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

Barbara E. Bierer, MD
Co-chair, JTF
Faculty Director, MRCT Center
Professor of Medicine, Harvard Medical School
bbierer@bwh.harvard.edu

Stephen Sonstein, PhD
Co-chair, JTF

Carmen Aldinger, PhD
Senior Administrative and Training Manager,
MRCT Center

2 May 2023

https://mrctcenter.org/clinical-trial-competency/
Virtual Meeting

- Please keep video on
- Please mute yourself unless you are speaking
- If you would like to speak, please **unmute and speak** or ‘**raise your Zoom hand**’ (and introduce yourself)
This meeting

• We are recording this meeting for internal purposes of note taking only.
• Recording will not be posted and will be deleted after the executive summary is finalized.

• We do wish to post slides and an executive summary of the meeting.
• We will follow up regarding permission to post the slides.
Disclaimer:

- The opinions contained herein are those of the presenters and are not intended to represent the position of Brigham and Women's Hospital, Harvard University, or any of the institutions or organizations represented today.

- The MRCT Center is supported by voluntary contributions from foundations, corporations, international organizations, academic institutions and government entities (see www.MRCTCenter.org) and by grants.

- We are committed to autonomy in our research and to transparency in our relationships. The MRCT Center—and its directors—retain responsibility and final control of the content of any products, results and deliverables.

- We have no personal financial conflicts of interests with the content of this presentation.

- Today’s meeting will be recorded for internal purposes.
The Multi-Regional Clinical Trials Center (MRCT Center)

The MRCT Center is a research and policy center focused on addressing the conduct, oversight, ethics and regulatory environment for clinical trials.

Our Vision
Improve the integrity, safety, and rigor of global clinical trials.

Our Mission
Engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.
## Agenda

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Speaker / Facilitator</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:00-9:10</td>
<td>Introduction</td>
<td>Barbara Bierer, MD&lt;br&gt;Co-Chair, JTF&lt;br&gt;Faculty Director, MRCT Center</td>
</tr>
<tr>
<td>9:10-9:35</td>
<td>JTF Updates (5 min each)</td>
<td>Lisa Palladino Kim, MS&lt;br&gt;Program Director&lt;br&gt;MS Clinical Research Management Program&lt;br&gt;Rutgers School of Health Professions</td>
</tr>
<tr>
<td></td>
<td>Use of the JTF Framework in Rutgers MS in CRM Program</td>
<td>Howard Fingert, MD, FACP&lt;br&gt;Vice President, Medical Oncology&lt;br&gt;ONO Pharmaceuticals Inc, USA</td>
</tr>
<tr>
<td></td>
<td>The JTF Framework and Clinical Development Teams in the Biopharmaceutical Industry: Harnessing innovation in data sciences</td>
<td>Christine Samara, MSc&lt;br&gt;Manager, Quality Assurance and Education, Odette Cancer Center Clinical Research Program,&lt;br&gt;Sunnybrook Research Institute, Toronto, Canada&lt;br&gt;Member on the 3CTN Performance Strategy Sub-Committee, Canadian Cancer Clinical Trial Network (3CTN), Canada</td>
</tr>
<tr>
<td></td>
<td>Integration of the JTF framework as part of the 3CTN’s grant objectives and its utilization at the Odette Cancer Centre in Toronto, Canada</td>
<td>Melanie Glättli, PhD&lt;br&gt;Life Sciences&lt;br&gt;SCTO Scientific Coordinator&lt;br&gt;Swiss Clinical Trial Organisation</td>
</tr>
<tr>
<td></td>
<td>Updates to the Arabic translation of the JTF Core Competency Framework</td>
<td>Jean Wang&lt;br&gt;CEO&lt;br&gt;Shanghai Xunyuan Information Technology Co., Ltd&lt;br&gt;Guo Fuzhen&lt;br&gt;China’s Clinical Trial Development Team&lt;br&gt;Capital Medical University &amp; Beijing Tiantan Hospital</td>
</tr>
<tr>
<td>9:35-9:45</td>
<td>Open Discussion</td>
<td>Stephen Sonstein, PhD&lt;br&gt;Co-Chair, JTF</td>
</tr>
<tr>
<td>Time</td>
<td>Topic</td>
<td>Speaker / Facilitator</td>
</tr>
<tr>
<td>------------</td>
<td>------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| 9:45-9:55  | Update: Data Management Task Force             | **Meredith Nahm Zozus, PhD**  
Professor, Div. Chief and Director of Clinical Research Informatics  
University of Texas Health Science Center San Antonio |
| 9:55-10:05 | Discussion                                      | **Barbara Bierer, MD**  
Co-Chair, JTF; Faculty Director, MRCT Center                                                                  |
| 10:05-10:15| Update: Assessment of competencies              | **Elias Samuels, PhD**  
Program Director of Workforce and Evaluation  
Michigan Institute for Clinical & Health Research  
University of Michigan  
**Susan Murphy, ScD, OTR**  
Director, Behavioral Research Innovation and Support Program, Michigan Institute of Clinical and Health Research (MICHR)  
Professor, Department of Physical Medicine and Rehabilitation, Department of Internal Medicine, Rheumatology Division  
University of Michigan |
| 10:15-10:25| Discussion                                      | **Stephen Sonstein, PhD**  
Co-Chair, JTF                                                                                                     |
| 10:25-10:40| Adaptations of the JTF Framework to Emergencies | **Barbara Bierer, MD**  
Co-Chair, JTF; Faculty Director, MRCT Center  
With comments by:  
**Prof. Sandor Kerpel-Fronius, MD, PhD, DSc**  
Semmelweis University  
Department of Pharmacology and Pharmacotherapy  
Budapest, Hungary |
| 10:40-10:50| Discussion                                      | **Barbara Bierer, MD**  
Co-Chair, JTF; Faculty Director, MRCT Center                                                                 |
| 10:50-11:00| Wrap up and next steps                         | **Stephen Sonstein, PhD & Barbara Bierer, MD**  
Co-Chairs, JTF                                                                                                    |
Professional competencies:
Joint Task Force Core Competency Framework for Clinical Research Professionals

