Executive Summary

of Joint Task Force for Clinical Trial Competency (JTF)

Biannual Global Meeting

November 14, 2023 9:00 – 11:00AM EST

1. **Barbara Bierer, JTF Co-Chair,** welcomed the attendees to the meeting and commented on the continuing growth and global representation of the JTF. After providing an overview of the activities of the MRCT Center, she reviewed the agenda for the meeting. She specifically noted the fact that the JTF Framework has been translated into 10 languages and several more are in process. This means that any future significant changes to the Framework will need to be widely discussed and vetted due to the need to provide multiple new translations. B. Bierer noted that JTF is represented in a Council for International Organizations of Medical Sciences (CIOMS) initiative to provide standards for education and training for health professionals in medicines development.

2. **Stephen Sonstein, JTF Co-Chair,** commented that the JTF Framework had incorporated several other competency frameworks during its development and would continue to serve as a basis for more specialized, role-dependent competency statements.

3. **Manju Bikkanuri, University of Texas,** provided an update on the efforts of the Data Management Task Force (see slides). The goal of the task force is to update the data management and informatics competencies and provide guidance for what every clinical research professional should know. The group is using a Delphi process consisting of four rounds and engaging nine participants of varying backgrounds. The process has resulted in a current listing of six main competencies and multiple sub-competencies. The sub-competencies are leveled to Fundamental, Skilled and Advanced utilizing Bloom's taxonomy verbs. Comments and questions from the attendees related to the potential overlap with other domains, the small number of participants and whether data reuse and retention were taken into consideration. One participant commented that a similar effort was occurring at Duke University for their internal position descriptions and B. Bierer offered to facilitate connecting the two groups in order to align the results.

4. **Susan Landis, Association of Clinical Research Professionals (ACRP),** discussed the efforts being undertaken by ACRP to address the workforce-related issues which have existed for some time, but have become critical since the COVID epidemic (see slides). ACRP has published a white paper ("Barriers to Bridges") and a recent publication has appeared in Society For Clinical Trials ("Now is the time to fix the clinical research workforce") addressing workforce issues in clinical research. ACRP has formed a consortium of representatives from academia, industry, and government to work on building a professional identity, change the hiring processes from "based on experience" to "based on competency," and to make the public more aware of clinical research as a profession. Underpinning these efforts are the JTF competencies. Comments from the attendees stressed the need to include high school teachers and counselors as well as the K-12 student body. One participant noted that she would like to talk offline about expansion of

the effort into Canada. Another participant noted that CANTRAIN would very much like to be involved in MRCT Center and ACRP workforce development efforts. B. Bierer will facilitate. S. Sonstein commented that in the past, there has been a push toward raising the entry level for most health professions. S. Landis noted that whatever the entry-level, we need to start with awareness of the profession while not reducing the need to be qualified. B. Bierer commented that involving public libraries may be useful.

5. **Barbara Bierer, MRCT Center,** reviewed the discussion that had occurred at the last global JTF meeting concerning whether and how to incorporate emergency preparedness competencies into the JTF Framework (see slides). During the following six months, an internal MRCT Center taskforce went through every competency and identified issues that relate to emergency preparedness. She noted that disruptions in clinical research can take many forms (e.g., pandemics, floods, hurricanes, natural and man-made disasters), vary in character, severity, and timing. Decisions need to be made concerning whether to pause or modify the study, continue or discontinue enrollment and treatment of enrolled participants, etc. Coordination must occur across sponsor, site, IRBs/Ethics Committees, and regulators. The taskforce concluded that new competencies are not needed, but that a structure, leadership, communication path and answers to specific questions, possibly as an appendix, relating to emergency preparedness, was necessary. A meeting participant commented that this is an opportunity for JTF to expand its footprint since sponsors and sites globally have experienced these issues and would add to the development of the appendix recommendations. Another participant noted that the COVID pandemic demanded immediate reactions, not planned deployment of resources, and that much has been learned; an appendix to the JTF framework would be timely and useful. This participant noted that a group from the Clinical and Translational Science Award (CTSA) has worked on team science-related competencies that could also be included as an appendix to the framework. B. Bierer asked whether anyone thinks other new competencies or additional appendices are necessary.

