

Executive Summary

Joint Task Force for Clinical Trial Competency (JTF) Biannual Global Meeting

December 10, 2024, 9:00-11:00 AM ET (Virtual)

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 conflicts of interest, an overview of the Multi-Regional Clinical Trials Center (MRCT Center), its mission, and vision, and a review of the Agenda.
2. Stephen Sonstein welcomed the group and announced the availability of an updated [PowerPoint presentation](#) on the JTF website that describes the Core Competency Framework, its history, potential uses with examples, and future efforts. It is freely available and may be used for onboarding, training, and education within academic programs. Dr. Sonstein encouraged the group to review the JTF website since it is constantly updated with new publications and content related to the JTF Framework.
3. Stephen Sonstein announced that JTF will be presenting a webinar on April 3, 2025, "Global Development of the Clinical Research Workforce." Lembit Rago, MD, PhD, Secretary General of the Council for International Organizations of Medical Sciences (CIOMS) will be the Keynote Speaker. Registration is free of charge and will be available on the [JTF website](#) or within the slide deck posted following this meeting.
4. Stephen Sonstein announced that in response to input from participants, we will change the timeframe for the next global JTF meeting to enable individuals from Western and Asian time zones to participate. The meeting has been scheduled for May 29, 2025. Registration will be available in 2025.
5. Monica Bogas, MD, Head of Clinical Operations, Roche Pharmaceutica Quimica, Lda, Portugal, presented how Roche and AICIB used the JTF Framework to enhance Clinical Trial Competency in Portugal. For over 15 years, Roche has maintained a strong partnership with research sites in Portuguese hospitals. AICIB is an independent, non-profit organization that functions as a consultancy and liaison between stakeholders in the clinical research enterprise in Europe. Roche noted that

there had been significant growth in the number of clinical trials conducted over the past 5 years in Europe, with several of the smaller countries (e.g., Denmark, Belgium, the Netherlands) having achieved very high rates of clinical trials per capita compared to larger countries (e.g., France, Germany). Portugal is rated in the middle. Their diagnostic assessment of why more trials were not sited in Portugal highlighted insufficient knowledge and the limited number of trained professionals. Working to address these needs, Roche and AICIB came across the MRCT Center and the JTF Framework but found no Portuguese translation. The translation of the Framework into Portuguese required minor modifications to adapt to the Portuguese regulatory agency. A survey was then conducted utilizing 10 research sites to identify gaps in knowledge. The survey was followed by a meeting with representatives from each of the sites to share survey results and brainstorm potential solutions. A publication describing the effort is in preparation, and Roche is planning initiatives for the coming year to develop training modules utilizing the JTF Framework and a certification program for clinical research professionals. In addition, onsite events for knowledge sharing, specialized training for DCT, and safety reporting are planned.

6. Benjamin P. Sablan, MD (BS), Director of the National Clinical Trials and Translation Center, University of the Philippines, Manila, presented Training Modules that are being developed in partnership with Japan and the ARISE network, all based on the JTF Framework. The development follows a survey of clinical research professionals and trial participants who identified training needs. The primary focus will be to train new investigators and trial participants in order to increase the number and quality of clinical trials in the Philippines.
7. Emily Drum, MPH, Program Manager, and Amin Yakubov, MPH, MBA, CCRP, Associate Director, Clinical and Translational Science Institute, NYU Langone Health, Brooklyn, NY, presented on their efforts to train community health workers (CHWs) for vital jobs in clinical research and their success in expanding the workforce directly into communities. They have developed free online training modules for CHWs based upon the JTF Framework. They recognized that incorporating CHWs into the workforce will enhance diversity, contribute to growth, and have a unique and vital role to play in the future of research teams. The training was developed utilizing the basic level competencies of the JTF Framework and is provided in two seminars: 1. Clinical Research 101 and 2. Clinical research history and diversity, which focuses on immigrant populations with whom they work in New York City. Developed on the recommendation of CHW partners, seminar 2 mainly contains modules that do not fit neatly into the existing JTF Framework, including myths and misconceptions, research access, and history of research ethics. The presenters proposed applying a health equity lens to the Framework as a whole. More than 600 participants, over 70% of whom are CHWs, have participated in the training. An exit survey reported that the training provided practical tips that can be used day to day. 71% of respondents