The JTF Core Competency Framework is made up of

8 Competency Domains, broad categories of knowledge, skills, and attitudes necessary for conducting clinical research
47 Competency Statements, specific skills and abilities related to clinical research

➢ Identify competency statements
➢ Align and Harmonize similar concepts
➢ Reviewing and revision with collaborators
Joint Task Force Core Competency Framework for Clinical Research Professionals

Forthcoming Q2-3 2023
- Chinese
- Vietnamese

Portuguese in progress
Open call: Frontiers in Pharmacology special issue

Research Topics

Building the Clinical Research Workforce: Challenges, Capacities and Competencies

Abstract Submission Deadline 01 June 2023
Manuscript Submission Deadline 17 September 2023

Open call: Frontiers in Pharmacology special issue

• Authors are encouraged to address the challenges, opportunities, novel approaches and progress toward closing the gaps and improving clinical research professional development across the workforce spectrum.

This Research Topic aims to collect articles on the following topics:

• Clinical research roles and professionalism
• Clinical research academic education, training and competency development, assessment
• Clinical research professional employment, retention, progression
• Diversity of the clinical research workforce
• Applications and contributions of the JTF Framework
• Clinical research workforce development in the setting of the evolving clinical research paradigm
• Clinical research team science, defining research teams, workforce spectrum
JTF Updates
Mapping Professional Competencies in a Clinical Research Management Master’s Level Program

Initiative was part of a NJ Acts Workforce Development Core 2021 Internship Program

Lisa Palladino Kim, MS
Program Director
Rutgers SHP MS in CRM Program
Presented to JTF Biannual Global Mtg on May 2, 2023

Confidential: Do not duplicate, copy, or distribute information contained in this presentation!
Student Intern
Lauren M. Castelli, MS, MBA
MS CRM Student 2022
Rutgers SHP MS in CRM

Mentor
Lisa Palladino Kim, MS
Program Director
Rutgers SHP MS in CRM

MS CRM Program
Website
Introducción

3 Niveles de Habilidades

47 Enunciados de Competencia: Habilidades y Competencias CRM Específicas, Actitudes y Competencias

8 Dominiós: Nombres de Categorías más amplias de Habilidades de Competencia, Conocimientos y Actitudes

Demanda de Habilidades CRM Cualificadas

Collaboración con la Industria

Accreditation

Joint Task Force (JTF)
Clinical Trial Competency Framework for Clinical Research Professionals

Necesidad Satisfecha
Methods

Build Excel Database

Map Assignments to Joint Task Force Domains, Competencies and Levels

Review and Finalize Course Maps with Professor(s)

CRM Courses
Fall 2020

Regulatory & Ethics

Research Design

Clinical Operations

Learning Outcome Assessments

Online Course Program

Graphics from BioRender
There is a new competency 5.7 that was not included in the Accreditation Appendix B version and therefore was not counted as a gap in this exercise.
JTF Domains Met in CRM Core Courses
Fundamental Skill Level

<table>
<thead>
<tr>
<th>JTF Domains</th>
<th>Reg and Ethics</th>
<th>Research and Design</th>
<th>Clin Ops</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scientific Concepts and Research Design</td>
<td>0</td>
<td>39</td>
<td>4</td>
</tr>
<tr>
<td>Ethical and Participant Safety Considerations</td>
<td>50</td>
<td>20</td>
<td>8</td>
</tr>
<tr>
<td>Medicines Development and Regulation</td>
<td>72</td>
<td>17</td>
<td>15</td>
</tr>
<tr>
<td>Clinical Trial Operations</td>
<td>34</td>
<td>7</td>
<td>29</td>
</tr>
<tr>
<td>Study and Site Management</td>
<td>21</td>
<td>0</td>
<td>25</td>
</tr>
<tr>
<td>Data Management and Informatics</td>
<td>0</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td>Leadership and Professionalism</td>
<td>0</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Communication and Teamwork</td>
<td>21</td>
<td>0</td>
<td>2</td>
</tr>
</tbody>
</table>
School of Health Professions

JTF Biannual Global Mtg 2023 May

Final Result Summary
Any additional questions, please contact:

Lisa Palladino Kim, M.S.
Program Director/Lecturer
M.S. in Clinical Research Management

E-mail crmprogram@shp.rutgers.edu
Howard Fingert
The JTF Framework and Clinical Development Teams in the Biopharmaceutical Industry: Harnessing innovation in data sciences

Howard Fingert, MD, FACP
Vice President Medical Oncology, ONO Pharmaceuticals, USA

Brief BIO:
Global Clinical Development of Heme-Lymphoma and Solid Tumor Therapies

Academic experiences:
- Training & research at UCLA, NCI, Harvard, MIT, other public & private organizations
- Former Assistant Professor Massachusetts General Hospital/ Harvard Med Schl
- NIH/NCI/ACS supported lab - translational research in cancer sciences

Industry career:
- 25 years global biopharma experience bringing products Phase 1 to commercialization
- Member ICH Expert Working Group to update ICH E8 Guidance for Protocols
- Biopharma Industry Representative to US FDA Oncology Drugs Advisory Committee (ODAC)
- Current Industry Representative to US National Cancer Advisory Board

The materials and views represent personal opinions of the presenter. All slides are for educational purposes and considered confidential & proprietary and must not be reproduced or distributed.
CONVERGENCE OF CORE COMPETENCIES BY CLINICAL RESEARCH TEAMS

Source: Joint Task Force of academia, biopharma industry, regulators sponsored by the Harvard Multi-Regional Clinical Trials (MRCT) Initiative

The JFT Framework, updated document, and domains reflect:

- Teams build on multi-disciplines, structure, constructive interaction
- Updates needed to manage the changing research landscape
- Deep learning builds on interfacing internal and external environments
Dr. Tachi Yamada inspires focused, deep, data-driven R&D decisions.

