MRCT Center Executive Committee (EC)
Hybrid Meeting
Summary
Thursday, June 22, 2023, 9:00 AM – 2:00 PM EDT

1. Welcome and Introductions

Ms. Sarah White, MRCT Center Executive Director, welcomed EC members to the hybrid meeting and asked participants to introduce themselves briefly.

Ms. White gave an overview of the agenda and provided several brief updates related to MRCT Center communications:

- MRCT Center Summer Student Researchers are designing and developing images to complement the Clinical Research Glossary definitions. An example sketch and final rendering were presented.
- Ms. White presented draft renderings of an animated storyboard to introduce the ICH E8 guideline that is being developed with an external consultant as part of the MRCT Center's work as an ICH Associate.
- The MRCT Center launched a new and redesigned website.
- The MRCT Center hosted a successful release of tools and resources related to its work on the ethical considerations for decentralized clinical trials in collaboration with Medable, Inc. Almost 800 people from around the world registered for and approximately 500 people logged into the launch webinar.

2. Horizon Scanning & Emerging Issues

MRCT Center leadership invited EC members to share their "top-of-mind" emerging issues. The following is a summary of the issues presented:

- Concerns about the healthcare industry's **environmental impact**, specifically the impact of clinical trials, were raised. The United States (U.S.) healthcare sector accounts for over 8% of the national carbon emissions and 25% of the total healthcare carbon emissions globally.[1] Some EC member companies have already implemented sustainability efforts in their manufacturing and real estate divisions, but less is being done in the R&D and patient care spaces. It is unclear how this will affect future patient

[1] Dzau VJ, Levine R, Barrett G, Witty A. Decarbonizing the U.S. health sector—a call to action. New England Journal of Medicine. 2021 Dec 2;385(23):2117-9.

care. For example, with the United Nations attempting to create a legally binding plastic agreement by 2024,[2] will single-use plastic syringes no longer be acceptable? Currently, there is not much runway to think about these considerations when designing and starting a trial. Additionally, EC members expressed uncertainty about the environmental impact of decentralized clinical trials (e.g. packaging associated with sending investigational products like infusions). Teams designing and executing clinical trials should be included in discussions about their company's carbon footprint.
    - EC members from academic medical centers highlighted that clinical operations likely account for most of the healthcare's contribution to carbon emissions. Regular hospital operations generate large volumes of laundry, use significant energy, rely on single-use products, and produce large amounts of waste. It is unclear what percentage of the carbon emissions come from clinical research specifically and how that would be measured independently from other parts of the healthcare system. Whatever the percentage, decreasing the environmental impact of clinical research would be beneficial and potentially be a model for efforts in other parts of healthcare.
    - The MRCT Center will explore an opportunity to host a more extended discussion about this issue to deepen the conversation and better understand the issues and concerns. EC members interested in participating, or inviting representatives to participate, should contact Sarah White.

- EC members continue to explore **diversity, equity, and inclusion (DEI)** efforts in the clinical research ecosystem both within the U.S. and globally.
    - Sponsors are working on inclusivity approaches such as de-gendering protocols.
    - There is a push to move beyond the U.S. focus on race and look at other underrepresented groups, such as gender and sexual minorities; what does equitable representation look like in clinical trials globally, and how should this information be collected?
        - Uganda's recently-passed anti-LGBTQIA+ law was brought up; under the new legislation, collecting information on gender and sexuality may be unlawful and dangerous to participants.[3] Similar pressures exist globally, including in the U.S.[4]

[2] The resolution adopted by the United Nations Environment Assembly on 2 March 2022 is available from https://wedocs.unep.org/xmlui/bitstream/handle/20.500.11822/39764/END%20PLASTIC%20POLLUTION%20-%20TOWARDS%20AN%20INTERNATIONAL%20LEGALLY%20BINDING%20INSTRUMENT%20-%20English.pdf?sequence=1&isAllowed=y

[3] Learn more at https://www.pbs.org/newshour/world/ugandas-new-anti-gay-legislation-includes-death-sentence-for-in-some-cases

[4] Learn more about the ongoing developments in the U.S. at https://www.pbs.org/newshour/politics/here-are-the-restrictions-on-transgender-people-that-are-moving-through-u-s-statehouses

    - In the past, scientists have argued that if there is no relevance from a scientific perspective, they do not feel the need to collect this information. This raises the concern, however, that companies may be unintentionally discriminating, especially with groups already marginalized by the healthcare system. The tension between scientific validity and social value warrants further discussion, particularly with respect to the LGBTQIA+ community.
    - Related to this are questions about best practices and education around DEI. Certain topics may be sensitive, and trial personnel should receive training on interacting respectfully when working with members of marginalized groups.

