

## Executive Summary

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

November 14, 2022; 9:00-11:00 AM EST

1. Barbara Bierer and Stephen Sonstein, JTF Co-Chairs, and Carmen Aldinger, MRCT Center Program Manager welcomed the attendees. Dr. Bierer reviewed the mission of the MRCT Center and its leadership of the JTF and informed that the JTF plans to convene global meetings such as this one approximately twice a year to review progress. The Presenters' slides will be provided with the Executive Summary and only the summary content, not detailed content, will be provided here.
2. Updates of JTF Activity were presented by the following:
  - a. Jesus Gomez-Navarro, Takeda Pharmaceuticals International, described the Takeda Knowledge Development Academy. This is an effort by Takeda to upgrade the skills of the organization's research teams to meet the challenges and opportunities of the future. The Academy was launched in March 2022 and consists of 3 pillars: (1) A Core Clinical Development curriculum that is based on the JTF Core Competency Framework; (2) a mechanism for knowledge and learning sharing; and (3) support for a community of learning and leadership by those who serve as faculty and knowledge providers. It is branded as "Bloom" and is organized into smartcards, pathways, and journeys. Next steps include building a knowledge management platform that links to the JTF competency framework and engaging Takeda's *R&D Learning Community of Practice*.
  - b. Allan Wilsdorf, French Clinical Research Infrastructure Network, discussed the many active efforts to translate the JTF Core Competency Framework into additional languages. The French translation has been published. The Italian translation is currently being finalized and proofread. New translations are being developed in Thai, Indonesian, and Vietnamese, translations that are being coordinated by the National Center for Global Health and Medicine's ARISE network, and Arabic and Dutch. In addition, the differences between the original English version and the Swiss adaptation are being mapped. Finally, the survey that had been conducted in France last year is currently being adapted for the private sector, with some modifications such as competencies for working with medical devices and using the JTF framework for the design of training programs specific to project managers.
  - c. Miwa Sonoda, National Center for Global Health and Medicine (Japan), presented the initial analysis of results of a Clinical Research Competency survey in Low- and Middle Income Countries. A self-assessment of the competence of clinical research professionals was conducted in Indonesia, Democratic Republic of Congo, Philippines, Thailand and Vietnam. The survey was based on the most recent JTF global survey. Competency scores were reported based upon academic degree, organizational

affiliation, role, research experience, clinical trial experience, possession of a certificate, and possession of a degree in clinical research. Statistical analysis of the results is currently underway, and a publication is being prepared.

- d. Melanie Glattli, Swiss Clinical Trial Organisation, described the adaptation of the JTF Framework to Switzerland. Minor changes from the JTF in wording content were integrated into a career development website with links to training opportunities and to physician scientists conducting clinical trials. Making the framework more visible and adapting the framework to observational studies and use of health data is being implemented.
  - e. Stephen Sonstein, MRCT Center, shared with the group the activities of the current workgroup within the Council for International Organizations of Medical Sciences (CIOMS) which is developing Standards of Education and Training for Health Professionals Participating in Medicines Development. Barbara Bierer, Stephen Sonstein and Honorio Silva are all serving on this workgroup. The motivation for formation of the workgroup was the general lack of understanding by health professionals of the process of medicines development and regulation. Much of the educational content being proposed is based on the JTF Framework, the IFAPP framework, and Pharmatrain. A final report is due in late Summer, 2023.
  - f. Open discussion followed the Update Presentations with the following comments:
    - i. One participant commented that, as a former nurse, she had no idea where medicines came from and that it would be a significant accomplishment to increase the knowledge base of health professionals in the area of medicines development.
    - ii. Another participant spoke of their use of the JTF Framework in undergraduate and graduate training in pharmacy, nursing, and medicine in Beirut, Lebanon.
    - iii. Another participant questioned Ms. Sonoda concerning the type of degree programs to which her survey respondents had matriculated as well as the differences between those with a certificate and those with an academic degree. Ms Sonoda commented that a degree in clinical research is uncommon in Asia and African countries and that further definition between operational certificates and science based degrees is probably appropriate.
3. Two new JTF initiatives have been proposed: (1) a Data Management and Informatics Task Force and (2) efforts to establish validated assessments of Clinical Research Competencies (i.e., in addition to self-assessments). Presentations on these topics were made by Meredith Nahm Zozus, Professor, Division Chief and Director of Clinical Research Informatics, University of Texas Health Science Center, San Antonio, Texas, and Elias Samuels, Program Director of Workforce and Evaluation, Michigan Institute for Clinical and Health Research, University of Michigan, Michigan.
- a. Meredith Zozus introduced the potential membership of the Data Management and Informatics Task Force and described the many changes to clinical trials that have occurred in data acquisition, management, and analysis that were the motivation for its formation. The efforts of the task force will include reviewing the Domain 6

competencies, determining whether modifications are necessary and, if needed, what they might be.