Distracting visions of can seen attractive but lead to shallow R&D decisions.

Dr. Tachi Yamada transitioned between academia - Industry former leader at U. Michigan GSK, Takeda, Gates Foundation:

“Beware of being a mile wide…but an inch deep.”
DATA SCIENCES, DEEP LEARNING IN ACADEMIA
Advancing multi-regional opportunities in medical research & care

Excerpts from on-line MIT course about Deep Learning and relevant informatics.
DATA-SHARING, HARDWARE-SHARING, DEEP LEARNING
Advancing multi-regional opportunities to accelerate progress in medical research & care

Why Now?

Neural Networks date back decades, so why the resurgence?

1. Big Data
   - Larger Datasets
   - Easier Collection & Storage

2. Hardware
   - Graphics Processing Units (GPUs)
   - Massively Parallelizable

3. Software
   - Improved Techniques
   - New Models
   - Toolboxes

![Vivli Logo]

A global clinical research data sharing platform

The Vivli team is dedicated to helping researchers share and access data from clinical trials to advance science.
Director Drug Discovery at a global biopharma company was quoted:

“Beyond the pharmaceutical industry, Mitsui plans to make the Tokyo-1 supercomputer accessible to medical-device companies and startups — and to connect Tokyo-1 customers to AI solutions developed by global healthcare startups ...NVIDIA will also connect Tokyo-1 users with the hundreds of global life science customers in its developer network.”
EXPANDING SKILLS FOR BIOPHARMACEUTICAL CLINICAL DEVELOPMENT

DATA SCIENCES ENABLE NEW R&D METHODS AND COMMERCIAL OPPORTUNITIES

COMPETENCIES FOR SUCCESS

- DATA SCIENCE - REGULATORY SCIENCE
- COMMUNICATION TEAMWORK
- DATA MANAGEMENT
- REGULATIONS GUIDANCES
- CLINICAL OPERATIONS PROTOCOL CONDUCT
- ETHICS PARTICIPANT SAFETY
Moderna 2\textsuperscript{nd}-Generation mRNA Cancer Vaccine Shows Promising but Modest Clinical Benefit

Abstract from American Assn. Cancer Research, April, 2023
- Full journal publication in press
- Phase 3 registration trial planned
EXAMPLE: ACTIONABLE MODERN DATA SCIENCES
Updated AI, Analytics, and Cloud Supercomputer Lead to patented 3\textsuperscript{rd}-Generation, off-the-shelf mRNA Vaccines

Older designs 15.5% population coverage

New Vaccine - 99.9% population coverage

Lower figure illustrates 3\textsuperscript{rd}-Generation, broad coverage & practical ‘off the shelf’ mRNA vaccine without the burdens from 2\textsuperscript{nd} generation, that required >1 month for surgery; biopsy processing; vaccine manufacture.
What sources and competencies are needed to ...  
- reduce risks  
- gain efficiencies  
- navigate to accelerate progress?

1. Advice from academic Professors who succeed only according to academic standards

2. Publications in news articles and blogs

3. Publications in peer-reviewed journals

4. Consultants or coworkers who simply repeat (outdated?) experiences without updated analyses

5. Collaborating TEAMS, structured to include updated biomedical, regulatory & data sciences
What sources and competencies are needed to ...  
- reduce risks, gain efficiencies  
- accelerate progress?

Best answer:  
Collaborating TEAMS, working together to apply updated biomedical, regulatory & data sciences
Christine Samara
3CTN Objectives

Christine Samara, 3CTN PSC member
Performance Strategy Sub-Committee (PSC)
The Canadian Cancer Clinical Trials Network (3CTN) is a pan-Canadian initiative to improve recruitment, efficiency and quality of academic clinical trials.

**Member Cancer Centres**
- Sites collaborate on common initiatives and share best practices via our innovative Network structure.

**Patient and Public Involvement (PPI)**
- Patient Representatives, Patient Groups, Advisory Committees
- Contribute a crucial perspective to clinical trials by providing feedback, insight, expertise and support towards trial activities and initiatives

**Governance and Scientific Oversight**
- Scientific Advisory Board and Directors ensure the appropriateness and optimal impact of the Network strategic plan and activities
- Governance Committees provide oversight for 3CTN management and support key functions: The trials Portfolio, Performance, PPI

**Coordinating Centre**
- Central support for operations, project management, strategic planning & governance and communications
Improving the performance and quality of academic, multi-centre trials on the 3CTN Portfolio is a shared priority for the current business period, 2022-2027

➢ Develop the clinical research professional core competency framework & development strategy for Network sites

Network-wide implementation of the Joint Task Force Core Competency Framework aims to