- **Trial regulations in Europe** have been slowing down research, causing a geographical shift in where clinical trials are conducted. Sponsors are concerned about the optics of this shift.
    - Many areas lack coordinated processes, and the roles and responsibilities of the various entities involved in clinical research are unclear.
    - Meeting participants specifically commented on issues with the implementation of the In Vitro Diagnostic Regulation (IVDR).[5]
        - The scientific, analytic, and clinical validity of *in vitro* diagnostics (IVDs) must be reviewed and approved before being used in trials. It is difficult, however, to get those data outside the context of a trial – especially in the case of companion diagnostics. This is further complicated because IVDs and clinical trials are approved by separate entities.
        - One participant shared that the European Federation of Pharmaceutical Industries and Associations is currently working on these issues.

- Concerns were also raised about what **appropriate patient engagement** looks like. Different organizations define patient engagement differently. Does patient engagement mean involving patients in designing the clinical trial? Does it mean asking them to provide stories and testimonials of their experience? Is this a challenge for MRCT Center to address, or should it be left to individual companies to create internal policies?
    - One EC member shared that their organization is producing internal policies on engaging with participants. These policies address certain issues, including when

[5] Consolidated text: Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (Text with EEA relevance) available from https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R0746-20230320&qid=1688157843208

participants can be included as authors in a publication and when testimonial pieces can be requested.
    - There is often an additional layer of complexity, as requests for testimonials typically come from sponsor marketing teams rather than clinical operations.
  - Currently, the Food and Drug Administration and other regulatory authorities do not offer clear guidance on patient engagement. One document released by the Secretary's Advisory Committee on Human Research Protections details how this relationship needs to be managed and the guardrails that should be implemented.[6]

- Many EC member organizations are grappling with the use and regulation of **Artificial Intelligence (AI)**. This has become increasingly important with recent improvements in generative AI models. AI is already used in many parts of healthcare, but generative AI raises a new set of ethical and regulatory issues.
  - What do organizations with a role in clinical research need to consider regarding AI use? Individuals from all parts of sponsor organizations should be involved in these discussions; AI ethics should not be another topic only bioethicists are expected to address.
  - Many countries and regions are creating their own AI legislature and frameworks. The level of harmonization among these regulations is unclear. It also remains to be seen if these guidelines specifically consider healthcare and, if they do, whether the guidance is general or if clinical research is addressed separately.
    - This could be the perfect time to explore and develop case studies and usage examples for AI before politicians create guidelines that do not consider the healthcare space sufficiently.
  - There are also questions about the transparency of AI. Will participants recognize when AI is being used? How should they be informed? Will this change researcher-participant interactions?
  - Organizations should consider both the AI tool itself and the use of the tool; both can have flaws.
  - Generative AI uses readily-available information to construct novel responses to user queries. EC members raised questions about the accuracy and bias of the information being used.

[6] See "SACHRP Recommendations. New Challenges in Interactions among Sponsors, Clinical Trial Sites, and Study Subjects," available from: https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-b-new-challenges-sponsor-clinical-trial-site-subject.html
Summary available from: https://www.ropesgray.com/en/newsroom/alerts/2021/may/new-sachrp-recommendations-on-interactions-among-sponsors-clinical-trial-sites-and-study-subjects

        - The data that generative AI systems use to do this are weighted by volume rather than quality or validity. This may create a situation of an "echo chamber" where the majority view will be further amplified even when it is incorrect. Outputs can only be as good as the data they use.
    - Questions were also raised about *when* AI should be used and how much human oversight there needs to be.
        - One frequently-raised concern is about the accuracy of these systems, yet it is not known how reliable humans are in creating informational documents compared to tools such as ChatGPT charged with the same task.
        - If there is human oversight on generative AI outputs, is there already some inherent bias about the quality of AI-produced materials? Do humans and generative AI programs make different kinds of mistakes?
        - Would using generative AI tools for writing emails or crafting plain-language summaries be appropriate?
        - Finally, if different organizations create their own unique AI programs, will people be more trusting of a certain company's AI over another?

