

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

May 20, 2022, 8:00-10:00AM EDT

Executive Summary

Dr. Barbara Bierer, JTF Co-Chair, opened the meeting with a welcome and an overview of the MRCT Center and its mission followed by a review of the Agenda (Appendix 1).

Stephen Sonstein, PhD, JTF Co-Chair, welcomed the participants (Appendix 2) and expressed his appreciation for over nine years of support and participation in the development of the JTF. He followed with an overview of the evolution of the JTF from its founding in 2013 to the present. This included:

- the publication of the JTF Framework that described the knowledge, skills, and attitudes required to conduct safe and quality clinical research
- the global distribution and growing integration of the Framework into the clinical research enterprise
- the translation of the Framework into multiple languages
- leveling of the Framework to describe Fundamental, Skilled and Advanced competency
- the addition of project management competencies
- the current organizational collaborations and professional publications
- the commitment and governance by the MRCT Center with the maintenance of a JTF website, convening efforts, coordination of multiple work streams, oversight of translations, and commitment to public access of materials.

Co-Chair Bierer introduced 5 speakers who described methods by which the JTF Framework has been utilized or has provided opportunities to improve the conduct of clinical research.

- Denise Snyder, MS, RD, CSO, Associate Dean of Clinical Research at Duke University School of Medicine described Duke's Workforce Engagement and Resilience (WE-R) Program. The program's objective, which is based upon the JTF Framework, is to create a professional identity for clinical research professionals, reduce the number of job descriptions, identify gaps in training, develop job portfolios, evaluate job performance, facilitate professional advancement and enhance retention. The program has been most successful and is well accepted by staff and management, has increased efficiency and reduced staff turnover.
- H. Robert Kolb, RN, MS, CCRC, Assistant Director of Clinical Research Services at the University of Florida Clinical Translational Science Institute described the Research Professionals Network, a multi-institutional collaboration which utilizes the JTF Framework as a basis for training and networking at six CTSA sites within the US. He suggested closer collaboration between MRCT Center, the JTF, and the Research Professionals Network.

- Carolynn Thomas Jones, DPN, MSPH, RN, CRN-BC, FAAN, Associate Professor of Clinical Nursing and Director, MS Program in Clinical Research, The Ohio State University, discussed the further development of Team Science Competencies for Clinical Research Professionals and the Expansion and Leveling of JTF Domains 7 and 8. She stressed the need for increased interdisciplinary activity and team integration within the NCATS academic clinical research enterprise. She described the work of a multi-institutional group that further defined and expanded the team science competency components of the JTF and suggested modification of the Framework to incorporate these additional competencies.
- Stephen Sonstein, PhD, Chair of the Committee on Accreditation of Academic Programs in Clinical Research discussed the creation of an accreditation process for academic programs sponsored by the Consortium of Academic Programs in Clinical Research and functioning under the Commission on Accreditation of Allied Health Education Programs (CAAHEP). The Standards for Accreditation of Academic Programs in Clinical Research is based upon the JTF Framework and requires that each accredited program have at least one learning objective which maps to each domain of the JTF Framework. Currently 4 academic programs are accredited and 8 additional programs are in process.
- Miwa Sonoda, RN, MPH, GDip (Clinical Trials), GDip (Global Health), Medical Science Liaison, National Center for Global Health and Medicine (NCGM), Japan, discussed the ARISE Alliance in Asia whose mission is to increase capacity to conduct clinical trials in Asia and Africa by facilitating the understanding of competencies. They have translated the JTF Framework into Thai, Indonesian, and Vietnamese, and are collaborating with Mr. Wilsdorf for the French translation (see below). They are conducting a survey of self-assessed competency of clinical research professionals in various low and middle income countries based upon the JTF survey format and in collaboration with MRCT Center.
- Allan Wilsdorf, Engr., MSc, Head of the Training and Education Unit of the French Clinical Research Infrastructure Network (F-CRIN) discussed their efforts to translate and disseminate the JTF Framework in as many languages as possible. The group is finalizing the translation into French, Portuguese, Italian and Russian and is in the process of working on additional translations into German, Korean, and Chinese. Additionally, they will be interfacing with the NCGM group to add Thai, Indonesian and Vietnamese. There has been a contact established to add translation into Arabic. A survey of clinical research professionals, using the JTF Survey Framework, is currently being analyzed to guide further training efforts.

