Executive Summary

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

June 2, 2025, 9:00–11:00 AM ET (Virtual)

On June 2, 2025, the Joint Task Force for Clinical Trial Competency (JTF) held its biannual global virtual meeting. The session included updates on the JTF framework, presentations on its application and development, and discussions regarding future directions.

Meeting Overview and Welcome

Barbara Bierer, MD, Co-Chair of the JTF, welcomed attendees and provided an introduction to the JTF and the MRCT Center. She emphasized the JTF's organic and international evolution, driven by the need to continually update competencies for clinical research professionals in a dynamic field. The JTF Framework consists of eight competency domains, each detailed with competencies at fundamental, skilled, and advanced levels. A key challenge mentioned was the high threshold for changing the framework due to its translation into 12 languages. The meeting agenda highlighted two aspects: integrating JTF competencies into an academic curriculum and professional development, and ongoing work on data management competencies and a patient partner project. The next meeting was announced for December 10, from 1-3 PM ET. The JTF biannual meetings alternate between morning and afternoon to accommodate the international audience.

Integrating JTF Competencies: Curriculum Design and Accreditation at Arizona State University

Kaushal Shah, PhD, from Arizona State University (ASU), discussed how ASU integrated the JTF Framework into its clinical research management and regulatory science programs. ASU adopted the JTF to align its curriculum, enhance credibility, set clear learner expectations, and streamline the accreditation process. Dr. Shah explained that the JTF Framework helps ensure students graduate with competencies valued by employers; it supports an outcome-based education approach. Future priorities include engaging stakeholders, implementing

new JTF competencies, maintaining accreditation, and defining excellence in clinical research education.

Comprehensive Leveling of the Clinical Research Professional Career Ladder at Johns Hopkins University

Anthony (Tony) Keyes, MBA, PMP, from Johns Hopkins Institute for Clinical & Translational Research, presented on the development of a leveled career ladder for clinical research professionals at Johns Hopkins University (JHU). The initiative aimed to address issues like inconsistent titles, variable compensation, and high attrition by establishing clear job descriptions aligned with competencies. JHU utilized the JTF Framework, along with resources from Duke University, ACRP, and Vanderbilt, to map 47 competencies across nine distinct job positions. This project, which took seven months of intensive work, has influenced a university-wide initiative to standardize job descriptions.

Data Management Competencies: Results from Delphi Study

Meredith Zozus, PhD, from the University of Texas Health San Antonio, provided an update on the Delphi study aimed at updating Domain 6 of the JTF Framework concerning data management and informatics. The study, initiated in 2023, has completed three rounds of the Delphi process, and the final report is currently undergoing member evaluation. The resulting competencies cover defining and generating data, data collection and processing, data use, statistical analysis, data re-use, study registration and data sharing, and leveraging information systems.

JTF-P3 (Patient Partner Project) Update

Sylvia Baedorf Kassis, MPH, from the MRCT Center, and Linda Hunter, MScN, PhD (C), National Manager of the Patient and Community Partner Stream at CANTRAIN, presented an update on the JTF Patient Partner Project (JTF-P3). This project focuses on co-creating clinical research competencies for patient partners and for research professionals engaging with them. The initiative originated from the recognized gap in the existing framework regarding the contributions and expectations of patient partners. The project involves a workgroup with international representation from the MRCT Center, EUPATI, and CANTRAIN, aiming to produce an addendum to the JTF framework and a publication by March 2026. Key milestones include compiling existing resources, thematic analysis, and workstreams for drafting additions aligned with Bloom's Taxonomy, with a focus on areas like diversity, cultural safety, and compensation. A Review Group, with international representation, is currently being recruited.

Discussion Highlights

The discussion session included reflections on the presentations. Stephen Sonstein congratulated ASU on its doctoral program and queried the role of doctorally prepared individuals in clinical trial management, which Kaushal Shah and Tony Keyes addressed by emphasizing leadership and advanced competencies. The conversation also touched upon the accessibility of professional advancement for individuals without formal degrees, with panelists agreeing on the importance of recognizing experience and providing opportunities. Meredith Zozus noted the fluidity in roles and the utility of competencies in articulating value across different levels. A meeting participant raised points about the input from the Society for Clinical Data Management (SCDM) in the Delphi study, which Dr. Zozus confirmed, and the increasing importance of quality risk management and critical-to-quality factors, which Linda Hunter suggested could potentially be integrated into the patient partner competencies. The discussion also touched upon academic program accreditation and the potential for broadening its scope to include Regulatory Sciences programs as well as the CTSA-sponsored programs.

Dr. Sonstein thanked the audience for the robust discussion and encouraged participants to reach out to the MRCT Center with ideas and suggestions, or to volunteer to present at the next meeting.

This summary was prepared with the assistance of Gemini AI and was reviewed by presenters.

Appendix: Agenda

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

June 2, 2025, 9:00-11:00 AM EDT

Time EDT	Topic	Speaker / Facilitator
9:00-9:10 AM	Welcome and Introduction Update from JTF webinar	**Barbara Bierer, MD** Co-Chair, JTF Faculty Director, MRCT Center **Stephen Sonstein, PhD**

		Co-Chair, JTF Consultant, MRCT Center
9:10-9:35 AM	Integrating JTF Competencies: Curriculum Design and Accreditation	**Kaushal Shah, PhD** Program Director, Clinical Research Management and Regulatory Science Programs Arizona State University
9:35-10:00 AM	Comprehensive leveling of the Clinical Research Professional Career Ladder at Johns Hopkins University	**Anthony (Tony) Keyes, MBA, PMP** Assistant Director of Research Workforce Operations Johns Hopkins Institute for Clinical & Translational Research
10:00-10:25 AM	Data Management Competencies: 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
10:25-10:50 AM	JTF-P3 (Patient Partner Project) Update	**Sylvia Baedorf Kassis, MPH** Program Director MRCT Center & **Linda Hunter** National Manager of the Patient and Community Partner Stream, Grant Co-Applicant CANTRAIN
10:50-11:00 AM	Discussion	**Barbara Bierer, MD** Co-Chair, JTF Faculty Director, MRCT Center **Stephen Sonstein, PhD** Co-Chair, JTF Consultant, MRCT Center