MRCT Center Executive Committee (EC)
Virtual Meeting
Summary
Tuesday, October 24, 2023, 11:00 AM – 12:00 PM EDT

1. Welcome and Updates

Ms. Sarah White, MRCT Center Executive Director, welcomed EC members and introduced the agenda for this meeting.

Ms. White asked new MRCT Center team members to introduce themselves:

- Jack Ferdman, Research Analyst
- Carolyn Chapman, Member of the Faculty, Harvard Medical School, and Lead Investigator, Brigham and Women's Hospital

Ms. White also recognized new EC members who were unable to participate in this Zoom call:

- Greg Licholai, Chief Medical and Innovation Officer of ICON, which is a new MRCT Center sponsor
- Owen Garrick, Dean of Clinical Trials, Mayo Clinic
- Ginny Beakes-Read, Head of Global Regulatory Policy and Intelligence, Johnson & Johnson

2. Considering new geographic regions for clinical research

Ms. Sarah White opened the discussion on "*Considering new geographic regions for clinical research,*" noting that we have heard from a number of sponsors that they are exploring options for new international clinical research sites. Such sites would both replace those in war zones (e.g., Ukraine and Russia) and develop capacity in underutilized, emerging markets with locations in select countries in Africa, Southeast Asia, and South America.

The MRCT Center capacity-building work has involved many geographic areas, including Africa, India, and elsewhere. Ms. White noted that the MRCT Center worked with Pfizer in Indonesia and Algeria and is currently working with the African Vaccine Regulatory Forum (AVAREF), the World Health Organization (WHO), and the Bill and Melinda Gates Foundation globally, and in multiple African countries. The MRCT Center has established and explored connections in various areas that have the potential to responsibly and reliably conduct trials. Mark Barnes,

Faculty Co-Director, has extensive on-the-ground experience in Nigeria, Botswana, Zimbabwe, Tanzania and Ethiopia. Further, we have heard from pharmaceutical sponsors that collaboration is critical; those involved in the dialogue have been very clear that no single entity needs to, or should have, a monopoly in any given region or site and that cooperation will assist in developing and sustaining operational excellence.

Ms. White then opened up the discussion, asking EC members to share their perspectives, with consideration of whether there may be a role for MRCT Center to play, aligning collaborative efforts in these new regions of interest.

Discussion and Feedback

One EC member noted that their organization has been looking at the geographic footprint for years, striving to be more inclusive in terms of diversity, and looking at sites that match the illness—Dengue was used as an example--with an interest in areas such as the Middle East and Africa. This EC member discussed utilizing their existing strengths in sub-Saharan Africa and Northern Africa as a hub from which to extend spokes to explore other areas. Further, this EC member's organization is exploring capacity building in places like India and Vietnam and discussed the challenge of understanding not only the regulatory environment but also the culture of different countries and sites within those countries, in addition to capacity building, sustainability considerations, and partnering to train people beyond use for a single study.

This EC member shared a recent highly collaborative meeting in Saudi Arabia—an area with considerable capacity but little experience-- that included the FDA and NIH. The MRCT Center was noted as a respected group in those regions. The imperative of collaboration was underscored, as the extent of capacity building and site opening and maintenance is too heavy a lift for any single entity. To that point, this EC member mentioned that there is a strong CRO footprint in these regions; there is much to be learned from CROs and their operational approaches.

The issue of access as it relates to site development and expansion was raised. While the intent is to run studies in areas where the product would be accessible after the study, access, for a variety of reasons, is not always the outcome. Another EC member amplified the issue and the importance of access as a consideration.

Two EC members--colleagues from another organization--talked about site development from two aspects: how to build regulatory oversight of clinical trials in terms of ethics and capacity and working to build clinical trial conduct capacity.

In terms of regulatory agencies, the heterogeneity of sub-Saharan countries was noted, with an example shared of South Africa's comprehensive regulatory oversight of many trials in contrast to some other countries with fewer trials and less capacity. WHO's regulatory benchmarking

tool was briefly discussed. This tool assesses and categorizes a country's regulatory maturity, with level 3 as the maturity goal the industry looks for to be comfortable with study placement in that region.

One EC member noted that they have learned several important points to share:

- Few COVID-19 vaccine trials were conducted in sub-Saharan Africa.
- Because trials were not conducted there, compelling scientific questions and equity issues were never answered (e.g., vaccine efficacy in populations with high incidence malnutrition).
- Non-communicable diseases will become the biggest killer in Africa by 2030 and will therefore need to be studied in Africa in order to understand the impact of comorbidities, environment, and social determinants of health on treatment efficacy and safety.