reported feeling confident that the training enhanced their roles, and many commented that it transformed their careers. 90% reported that they would recommend the training to other CHWs. The training modules, [available for anyone](#) to take, are presented on Langone's preferred technology platform, REACH, but their hope is to partner with organizations nationally and globally to improve access. Dr. Sonstein commented that there seems to be considerable overlap with CANTRAIN's efforts and MRCT Center's patient partners work; efforts should be made to collaborate across the initiatives.

- 8.** Meredith Zozus, Professor, University of Texas, Long School of Medicine, San Antonio, TX, presented an update from the JTF Data Management Task Force. Dr. Zozus reviewed the six competencies that were developed, each of which had gone through 3 rounds of a Delphi consensus process. A visual representation of the results showed the ratings for each statement ranging from too easy, to just right, to too hard. A final review by the Delphi group will be followed by review by the Task Force leadership before a final product is recommended. Dr. Bierer commented that an immense amount of work had gone into this effort which was worthy of a longer discussion once final recommendations were made.
- 9.** Sylvia Baedorf Kassis, MPH, Program Director, MRCT Center, presented the current status of the Patients Participants Task Force which has recently been created. Ms. Baedorf Kassis reviewed her background in the area of clinical research and described the task force as a global collaborative effort with multinational leadership consisting of CANTRAIN, EUPATI, and the MRCT Center. The goal of the Task Force is to create a set of competencies that are oriented toward patient partners and clinical research team members who engage with patient partners. Ms. Baedorf Kassis presented a timeline for the effort that is predicted to last over 15 months. She is currently recruiting Clinical Research Professionals (CRPs) and patient partners to serve on the task force and intends to have a significant international representation, especially from the global South. She extended the invitation to those interested to contact her via email at SBAEDORFKASSIS@BWH.HARVARD.EDU.
- 10.**Carolynn Thomas Jones, DNP, Clinical Professor, Ohio State University, presented on Team Science Competencies for Clinical Research Professionals: A Multi-levelled Delphi Approach. Dr. Thomas Jones reviewed her participation in the initial development of the JTF Framework and the recent accreditation of the academic program in clinical research at Ohio State University that is based on the JTF Framework. Dr. Thomas Jones described the Delphi process which developed the Team Science competencies for CRPs. These competencies are an expansion of Domains 7 and 8 of the JTF Framework. A literature review revealed that most of the training relating to clinical research was focused on Domains 1 through 6 and that there was very little published on Domain 7 (Research and Professionalism) or Domain

8 (Communication and Teamwork) although competency in both domains is essential for CRP team members. A working group was formed in 2022 to develop Team Science Competencies. A Redcap survey was created and distributed for one month, and it received 223 responses that identified 5 individual competencies and 8 team competencies. These were expanded into 59 SMART (e.g., **s**pecific, **m**easurable, **a**chievable, **r**elevant, and **t**ime-bound) skills and 177 examples (see slide). Examples are active listening and relational openness. 207 individuals responded that they used these skills weekly or daily in their work, but that they had received little or no training in the areas. A [publication](#) was developed from the results of the survey. The next effort is to create Team Science Training. Dr. Thomas Jones requested that the publication be highlighted on the JTF website.