➢ Promote the capacity for high-quality cancer clinical research
➢ Highlight identified core competency gaps – both locally and shared, and
➢ Link to available, best-practice training and education resources by core competency domain/sub-domain
<table>
<thead>
<tr>
<th>Domain/Sub-Domain</th>
<th>Domain Category</th>
<th>Core Competency Statement</th>
<th># Sites Reporting</th>
<th>Impact</th>
<th>Effort</th>
<th>Ranked Priority</th>
</tr>
</thead>
<tbody>
<tr>
<td>D4 - 4.1</td>
<td>Clinical Study Operations (GCP)</td>
<td>Explain how the design, purpose, and conduct of individual clinical studies fit into the goal of developing a new intervention</td>
<td>3</td>
<td>High</td>
<td>Low</td>
<td>5</td>
</tr>
<tr>
<td>D4 – 4.7</td>
<td>Clinical Study Operations (GCP)</td>
<td>Describe how global regulations and guidelines assure human subject protection and privacy during the conduct of clinical studies</td>
<td>6</td>
<td>High</td>
<td>Low</td>
<td>4</td>
</tr>
<tr>
<td>D4 – 4.8</td>
<td>Clinical Study Operations (GCP)</td>
<td>Describe the role and process of monitoring a clinical study</td>
<td>3</td>
<td>High</td>
<td>Low</td>
<td>3</td>
</tr>
<tr>
<td>D5 – 5.5</td>
<td>Study and Site Management</td>
<td>Identify the legal responsibilities, liabilities and accountabilities that are involved in the conduct of clinical studies</td>
<td>11</td>
<td>High</td>
<td>Low</td>
<td>2</td>
</tr>
<tr>
<td>D6 – 6.1</td>
<td>Data Management &amp; Informatics</td>
<td>Describe the role and importance of statistics and informatics in clinical studies</td>
<td>6</td>
<td>High</td>
<td>Low</td>
<td>6</td>
</tr>
<tr>
<td>D6 – 6.3</td>
<td>Data Management and Informatics</td>
<td>Describe best practices and resources required for standardizing data collection, capture, management, analysis, and reporting</td>
<td>10</td>
<td>High</td>
<td>Low</td>
<td>1</td>
</tr>
<tr>
<td>Rank</td>
<td>Initiative</td>
<td>Description</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>------</td>
<td>------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Training/education</td>
<td>Provide training opportunities for clinical research professionals</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Share job description/salary ranges</td>
<td>Provide platform to share job description, salary ranges</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Mentorship</td>
<td>Connect requests for mentors with targeted expertise</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Role-specific Development Pathway</td>
<td>Role specific framework for professional growth and development</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Integration of the JTF as a 3CTN Objective and its utilization at the Odette Cancer Center in Toronto, Canada.

Sunnybrook Research Institute
Sunnybrook Health Science Center

Christine Samara
Manager, Quality Assurance and Education
Odette Cancer Centre Clinical Research Program
Tertiary Hospital
Toronto, Ontario. Canada

- Internationally recognized health science center
- Affiliated with University of Toronto (UofT)
- Leading research institute
New Training Initiative Focus
JTF Core competencies for CRP @ SRI OCC CR

• August 2021 as part of the onboarding & training of new staff

• 3CTN Grant Cycle (2022-2027) – Application Dec 2021

Ongoing efforts to improve the efficiency and effectiveness of clinical trial sites across the Network

– Diagnostic tool for sites to assess areas of competency and deficiency within their clinical trial staff
– Promote a competency framework for clinical research professionals
– Identify area (s) of potential improvement for their trial unit
NCC – Network Cancer Center / NACC – Network Affiliate Cancer Centers

NCCs are larger centres with capabilities to recruit cancer patients to a broad portfolio of trials, and to work with Network Affiliated Cancer Centres (NACCs) to ensure broader patient access to trials.
SRI – OCC
Use of the JTF Core Competency Framework

1. Define professional roles
   - Revised Job Titles and Job Description
   - Created a mechanism for growth

<table>
<thead>
<tr>
<th>Data Manager</th>
<th>CRA I *</th>
<th>CRA II *</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supervisor</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Protocol Activator
SRI – OCC
Use of the JTF Core Competency Framework

2. Identify training and educational requirements

- Revamped the onboarding plan
- N2 Source, CRF and Good Data Management
- CITI Clinical Research Coordinator
- Increased time spent on shadowing various tasks
- Therapeutic Area Training
- Overview on different study designs
SRI – OCC
Use of the JTF Core Competency Framework

3. Outline continuing professional development
   ▶ Customize training, mentoring and coaching for various new tasks and job responsibilities
   ▶ Solicit feedback from staff on training needs
   ▶ Share new training platforms and initiatives as needed

4. Interdisciplinary Collaboration
   ▶ Build bridges across departments and various stakeholders
   ▶ Enhance communication
   ▶ Share knowledge, experience and best practices
SRI – OCC
Use of the JTF Core Competency Framework

5. Focus

- Interpersonal skills (negotiating, influencing, resolving conflict, etc.)
- Effective and efficient communication and teamwork
- Professional communication practices in written and verbal interactions
SRI – OCC
Use of the JTF Core Competency Framework

6. Evaluate on the job performance
   - Developed a Performance Evaluation Tool
   - Ready to pilot

---

**Employee Performance Review (Data Manager / Clinical Research Associate I / Clinical Research Associate II)**

Instructions: The performance evaluation is divided into 3 components:
- Self-assessment: Employee to review and complete the performance evaluation and send back to the Supervisor, if applicable, or DSL/CTPL*  
- Supervisor and DSL/CTPL to review the employee’s self-assessment and add feedback and comments  
- DSL/CTPL or delegate to set up meeting with Employee to discuss feedback and future development

---

* Disease Site Lead / Clinical Trial Physician Lead

---

**Employee Information**

<table>
<thead>
<tr>
<th>Name of Employee: Click here to enter text.</th>
<th>Employee Title: Click here to enter text.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Review: Click here to enter text.</td>
<td>Date of Review: Click here to enter text.</td>
</tr>
<tr>
<td>Line of Review: Click here to enter text.</td>
<td>Next Review: Click here to enter text.</td>
</tr>
</tbody>
</table>

---

**Employee Performance Evaluation – Core Competency Domains for Clinical Research Professionals**
Employee Performance Review

