



Executive Summary

of Joint Task Force for Clinical Trial Competency (JTF)

Biannual Global Meeting

June 6, 2024, 9:00 - 11:00AM EDT

- 1. Barbara Bierer welcomed the attendees to the meeting and commented on the continuing growth of the JTF. She announced that this meeting would be recorded and that the presentation slides and recordings would be available with permission from the presenters. After providing an overview of MRCT Center activities, she reviewed the agenda, noting that 2024 is the 10-year anniversary of the JTF. The landing page of the JTF website (https://mrctcenter.org/clinical-trial-competency/) now contains a celebratory entry with an overview of the 10 years of JTF activity and testimonials from noted contributors. Barbara Bierer invited participants to send a few sentences describing how your organization has applied the JTF, a testimonial that can be added to the website. Stephen Sonstein commented that it is wonderful to have spent 10 years and seen the evolution of the JTF, its global recognition and its implementation throughout the clinical research enterprise, and the continuing growth of biannual meetings.
- 2. Bruno Battistini, Executive Director and Chief Business Officer of the Canadian Consortium of Clinical Trial Training (CANTRAIN) began his presentation by explaining that the Canadian government realized that the response to the COVID pandemic was problematic and that there had been a significant reduction of Canadian clinical trials over the past decade. In response, the government allocated \$2.2 billion to correct the situation. The strategic plan developed is to improve health and well-being through clinical research. The first part of the pan-Canadian CANTRAIN investment consists of \$150 million to support a consortium to accelerate clinical trials that includes seven clinical trial training programs. CANTRAIN is one of, and the biggest of, the training programs and is implementing courses, webinars via a learning management system platform, and 22 clinical trial projects, all launched on January 19, 2023. Members and partners include federal funders, provincial funders, health charities, community partners, public academic institutions, health authorities, research centers and institutes, private pharmaceutical industry, and contract research organization, and the list continues to grow. CANTRAIN created a bilingual website and free training programs for Canadian public institutions, hospitals, research centers, patients, and community partners. The training programs are presented at the fundamental, intermediate, and expert levels inspired by the JTF. There are 4 streams of learners (Graduate and Postdoc Trainees, Clinical Research Professionals, Trialists, and Community Partners) supplemented by mentors. Studentships, Fellowships and several Internships awards are available, providing financial support to the above programs.
- 3. Lisa Goos, Chief Operating Officer, CANTRAIN, described the 4 streams of learning which are based upon the JTF Framework as a cornerstone (see slide). All of the learning streams have a common core and focus on competencies, combining knowledge and the opportunity to engage, supplemented by mentorship. The learning stream for patient advocates is similar to EUPATI and includes a patient fellowship program. CANTRAIN wishes to collaborate with the MRCT Center to participate in the JTF developmental efforts.





a. Questions – Stephen Sonstein inquired as to the type of documentation for those who participate in various streams and whether there is collaboration with the academic programs in clinical research that exist in Canada. Lisa Goos responded that there was no intention of CANTRAIN competing with academic programs, but that those who complete CANTRAIN training will receive certificates of completion. CANTRAIN is also seeking formal accreditation and is currently certified by TransCelerate for ICH GCPs. Barbara Bierer inquired as to whether the grant includes compensation of mentors and patient partners. Bruno Battistini responded that mentors were not compensated, because most were faculty members who received recognition in workload reduction and toward professional advancement. Patient partners are, however, compensated. Currently, several industry partners are invited to visit and participate so that the CTTP and Platform are sustainable and continue to be free for the public sector.