6. **Melanie Glaettli, Swiss Clinical Trial Organisation,** presented on "Competencies for non-interventional research projects in the Swiss regulatory context" (see slides). This content had been presented previously and has been updated following feedback. Since more than 75% of clinical research projects in Switzerland are non-interventional and undertaken mostly by novice researchers, a mandate was received from the Federal Office of Public Health (FOPH) in Switzerland to develop a website for young researchers based upon the JTF framework, but with the inclusion of specific Swiss laws and procedures. The resulting framework maintained the eight JTF domains, but the number of competencies was reduced. There was no mention of investigational products or references to GCPs. In addition, the leveling of proficiencies was removed. Data management was divided into collection of data and further use of data. Switzerland has different consent forms. The group would like to have comments from the JTF prior to publication and further dissemination. B. Bierer inquired as to which languages the guidelines would be available. M. Glaettli responded that everything was in English, but that French, German and Italian would be most appropriate for the researchers in Switzerland. Another participant questioned whether similar frameworks were planned for clinical

coordinators. M.Glaettli responded that the mandate was only related to PIs but collaboration with the Swiss Study Coordinators group was initiated.

7. **Christine Samara, Odette Cancer Center,** gave an update on the use of the JTF Framework in Canada under the Canadian Cancer Clinical Trials Network (3CTN) (see slides). The Canadian Cancer Clinical Trials Network (3CTN) received a grant to focus and provide recommendations of clinical research core competencies for clinical research professionals across network sites. Following an assessment survey, gaps were identified, and recommendations were developed relating to onboarding, training, and education. The JTF Framework was used as a basis for the recommendations. As a result, the 3CTN has facilitated sharing of best practice learning and training resources, expertise across the Network and created a 3CTN Core Competency Report to enable direct links to learning resources associated with each sub-domain into a single tool. Future efforts will include a re-assessment after three years to track overall changes of competency statement gap areas from 2022 survey and identify any emerging gaps. A publication is being finalized by 3CTN, which discusses the use of the JTF Framework in Canada under 3CTN. **Barbara Bierer requested that the MRCT Center be informed when manuscripts are accepted** so that they can be posted on JTF website, which will also help with the dissemination of training opportunities.

   At the institutional level, Odette Cancer Centre being one of the 3CTN network sites applying the JTF Framework, used the framework to develop a Professional Development Review tool for staff which was piloted in 2023. S.Sonstein commented that there were validity issues related to self-assessment and that he would be interested to see comparisons to assessments by supervisors. B.Bierer noted that if one knew that their supervisor was reviewing their self-assessment, the assessment itself might change. S. Sonstein commented that it would be interesting to assess the competencies of supervisors since they automatically rate themselves high, even higher than PIs. B. Bierer asked whether training in Canada was in French as well as English. C. Samara responded that it is available only in English for now, but CANTRAIN, a new training platform in Canada, intends to translate trainings into French.

   C. Samara gave an update on the Arabic translation of the JTF Framework (see slides). The translation was initiated in November 2022, an initial draft was completed in April 2023 and a translation of all domains was completed in September 2023 and submitted for validation by industry, university and research organizations. A follow-up meeting in Dubai is scheduled by the end of November to review the validation of the translation, and a final product is anticipated by early 2024.

8. **Stephen Sonstein and Barbara Bierer, JTF Co-Chairs,** opened the floor to discussion by the attendees.
   - B.Bierer introduced Meredith Zozus, who is chair of the Data Management Task Force. S.Sonstein inquired whether the QR code on Manju's slides which led to the JTF website was available for general use. Meredith replied affirmatively.
   - A meeting participant asked about criteria for appendices development for the Framework. B.Bierer responded that we do not know yet, but will develop a process. S.Sonstein reiterated that it was important not to change the structure of the

Framework, although when competencies were developed, they were intended to be a core structure from which other more specific uses could be adapted. ACRP's role-based competencies and the Swiss modifications are examples.

- A meeting participant brought up the subject of competencies for patient partners who are assisting in protocol design and patient engagement. The group agreed that this was a different role, and we needed to discuss whether this would be an appendix or another framework. We will add it to the discussion next meeting.

- B.Bierer commented that we should consider whether the JTF website should include links to learning tools and case studies. A participant commented that they had considered adding those links to their website, but that it was not an easy thing to do. Also, it would be useful to highlight which competencies were mostly used by coordinators, data managers, and others in a similar manner to the ACRP role-based competencies.

- S.Sonstein questioned M.Zozus about the structure of the data management and informatics competencies. The current JTF framework has domains with multiple competencies which are leveled Fundamental, Skilled and Advanced. The Data Management proposal has competencies and sub-competencies which are then leveled. M.Zozus responded that the group didn't intend to be different from the other domains but that the sub-competencies are more numerous than the statements under each current competency. The issue will be resolved so that the revised Data Management competencies are aligned with the rest of the Framework. Further discussion is necessary and the group will pause to increase alignment prior to round 3 of the Delphi.