An open discussion, Envisioning the Future of the JTF, was moderated by Barbara Bierer and Stephen Sonstein relating to the following:

Future Updates and JTF Development

- Future JTF Updates and Development. The suggestion was made to limit major changes to every 3-5 years given the need to translate into multiple languages and maintain concordance between the many languages.
- Value of self-assessed competency surveys is questionable – there is a need for more formal measures of successful performance.
- Special projects can be done that focus on certain domains where additional competency is suggested, e.g., data management, team science, competency assessment index.

- There are opportunities for further collaboration with Africa.
- Clinical Research itself is evolving rapidly. JTF will need to accommodate to future changes in pharma and technology. JTF needs to consider where the field is going, and whether the JTF Framework should be revised to reflect the changes, over the next 5 years.
- Training needs must have a hands-on component, not just theoretical reading or virtual lectures. Certification is important.

Professional Development

- How are industry partners using competencies? Academic programs aim to provide students with abilities to enter industry that are different from academia. Optimally would have greater industry representation on JTF.
- Started using JTF framework in Middle East and has 50 staff that are being evaluated using Framework, modifying job descriptions and upward mobility criteria. Can provide support for Arabic translation.
- In industry there is need to “unlearn” certain erroneous and problematic methods. Reiterates need for hard data, not just surveys.

Translations

- MRCT Center will continue to coordinate in collaboration with A. Wilsdorf and others who have expressed interest in working on translations.
- Request to further populate website. MRCT Center is happy to link to publications. If JTF decides to post potential trainings on the website, the trainings must be qualified, curated, and vetted by JTF and must be available free of charge. JTF is a non-profit consortium that seeks to advance professional clinical research competencies world-wide.

Governance and Organization

- Until now organic collaborative that has come together for common purpose, people volunteered time, not strict with representation. JTF should have further discussion.
- Need further discussion of linkage with NCATS, although NCATS is US, and JTF is international.
- Would be helpful to provide road map for curriculum with links to training for each domain and level.
- Referred to Diamond Portal where training can be uploaded. JTF does not want to take this on at this time. Diamond Portal has moved to new host, hoping to update.
- ACRP looking to align training to competencies. Want to include JTF in further discussions.
- Important to talk about how to interface and develop tools for assessing competencies; integrate industry and provide hands on experiences and added technology based competencies.
- MRCT Center’s online ICH E6(R2) online training may be an example of collecting hard data and potential certification.

Concluding Remarks

- The Co-Chairs were impressed by JTF progress since the 2016 meeting in Boston and today. MRCT Center will continue to support the JTF as an independent convener. Realizes there is further work to be done relating to the JTF Framework. We are not making any decisions today, but we do need to determine how to work together better and more closely. Several initiatives that everyone is working on: performance based assessment; online training. Important to

maintain initial JTF concept: global competencies with no geographic boundaries, ensure dissemination, global reach.

- Next steps: MRCT Center will reach out to various participants of today's meeting concerning further defining next steps. Will have another JTF Global Meeting in September or October. Please reach out to Barbara Bierer, Stephen Sonstein, and/or Carmen Aldinger if you wish to discuss and/or have ideas.
- Many thanks for your time and interest and for all of the work that you do.

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Appendix 1

Joint Task Force for Clinical Trial Competency (JTF)

Strategic Global Virtual Meeting

May 20, 2022, 8:00-10:00 AM EDT

Time	Topic	Speaker / Facilitator
8:00 – 8:20 AM	Introductions	Barbara Bierer, MD Co-Chair, JTF Faculty Director, MRCT Center
8:20 – 8:35 AM	Overview of JTF Accomplishments	Stephen Sonstein, PhD Co-Chair, JTF
8:35 – 9:10 AM	JTF Core Competency Framework: Utility and Opportunity Each speaker: 3-5 min	Facilitator: Barbara Bierer, MD Co-Chair, JTF Faculty Director, MRCT Center
	Duke's Workforce Engagement & Resilience (WE-R) Program	Denise Snyder, MS, RD, CSO Associate Dean of Clinical Research Duke Office of Clinical Research (DOCR) Duke University School of Medicine
	Community of Practice & JTF Competency Framework: The Research Professionals Network Workshops	H. Robert Kolb, RN, MS, CCRC Assistant Director Clinical Research Services / Research Participant Advocate Director, Clinical Research Professionals' Programing Translational Workforce Directorate University of Florida Clinical Translational Science Institute

