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:** Barbara Bierer, MRCT Center & 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 Demonstration of a Microsoft-enabled Informed Consent Application** This application was developed as part of the Informed Consent Reimagined MRCT Center project. **Panelist** • Tianna Umann, Microsoft **Moderator:** Barbara Bierer, MRCT Center
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**

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Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

MRCT Center 2026 Annual Symposium

Thursday, October 22, 2026
International Data Sharing: Cross-Border Considerations
Co-organized with Vivli

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

8:30 – 9:00	**Breakfast & Registration**
9:00 – 9:45	**Keynote** **Charlie Blanchard, Associate Vice President, Head of Global Privacy & Data Protection, Amgen**
9:45 –10:45	**Panel 1** **Recent U.S. Developments Affecting International Data Sharing** Health and research data are increasingly viewed not only as scientific resources but also as strategic assets. Recent developments, including the DOJ Final Rule on bulk sensitive personal data and legislation such as BIOSECURE, reflect a growing emphasis on national security within data governance. These changes are creating new expectations around cross-border data transfers, international collaborations, and organizational risk management. This panel will explore how security considerations are reshaping the data sharing landscape and what these developments mean for researchers, academic medical centers, and industry sponsors operating in a global environment. **Panelists:** • Jacquelyn Godin, Dana Farber Cancer Institute • Katherine Wang, Ropes & Gray • TBD

	Moderator: David Peloquin, Ropes & Gray
10:45–11:00	**Break**
11:00–12:00	**Panel 2** **European Health Data Space (EHDS)** The European Health Data Space represents one of the most ambitious efforts to create a framework for health data access and secondary use. While often discussed alongside GDPR, EHDS reflects a broader vision for how health data can support research, innovation, and public benefit while remaining subject to structured governance. This panel will examine the goals of EHDS, its implementation timeline, and its implications for organizations engaged in international research. Discussion will also explore whether EHDS signals a broader shift toward digital sovereignty and how its influence may extend beyond Europe. **Panelists:** • Jennifer O'Callaghan, Vivli Europe • Crispin Woolston, Sanofi • TBD **Moderator:** Barbara Bierer, MRCT Center
12:00–12:45	**Lunch**
12:45–1:45	**Panel 3** **Challenges in deploying electronic health records (EHRs) in U.S. clinical trials** As research increasingly relies on real-world data, attention is shifting from policy frameworks to the practical infrastructure needed to support trusted data access and use at scale. Health Information Exchanges and emerging initiatives such as Operation Trailblazer highlight both the opportunities and challenges of connecting clinical care and research ecosystems. This panel will examine how future clinical trial ecosystems can be

	engineered to enable efficient, predictable, and secure data flows, the barriers that continue to limit interoperability, and the potential for EHR-enabled approaches to transform clinical trial recruitment and evidence generation. **Panelists:** • Jill DeGraff, b.well • Jonathan Walland, Truveta • TBD **Moderators:** David Peloquin, Ropes & Gray & Barbara Bierer, MRCT Center
1:45–2:00	**Closing Remarks**