MRCT Center Executive Committee (EC)
Virtual Meeting
Summary
Tuesday, March 21, 2023, 11:00 AM – 12:00 PM EDT

1. Welcome and Introductions

Ms. Sarah White, MRCT Center Executive Director, welcomed EC members and mentioned that Mark Barnes was traveling and thus unavailable to join. Then Ms. White introduced the agenda for this meeting.

Ms. White asked first-time EC participants to introduce themselves:

- Maureen Kashuba, Associate Director, leading health literacy projects and plain language summaries at Merck
- Naveen Pereira, Professor of Medicine, Interim Co-Chair of Clinical Trials and Strategic Governance Committee, Chair of Clinical Trials Operations Committee, Mayo Clinic

Ms. White reminded EC members that the MRCT Center is planning an in-person EC meeting on June 22, 2023. This will be preceded by a cocktail reception and dinner on June 21, jointly with the MRCT Center External Advisory Board. For planning purposes, an email was sent to EC members during the EC meeting by Carmen Aldinger to inquire who plans to attend in person. [Please do respond if you have not had a chance to respond as yet.]

2. Clinical Research Glossary Collaboration with Clinical Data Interchange Standards Consortium (CDISC)

Ms. Sylvia Baedorf Kassis, MRCT Center Program Director, began this part of the meeting with a summary of the MRCT Center Clinical Research Glossary (CRG) process and the work completed since 2020. This project has a diverse multi-stakeholder workgroup, which includes patients and patient advocates. Each CRG word goes through a consensus process that elicits written feedback and discussion with the CRG Development and Review teams.

Ms. Baedorf Kassis announced a new collaboration between the MRCT Center and CDISC. CDISC will incorporate the CRG as one of its standards and link the plain language definitions to CDISC's controlled terminology that already exists or will be created. With this collaboration, the already robust MRCT Center process will now include a CDISC representative in discussions and their quarterly public review, which allows users to provide input on the definitions for MRCT Center consideration. The first of these public

reviews of the 53 existing plain language definitions began on March 24th and can be accessed at this link. Everyone is invited to provide feedback.

Additional information will follow, including:

1. An MRCT Center and CDISC Webinar
2. An article featured in the Patient Engagement section of the DIA's Global Forum
3. MRCT Center Newsletter announcement

Additional words will proceed to CDISC public review periodically. All the definitions (~200) are expected to be available at the end of this year or early next year as a CDISC standard on their website and on a new MRCT Center Glossary Website with improved functionality. More terms and definitions will be continuously added in the future. Ms. Baedorf Kassis asked any EC members or their colleagues to contact her if they wanted to participate.

In addition to the terms and their definitions, the glossary provides additional supportive information like use in a sentence and pronunciation guide. A unique feature of the glossary is an image associated with each term. This can help support different learning styles and also encourages more visitor traffic. Currently, the images on the glossary can only be used by the MRCT Center. Ms. Baedorf Kassis shared her vision of an image library that is freely available for anyone to use. She asked the EC members to contact her if they had any suggestions on how this could be done.

Along with the already existing supportive information, it was noted that there are ongoing considerations for translations of this glossary. This may include translations to Spanish and other languages needed. Dr. Bierer wants to ensure that all translations remain faithful to the purpose of this glossary and are truly plain language definitions.

Maureen Kashuba, a workgroup member and a representative from Merck, briefly described her experience working on the glossary. She emphasized the robust review process all the terms go through at the MRCT Center and the diverse perspectives received during the review. Ms. Kashuba reiterated the need for organizational health literacy, which should not be a competitive space, and this glossary's critical role in achieving this goal.

Discussion and Feedback

- One EC member commented that, although this is in English, even the United States has regional colloquialisms and wondered if that was considered when creating these definitions. Ms. Baedorf Kassis agreed with this important fact and explained that the CRG's workgroup includes perspectives across the United States, but such an effort can never be exhaustive. That is an additional advantage of CDISC's public release for feedback. Notably, the workgroup tends to avoid regional colloquialisms

when creating definitions and phrases that may be confusing for translations or for English learners (i.e., "carry out" research).

- Another EC member suggested that this project may benefit from exploring how Artificial Intelligence (AI) programs, like ChatGPT, may define some of the terms in the glossary and leverage them for future use. The member believed this could also be a method to detect biases on the internet as AI programs obtain data from the internet. Additionally, this EC member recommended that the MRCT Center CRG team look into using DALL-E, an AI system that creates images using natural language descriptions, to create freely reusable images for the glossary.

Ms. Baedorf Kassis ended the session by asking the EC members to consider how to integrate the glossary and its CDISC standard into their workflow and asked that anyone interested in the project contact her.