4. Scheduled Data Management Update was not presented

- 5. Stephen Sonstein, Co-chair, JTF, presented an update on the Council for International Organizations of Medical Sciences (CIOMS) workgroup effort in which he, Barbara Bierer, and others were participating. He described the formation and evolution of CIOMS and the rationale for creating the workgroup with the mission to develop "Standards of Education and Training for Health Care Professionals." The workgroup is represented globally by colleagues from academia, industry, regulatory bodies and clinicians. The workgroup has agreed to base the published competency frameworks on IFAPP, JTF, RAPS and EUPATI, supplemented as necessary. Discussions occur online and face-to-face. Another workgroup meeting is scheduled in October 2024, followed by a release of the standards in 2025 and an opportunity for public comment. Stephen Sonstein commented on the similarity of the CANTRAIN and the CIOMS efforts. A member of the workgroup acknowledged the value of the IFAPP and JTF frameworks and commented that the progress of the CANTRAIN model could be emulated by CIOMS. Barbara Bierer commented that when the CIOMS document is available for public comment, it will be sent to all JTF registrants.
- 6. Christine Samara, who coordinated the Arabic translation of the JTF Framework with the Ministry of Health and Prevention, United Arab Emirates (UAE), acknowledged those who participated in the translation, currently posted on the JTF website, and shared that dissemination of the framework is now occurring within UAE and the region. She then described her participation in the Canadian Cancer Clinical Trials Network (3CTN), which assesses the competency level of staff at network oncology sites using the JTF Framework. They are hoping to track changes and present data following their 3-year grant-funded effort. 3CTN was involved with ECRIN in the review of the French translation of the JTF Framework, revisions posted recently on the JTF website. Christine Samara mentioned the collaborative publication with 3CTN and its inclusion in a recent *Frontiers* special issue of 12 publications, which included many JTF publications. Barbara Bierer noted that the publications from *Frontiers* were listed on the JTF website and urged any other participants who have published articles involving the use of the JTF Framework to please contact the MRCT Center.
- 7. Amy Fox, PhD, presented the content of her recently completed dissertation, "How a competency-based program will contribute to early clinical research professionals' training." Her work included a survey of 92 health professionals who commented on their education, experiential learning, and relative competency based on the JTF Framework. Her conclusion was that being certified more than 2 years and being a CRP for more than 5 years, in addition to on-the-job training, provided the CRP higher scores





of self-perceived competency than formal education. Stephen Sonstein commented that it was encouraging to know that the efforts of the JTF were being expanded through dissertations and theses from graduate-level students.

8. Stephen Sonstein provided a brief summation of the day's presentations and urged the group to visit the JTF website and review the 10-year JTF anniversary comments and testimonials. Barbara Bierer gave thanks to all for attending and requested participants to notify <u>Carmen Aldinger</u> at the MRCT Center of things relevant to share at the next semi-annual meeting. Bruno Battistini shared in the chat: https://www.innovationnewsnetwork.com/cantrain-clinical-trial-training-programmes/48074/.

Appendix 1: Agenda

Joint Task Force for Clinical Trial Competency (JTF) Biannual Global Meeting June 6, 2024, 9:00-11:00 AM EDT

Time	Topic	Speaker / Facilitator
9:00-9:15	Introduction Overview	Barbara Bierer, MD
	JTF 10 th anniversary	Co-Chair, JTF Faculty Director, MRCT Center
JTF Updates a	nd discussion	
9:15-10:00	CANTRAIN CANadian Consortium of Clinical Trial TRAINing	Bruno Battistini, PhD National Executive Director & Chief Business Officer, Lisa Goos, PhD Chief Operating Officer, Excused: Pr. Jean Bourbeau, MD, MSc, FRCPC, FCAHS NPI & Ntl Lead Linda Hunter, RN MScN, PhD(c), Ntl Stream Coordinator
10:00-10:10	Data Management update: Results from Delphi	Meredith Zozus, PhD Professor, Division Chief, Clinical Research Informatics University of Texas (UT) Health San Antonio, Long School of Medicine, Department of Population Health Sciences
10:10-10:20	CIOMS Update	Stephen Sonstein, PhD Co-Chair, JTF





10:20-10:30	Updates:(1) Deploying the JTF Framework across the world: Arabic translation; (2) 3CTN Updates	Christine Samara, MSc Coordinator of the Arabic Translation with the Ministry of Health and Prevention, United Arab Emirates, Member of the 3CTN Performance Strategy Sub- Committee, Canadian Cancer Clinical Trial Network (3CTN), Canada
10:30-10:40	How a competency-based program will contribute to early clinical research professionals' training	Amy Fox, PhD Capella University
10:40-11:00	Open discussion and Wrap-up	Stephen Sonstein, PhD & Barbara Bierer, MD Co-Chairs, JTF