- A participant asked whether anyone was working on competencies related to other professionals that support the clinical trials team, such as legal support. B.Bierer will put this on the agenda for the global meeting.

- B.Bierer thanked everyone for their input and noted that the discussions were getting deeper and more critical to have. She was appreciative of the international participation and for everyone's commitment to the JTF. S.Sonstein agreed and is looking forward to the next meeting.

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Appendix 1: Agenda

Joint Task Force for Clinical Trial Competency

(JTF) Biannual Global Meeting

November 14, 2023, 9:00-11:00 AM
EST

Time	Topic	Speaker / Facilitator
9:00-9:15	Introduction Overview	**Barbara Bierer, MD** Co-Chair, JTF Faculty Director, MRCT Center
JTF Updates and discussion		
9:15-9:30	Data Management update: Results from Delphi	**Manju Bikkanuri, MD, MPH** Clinical Research Informatics Specialist University of Texas (UT) Health San Antonio, Long School of Medicine, Department of Population Health Sciences
9:30-9:45	Workforce development for clinical research	**Susan Landis, BA** Executive Director Association of Clinical Research Professionals (ACRP)
9:45-10:00	Emergency Preparedness	**Barbara Bierer, MD** Faculty Director MRCT Center
10:00-10:15	Competencies for non-interventional research projects in the Swiss regulatory context	**Melanie Glaettli, PhD** Scientific Coordinator, Swiss Clinical Trial Organisation (SCTO)

| 10:15-10:30 | Update on the use of the JTF framework in Canada under 3CTN
Update on the Arabic translation | **Christine Samara, MSc**
Manager, Quality Assurance and Education, Odette Cancer Center Clinical Research Program, Sunnybrook Research Institute, Toronto, Canada
Member on the 3CTN Performance Strategy Sub-Committee, Canadian Cancer Clinical Trial Network (3CTN), Canada
Coordinating the Arabic Translation with the Ministry of Health and Prevention, United Arab Emirates |
| 10:30-11:00 | Open discussion | **Stephen Sonstein, PhD & Barbara Bierer, MD**
Co-Chairs, JTF |

Appendix 2: Participants

	First Name:	**Last Name:**	**Company or Organization:**
1.	Muhammad	Alanjiro	Integral University Nigeria
2.	Carmen	Aldinger	MRCT Center
3.	Katie	Bainbridge	CANTRAIN
4.	Romiya	Barry	R&D Health Sciences LLC
5.	Kristin	Bartlett	MRCT Center BWH
6.	Barbara	Bierer	MRCT Center
7.	Manju	Bikkanuri	University Texas Health Sciences Center San Antonio
8.	Karla	Damus	BU School of Medicine, Office of Human Research Affairs
9.	Amy	Fox Capella	Capella University
10.	Stephanie	Freel	Duke University School of Medicine
11.	Kristin	Gaffney	UAMS
12.	Melanie	Glaettli	Swiss Clinical Trial Organisation
13.	Sean	Hildebrandt	Mayo Clinic
14.	Casey	Jackson	UMB
15.	Jaehong	Jeong	Daegu Catholic University Medical Center / Comprehensive and Integrative Medicine Institute (DCUMC/CIMI)
16.	Carolynn	Jones	The Ohio State University
17.	Susan	Landis	ACRP
18.	Mei	Li	CANTRAIN
19.	Shirley	Longinotti	University of Pittsburgh

20.	Sifa	Muchanga	National Center For Global Health and Medicine, Japan
21.	Monique	Ostrout	CANTRAIN
22.	Lisa	Palladino Kim	Rutgers SHP MS in CRM program
23.	Maria	Rocha	Sunovion
24.	Bernd	Rosenkranz	Fundisa African Academy of Medicines Development
25.	Christine	Samara	Odette Cancer Centre, Sunnybrook Research Institute and 3CTN
26.	Im Hee	Shin	Daegu Catholic Univ. Medical Center(DCUMC)/ Comprehensive and Integrative Medicine Institute(CIMI)
27.	Stephen	Sonstein	MRCT Center
28.	Marissa	Stroo	Duke
29.	Munenori	Takata	TOHOKU UNVERSITY HOSPITAL
30.	Kathy	Thoma	The George Washington University
31.	Sharleen	Traynor	Durham Technical Community College
32.	Maria	Umano	National Center for Global Health and Medicine
33.	Kelly	Unsworth	University of Rochester
34.	Rosely	Yamamura	BP, Brazil
35.	Meredith	Zozus	University of Texas Health Science Center at San Antonio