	Developing Team Science Competencies for Clinical Research Professionals- Expanding and Leveling JTF Domains 7 & 8	Carolynn Thomas Jones, DNP, MSPH, RN, CRN-BC, FAAN Associate Professor of Clinical Nursing, OSU College of Nursing Director, OSU Master of Clinical Research, Co-Director, Workforce Development, OSU CCTS The Ohio State University
	Accreditation of Academic Programs in Clinical Research,	Stephen Sonstein, PhD Chair, Committee on Accreditation of Academic Programs in Clinical Research (CAAPCR)
	How can we develop competent clinical research professionals in LMICs?: Promotion of the JTF Core Competency Framework in Asia and Africa	Miwa Sonoda, RN, MPH, GDip (Clinical Trial), GDip (Global Health) Medical Science Liaison Department of International Trials, Center for Clinical Sciences National Center for Global Health and Medicine (NCGM), Japan
	Deploying the JTF Framework across the world – Translations and applications	Allan Wilsdorf, Engr., MSc Head of the Training & Education Unit French Clinical Research Infrastructure Network (F-CRIN)
9:10 – 9:50 AM	JTF: Envisioning the Future	Open Discussion Moderators: Barbara Bierer, MD & Stephen Sonstein, PhD Co-Chairs, JTF
9:50 – 10:00 AM	Concluding Remarks	Barbara Bierer, MD & Stephen Sonstein, PhD Co-Chairs, JTF

Appendix 2

Participants JTF Meeting, May 20, 2022

1. Alan Mal (SiCRES), Mahidol University, Thailand
2. Allan Wildorf, F-CRIN (French Clinical Research Infrastructure Network)
3. Barbara Bierer, MRCT Center
4. Bernd Rosenkranz, Fundisa Academy, Capetown, South Africa
5. Carmen Aldinger, MRCT Center
6. Carolynn Jones, The Ohio State University
7. Charles Schmidt, Hospital de Clinicas, Sao Paulo, Brazil
8. Christine Samara, Odette Cancer Center, Toronto, Canada
9. Denise Snyder, Duke University
10. Elias Morrel Samuels, University of Michigan
11. Elyse Summers, Association for the Accreditation of Human Research Protection Programs (AAHRPP)
12. Eric Kupferberg, CITI Program
13. Ginny Beakes-Read, Amgen
14. Honorio Silva, International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP)
15. Howard Fingert, Consultant
16. Ian Cabaluna, University of the Philippines Manila
17. Janette Panhuis, Population Health Research Institute, Canada
18. Jean Rowan, Eastern Michigan University
19. Karen Hartman, Mayo Clinic
20. Kathy Thoma, George Washington University
21. Kirsten Grubic, Population Health Research Institute (PHRI), Canada
22. Laura's iPhone, assuming: Laura Meiners, Mayo Clinic
23. Lisa's iPhone, assuming: Lisa Marsh, formerly at Medpace
24. Lisa Palladino Kim, Rutgers University
25. Maria Umano, NCGM Japan, Regional Manager the Philippines
26. Maire-Joelle (Sifa) Muchanga, NCGM Japan, Regional Manager Democratic Republic of Congo
27. Marlinang Siburian, NCGM Japan, Regional Manager Indonesia
28. Matilde Damian, Association of Clinical Research Professionals (APEIC), Mexico
29. Mary-Tara Roth, Boston University
30. Mieko Hamana, National Center for Global Health and Medicine (NCGM), Japan
31. Miwa Sonoda, National Center for Global Health and Medicine (NCGM), Japan

32. Nattha Kerdsakundee, NCGM, Regional Manager Thai
33. Nita Ichhpurani, Consultant
34. Rebecca Brouwer, Duke University
35. Rebecca Kottschade, Mayo Clinic
36. Robert Kolb, University of Florida
37. Roshan Padbidri, Tech Observer, formerly Anidan Group, Singapore
38. Sharleen Traynor, Durham Tech
39. Stephanie A. Freel, Duke University
40. Stephen Sonstein, MRCT Center Consultant
41. Susan Landis, Association of Clinical Research Professionals (ACRP)
42. Vishal Goyal, Drugs for Neglected Diseases Initiative, Geneva
43. Yves Lula, University of Kinshasa