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

MRCT Center 2026 Annual Symposium

Wednesday, October 21, 2026

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** **Karim Mikhail, Director of the Center for Biologics Evaluation and Research (CBER), U.S. Food and Drug Administration** Operation TrialBlazer Update
9:30 –10:45	**Panel 1** **Response to Keynote: Ideation to Implementation and Scale** Panelists will respond to the keynote, which will discuss Operation TrialBlazer, a roadmap for maintaining U.S. leadership in early clinical research and development, as well as planned initiatives. **Panelists:** • Ginny Beakes-Read, Johnson & Johnson • Karen Hartman, Mayo Clinic • Jennifer Sheller, Merck **Moderators: Barbara Bierer, MRCT Center & Mark Barnes, Ropes & Gray / MRCT Center**
10:45–11:00	**Break**
11:00–12:15	**Panel 2** **Returning Summary Results to Participants: Lessons from the EU and UK Experience: Optimizing for US Application**

	The United States NIH has released a draft policy on the return of study summary results to participants, and there are lessons we can learn from our global colleagues who have gone before us. This panel will feature participant, researcher, and regulator perspectives from the European Union and the United Kingdom. Following each panelist's introductory remarks, a moderated discussion will delve deeper into their experience with returning aggregate results, what they wish they had known or done differently when the return of results process was first envisioned, and what they recommend for those who are just getting started. **Panelists:** • Adam Berger, U.S. National Institutes of Health • Johanna Blom, University of Modena, Italy • Clive Collett, Health Research Authority, UK • Veronica Popa, EURORDIS **Moderator:** Sylvia Baedorf Kassis, MRCT Center
12:15–1:15	**Lunch for All Attendees**
1:15–2:30	**Panel 3** **Post-trial Obligations: An Integrated Decision Model for Clinical Trial Placement** This panel explores the circumstances that challenge placement of clinical trials, the ability to achieve durable access in a country or community where a trial may be conducted, and the acceptability of reciprocal benefits when durable access is not, or will not be, realistic. The panel will also reflect upon the MRCT Center's draft Integrated Decision Model for Clinical Trial Placement, developed by a small team of the MRCT Center's PTR Taskforce, and designed to guide sponsors as they grapple with this deeply complex challenge. **Panelists:** • Ginny Acha, Merck • Joseph Ali, Johns Hopkins University • Karla Childers, Johnson & Johnson

	Moderator: Sarah White, MRCT Center
2:30–3:15	**Panel 4** **MRCT Center Updates** Select MRCT Center initiatives from across our portfolio: • AI and the Administration of Research • Childhood Cancer Academic–Industry Collaborative Platform Trials (C3PT) • Proportionate Oversight in Decentralized Clinical Trials • TRACE
3:15–3:30	**Break**
3:30–4:45	**Panel 5** **Interactive session**
4:45–5:00	**Wrap-up and closing** • Sarah White, MRCT Center • Barbara Bierer, MRCT Center • Mark Barnes, Ropes & Gray and MRCT Center
5:00–6:00	**Cocktails**