- Other topics that arose included the following:
    - **Genetic medicine:** What are the ethical considerations of genetic screening, result disclosure, and the move toward precision medicine?
        - Genetic screening needs to be done for both scientific and clinical purposes, yet the results can create new considerations (e.g., certain markers may disqualify individuals from receiving life insurance).
        - How are these tests regulated, and how do those regulations need to change?
    - Blurring of the **line between research and clinical care**
        - Developments in clinical trial design and technologies are making the distinction between research and clinical practice less clear in a number of ways.
        - Certain groups are addressing this blur. The annual Clinical Research as a Care Option (CRAACO®) conference is an example.
        - This is the topic of the June 27, 2023, MRCT Center Bioethics Collaborative.
    - Along with AI, EC members raised the topic of **automation and operational efficiency** in executing clinical trials.
    - Inclusion of under-insured and uninsured people continues to be a topic of discussion.

- The American Cancer Society is working with Congress to create **tax exemptions** for payment to participants exceeding $600 to encourage (or at least not discourage) the participation of economically disadvantaged participants.
- The operational and ethical issues around involving **unhoused people in clinical research.**
  - How can unhoused persons be equitably and safely included in clinical trials?
  - How will sponsors' methods and policies on inclusion impact public opinion?
- **Localization** of clinical trials in countries other than the U.S.:
  - More and more countries globally require localization of clinical trials (i.e., trials must be conducted in-country) to obtain regulatory approval. This requires reevaluating the balance of requirements, infrastructure, and expertise. Some countries also ask sponsors to manufacture their products in-country to obtain regulatory approval.
  - These regulations affect capacity-building efforts, site selection decisions, and research on rare diseases where a country may only have one participant. Is this a fundamental challenge to ICH E17?

3. Discussion of Ongoing Work

International Framework for Specimen Sharing – the Seattle Principles

Mr. Mark Barnes, MRCT Center Faculty Co-Director and Ropes & Gray Partner, provided an overview of ethical principles for banking, and secondary research use of human biospecimens, tentatively termed "*The Seattle Principles."* Dr. Annette Schmid of Takeda provided preliminary background; both Mr. Barnes and Dr. Schmid offered input to the discussion that followed.

Several organizations have been collaborating over the past 2 years, including ISBER, the MRCT Center, Ropes & Gray, RIKEN, and others to discuss the ethical and policy issues related to the critical practices of biobanking, data sharing and the downstream uses of data including secondary research use of human biospecimens. Because there is no regulatory jurisdiction and no means to ensure governments follow any specific dicta, the need to develop these guiding principles is paramount.

The principles are a work in progress; further input from involved and impacted stakeholders is invited, detailed below. The principles include the applicable ethical and pragmatic issues and policy pre-suppositions that researchers and research institutions can

follow. Acceptance and adherence to said principles could positively impact policy-making and laws across national governments, thereby promoting stronger ethics in science itself.

The Seattle Principles as they currently stand:

1. *Transparency to Donors*
2. *Respect for Broad Consent of Donors*
3. *Respecting the Scope of Consent*
4. *Respecting Withdrawal of Consent for Future Research*
5. *Safeguarding the Welfare of Specific Communities*
6. *Human Welfare Protection*
7. *Donor Privacy*
8. *Specific Consideration of Genetic/Genomic Research--*
9. *Protecting Donors by Returning Clinical Actionable Research Results*
10. *Ensuring Responsible Use of Biospecimen Resources*
11. *Governance and Oversight*

Each of these principles is annotated with a brief synopsis. In advance of the discussion, the fact that this is the start of the effort was reiterated. There is a need to have a strategy discussion with ISBER and others to address whom to involve and how to take this to the next level.

Discussion and Feedback:

- An EC member asked about the **return of results**. The answer included (noting that ICF does not typically disclose what will happen to a specimen that will be retained) that ICF should provide further detail and direction about the return of results. The role of additional governance and oversight to be offered by IRBs and regulatory bodies was also raised in the context of the lack of clarity with ICF.
- Another EC member questioned **other uses for deidentified data**, such as commercial purposes. The answer and ensuing discussion raised further issues such as the deidentification of tissue in excess of clinical needs, what is considered deidentified, and how this applies to genetic information. Additional questions included issues related to the sensitivity of donors who do not wish their tissue to be used for commercial purposes. There was general agreement that simply deidentifying data is insufficient to address the multiple questions and potential concerns regarding harm to patients; the hope is that the proposed Principles will provide substantive guidance.
- A question was asked whether the intent of the Principles is for IRBs/ECs to make decisions on the use(s) of deidentified data or whether it is to remove the need for EC review. How might this play out from jurisdiction to jurisdiction?

