Executive Summary

Joint Task Force for Clinical Trial Competency (JTF)

Biannual Global Meeting

May 2, 2023, 9:00 – 11:00 AM EDT

1. Barbara Bierer opened the meeting with a welcome to the attendees, an introduction of Co-Chair Stephen Sonstein and Project Manager Carmen Aldinger, a disclaimer concerning conflict of interest, an overview of the Multi-Regional Clinical Trials Center (MRCT Center) and its mission, and a review of the Agenda.
2. There have been translations of the JTF Framework into 8 different languages and, hopefully, within the next few months, Chinese. Given the impact on translations, Dr. Bierer reminded those who propose updating the JTF Framework to coordinate through MRCT Center.
3. Dr. Bierer and Dr. Sonstein are participating in the editing and publication of a supplement to *Frontiers in Pharmacology* which discusses the current issues in clinical research workforce development. An invitation to submit a manuscript will be sent to the meeting attendees. Dr. Bierer and Dr. Sonstein will be happy to discuss submission further with those interested. The deadline for submission of manuscripts is September 17, 2023, and an abstract is due on June 1, 2023.
4. JTF Updates
    a. **Lisa Palladino Kim, Rutgers School of Health Professions**, presented that the Rutgers Master of Science in Clinical Research Management Program was at an 89% fulfillment rate when their curriculum was analyzed and mapped to the JTF Clinical Research Professional Competency Framework. The analysis and mapping were based on two introductory courses and one advanced core course. The results also showed the introductory courses mapped more to the fundamental and skilled levels while the advanced course mapped more to the advanced level. Their goal is to use this outcome when seeking accreditation from by the Commission on Accreditation of Academic Programs in Clinical Research (https://www.caahep.org/).
    b. **Howard Fingert, ONO Pharmaceuticals**, presented on the significance of the JTF Framework to Clinical Development Teams in the Biopharmaceutical Industry, especially regarding data sciences and "deep learning." The JTF Framework and Vivli (https://vivli.org/) can help reduce the silos which exist in the industry and facilitate team collaboration enabling smarter decision making. Dr. Bierer commented that it may be appropriate to review the competencies in Domain 8 – Leadership and Professionalism – to make sure that they reflect current requirements.
    c. **Christine Samara, Manager at Odette Cancer Centre and member of the 3CTN Strategic Performance Committee,** discussed the use of the JTF Framework in Canada, as part of the Canadian Cancer Clinical Trial Network (3CTN)'s grant objective for network sites as well as within the Odette Cancer Center, one of the 3CTN network site and leading research center in Toronto. 3CTN provides support for clinical trials infrastructure and through their current grant iteration (2022-2027), they have adopted the JTF framework. They conducted a gap analysis with all network sites and their affiliates, as part of the grant application process, to

assess gaps in competencies of clinical research professionals and training needs. The main priority areas for training and development was noted in Investigational Product Development and Regulation; Scientific Concepts and Research Design; and Study and Site Management. Through their Strategic Performance Committee, 3CTN developed a resource platform to all network sites with training opportunities for each of the 8 domains. In terms of the use of the JTF at the Odette Cancer Centre, the framework has been used since 2021 in supporting the revisions of job descriptions, defining roles of supervisors, creating tools for performance evaluation, revamping the onboarding process and focusing on professional development primarily in interpersonal skills, teamwork, and communication. As a personal initiative, Ms. Samara is working with the Ministry of Health in the United Arab Emirates to develop an Arabic translation of the JTF Framework. An initial draft is expected in June, 2023.

d. **Melanie Glättli, Swiss Clinical Trial Organisation**, spoke of the adaptation of the JTF Framework to non-interventional research conducted by the Education platform of the Swiss Clinical Trial Organisation. At the last global meeting of the JTF, she spoke of the adaptation of the Framework to Swiss legal ordinances relating to clinical trials. Additional efforts rendered the Framework more applicable to young researchers who usually start with non-interventional research projects. The resulting adaptations included shorter statements of competency but remained faithful to the JTF Framework. Dr. Bierer commented that it was always the intention of the JTF to include non-interventional research and that it would be very important to review the modifications to ensure that the spirit of the Framework is captured or whether it is applied differently.

e. Dr. Bierer explained that two teams in China had independently contacted the MRCT Center, wishing to develop Chinese translations of the Framework. They were **Jean Wang, CEO of Shanghai Xunyuan Information Technology Co., Ltd., and Guo Fuzhen of the China Clinical Trial Development Team at Capital Medical University and Beijing Tiantan Hospital**. Both groups agreed to collaborate on the effort and to independently validate the translation. Jean Wang and Guo Fuzhen each provided an overview of their institutions and their missions. The translations already exist as first drafts. A revision will be available in May with a final product proposed in June. Efforts are expected to result in the development of graduate-level courses, competency assessment standards, and training programs to facilitate the integration of the JTF Framework into Chinese clinical trials.