Two level review

- Self assessment
- Review of self assessment by DSL/CTPL (along with Supervisor feedback, as applicable)

<table>
<thead>
<tr>
<th>Self assessment</th>
<th>Reviewers</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Honest assessment</td>
<td>✓ Feedback from employee</td>
</tr>
<tr>
<td>✓ Self reflect / consider strengths and areas of improvement</td>
<td>✓ How employee see themselves (team and organization)</td>
</tr>
<tr>
<td>✓ Personal growth</td>
<td>✓ Motivation (beyond salary)</td>
</tr>
<tr>
<td>✓ Self awareness</td>
<td>✓ Achievements</td>
</tr>
<tr>
<td>✓ Opportunity to list goals and objectives for the upcoming year</td>
<td>✓ Growth</td>
</tr>
</tbody>
</table>
Deploying the JTF framework across the world

Arabic Translation

Christine Samara
Arabic translation of the MRCT JTF Core Competency Framework is

• Coordinated by Christine Samara

• Led by the UAE Ministry of Health and Prevention
  • Dr. Khalil Qayed, Director National Center for Health Research
  • Dr. Ahmed Radeef Ibrahim Alosi, Research Consultant
✓ Identified the organization for collaboration - Initial contact and agreement November – December 2022 with Dr. Khalil Qayed

✓ Initiated translation – February 2023, led by Dr. Ahmed Alosi

✓ Discussed the plan for document translation and progress on April 11, 2023 (Received preliminary draft of 3 domains)

✓ Finalize the initial complete draft for all domains: anticipated June 2023

✓ Start the revision and validation: expected July 2023
Adapting the JTF framework to non-interventional clinical research

Core Competencies for HRO research projects

JTF Strategic Global Meeting, May 2, 2023
Melanie Glaettli, Swiss Clinical Trial Organisation (SCTO)
Competency framework – mandate and adaptation

Clinical Research Core Competencies Framework for clinical trials

Implemented on cr-careers.ch

Making the framework more visible

Adapting the framework to non-interventional research projects

Swiss Medical Weekly publication
# Swiss legal framework for human research

<table>
<thead>
<tr>
<th>Human Research Act (HRA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>with human beings</td>
</tr>
<tr>
<td>Clinical Trials Ordinance (ClinO)</td>
</tr>
<tr>
<td>Medicinal products</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>Transplant products, transplantation</td>
</tr>
<tr>
<td>Gene therapies</td>
</tr>
</tbody>
</table>
An adaptation to HRO projects, why?

- > 75% research projects submitted to ECs are non-interventional (follow Human Research Ordinance, HRO)
- Consulted physician-scientists welcomed the idea
- More accessible and suitable for young researchers
- Useful for other health researchers (not only MDs)
- Mandate from our Board of CTU Directors (BCD) → develop tools to enhance quality of HRO projects

Raise the awareness of developing the competencies necessary to conduct non-interventional research projects
How are we adapting the Framework?

We aim for a **simple framework** with:

- shorter statements
- 2 columns for:
  - Collection of data and/or biological material (HRO, chapter 2)
  - Further use data and/or biological material samples (HRO, chapter 3)

**Next steps**

- Review & have it approved by other Platforms (RA, PM) and stakeholders
- Implement it on [cr-careers.ch](http://cr-careers.ch) and further disseminate via NL, Tools & Resources website, etc.
2 — Ethics and participant rights

Encompasses the care of patients, their rights, and aspects of participant protection in the conduct of a clinical trial.

- Explain the evolution of the regulatory framework ensuring the protection of participants.
- Differentiate between standard of care and clinical trial activities.
- Define "clinical equipoise", the "uncertainty principle", and "therapeutic misconception".
- Apply principles and regulations of trial participant protections and privacy.
- Explain the evolution of the requirement for an Informed Consent Form (ICF) for trial participants.
- Describe the ethical issues involved when dealing with vulnerable populations.
- Evaluate and apply an understanding of the relevant ethical issues and cultural variation.
- Summarise the principles and methods of distributing and balancing risks and benefits.
## 2.4 Evolution of Requirements for Informed Consent Form

<table>
<thead>
<tr>
<th>Collection of data and/or samples</th>
<th>Further use of data and/or samples</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>(HRO, chapter 2)</em></td>
<td><em>(HRO, chapter 3)</em></td>
</tr>
</tbody>
</table>

1. Identify the historical events and key documents, which have led to the development of the current informed consent regulations.

2. Recognise the critical nature of communicating the potential risks or hazards as well as the benefits of a research project using terminology and a manner that is understandable by potential participants during the informed consent process.

3. Apply knowledge of the current national and international regulations, especially concerning data protection measures, when drafting an ICF for a research project.

4. Implement processes and control measures to ensure participant protection regulations' requirements are met.

**Example:** Researcher composes and evaluates the ICF in relationship to the protocol to assure that it not only meets current regulations and guidelines but also provides the information needed for a potential participant to make an informed decision.

---

**Further statements need to be considered:**

1. Investigate whether sites to be included in the research project have implemented the [General Consent (GC)](HRA, Art. 34) allowing the further use of health-related data and biological material already collected during standard of care for research purposes.

2. Develop an appropriate information form (and/or consent form) according to the type of data (genetic versus non-genetic and coded versus uncoded) to be reused in the project *(HRO, Art. 28-32)*.

3. Assess surrogate consent by the ethics committee *(HRA Art. 54)* allowing exceptional further use of data without consent by participants.

