MRCT Center Executive Committee (EC)
Virtual Meeting
Summary
Tuesday, January 23, 2024, 11:00 AM – 12:00 PM EST

1. Welcome and Updates

Ms. Sarah White, MRCT Center Executive Director, Dr. Barbara Bierer, MRCT Center Faculty Director, and Mr. Mark Barnes, MRCT Center Faculty Co-Director, welcomed EC members to this meeting. Ms. White introduced the agenda for the meeting.

Ms. White introduced Bristol Myers Squibb as a new Executive Committee member.

- Jean Sposaro, Director, Global Clinical Trial Industry Collaborations, attended the EC meeting
- BMS will also be represented by Moke Sharma, Senior Vice President, Head of Development Operations and Head of Development Quantum Leap, and/or Elspeth Carnan, Vice President, Head of Trial Delivery Support

Ms. White also asked new EC representatives to introduce themselves:

- Christina Archer, Vice President of Alexion Development Operations
- Barbara Valastro, Head R&D Patient Science, Chief Medical Office, AstraZeneca
- Sandra Amaro, Head of Clinical Trial Diversity, Pfizer

2. DEI: reflecting on organization efforts; how to bring it full-circle to the patient/community

Dr. Barbara Bierer opened the discussion by reflecting on the MRCT Center Annual Meeting, where concerns were voiced by various EC/SC members regarding the challenges of implementing and coordinating Diversity, Equity, and Inclusion (DEI) efforts at different organizational levels. The primary goal was to gain a comprehensive understanding of these challenges. Key questions were posed to assess the effectiveness of central DEI teams in disseminating efforts to therapeutic areas and sites, identifying gaps in the process, and establishing a feedback system. The collaborative efforts within organizations to address persistent challenges were also explored.

Discussion

During the discussion, one EC member expressed the prevalent desire for more clarity from the FDA regarding requirements, citing the challenge of achieving organizational change amid the vagueness. It was mentioned that during the Annual Meeting, Lola Fashoyin-Aje from the FDA had emphasized the need for actionable plans, highlighting the specificity lacking in the current approach to the Diversity Action Plan (DAP). Dr. Bierer suggested that further clarity might come through experience and FDA feedback received in response to those DAPs submitted in the last year.

Another EC member noted the ongoing effort to build centralized capabilities, raising questions about implementation and turning plans into impactful actions at the local level. While acknowledging the commendable diversity-focused efforts, another EC member questioned how to assess effectively the value of participation for both individuals and communities. An EC member shared the need for foundational shifts at and within organizations, including trust-building and community engagement. They underscored the transformative nature of this process and the necessity for robust support systems.

The concern over the sustainability of DEI efforts took center stage as another EC member stressed the importance of transcending mere numerical targets, redirecting the focus toward safety, and addressing the needs of product users. The need to develop training materials and consider safety as a key objective was emphasized. A discussion ensued on community engagement, with an EC member highlighting the imperative to understand the European context and their involvement in a global trial. Another EC member highlighted communication challenges between sites, CROs, and sponsors, emphasizing the need for improved follow-up in communities and addressing costs of investment in the communities. Finally, another EC member stressed the role of sites as direct links to patients, calling for investments in non-transactional, non-study-related relationships and recognizing variations in diverse recruitment across therapeutic areas, citing oncology as an example.

Dr. Barbara Bierer concluded the discussion by mentioning upcoming collaborative efforts (e.g., the Diversity Convergence Project, discussed at the Annual Meeting) and noted one effort involving the impact of clinical trial compensation on entitlements and engagement with the Financial Neutrality group, led by Lungevity and on which group many of the EC members serve. Further communication will be initiated with selected participants for more in-depth discussions.

3. MRCT Center Brief Updates

Environmental Impact of Research

Dr. Bierer provided a brief update on Environmental Sustainability in Clinical Trials by noting that we have been hearing about the importance of this topic from EC/SC members over the past six or more months. We recently hosted four preliminary scoping calls with representation from the UK, Europe, South Africa, and the US, and we continue to seek additional experts. We are exploring this complex set of issues to determine if there is a role for the MRCT Center to play and if so, what that might look like.