- i. Asked what a re-visioning of Domain 6 might look like, Dr. Zozus commented that it was necessary to focus on how data sources integrate with one another in being cleaned, reformatted, redesigned, validated, stored, and kept secure as part of the task force recommendations.
  - ii. A participant commented in the chat that there was a rising role of artificial intelligence in clinical trials and that incorporation of this issue will be important.
  - iii. Dr. Zozus informed that she is working to integrate informatics in an applied manner to clinical trial data collection.
  - iv. One participant inquired whether Dr. Zozus was involved in developing the Society for Clinical Data Management (SCDM) white paper. Dr. Zozus responded that she was a reviewer of the paper, that the white paper represents primarily the perspective of the industry, and that the academic community many see the issues differently. Link to the white paper: (<https://scdm.org/6588/>).
  - v. Another participant commented that there was a significant unmet need to revamp the academic coursework in data management and that no new textbooks were available.
  - vi. Barbara Bierer reiterated the outcome and goals of the task force as well as defining and leveling competencies related to data management; development of a course would not be the role of the JTF. Dr. Bierer mentioned that the JTF should be future-oriented to prepare the field for tomorrow and that the area of data management and informatics is an important and rapidly evolving area.
- b. Elias Samuels presented his personal views concerning the standard questions which are asked concerning competency assessments generally, namely: why, what, when, whom and how. Why: need assessments of formative and summative measures to facilitate onboarding, upward mobility and promotion, and content of training, to determine gaps in the field, and to decide what the next generation needs to know. What: issues related to subjective and objective assessment, citing two publications (see slides) of examples that have been validated. When: pre- and post- learning experience or employment should be assessed often and no less than every few years. The more complex the material, the more frequent the assessment. He cited portfolios of professional development as a welcome addition. Who: assessments needed of practitioners, mentors, supervisors, and staff in clinical research. Citing the recent JTF survey publication of self-assessed competencies as related to roles in the workforce, Dr. Samuels related that it was necessary to understand the variations in competency. How: factor analysis, look for differences between and within groups and changes over time; demonstrate that assessments are predictive of outcomes we want to achieve. Dr. Samuels acknowledged that there are big gaps relating to objective measures and cited a publication relating to the issue (see slides).

- i. Asked what the roadmap for assessment is other than self-assessment, Dr. Samuels commented that subjective assessments are easier to administer, but that objective measures of knowledge and skill are necessary to apply worldwide for the roles in clinical research.
- ii. Dr. Sonstein commented that there was a wealth of assessment data in the industry environment, but that they were not generally available. It would be nice to hear from the industrial sector on how they evaluate competencies for both the entry level as well as for advancement.
- iii. One participant asked about the next steps to explore objective assessment and inquired if we could start a pilot.
- iv. Dr. Samuels commented that he would appreciate knowing what industry is doing concerning competency assessment. He commented on the assessment measures being undertaken at University of Michigan that include videos of case studies followed by examinations. They are time intensive and administratively burdensome.
- v. Asked to comment on assessment of personnel at Takeda, Dr. Gomez-Navarro replied that there should be no differences between industry, academic, government, and sites in their evaluation of competency.
- vi. A participant mentioned that the ACRP assessment tool was first developed in a role-based framework but is moving to being task based and greater objectivity.
- vii. Another participant commented that Duke University has also developed task-based assessment tools that are significantly more objective, but that they were time intensive. They are working with experts to develop updated questions that are less time consuming. She also commented that everyone does not do well in a testing setting and that a model that works for all needs to be developed. Feedback from those who have gone through the assessment has been very valuable.
- viii. Dr. Bierer commented that the high cost of certification is concerning for global access.
- ix. A participant shared that the pilot which ACRP conducted with academic programs in North Carolina showed that 47% of graduates with no experience were able to pass the standard certification examination. Academic programs were surprised at the low number; ARCP was encouraged that almost 50% could pass. A participant commented that there was no differentiation between programs with a hands-on experience and those without. Further expansion of the pilot should differentiate these issues.

#### 4. Next Steps

- a. The JTF Co-Chairs mentioned that a future issue to be discussed by the JTF was the criteria needed for modification of the competencies framework given the need for concomitant modification of the many translations.
- b. The next meeting of the Global JTF will be in March or April, 2023.
- c. The JTF Co-Chairs expressed their appreciation of the time and effort devoted to this meeting by all of those involved.

