

Annual Symposium Agenda

Wednesday, October 21, 2026

7:45 – 8:15	Breakfast & Registration
8:15 – 8:30	Welcoming Remarks • Joshua Levy, <i>Ropes & Gray</i> • Barbara Bierer, <i>MRCT Center</i> • Mark Barnes, <i>Ropes & Gray and MRCT Center</i>
8:30 – 9:30	Keynote Karim Mikhail, B.Pharm, MSc , <i>Director of the Center for Biologics Evaluation and Research (CBER), U.S. Food and Drug Administration</i> 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, <i>Johnson & Johnson</i> • Karen Hartman, <i>Mayo Clinic</i> • Jennifer Sheller, <i>Merck, known as MSD outside of the United States and Canada</i> • Karim Mikhail, <i>CBER/FDA</i> Moderators: Barbara Bierer, <i>MRCT Center</i> & Mark Barnes, <i>Ropes & Gray / MRCT Center</i>
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, <i>U.S. National Institutes of Health</i> • Johanna Blom, <i>University of Modena, Italy</i> • Clive Collett, <i>Health Research Authority, UK</i> • Veronica Popa, <i>EURORDIS</i> Moderator: Barbara Bierer, <i>MRCT Center</i> & Sylvia Baedorf Kassis, <i>MRCT Center</i>
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: • Virginia Acha, <i>Merck, known as MSD outside of the United States and Canada</i> • Joseph Ali, <i>Johns Hopkins University</i> • Karla Childers, <i>Johnson & Johnson</i> Moderator: Sarah White, <i>MRCT Center</i>
2:30 – 3:15	Panel 4 MRCT Center Updates Select MRCT Center initiatives from across our portfolio: • AI Initiatives in Clinical Research • Childhood Cancer Academic–Industry Collaborative Platform Trials (C3PT) • Trial Regulatory and Clinical Ethics Optimization (TRACE) • Proportionate Oversight in Decentralized Clinical Moderator: Sarah White, <i>MRCT Center</i>
3:15 – 3:30	Break
3:30 – 4:45	Panel 5 Informed Consent, Reimagined: AI-Enhanced Prototype Demo with Microsoft This session will showcase a prototype that uses AI to help potential research participants better understand study procedures, risks, benefits, alternatives, and their rights with multimodal content. Developed as part of the <i>Informed Consent, Reimagined</i> project, this session will demonstrate how a dynamic, fit-for-purpose informed consent process can enhance participant-centered research while maintaining compliance with protocol and regulatory requirements. Presenter: • Tianna Umann, <i>Microsoft</i> Moderator: Barbara Bierer, <i>MRCT Center</i>
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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Speaker and
Moderator
Biographies



International Data Sharing: Cross-Border Considerations

Thursday, October 22, 2026

8:30 – 9:00	Breakfast & Registration
9:00 – 9:45	Keynote Sharing Is Caring. So Why Is Trusted Sharing Getting Harder? A Privacy Officer's View from the Intersection of Science, Privacy and Sovereignty Charlie Blanchard, <i>Associate Vice President, Head of Global Privacy & Data Protection, Amgen</i> Health data are more valuable, more connected, and easier to share than ever, yet trusted sharing is becoming more difficult. This keynote explores why, tracing the shift from discrete clinical trial datasets to interconnected health-data ecosystems and the growing importance of privacy, sovereignty, national security, and institutional trust. It asks a practical question at the heart of modern data governance: how can we enable high-value science while preserving the protections and confidence that make responsible data use possible?
9:45 – 10:45	Panel 1 Recent U.S. Developments Affecting International Data Sharing This panel will explore how recent developments affecting international data sharing, such as the DOJ Data Security Program, NIH biospecimen-sharing restrictions, BIOSECURE, and other emerging national security-related initiatives 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: • Sara Berkson, <i>Vertex</i> • Jacquelyn Godin, <i>Dana-Farber Cancer Institute</i> • Katherine Wang, <i>Ropes & Gray</i> Moderator: David Peloquin, <i>Ropes & Gray</i>
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 for research, innovation, and public benefit. This panel will examine the goals of EHDS, its implementation timeline, its implications for organizations engaged in international research, and how its influence may extend beyond Europe.



	Panelists: • Virginia Acha, Merck, known as MSD outside of the United States and Canada • Jennifer O’Callaghan, Vivli Europe • Crispin Woolston, Sanofi 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 This panel will provide an overview of the pathways that enable the use of health data for research and clinical trials. Panelists will discuss key regulatory and policy developments, explore emerging models for connecting clinical care and research, and examine how EHR-enabled and consumer-mediated approaches may support clinical trial recruitment, participation, and evidence generation. Panelists: • Jill DeGraff, b.well • Jason Funderburk, Office of the National Coordinator for Health Information Technology • Anthony Polizzi, Centers for Medicare & Medicaid Services • Jonathan Walland, Truveta Moderators: David Peloquin, Ropes & Gray and Barbara Bierer, MRCT Center
1:45 – 2:00	Closing Remarks



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