- 11.** Barbara Bierer, MD, Faculty Director, MRCT Center, Co-Chair, JTF led a Discussion and Wrap-up of the meeting, acknowledging that significant efforts have been made in the 6 months since the last semi-annual meeting. Ms. Baedorf Kassis shared that there were many potential opportunities for collaboration between the groups working with the CHW, Team Science, and Patient Partners and asked how to move forward to remain in communication. Dr. Bierer shared that the MRCT Center would be happy to explore setting up meetings for such collaboration. She also noted that JTF was always willing to consider updating the competencies but was wary about adding additional domains to the “wheel” given the work that has already been expended in translation. The JTF sets standards, but it will not develop specific training modules nor be responsible for credentialing or creating a credentialing effort; that work should be done by others. She encouraged individuals who have ideas to bring them forward at semi-annual meetings as well as via direct contact with JTF. Dr. Sonstein commented that there was continuing interest in the assessment of competencies and was looking forward to the publication of the data presented by Dr. Sablan and Dr. Bogas. He also reflected on the composition of the semi-annual meeting participants as being heavily represented by academic institutions, but that participation by corporate entities was increasing; he is looking forward to continued interest by this group. Dr. Sonstein reiterated the announcement of the April 2025 webinar and its keynote speaker, Dr. Lembit Rago from CIOMS, and encouraged individuals to register; this would be an excellent learning opportunity for students in academic programs.

Although the NIH does not endorse individual frameworks and tools, Dr. Bierer noted that NIH had endorsed the JTF Framework through issuing a grant to develop training based on the competencies. She agreed with Dr. Sonstein that there was insufficient corporate engagement. A meeting participant referred to an NCATS publication defining competencies for CRPs that were based on the JTF Framework. Another NCATS effort was the DIAMOND portal that contained 350 modules. The participant

noted that the portal still exists, but the website has not been updated and many links are broken. Several people mentioned the adoption of the JTF Framework by ACRP. Dr. Sonstein acknowledged that ACRP was one of the first to integrate the JTF framework into their organization. ACRP has based its annual meeting format on the 8 JTF Domains, and its certification program was revised based on the JTF Framework. He also welcomed Troy Kieser as the new representative to the JTF from ACRP.

Dr. Bierer ended the meeting by encouraging all to attend the April Webinar, to feel free to invite students and reiterating that the next semi-annual meeting of the JTF will be at a later time to accommodate different time zones. She wished everyone happy holidays and thanked them for participating.

Appendix: Agenda

Joint Task Force for Clinical Trial Competency (JTF) Biannual Global Meeting

December 10, 2024, 9:00-11:00 AM EST

Time	Topic	Speaker / Facilitator
9:00-9:15	Introduction Overview JTF Slide deck JTF Webinar	Barbara Bierer, MD Co-Chair, JTF Faculty Director, MRCT Center Stephen Sonstein, PhD Co-Chair, JTF Consultant, MRCT Center
Use of the JTF Framework		
9:15-9:30	Training modules using the JTF Framework	Benjamin P. Sablan, JR., MD, MDM Director National Clinical Trials and Translation Center University of the Philippines Manila
9:30-9:45	How ROCHE and AICIB Used the JTF Framework to Enhance Clinical Trial Competency in Portugal	Mónica Bogas, MD Head of Clinical Operations Roche Farmacêutica Química, Lda Portugal

9:45-10:00	Training Community Health Workers for the Vital Jobs in Clinical Research and Expanding the Workforce Directly into Communities	<p>Amin Yakubov, MPH, MBA, ACRP-CP Associate Director- Research Operations Clinical & Translational Science Institute (CTSI), NYU Langone Health Brooklyn</p> <p>Emily Drum, MPH Program Manager, Research Education and Strategic Initiatives Clinical & Translational Science Institute (CTSI), NYU Langone Health Brooklyn</p>
Updates to the JTF Framework		
10:00-10:15	Data Management update: Results from Delphi	<p>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</p>
10:15-10:30	Patient Participants Task Force	<p>Sylvia Baedorf Kassis, MPH Program Director Multi-Regional Clinical Trials Center of Brigham and Women’s Hospital and Harvard</p>
10:30-10:45	Team Science Competencies for Clinical Research Professionals: A Multi-Leveled Delphi Approach	<p>Carolynn Thomas Jones, DNP, MSPH, RN, CRN-BC, FAAN Clinical Professor, College of Nursing Director, Master of Clinical Research, College of Nursing Co-Director of Workforce Development, OSU Clinical Translational Science Institute The Ohio State University</p>
10:45-11:00	Discussion and Wrap-up	<p>Barbara Bierer, MD Co-Chair, JTF Faculty Director, MRCT Center</p>