## Appendix 1: Agenda

### Joint Task Force for Clinical Trial Competency (JTF)

#### Strategic Global Virtual Meeting

**November 14, 2022, 9:00-11:00 AM EST**

Time	Topic	Speaker / Facilitator
9:00-9:10	Introduction Overview	<b>Barbara Bierer, MD</b> Co-Chair, JTF Faculty Director, MRCT Center
9:10-9:50	JTF Updates: <i>Each speaker presents a 3-5 min update on their particular topic</i>	
	Integrating JTF Framework into Takeda's R&D's Knowledge Development Academy (KDA)	<b>Jesús Gómez-Navarro, M.D.</b> Distinguished R&D Fellow Scientific Advisor, Takeda Physician Scientist Accelerator Program Takeda Pharmaceuticals International, Co.
	Update on Translations	<b>Allan Wilsdorf, Engr., MSc</b> Head of the Training & Education Unit French Clinical Research Infrastructure Network (F-CRIN)
	JTF Competency survey in Low-and Middle Income Countries: Initial Analysis of Results	<b>Miwa Sonoda, RN, MPH, GDip (Clinical Trial), GDip (Global Health)</b> Deputy Director General of ARISE Secretariat Medical Science Liaison Department of International Trials, Center for Clinical Sciences National Center for Global Health and Medicine (NCGM), Japan
	Clinical Research Core Competencies: an adaptation of the JTF Framework to Switzerland	<b>Melanie Glättli, PhD</b> Scientific Coordinator Swiss Clinical Trial Organisation
	Update from CIOMS (Council for International Organizations of Medical Sciences) meeting	<b>Stephen Sonstein, PhD</b> Co-Chair, JTF

	Discussion	<b>Barbara Bierer, MD</b> Co-Chair, JTF Faculty Director, MRCT Center
9:50-10:15	Data Management Task Force <i>10-12 min presentation about proposed data management task force, e.g.,</i> <ul style="list-style-type: none"> <li>• <i>Motivation for task force</i></li> <li>• <i>Mandate of task force</i></li> <li>• <i>Structure of task force</i></li> <li>• <i>Launch of task force</i></li> </ul>	<b>Meredith Nahm Zozus, PhD</b> Professor, Div. Chief and Director of Clinical Research Informatics University of Texas Health Science Center San Antonio
	Discussion	<b>Barbara Bierer, MD</b> Co-Chair, JTF Faculty Director, MRCT Center
10:15-10:45	Assessment of competencies <i>10-12 min presentation on the assessment of competencies, may include:</i> <ul style="list-style-type: none"> <li>• <i>Need for objective assessment methods to measure competencies</i></li> <li>• <i>Need for reliable and valid measures</i></li> <li>• <i>Proposed process</i></li> </ul>	<b>Elias Samuels, PhD</b> Program Director of Workforce and Evaluation Michigan Institute for Clinical & Health Research University of Michigan
	Discussion	<b>Stephen Sonstein, PhD</b> Co-Chair, JTF
10:45-11:00	Wrap up and next steps <ul style="list-style-type: none"> <li>• <i>Process for making changes to Framework going forward</i></li> <li>• <i>Plan JTF meetings every 6 months</i></li> </ul>	<b>Barbara Bierer, MD &amp; Stephen Sonstein, PhD</b> Co-Chairs, JTF

## Appendix 2: Participants

1. Allan Wilsdorf, F-CRIN (French Clinical Research Infrastructure Network)
2. Barbara Bierer, MRCT Center
3. Birdie
4. Bridget Gonzalez, ACRP (Association of Clinical Research Professionals)
5. Bob Kolb, Retired
6. Carmen Aldinger, MRCT Center
- 7.Carolynn Jones, The Ohio State University
8. Christine Samara, Odette Cancer Center, Toronto, Canada
9. Denise Snyder, Duke University
10. Elias Morrel Samuels, University of Michigan
11. Ginny Beakes-Read, Amgen
12. Honorio Silva, International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP)
13. Jean Rowan, Eastern Michigan University
14. Jesus Gomez-Navarro, Takeda
15. Karen Hartman, Mayo Clinic
16. Kathy Thoma, George Washington University
17. Kirsten Grubic, Population Health Research Institute (PHRI), Canada
18. Laurie Halloran, Halloran Consulting
19. Lisa Marsh, formerly at Medpace
20. Lisa Palladino Kim, Rutgers University
21. Marlinang Siburian, NCGM Japan, Regional Manager Indonesia
22. Mary-Tara Roth, Boston University
23. Melanie Glättli, Swiss Clinical Trial Organisation
24. Meredith Zozus, University of Texas
25. Miwa Sonoda, National Center for Global Health and Medicine (NCGM), Japan
26. Rana Leed, Boston University
27. Romiya Glover Barry, George Washington University
28. Roshan Padbidri, Tech Observer, formerly Anidan Group, Singapore
29. Sarah White, MRCT Center
30. Sifa Muchanga, NCGM Japan, Regional Manager DRC
31. Sharleen Traynor, Durham Tech
32. Sherry Keramidas, AOTA (American Occupational Therapy Association)
33. Shiva Kalinga, Takeda
34. Stephanie Freel, Duke University
35. Stephen Sonstein, MRCT Center Consultant

- 36. Susan Landis, ACRP
- 37. Tona Lutete, University of Kinshasa, DR Congo
- 38. Yves Lula, University of Kinshasa, DR Congo