**Example:** Researcher contacts person in charge of the institutional General Consent (GC) to assess whether further use project can be carried out with the use of GC.
Thank you for your attention
Collaboration on Implementing the JTF Framework in China

Beijing Tiantan Hospital, Capital Medical University & XunYuan Information Technology Co., Ltd.
Content

➢ Introduction of XunYuan and Beijing Tiantan Hospital
➢ Implementing Plan of JTF Framework in China
About Xunyuan

- Established in 2015
- Partner of competence development for 20+ sponsors, CROs and hospitals in China
- Pioneer in Independent/Freelancing Clinical Research Market in CHINA.
- Independent Quality Assurance and Inspection Readiness Services
Jean Wang
Funder & Principal Trainer

- 8+ years experience of the clinical research training
- Speech content sharpener, "Ma Xujun New Year's Speech" content partner;
- The situational leadership II ® II certified trainer
China's Clinical Trial Development Team of Beijing Tiantan Hospital & Capital Medical University
Capital Medical University (CCMU)

- The largest affiliated hospital cluster in China
- The highest number of clinical trial institutions
- Five National Medical Centers
- Six National Clinical Medical Research Centers
Beijing Tiantan Hospital & NCRC-ND

Beijing Tiantan Hospital

- A Grade-3 Class-A hospital with a neurosurgery unit and a leading characteristic neuroscience cluster
- “Noble Medical Ethics, Persistent Excellence, Rigorousness and Practicality, Diligence and Honesty”
- Awards: Highest Science and Technology Award and First-Class / Second-Class Prizes for the State Scientific and Technological Progress Award …

China National Clinical Research Center for Neurological Diseases

- The first clinical medical research center for neurological diseases identified in China
- A large internationally standardized clinical and sample resource pool
- A national science and technology construction base
- The center collaborative research network
Establishment, Positioning & Targets

• The Department of Clinical Epidemiology and Clinical Trials of Capital Medical University was formally established on May 20, 2020.

• It serves as a university-wide resource integration platform for clinical epidemiology and clinical trials, aiming at cultivating high-level clinical scientists and creating a more pleasant research atmosphere, thus promoting the development of clinical research in China.
Compositions of Department

- **Affiliated to Beijing Tiantan Hospital**
- **Consisting 32 Clinical medical schools, Affiliated hospitals, Teaching hospitals & Schools**

  Beijing Tiantan Hospital, Xuanwu Hospital, Beijing Friendship Hospital, Beijing Chaoyang Hospital, Beijing Tongren Hospital, Beijing Anzhen Hospital, Fuxing Hospital, Beijing Youan Hospital, Beijing Chest Hospital, Sanbo Brain Hospital, Beijing Children's Hospital, Beijing Stomatological Hospital, Beijing Anding Hospital, Beijing Obstetrics and Gynecology Hospital, Beijing Traditional Chinese Medicine Hospital, Beijing Shijitan Hospital, Beijing Rehabilitation Hospital, Beijing Luhe Hospital, China Rehabilitation Research Center, China-Japan Friendship Hospital, Fengtai Teaching Hospital, Electric Power Teaching Hospital, Shijing Teaching Hill Hospital, Miyun Teaching Hospital, Daxing Teaching Hospital, Liangxiang Teaching Hospital, Huairou Teaching Hospital, Changping Teaching Hospital, Yanqing Teaching Hospital, Mentougou Teaching Hospital, Shunyi Teaching Hospital, School of Public Health...

- **Plays an important role in clinical teaching for the whole university**
Education & Training Programs

Education Types

- **Five Postgraduate Students**
  - Academic Education
  - Master & Doctor Conferrable Spots

- **Broad Physician Scientist**
  - Non-academic Education
  - Clinical Scientist Training Program

Public Training Program

- **For Clinical Scientists**
- **64 Sessions Until Now**
- **Every Wednesday Night**

- **More Professional Research Teams**
- **More Experinced Clinical Scientists**
- **Better Clinical Research Atmosphere**
### Implementing Plan of JTF Framework in China

#### Step 1: Translate the JTF Framework into Chinese

<table>
<thead>
<tr>
<th>April</th>
<th>May</th>
<th>Jun</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The 1st Translation</td>
<td></td>
</tr>
<tr>
<td>The 1st Round Discussion</td>
<td>Translation Revision</td>
<td>Internal Team Review</td>
</tr>
<tr>
<td>JTF Team Review and Finalization</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Step 2: Moving Forward with a Clear Strategy

➢ Use JTF core competency assessment to evaluate the competence level and role relevance of Chinese clinical trial personnel.

➢ Understand the competency requirements of Chinese clinical trial personnel and develop training plans based on the JTF core competency framework.

➢ Develop graduate courses and assessment standards that are consistent with the 8 domains of JTF.

➢ Develop training program to professionals working in pharmaceutical company and CROs.

➢ Integrate JTF into the professional qualification certification of Chinese clinical trials.
Let’s Work Together

For a Better Future of Clinical Research
Discussion
Update: Data Management Task Force: Meredith Zozus
Quick Update

JTF Data Management Competencies
Goal:

to update the Data Management and Informatics JTF Competencies.

Competencies are for Clinical Research Professionals such as

- Site PIs,
- Study Coordinators,
- Clinical Trial Monitors,
- Statisticians,
- Site Data Managers, ...

AKA:

What every Clinical Research Professional should know about Informatics and Data Management
Status

• Team of 12 participants agreed to participate
• Plus 2: Dr. Bikkanuri and myself
• Plus 2: Drs. Sonstein and Bierer

• Kick-off call held 2 weeks ago
• Implementing the first questionnaire in REDCap now.

• Plan: draft report to JTF for an internal peer review late summer.
Delphi Process

**Round 1:** Free text, “Blue Sky” input re leveled Data Management and Informatics competencies for Clinical Research Professionals.