On the preliminary calls, we heard that clinical trials contribute only a small percentage of greenhouse gas (GHG) emissions of the overall emissions from healthcare (estimated to contribute 8-12% of overall GHG emissions). Few groups are solely focused on the sustainability of the clinical trial enterprise, and most of the people we have spoken with felt that every small effort contributes in important ways to the overall sustainability effort. Further, we heard that the work is localized and poorly coordinated across large regions. There is not one single US-based institution or organization leading a sustainability in clinical trials effort, and we heard repeatedly that all stakeholders, at all stages along the clinical research lifecycle, represent opportunities for improvement. Further, the sentiment expressed was that no single entity can tackle this successfully, and importantly, there is an appetite for multi-stakeholder discussion forums.

A number of opportunities to act and intervene exist, including the need to systematically address the "low hanging fruit" actions such as those that are travel related (reducing travel, transportation choices, route planning amongst others) . Dr. Bierer noted broader areas that represent additional opportunities, including but not limited to ensuring that only informative and necessary trials that generate reasonable data be conducted. There is also a role for ethics committees to play by requiring proposals to include trial design that takes GHG emissions reductions into account. Further choices to be explored include how to ensure manufacturing and supply chain; vendor choice and procurement; travel; Decentralized Clinical Trials (DCTs); packing, packaging, and waste; and energy sources.

Discussion and Feedback
Several EC members spoke to or included in the zoom chat: their interest in the issues; that others in their organizations may have expertise and interest in these issues; and Institute for Healthcare Improvement is working on the reuse of clinical trials data. In closing, Dr. Bierer noted it preliminarily appears there is potential for the MRCT Center to make meaningful contributions and progress in this space.

Post-Trial/Continued Access Task Force: Medical Devices Conference

Ms. White provided updates on the Post-Trial Continued Access to Medicines and Devices project that is currently ongoing with a task force including some EC members. This year, one of the challenges the project is aiming to tackle is continued access to and maintenance of implanted/attached investigational devices.

The first iteration of this project in 2017 had explicitly carved out devices from the project's scope. With this current project update, the task force is aware of the need to include the perspectives of med-tech experts and device companies in the work to understand better the unique challenges and the similarities and differences between devices and medicines.

To tackle this challenge, the task force has decided to host a half-day or full-day conference, with the date to be determined. Current task force members, if interested, are transitioning to the role of a planning committee where additional device experts are needed. The role of the planning committee will be twofold. First, the planning committee will help prepare for the device conference. Second, the task force is finalizing two deliverables – a Principles & Analysis and a Framework of Responsibilities. Prior to dissemination, the task force would like device experts on the planning committee to review these two deliverables to ensure that both medicines and devices are adequately addressed.

The MRCT Center requests recommendations for contacts and content experts in the med-tech/device space who are interested in joining the planning committee. Ms. Karla Childers, co-lead of this project, added some examples of individuals working on high-risk devices and/or the clinical operations of these studies. If EC members would like to set up an exploratory conversation or recommend contacts, please email Ms. White at sawhite@bwh.harvard.edu.

Pediatric Platform Trials Conference

Dr. Barbara Bierer, provided a brief update on the topic of Platform Trials for Pediatric Medicines Development, linking this to the overall pediatrics program at the MRCT Center. Dr. Bierer emphasized the promise of platform trials in consideration of the pressing need to develop expedited processes and collect better data, particularly for products for which the FDA and the EMA require development (pediatric indications of adult products). In brief, platform studies that evaluate more than one investigational product simultaneously can offer substantial efficiencies if companies were able to collaborate, speeding the delivery of safe and effective medicines to children. We collectively need to understand the

challenges in developing platform studies—and master protocols—for pediatrics. In response to this need, we are exploring an opportunity to host a 2-day in-person workshop (Fall 2024 in the Washington, DC area) to explore how multi-sponsor pediatric platform trials can be leveraged to speed the delivery of innovative therapies to children.

The goals of such an effort would be to:

- Develop the principles, ethical foundation, and operational considerations upon which platform trials can be pursued for regulated studies of pediatric investigational products,
- Identify knowledge gaps that impact clinical trial planning, and
- Recommend actionable approaches to address these gaps.

The potential output of such an effort would be to construct a framework that could be used by multi-stakeholders (investigators, funding agencies, and sponsors) to support further advancement of platform trials in pediatric product development. At present, we are working with Johnson and Johnson and others. Our internal institutional parameters require us to obtain support from more than one sponsor, and we are eager to hear from those who may wish to support and participate in this effort.