5. Dr. Sonstein introduced the two **workgroups** that had previously been created, one led by Meredith Nahm Zozus to assess the current content of Domain 6 – Data Management and Informatics and a second led by Elias Samuels and Susan Murphy to address the need for more objective methods of assessing clinical research competency in individuals and groups. Updates on the efforts of both of these groups were presented.

   a. **Meredith Zozus, University of Texas, San Antonio,** explained that the goals of the **Data Management and Informatics workgroup** were to update the Domain 6 competencies and to make sure that they reflected what every clinical research professional should generally understand about informatics and data management in order to better design and report clinical studies. She and her colleague Manju Bikkanuri at UT Health San Antonio have recruited a global team of 12 participants representing 6 countries and academic, corporate, and governmental perspectives. The group agreed to utilize a Delphi Process consisting of 4 rounds to create, modify, and produce agreement on data management and informatics

competencies. A report is anticipated in late summer. Dr. Bierer and Dr. Sonstein thanked Dr. Zozus for her efforts and agreed that it was important not to teach only statistics and informatics, but to define what the clinical research professional needed to know about data management and informatics. Dr. Bierer suggested that anyone who is interested in reviewing the product of this effort contact the MRCT Center. One participant commented that two levels needed to be addressed: the level of understanding that data coordinators who support study data collection differ from that of the informaticists designing study data flow and also from the statistician who analyzed the data. Dr. Zozus reported that these are questioned separately in round one of the Delphi and agreed that each career track has different levels of required competency.

b. **Elias Samuels, University of Michigan,** discussed the need for more **objective methods of assessing competency** and cited a review of the literature which showed that clinical and translational research was behind the curve in competency assessment when compared to other fields. This was due to the fact that subjective assessments are relatively simple and easy to design and validate compared to objective assessments. He presented 4 models of validation and two literature citations that addressed the issue.

Susan Murphy, University of Michigan, suggested that **behavioral and social science research (BSSR)** workforce development can be enhanced using the JTF Framework. Although the JTF Framework competencies might need to be tailored for BSSR, the same domains should be maintained. Previous efforts had utilized ICH GCP principles and adapted them to the needs of behavioral investigators. A next step would be identification of specific competencies for BSSR research. Dr. Murphy has worked with NIH to adapt their protocol template to BSSR research. She also stressed that identifying models for validity testing was important and that there were challenges relating to objective assessment both at the personal level and at the study level. Existing assessments are not validated. Previous studies have attempted to link reporting of adverse events to competency, but it was not determined whether reduction or increases in adverse event reporting indicated better-trained staff. She is currently conducting a new study at the University of Michigan to address this issue.

Drs Samuel and Murphy shared the following references:

- Murphy, S., Samuels, E., Kolb, H., Behar-Horenstein, L., Champagne, E., Byks-Jazayeri, C., . . . Dubocovich, M. (2018). Best Practices in Social and Behavioral Research: A multisite pilot evaluation of the good clinical practice online training course. *Journal of Clinical and Translational Science*, 2(2), 95-102. doi:10.1017/cts.2018.27
- Murphy, S.L., Byks-Jazayeri, C., Calvin-Naylor, N.A., Divecha, V., Anderson, E., Eakin, B.L., Fair, A.S., & Denton, L.R. (2017). Best practices in social and behavioral research: report from the Enhancing Clinical Research Professional's Training and Qualifications project. *Journal of Clinical and Translational Science*, 1, 26 - 32.

Dr. Sonstein commented that this workgroup is evolving somewhat differently than originally envisioned with its focus on BSSR. Dr. Bierer asked how we should proceed since we cannot conduct objective assessments of individuals. Dr. Murphy agreed and suggested that much work needed to be done to figure out the nuances of how BSSR differs from biomedical clinical research, that compliance is an additional issue, and that the current tools do not fit well. A participant commented that her institution had incorporated competency

assessments into their tier advancement model and had tailored it to the actual work as part of leadership. They had published on the model and provided a citation of the publication: Professional Development for Clinical Research Professionals: Implementation of a Competency-Based Assessment Model.