- An EC member added questions about purchasing commercially-available biospecimens for assay development.
- The additional challenges of **clinically versus individually significant findings/variants** (e.g., an individual with Huntington's Disease or at risk for frontotemporal dementia who may want to know), not entirely covered by the principles, was also raised. If results are disclosed, is it to the patient or the provider? Concerns exist about results validation which could add anxiety and stress to patients and families. One EC member noted the use of genetic counselors for this type of discussion at their organization. An example to illustrate the multi-layered complexity of these questions was a proposal in the mid-1980s to conduct HIV testing in a large Hepatitis C data set to determine better when HIV entered the American population (ultimately, the Hep C samples were deidentified, all links broken, and then the HIV testing was conducted). Clarification was offered that the Seattle Principles are principles and, as such, will not address many of the noted operational complexities which researchers must proactively address.

The final portion of the discussion centered on the **next steps** in the form of public comment versus vetting by an assembled expert group versus releasing with endorsement by others. An invitation to EC members to offer substantive and critical feedback by email and further discussion, including other key stakeholders, was offered, emphasizing that the right global collaborators must be brought in. An EC member noted that academic medical centers and other organizations that maintain biobanks may offer different perspectives.

Diversity Convergence Initiative

Ms. White introduced the Diversity Convergence Initiative: Diversity in Clinical Research. The aim of the project is to achieve system-wide changes and implementation of best practices to promote diversity, inclusion, and equity (DEI) across the research enterprise in the U.S. The convening organizations are i) Clinical Trials Transformation Initiative (CTTI), ii) Milken Institute FasterCures, iii) the MRCT Center, and iv) the National Academies of Science, Engineering, and Medicine (NASEM). These organizations are uniquely positioned to strategically co-convene groups from across the clinical trials enterprise to advance a leadership-driven call to action that aligns shared goals and accountability to achieve racial and ethnic diversity in clinical trials.

Ms. White provided a project update highlighting progress made thus far and outlined the planned future directions. The representatives from the founding organizations hosted a meeting on June 12, 2023, with leaders of select organizations that have publicly committed to DEI in research. This initial meeting focused on the goals and accountability needed for driving system-level changes. The next planned meeting will be held on September 22,

2023, at the NASEM offices and hosted by the MRCT Center. The goal of the meeting is to refine and set priorities for shared goals and begin a discussion of metrics for accountability. A survey will be distributed to all attendees to collect information on the impact and readiness of several focus areas. Prior to the discussion, Ms. White posed some questions: How do we make significant progress related to DEI in the US? What are the system-level changes within clinical research enterprise?

Discussion and Feedback

EC/SC members provided brief comments and questions.

- The FDORA Act mandates drug and device studies to develop and implement DEI plans. Despite the requirement, the issue of diversity in clinical trials still exists. EC members emphasized the need for Federal policy and regulatory changes prioritizing commitment and accountability of DEI plans for clinical trials. EC members additionally emphasized the need for taking a collaborative approach to policy issues and exploring opportunities for public-private partnerships.
- EC members discussed the need for a report specific to the U.S. population from global studies, as the current NIH report is diluted by global data and does not provide a true picture of the inclusion of minoritized U.S. populations.
- There was robust discussion on barriers to DEI. EC members identified several obstacles, including a lack of clinical trial awareness among the participants, systemic racism embedded in the healthcare system, trust issues, and a lack of a diverse workforce. EC members emphasized the need for strategic plans that focus on increasing capacity building, research education, community engagement, and increasing workforce diversity to address the DEI issue in the clinical trial arena.
- Additionally, the issue of reimbursement was discussed. In the U.S., compensation over $600 in one calendar year to research participants is considered taxable income by IRS. The cost of standard of care (SOC) care and procedures included in trials but potentially paid by third-party payers adds complexity and further disenfranchises populations who are underinsured or uninsured. In addition, insurance companies in the U.S. vary in their approach to covering SOC within a clinical trial. EC members endorsed policy-level changes and standardization of the reimbursement and compensations for clinical trial participants.

The discussion concluded with a consensus on the need for a framework to collaborate with government agencies to address policy changes, specifically in clinical trial reimbursement, compensations, and DEI initiatives.