**Round 2:** Two-dimensional rating
   1. importance of the competency regardless of the indicated level and
   2. level of agreement with the competency at each indicated level
   PLUS comment fields to explain low importance and disagreement

**Round 3:** participants receive their results versus aggregate and are free to change their two-dimensional rating.

**Round 4:**
   - If significant disagreement: calls with individual participants to discuss their remaining differences and to perform additional member-checking if needed.
   - If minor disagreement or group is split on issues: from 1 to 3 group calls

**Analysis following Round 4:** group vetted draft competencies

**Peer-review of results:** review of the initial draft by the larger JTF. 

*Late Summer.*
**Group Members**

- **Philippe Andry**, p.andry@accelsiors.com  
  VP Data Mgt. and Data Integration, Accelsiors, significant experience in Europe

- **Kaye Fendt, MS**, Kaye.Fendt@msn.com  
  Former FDA and NIH, Statistics and Data Mgt.

- **Susan Fenton, PhD**, Susan.H.Fenton@uth.tmc.edu  
  Assoc. Professor and Assoc. Dean for Academic and Curricular Affairs, UT Health Science Center Houston

- **Susan Howard**, Susan.Howard@adaptimmune.com  
  Adaptimmune, Small Biotech, Data Management

- **Rick Ittenbach, PhD**, Richard.Ittenbach@cchmc.org  
  Cincinnati Children’s Hospital, Statistics and Data Mgt.; Academia

- **Yiannis Karageorgos**, yiannis.karageorgos@gmail.com  
  Former BMS, Current IQVIA (CRO), Data Management, Europe

- **Michelle Kelly**, Michelle.Kelly@ppdi.com  
  Senior Director, Clinical Data Systems at PPD/ThermoFisher, CRO, Data Mgt.

- **Muayad Maallah, MD**, maallah@uthscsa.edu  
  Research Informatics, Univ. of Texas Health Science Center San Antonio, significant experience in Middle East

- **Blandina T Mmbaga, MD,** blaymt@gmail.com  
  Kilimanjaro Clinical Research Institute (KcRI)

- **Steve Wilson, DrPH**, stephen.wilson@fda.hhs.gov  
  FDA, Statistics

- **Meredith Zozus, PhD**, Zozus@uthscsa.edu  
  Univ. of Texas Health Science Center San Antonio, Clinical Research Informatics and Data Mgt.

---

**JTF Leaders**

Steve Sonstein ssonstein@gmail.com  
Barbara E. Bierer, MD bbierer@bwh.harvard.edu

---

**Delphi Leader**

Manju Bikkanuri, MD bikkanuri@uthscsa.edu
Discussion
Update: Assessment of Competencies:
Elias Samuels & Susan Murphy
Updating Assessments of JTF Competencies

Presentation to the Joint Task Force for Clinical Trial Competency (JTF)
Biannual Global meeting
May 2, 2023

Elias M. Samuels, PhD
Director of Evaluation & Quality improvement
UM Michigan Institute for Clinical and Heath Research

Susan Murphy, ScD, OTR
Professor, Department of Physical Medicine and Rehabilitation, Internal Medicine,
Director, Behavioral Research Innovation and Support Program
UM Michigan Institute for Clinical and Heath Research
Presentation Outline

• Need for objective competency assessments

• Methods for validating objective assessments

• Applying JTF Competency Framework to BSSR

• Potential next steps

• Challenges
Objective assessments of CTR competence are needed

While **objective** assessments of competence are increasingly published in health research, **subjective** assessments of competency are published comparatively infrequently.

CTR is lagging this trend.

Of the 28 publications listed on the JTF website, the need for objective assessments is widely noted & most of the validated competency assessments published are subjective.
Subjective vs objective assessments of competence
Subjective measures of comprehension & skill include

• learning outcomes: ‘As a result of this course I can…’
• self-efficacy: ‘How confident are you in your ability to…’
• expert ratings: ‘How well does _____ understand…’

Objective measures of comprehension & skill include

• ‘See One, Do One, Teach One’
• knowledge checks & competency-based tests
• programmatic benchmarks & milestones
• tests of skill with validated interpretations & applications
Objective assessments of CTR competency, ...

are comparatively difficult to design, administer and validate, yet


are needed for more rigorous evaluation & quality improvement


Objective competency assessments should be validated using complimentary theoretical models

The Content-Criterion Model
Validate assessments can predict related measures and outcomes

The Construct Model
Validate that assessments measure coherent and comprehensive constructs

The Unified Construct Model
Validate that assessments have theoretically sound construct and content validity

The Argument-Based Approach to Validation
Validate that assessments produce evidence of practical value for specific applications


Adapting JTF Competency framework for Behavioral & Social Science Research (BSSR) studies

- Right framework, but needs tailoring
  - Competency domains align with BSSR rigor
  - Competencies and knowledge needed to perform them is different

- BSSR nuances
  - Lower risk
  - Participatory approach involving community/stakeholders
  - Instead of safety being priority, acceptability and feasibility needed for translation
Clinical Study Operations - BSSR Nuances

- Adapted GCP was needed
- Parallel training was developed
- Assessment of BSSR competency

Potential Next Steps for Assessment

1. Define BSSR competencies
   • Look to adapted tools – NIH template, CONSORT
   • Additional workforce development projects

2. Operationally define knowledge and tasks that lead to competencies
   • Perhaps study specific quality metrics, may be very different depending on study type
     • CBPR study conduct
     • Study requiring handing of mobile device data

3. Identify models & methods for validity testing
Challenges to using objective assessments

• Evaluating impact at the person level or study level?
  • Existing assessments are not validated for all CT researchers

• Study level – Auditing – can be problematic
  • Adverse Event Conundrum – are more AEs a sign of better or worse quality of study?
  • What should measurable trends in outcomes be compared to?