6. Dr. Bierer discussed a potential new project: how to align competencies to address the issue of conducting clinical trials during **emergencies** (e.g., natural disasters such as floods and pandemics or man-made disasters such as war). It is necessary to review the JTF to determine if it is reflective of competencies in emergencies.
    a. **Sandor Kerpel-Fronius, Semmelweis University, Budapest,** has addressed this issue with CIOMS, has published on the issue, and presented his perspectives. He used the current emergency in Ukraine as an example. There are two vulnerable populations, those in Ukraine whose clinical trials have been interrupted by warfare, and those in Russia who have been affected by economic sanctions. During a developing disaster, the extent is unknown, contact may be lost, and the staff has to figure out what is happening, respond based upon their experience and Good Clinical Practice (GCP). If the participants have serious diseases, their future may be dependent on the treatment offered in the clinical trial, and the sponsor should help to continue the trial. Discussion with Ukrainian clinical researchers reflected the need to receive advice from the sponsors. It was suggested to CIOMS to create a working group for providing recommendations for emergency circumstances in line with existing GCP principles.
    b. **Dr. Bierer** appreciated Dr. Kerpel-Fronius for bringing this to the attention of the JTF. She reflected that emergencies are different in scale (e.g., COVID, the war in Ukraine, a power outage, or flood) and the response should reflect the type, scope, and severity of the emergency. It would be important to develop a plan to anticipate what might be needed and to coordinate a response team. She suggested reviewing the JTF Framework to determine what special competencies might be needed for emergencies. Emergency preparedness competencies might be indicated by a "Red Cross" button or another designation, possibly arrayed to fundamental/skilled/advanced levels. Dr. Sonstein suggested that responses from the attendees would be welcome. Dr. Bierer noted that she had gone through the Framework with this subject in mind and that many of the issues related to emergencies did not fit well into the JTF competency framework. She suggested that it may be appropriate to create an Appendix to the JTF Framework (e.g., how to think about the situation and be prepared, which could then be executed through individuals involved in the trial and/or teams prepared for these events). Dr. Kerpel-Fronius reiterated that sponsors have to think about this as well. A meeting participant commented that, as a medical monitor, she had dealt with emergencies at the individual subject level and that integrating a JTF appendix of emergency considerations would be useful. Such an appendix would need to address ethics, risk/benefit considerations, and agreement with participants. She would be interested in participating in such an effort. Dr. Bierer reflected that even if nothing in the Framework needed to be changed that it is the right moment to pause to think this through, having lived through the last 3 years with COVID, war, and severe weather conditions. The MRCT Center is currently initiating a project on emergency preparedness and rapid response. Another meeting participant endorsed the idea of an Appendix citing much of the experience during

COVID. Additional volunteers offered to serve on a subgroup to further discuss this subject. The MRCT Center will organize a call.

7. Dr. Bierer and Dr. Sonstein proceeded to a **Wrap-up and next steps**. Dr. Bierer commented that we had planned the global meetings as a 2-hour semi-annual event but that since they had become so content-rich it might be necessary to adjust. Several participants commented, and Dr. Bierer decided to retain the 2-hour format for the next meeting and attempt to do more work outside of the global meetings. Drs. Sonstein, Bierer and Aldinger are always available to discuss any new ideas, translations, or other suggested work related to the JTF Framework. Dr. Sonstein commented that it seemed we needed more clarity concerning assessment and that there was potential for collaboration with the Swiss Clinical Trial Organisation. He also encouraged the team from UAE to stay in contact concerning the Arabic translation.

The meeting was adjourned at 11:00 AM EDT.

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Appendix 1: Agenda

Joint Task Force for Clinical Trial Competency (JTF)

Biannual Global Meeting

May 2, 2023, 9:00-11:00 AM EDT

Time	Topic	Speaker / Facilitator
9:00-9:10	Introduction Overview	**Barbara Bierer, MD** Co-Chair, JTF Faculty Director, MRCT Center
9:10-9:35	JTF Updates: *Each speaker is allotted 5 min*	
	Use of the JTF Framework in Rutgers MS in CRM Program	**Lisa Palladino Kim, MS** Program Director MS Clinical Research Management Program Rutgers School of Health Professions
	The JTF Framework and Clinical Development Teams in the Biopharmaceutical Industry: Harnessing innovation in data sciences	**Howard Fingert, MD, FACP** Vice President, Medical Oncology ONO Pharmaceuticals Inc, USA
	Integration of the JTF framework as part of the 3CTN's grant objectives and its utilization at the Odette Cancer Centre in Toronto, Canada Updates to the Arabic translation of the JTF Core Competency Framework	**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
	Adapting the JTF framework to non-interventional clinical research	**Melanie Glättli, PhD Life Sciences** SCTO Scientific Coordinator Swiss Clinical Trial Organisation
	Collaboration on Implementing the JTF Framework in China	**Jean Wang** CEO Shanghai Xunyuan Information Technology Co., Ltd **Guo Fuzhen** China's Clinical Trial Development Team Capital Medical University & Beijing Tiantan Hospital