Diversity, Inclusion and Equity in Clinical Research: Diversity Action Plan (DAP) & Global DEI

Dr. Barbara Bierer continued the discussion regarding the direction of DEI work within the MRCT Center. The ongoing efforts include addressing disability and LGBTQIA+ inclusion, along with considering global DEI (GDEI). However, GDEI brings unique considerations due to differing priorities across countries, different minoritized populations, regulatory requirements/guidance, and the absence of standard race and ethnicity categories outside of the US. For example, in conversations with individuals during the scoping phase, a representative from India identified women as the priority underserved group in their country, while a representative from Latin America highlighted issues related to income and socioeconomic status. Complicating the conversation is the categorization of race and ethnicity set by the Office of Management and Budget (OMB) for the U.S., terms that do not resonate outside of U.S. borders. While the principles outlined in the MRCT Center *Achieving Diversity, Inclusion, and Equity in Clinical Research* Guidance Document broadly apply to DEI processes and planning, there is a need to develop tools that facilitate a global perspective.

Currently, the FDA is the only regulatory authority that explicitly requires a Diversity Action plan (DAP), which predominantly focuses on race and ethnicity. However, in the context of multi-regional clinical trials (MRCTs), it is crucial to avoid treating this as a plan applicable only to the United States. It is also important that the DEI goals and actions outlined in DAPs are considerate of the independent needs of countries and cultures outside the U.S. Essentially, the U.S. DAPs should not be using other countries' populations just to meet race-focused U.S. diversity goals While pharmaceutical companies are not expected to address all social justice and healthcare issues, they should strive not to exacerbate them.

Katharine Wright, a former Nuffield scholar and bioethicist, has been working with the MRCT Center to develop resources on GDEI for different stakeholders, including pharmaceutical companies, contract research organizations (CROs), and academic organizations. Focus areas for this work include a potential roadmap for GDEI planning, ethical considerations for work in GDEI, and envisioning what different paths for clinical research capacity strengthening in low- and middle-income countries may look like. It is important to consider the specific disease being studied and the epidemiology to guide targeted approaches. When conducting MRCTs as pivotal trials, the choice of the country must align with the clinical need while ensuring that the population is not exploited. This requires having a sustained presence on the ground in the targeted area and among participant communities. The same considerations applied in the U.S. should be applied in the country where the trial is conducted to avoid exacerbating existing inequities within that population.

Discussion and Feedback:
A number of questions were posed to EC members, including if there are specific initiatives their companies are implementing to align with FDA's DAP, if there are specific areas of improvement, and if there are particular tools that they think would be helpful.

- While acknowledging the significance of addressing social concerns, one EC member raised the question of the purpose of DAPs and expansion to GDEI if there are no specific scientific implications involved.
    - It was acknowledged that large knowledge gaps exist regarding how safe and efficacious drugs and other products are for populations other than white people, and often specifically white men. This lack of knowledge often leads to physicians lacking clarity when prescribing medications for specific populations due to the absence of testing in those groups. To address this issue, conducting PK/PD studies in diverse populations early on to evaluate potential toxicity was suggested as a helpful solution. And, if only from a biological diversity perspective, including diverse participants from countries outside the U.S. is important to understand the heterogeneity of treatment effect better.
    - Due to limited sample sizes, conducting statistical analyses becomes challenging for sub-group analyses. To address this issue, clinical trialists are encouraged to collaborate with statistical groups and consider adopting a Bayesian approach, which may be acceptable to the FDA.

Ms. White inquired about whether companies have standard DAP templates that are then completed for different therapeutic areas and/or specific trials and, if so, whether the therapeutic area DAPs are subsequently consolidated/reviewed centrally within the company.

- In one of the EC companies, there is a standardized template across the organization. Teams focus on the priorities of the patient groups and look at differences across each drug/biologic under development. They then look at the plan more holistically from a global perspective honing in on the therapeutic areas.
- At another organization, the template comes from the global clinical development unit, and the structure is fairly set, but the therapeutic area leads will tailor it as needed. The epidemiology data on the disease or condition is provided as available to inform the knowledge base, but that data are incomplete. The DEI team will ultimately look at the DAP and treat it as a living document that's constantly updated.

Dr. Bierer asked who makes the country-specific site decisions that inform the denominator.

- One EC member responded that it is a collaboration. The DEI team works hand in hand with the feasibility team(s). There is a separate team that does more of the

clinical operations work. The collaborative DAP effort across all three teams is finally endorsed by the global portfolio lead.

- Another EC member commented that it is important that DAPs contain benchmarking to evaluate performance.
- An EC member also discussed their health equity team's objective to obtain improved data in order to assess disease prevalence and incidence accurately. They highlighted additional dimensions they are working on, such as LGBTQIA+ and GDEI, acknowledging that every country presents different aspects of diversity. Another aspect mentioned was intercountry diversity. Furthermore, emphasis is placed on connecting with communities and adopting a mindset centered around their needs. However, trust and sustainability challenges arise when companies end trials early or withdraw from pursuing a product.