3. Programmatic Updates and Plans: Diversity, Equity, Inclusion (DEI) in Clinical Research

MRCT Center Diversity Action Plan Template

Dr. Barbara Bierer, MRCT Center Faculty Director, presented the proposed MRCT Center Model Diversity Action Plan intended for FDA submission. The Food and Drug Omnibus Reform Act of 2022 (FDORA) of December 29, 2022, defines a requirement to submit a diversity action plan for late-stage drug trials, including all Phase 3 trials and most device studies. Public workshops are forthcoming and will be coordinated by CTTI by the end of 2023. The FDA will provide additional guidance for this requirement in the future.

Released in 2020, the MRCT Center developed a Recruitment Strategy Document (RSD) as part of its DEI portfolio of tools. This document embedded elements of a diversity action plan into a much more robust recruitment strategy, addressing questions of site evaluation, target population, site selection, and more.

The MRCT Center plans to modify the RSD document into a more directed diversity strategy plan that aligns with the requirements of the FDA, as articulated in FDORA. Dr. Bierer concluded by requesting (redacted) Diversity Action Plan templates to aid in developing this resource.

Effort and Tools Convergence: CTTI, MRCT Center, Faster Cures, NASEM (Drug Forum), and others

Dr. Bierer shared updates on a collaborative initiative between CTTI, the MRCT Center, Faster Cures, NASEM, and other groups related to Diversity, Equity, and Inclusion (DEI) in

clinical research with a focus on the US. The objective of this collaboration is to create a coordinated strategy to compile, implement, and measure the impact of resources and best practices related to DEI across the clinical trials ecosystem. This initiative will focus on US populations, concentrating on racial and ethnic diversity in response to the Food and Drug Omnibus Reform Act (FDORA) enacted in December 2022. The group will work to align the efforts of each organization to leverage complementary work in this area. Dr. Bierer also noted that the U.S. Office for Management and Budget (OMB) has recently published Initial Proposals For Updating OMB's Race and Ethnicity Statistical Standards, which are open for public comment until April 12, 2023.

Discussion and Feedback
One EC member shared that their organization plans to submit comments; other EC members will follow up with the MRCT Center if they also plan to comment.

4. PI Oversight in Decentralized Clinical Trials (DCT)

Dr. Bierer discussed the recent work that the MRCT Center has done with Medable in coordinating a working group to address how IRBs/ECs review DCTs– trials executed remotely in part or in whole through telemedicine, mobile technologies, local sites, and local or home healthcare providers. From this collaboration, specific tools and points to consider have been developed and are due for release in Q2-3, 2023.

An ongoing collaboration of the MRCT Center, Medable, and CVS Health aims to determine the nature of PI oversight and responsibilities in DCTs. A survey was developed by Medable and CVS Health and distributed to PIs, healthcare providers, and sponsors to understand their perspectives on responsibilities, oversight, and challenges in executing DCTs. There were questions around operational considerations for the FDA form 1572 and the definition of an investigator. The survey found significant differences in respondents' perspectives of oversight in trials across the spectrum, including the risk of Investigational Medicinal Product (IMP), operational elements of DCTs, trial phase and severity of risk, and participant access to trials. Medable, MRCT Center, and CVS Health presented survey results to FDA colleagues in mid-March. FDA encouraged the collaboration to continue the work, including doing a first pass at revising FDA Form 1572 as well as analyzing what responsible PI oversight should look like. There is a planned public meeting in June of this year, and the team is meeting in person in Texas next month (April) to develop a core orientation.

Discussion and Feedback
An EC member asked whether the team is considering non-US-based PIs and what they can/can't sign when redoing FDA Form 1572. Dr. Bierer responded that while the global

issues are core for the MRCT Center, they are less so for Medable and CVS Health at this time, so the form re-design is mainly focused on defining US trials.

5. Closing

Ms. White showed a slide with dates for the upcoming EC/SC meetings throughout 2023 and the upcoming Bioethics Collaborative (BC) and Research, Development, and Regulatory Roundtable (R3) meetings. She mentioned that the June R3 meeting would be in-person in Boston. Topics for BC meetings for the rest of the year will be decided shortly. Dr. Bierer encouraged EC members to contact the MRCT Center with questions or comments.

Executive Committee Meeting participants:

First name	Last name	Organization
Karla	Childers	Johnson & Johnson
Janis	Grechko	Alexion
Patrick	Holmes	Pfizer
Maureen	Kashuba	Merck
Murray	Lumpkin	Gates Foundation
Naveen	Pereira	Mayo Clinic
Benjamin	Rotz	Eli Lilly
Annette	Schmid	Takeda
MRCT Center		
Carmen Aldinger, Sylvia Baedorf Kassis, Kristin Bartlett, Barbara Bierer, Samjhana Bogati, Nannie Clough, Willyanne DeCormier Plosky, Sarah Evenson, Elisa Koppelman, Lauren Otterman, Juliette Pluviose-Philip, Kayleigh To, Sarah White		