9:35-9:45	Open Discussion	**Stephen Sonstein, PhD** Co-Chair, JTF
9:45-9:55	Update: Data Management Task Force	**Meredith Nahm Zozus, PhD** Professor, Div. Chief and Director of Clinical Research Informatics University of Texas Health Science Center San Antonio
9:55-10:05	Discussion	**Barbara Bierer, MD** Co-Chair, JTF Faculty Director, MRCT Center
10:05-10:15	Update: Assessment of competencies	**Elias Samuels, PhD** Program Director of Workforce and Evaluation Michigan Institute for Clinical & Health Research University of Michigan **Susan Murphy, ScD, OTR** Director, Behavioral Research Innovation and Support Program, Michigan Institute of Clinical and Health Research (MICHR) Professor, Department of Physical Medicine and Rehabilitation, Department of Internal Medicine, Rheumatology Division University of Michigan
10:15-10:25	Discussion	**Stephen Sonstein, PhD** Co-Chair, JTF
10:25-10:40	Adaptations of the JTF Framework to Emergencies	**Barbara Bierer, MD** Co-Chair, JTF Faculty Director, MRCT Center **With comments by:** **Prof. Sandor Kerpel-Fronius, MD, PhD, DSc** Semmelweis University Department of Pharmacology and Pharmacotherapy Budapest, Hungary
10:40-10:50	Discussion	**Barbara Bierer, MD** Co-Chair, JTF Faculty Director, MRCT Center
10:50-11:00	Wrap-up and next steps	**Stephen Sonstein, PhD & Barbara Bierer, MD** Co-Chairs, JTF

Appendix 2: Participants

1. Aly Radwa, George Washington University School of Medicine
2. Carmen Aldinger, MRCT Center
3. Barbara Bierer, MRCT Center
4. Bernd Rosenkranz, Fundisa African Academy of Medicines, South Africa
5. Birdie
6. Carolynn Jones, The Ohio State University
7. Christine Samara, Odette Cancer Center, Canada
8. Denise Snyder, Duke University
9. Elias Samuels, University of Michigan
10. Elyse Summers, AAHRPP
11. Eric Kupferberg, CITI Program
12. Ginny Beakes-Read, Amgen
13. Guo Fuzhen, Capital Medical University and Beijing Tiantan Hospital, China
14. Hayat Ahmed, MRCT Center
15. Honorio Silva, International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP)
16. Howard Fingert, ONO Pharmaceuticals
17. Ian Theodore Cabaluna, University of the Philippines, National Institutes of Health, Philippines
18. Jamil Munanza, McMaster University, Canada
19. Jean Rowan, Eastern Michigan University
20. Jean Wang, Shanghai Xunyuan Information Technology Co., Ltd, China
21. Kathy Thoma, George Washington University School of Medicine
22. Laurie Halloran, Halloran Consulting Group
23. Lisa Marsh, Clinical Research Professional
24. Lisa Palladino Kim, Rutgers University
25. Manju Bikkanuri, University of Texas
26. Marlinang Siburian, National Center for Global Health and Medicine (NCGM), Japan
27. Mary-Tara Roth, Boston University
28. Melanie Glaettli, Swiss Clinical Trial Organisation, Switzerland
29. Meredith Zozus, University of Texas
30. Missy Heidelberg, Takeda
31. Miwa Sonoda, National Center for Global Health and Medicine (NCGM), Japan
32. Roshan Padbidri, Tech Observer, Singapore
33. Sandor Kerpel-Fronius, Semmelweis University, Hungary
34. Sean Hildebrandt, Mayo Clinic
35. Sharleen Traynor, Durham Tech
36. Shiva Kalinga, Takeda
37. Sifa Muchanga, National Center for Global Health and Medicine (NCGM), Japan

38. Stephanie Freel, Duke University
39. Susan Landis, ACRP
40. Susan Murphy, University of Michigan