Dr. Bierer stated that in order to make informed decisions, it is important to establish a shared understanding of the specific information required. One aspect to consider is the reliability and trustworthiness of the estimates of site capacity in conducting clinical trials obtained from various sites. When engaging with academic centers, it is apparent that some often lack the necessary breakdown of data by disease or subtype and demographic, and some do not have a centralized process at all. When different companies approach sites with varying requirements, it can pose challenges for the sites to accommodate these individual requests. Thus, having a shared site feasibility template for academic sites would be helpful.

- An EC member mentioned that their organization utilizes dashboards to access data related to catchment areas and patient information and track participation in clinical research studies and trials– specifically for cancer centers. And it is important for the organization to accommodate health care needs if they are seeking them- not just for the clinical trial. The MRCT Center could help coordinate and formulate these site expectations.

The MRCT Center has created a preliminary template for the Diversity Action Plan (DAP). In our ongoing efforts to enhance its effectiveness, we seek to incorporate insights from additional DAPs. We kindly request your assistance in providing us with DAPs, which will, of course, be confidential and anonymized. We anticipate circulating the initial draft of the updated DAP within the next few weeks.

4. Discussion related to further distinguishing the Executive Committee (EC) from the Steering Committee (SC)

Ms. White explained the proposed changes to distinguish the EC from the SC further:

- 6 virtual meetings (instead of currently 5 virtual meetings/year) + 2 in-person/year
- The June in-person meeting overlaps with the annual EAB meeting
- R3 membership included in EC sponsorship
- Private project launch presentations with internal teams
- EC sponsors to serve on MRCT Center conference/meeting planning committees

These changes were also welcomed by the MRCT Center External Advisory Board (EAB).

Discussion and Feedback

- EC members appreciated R3 membership and engagement in planning to be included in EC membership.
- One EC member asked about the differences between EC and SC.
    - The MRCT Center has more virtual and in-person meetings with the EC versus SC as well as informal ways to engage EC members.
    - The MRCT Center has far closer collaboration with EC members.
- Discussion emphasized the value of being 'part of the work.' The reports and frameworks only go so far, the discussion enables learning, sharing, and understanding. One EC member referred to this as 'in-the-room value.'
- An EC member mentioned that a recent Zoom call with representatives from this EC organization helped raise the level of collaboration and made a point internally of the value of these contributions.
- Since the COVID-19 pandemic and with economic challenges, more EC members had to justify the value of MRCT Center sponsorship. This distinction is helpful.
- Another EC member mentioned that the variety of sponsors adds value to this forum.

Dr. Barbara Bierer asked if there are other ways the MRCT Center can help its EC members make a case internally to their company.

- One EC member suggested challenging the MRCT Center model of making materials available free of charge, suggesting that the Center should consider charging for its materials.
- One EC member suggested partnering with FDA, and another EC member mentioned that the Seattle Principles were a great example of collaboration with regulators.
- Another EC member suggested clearly distinguishing the MRCT Center EC from other existing groups such as TransCelerate (which includes only pharma participants) and CTTI.
- An EC member remarked that the EC is characterized by openness and mutual sharing that she has not experienced in other groups. There is value for EC members to participate in the meetings.

5. Wrap up and Closing

Ms. White presented the dates for the remaining EC meetings in 2023, the upcoming Bioethics Collaborative (BC), and Research, Development, and Regulatory Roundtable (R3) meetings.

Executive Committee Meeting participants:

First name	Last name	Organization
Maria	Apostolaros	PhRMA
Ramona	Burress	Takeda
Karla	Childers	Johnson & Johnson
Wendy	Erler	Alexion/AstraZeneca
Patrick	Frey	Amgen
Karen	Hartman	Mayo Clinic
Bob	Imberman	Takeda
Diana	Pankevich	Pfizer
David	Peloquin	Ropes & Gray LLP
Naveen	Pereira	Mayo Clinic
Matt	Rotelli	Eli Lilly
Ben	Rotz	Eli Lilly
Annette	Schmid	Takeda
Natalie	Zaidman	Pfizer
MRCT Center		
Hayat Ahmed, Carmen Aldinger, Sylvia Baedorf Kassis, Mark Barnes, Kristin Bartlett, Barbara Bierer, Samjhana Bogati, Nannie Clough, Willyanne DeCormier Plosky, Sarah Evenson, Elisa Koppelman, Kayleigh To, Sarah White		