Pediatrics Website Launch

Dr. Barbara Bierer, shared that the new webpage for the MRCT Center project, *Promoting Global Clinical Research in Children,* will be premiered in the coming weeks and will showcase the array of deliverables—publications, webinar recordings and summaries, principles, a toolkit and array of educational materials--produced thus far in the effort. Work continues with Health Technology Assessment (HTA) effort and specifically, an upcoming panel discussion at DIA in Brussels. The time was short and there were no questions or comments from the group.

Topics for Research, Development, & Regulatory Roundtable (R3)

Mr. David Peloquin, MRCT Center Senior Advisor, presented briefly on the four R3 meetings planned for 2024:

- **March 22 from 9:00 AM to 11:30 AM:** Expanded Access (Compassionate Use) for Drugs and Devices
    - This meeting will address available frameworks, differences in expanded use regulations for drugs in devices, and other current issues.

  - The original date of this meeting was March 21, however, an EC member shared in the Zoom chat that the Operationalize Expanded Access Programs Summit is taking place in Boston from March 19-21. **We have now rescheduled for March 22**, as listed above.
- **May 3 from 1:30 to 4:00 PM:** Real World Evidence
  - We will discuss the guidance documents released by the FDA on real-world evidence in the latter half of 2023 and address questions about the point at which certain data collection activities become clinical investigations requiring IRB review and oversight. Trends in subject-directed recruitment materials and testimonials will also be addressed.
- **October 10 from 1:00 PM to 3:30 PM:** (1) Laboratory Developed Tests and (2) Patient-directed Materials
- **December 12 from 1:00 PM to 3:30 PM:** TBA
  - The topic of the December R3 meeting has not been decided.

Meeting participants were reminded that the R3 is now included with EC membership. Most organizations have a designated R3 representative. We encourage the EC representatives to communicate with R3 representatives to stay up to date on meeting content.

Diversity Convergence

Dr. Barbara Bierer mentioned that the MRCT Center has been working with FasterCures, the National Academies of Sciences, Engineering, and Medicine (NASEM), and the Clinical Trials Transformation Initiative (CTTI) on a national framework to improve diversity and inclusion in clinical trials. A public workshop will be held on **April 23, 2024**, at NASEM to develop action plans, followed on **May 20, 2024**, Clinical Trials Day, by a meeting at FDA where we are inviting federal agencies to address their commitments and action plans to promote diverse representation in clinical trials. Dr. Bierer encouraged EC members to think about their own DEI commitments this year. We intend to include a focus on DEI annually going forward on Clinical Trials Day in May. The MRCT Center will send a save the date calendar invite.

4. Closing

Ms. White reviewed the upcoming EC and EC/SC meetings and asked EC members who do not have these meetings on their calendars to reach out to herself or to Carmen Aldinger. The next meeting will be an EC/SC meeting at the end of February. Ms. White also showed

the upcoming dates for the Bioethics Collaborative (BC) and Research, Development, & Regulatory Roundtable (R3) and thanked everybody for their participation.

Executive Committee Meeting participants:

First name	Last name	Organization
Sandy	Amaro	Pfizer
Maria	Apostolaros	PhRMA
Stacey	Bledsoe	Gilead
Ginny	Beakes-Read	Johnson & Johnson
Karla	Childers	Johnson & Johnson
Luther	Clark	Merck
Wendy	Erler	Alexion/AstraZeneca
Karen	Hartman	Mayo Clinic
Sheryl	Jacobs	Amgen
Gregory	Licholai	ICON plc
Murray	Lumpkin	Bill & Melinda Gates Foundation
Diana	Pankevich	Pfizer
Ben	Rotz	Eli Lilly
Annette	Schmid	Takeda
Sonia	Sethi	Alexion
Jean	Sposaro	Bristol Myers Squibb
Barbara	Valastro	AstraZeneca
MRCT Center		
Hayat Ahmed, Carmen Aldinger, Sylvia Baedorf Kassis, Mark Barnes, Kristin Bartlett, Barbara Bierer, Carolyn Chapman, Erin Chaves, Nannie Clough, Willyanne DeCormier Plosky, Sarah Evenson, Jack Ferdman, Elisa Koppelman, Alyssa Panton, David Peloquin, Kayleigh To, Sarah White.		