This EC member also shared that Dr. Bierer and her team have been steadfast in working on ethics oversight in many of these areas, which is far less standardized than the regulatory pieces.

An EC colleague discussed the importance of studying the clinical research landscape and underscored the variability in capacity. Africa is felt to have a high potential to leapfrog across some of the challenges experienced in many high-income countries. In this regard, a systems-wide approach is desired with investment in resource development that will support the sustainability of sponsors to work with research centers, with an interest in R & D, and recognition that being a sponsor is fundamentally different from participating as a research center. Further, attention is needed to develop research trials in the pipeline, identify appropriate research centers, and connect those research centers with funders and sponsors.

Lastly, another EC member made a parallel push in rare disease clinical trials where burdens are even greater. Few companies to date have found a viable path forward to study rare diseases in Africa. The desire to work with the MRCT Center to explore what would make this feasible was expressed.

Dr. Bierer responded to the above discussion by asking if there was interest in convening a group to specifically discuss these issues at the upcoming annual meeting, and Mr. Mark Barnes concurred that a follow-up conversation on how to operationalize this would be appropriate.

3. ORI's NPRM Public Health Service Policies on Research Misconduct: Key issues

Mr. Barnes described the responsibilities and jurisdiction of the Office of Research Integrity (ORI), which sits within the US Department of Health and Human Services. ORI propagates standards of conduct for research funded by the U.S. Public Health Service, which includes NIH. Mr. Barnes explained that, despite its limited direct jurisdiction, ORI standards and

practices regarding research integrity are largely followed by research integrity offices within other large federal agencies. ORI jurisdiction would extend to life sciences industry entities, if they receive federal research funds from, for example, NIH or FDA; and ORI standards would typically apply to research practices in industry-funded clinical trials that occur at an academic medical center that receives any NIH or other PHS funding.

ORI standards include strong procedural protections for researchers who are respondents in research misconduct cases. Recently, ORI proposed several updates to its official misconduct policy, which are open to public comment. The comment period opened on October 6, 2023, and closes on December 5, 2023. Mr. Barnes explained that the MRCT Center has already submitted joint comments with the law firm of Ropes & Gray on a prior ORI request for information about changes to the ORI regulations, and will collaborate in preparing comments to this current NPRM; additional comments from our EC partners are encouraged. Earlier comments from the MRCT Center recommended further defining the term "recklessness" to accompany the proposed policy's "intentionally, knowingly, or recklessly" standard.

Dr. Bierer expressed additional concerns regarding the proposed new rule, for example, its requirement that transcripts of interviews conducted during inquiries/investigations into research misconduct be fully available to all respondents. She opined that this might well deter complainants and witnesses from instigating or participating in research misconduct proceedings.

The MRCT Center and Ropes & Gray will share a draft of their comments with the EC/SC representatives. The notice of proposed rulemaking may be viewed here.

Discussion and Feedback

A member of the Executive Committee recommended contacting Bioethics International to engage with them on this proposal.

4. India: The Digital Personal Data Protection Act, 2023

There was insufficient time to discuss this topic during this meeting. Dr. Barbara Bierer, who reviewed India's Digital Personal Data Protection Act of 2023 and prepared summary slides, offered to set up a separate conference call for those interested.

5. Closing

Ms. White discussed the MRCT Center Annual Meeting in December 2023, which is a 2.5-day program, starting on Tuesday, December 12, with an EC/SC meeting. Peter Arlett from EMA will join Tuesday late afternoon, stay for dinner, and give the keynote lecture on Wednesday. Wednesday, December 13, is the Annual Meeting, followed by the Research, Development, & Regulatory Roundtable (R3) that is, on this occasion, open to the public. Thursday, December 14, features a half-day Bioethics Collaborative (BC) session that is also open to the public on this occasion. Dr. Bierer added that a dinner will be held on Tuesday evening, December 12, for EC/SC and Annual Meeting speakers.

Executive Committee Meeting participants:

First name	Last name	Organization
Stacey	Bledsoe	Gilead
Karla	Childers	Johnson & Johnson
Wendy	Erler	Alexion/AstraZeneca
Kelly	Hanlon	Amgen
Karen	Hartman	Mayo Clinic
Andy	Lee	Merck
Murray	Lumpkin	Bill & Melinda Gates Foundation
Chelsea	O'Connell	Amgen
Thy	Pham	Bill & Melinda Gates Foundation
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, Carolyn Chapman, Erin Chaves, Nannie Clough, Willyanne DeCormier Plosky, Sarah Evenson, Jack Ferdman, Elisa Koppelman, Kayleigh To, Sarah White.		