape informed consent in clinical research. This session intends to provoke a forward-looking discussion about the opportunities and challenges of redesigning the informed consent process with AI tools, including perspectives on participant-centered design, ethical considerations, and regulatory implications. **Panelists:** • Megan Doerr, SAGE Bionetworks • Michael Cohen-Wolkowiez, Duke University • Cristin Freeman, Bristol Myers Squibb **Moderator:** Barbara Bierer, MRCT Center
12:45-1:45	**Lunch for All Attendees**
1:45-3:00	**Panel 3** **Cell and Gene Therapies Long-Term Follow-Up (LTFU): Key Deliverables and the Path Forward** In this session, we will provide an overview of draft resources developed by the MRCT Center LTFU Working Group that aim to improve the design, conduct, and reporting of LTFU studies and decrease the significant burden on patients as well as sponsors. A panel of experts, including members of the working group, will discuss the resources, brainstorm innovative approaches and

	solutions for LTFU for GTs, and consider next steps. **Panelists:** • Pamela Tenaerts, Chief Medical Officer, Medable • Daniel Kavanagh, Senior Scientific Advisor, Gene Therapy, Vaccines & Biologics, WCG • Lara Gehl, Bristol Myers Squibb **Moderator:** Carolyn Chapman, MRCT Center

3:00-3:45	**MRCT Center Updates**
	
	Select MRCT Center initiatives
	
	• Representation in Research
	  o Willyanne DeCormier Plosky, MRCT Center
	• Capacity building, TRACE Project
	  o Sarah White, MRCT Center
	• Joint Task Force for Clinical Trial Competency (JTF)
	  o Sylvia Baedorf Kassis, MRCT Center
	• Promoting Global Clinical Research in Children
	  o Lisa Koppelman, MRCT Center
	• European Health Data Space (EHDS)
	  o Barbara Bierer, MRCT Center

3:45-4:00	**Break**
4:00–5:15	**Reinventing Informed Consent: Interactive Session** This is an interactive session focused on rethinking, reinventing, and innovating the consent 'form' and 'process' from the ground up. Participants will explore varying structural and technological changes to consent for interventional clinical trials. Through brainstorming, discussion, prioritization, and interaction, participants will identify opportunities for feasible and impactful innovations in informed consent, laying the groundwork for our next major project. **Moderator:** Barbara Bierer, MRCT Center

5:15-5:30	**Wrap-up and closing** • Sarah White, MRCT Center • Barbara Bierer, MRCT Center • Mark Barnes, Ropes & Gray and MRCT Center
5:30-6:30	**Cocktails**

Thursday, October 23, 2025

Loeb House at Harvard University, 17 Quincy Street, Cambridge, MA 02138

2025 Vivli Annual Meeting, "Data in Action: From Contribution to Impact

On Thursday, October 23, the MRCT Center will be holding a joint event with Vivli. During this meeting, participants will explore how researchers, data contributors, and funders are transforming clinical trial data into real-world health impact, hear how platforms like Vivli are enabling responsible data sharing and fostering a cycle of data re-use, and learn about success stories of groundbreaking data challenges and how they are shaping new developments in various fields of medicine. This event is complimentary and open to all Symposium registrants.

For more information, please visit: https://vivli.org/data-in-action-from-contribution-to-impact/