• New study at UMich
  • Examining research compliance issues in BSSR trials
    • Partnership of MICHR with research compliance office
  • Help identify strategies to improve competencies
  • Can lead to an objective assessment strategy
Thank you for your time & interest

CONTACT INFORMATION:
Elias Samuels, PhD (eliasms@med.umich.edu)

Susan Murphy, ScD, OTR (sumurphy@med.umich.edu)
Discussion
Adaptation of the JTF Framework to Emergencies: Sandor Kerpel-Fronius & Barbara Bierer
Recommendation for developing a practical guidance for managing clinical trials in times of crisis

Sándor Kerpel-Fronius, M.D., D.Sc., FFPM
Semmelweis University
Department of Pharmacology and Pharmacotherapy
Budapest, Hungary
Email: kerpel-fronius.sandor@med.semmelweis-uni.hu
Vulnerable patients who already entered clinical trials

Vulnerable patients due to war and destruction

Vulnerable patients due to economic sanctions
Main ethical conclusion and recommendation of the IFAPP Ethics Working Group

- According to International Ethical Guidelines for Health-related Research Involving Humans [Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO) (2016)]
  - “the judgment that groups are vulnerable is context dependent and requires empirical evidence to document the need for special protections.”

- Based on this principle the IFAPP Ethics Working Group postulated that seriously ill participants enrolled already into clinical trials performed in countries involved in armed conflicts, economic sanctions hitting healthcare or natural disasters should be considered belonging to a vulnerable patient population

- The investigational treatment might be the last chance for these patients to obtain therapeutic benefit for their disease
Phases of trial management in times of war
The experience in Ukraine

1. Emergency trial management during the initial „chaotic” phase of a developing disaster
2. Trial management under continuing development of a disaster
3. Consolidation, return to normal trial management
Emergency trial management during the initial “chaotic” phase of a developing disaster

<table>
<thead>
<tr>
<th>Investigator site</th>
<th>Sponsor</th>
</tr>
</thead>
</table>
| • Unfolding disaster, extent unknown  
  • Contact with the sponsor either non-existent or sporadic and inadequate | • Unfolding disaster, extent unknown  
  • Contact with investigator site either non-existent or sporadic and inadequate |

Evaluation of the effects of the disaster on the staff, healthcare facilities and social infrastructure

Information gathering concerning the effects of the disaster on the staff, healthcare facilities and social infrastructure

Ethically motivated emergency clinical decisions
• Clinical activities impossible  
• Stopping clinical trials and providing best treatment outside the trials  
• *Continuation of already initiated trial treatments if possible*  
• Modified GCP level documentation of trials

Ethical and scientific evaluation of possible management changes without destroying the scientific value of the study
• Closing the trial if trial treatment is impossible  
• Provide guidance for GCP conform trial management under altered circumstances  
• Organize transfer of participants to alternate research sites
Primary recommendation for ongoing clinical trials in times of emergency

- The continuation of already initiated trial treatments for the benefit of the patients is the primary ethical obligation of clinical investigators in case of war, economic sanctions or natural catastrophes.
Suggested cooperation with CIOMS
Developing a guidance for the conduct of clinical trials in crisis situations

- February 20, 2023. Recommendation for a CIOMS-hosted Working Group to Develop Guidance for Health-related Research in Times of Crisis
  - Joint recommendation by IFAPP, UCRSI and MRCT
- March 31, 2023. Further clarification of the goals of the suggested Guidance for Health-related Research in Times of Crisis Contact with Dr. Lembit Rägo, Secretary General of CIOMS

- Concerns:
  - Most of the participants of the CIOMS Executive Board considered that the present ethical guidance’s provide adequate background for correctly performing clinical trials even under crisis situation.
  - They were concerned that our intention is to develop a specific “crisis related additional ethical guidance”.

© 2022 DIA, Inc. All rights reserved.

Kerpel-Fronius S.  106
Suggested cooperation with CIOMS
Developing a guidance for the conduct of clinical trials in crisis situations

- March 31, 2023. Further clarification of the goals of the suggested Guidance for Health-related Research in Times of Crisis

Answers:

- According to our opinion, a list of detailed practical recommendation how to overcome difficulties created by external circumstances *in agreement with the spirit of the accepted ethical guidelines* could be very useful for ethics committee members, investigators and sponsors.

- Such guidance would be especially needed in times when a crisis develops and rapid actions are required to keep trials going in a modified but still GCP conform way.

- The experience obtained in Ukraine showed convincingly the outstanding importance of rapidly communicated practical, GCP conform suggestions to the investigators by the local regulatory authorities.

- A joint TC with the CIOMS Executive Board is planned to discuss pros and cons concerning our proposal.
Adapting the JTF Framework to Emergencies

• Not all emergencies are the same
  ➢ Variably variable in type
    ❖ Natural disasters (e.g., earthquakes, hurricanes, floods)
    ❖ War, conflict
    ❖ Public health crises (e.g., pandemics, epidemics)
    ❖ Other disruptive events (e.g., 9/11)

• Emergencies occur at different scales
  ➢ Variable in intensity, from catastrophic (e.g., Covid-19, war in Ukraine) to relatively minor

• Responses should reflect the type and extent of the emergency

• Preparedness is necessary as disruption is unpredictable

Are different competencies necessary?
Adapting the JTF Framework to Emergencies

- Proposal: review JTF framework (both domains and more specifically the competencies) to determine if:
  - Determine whether there are specialized professional competencies in the context of emergencies and whether those competencies differ by type of emergency
  - Review each competency to determine adjustments.
  - Anticipate no change to competency itself, but additional skills needed

Domain 1: Scientific Concepts and Research Design
Encompasses knowledge of scientific concepts related to the design and analysis of clinical trials

- 1.1 Apply Principles of biomedical science to investigational product discovery and development and health-related behavioral interventions
- 1.2 Identify Scientific Questions that are Potentially Testable Clinical Research Hypotheses
- 1.3 Identify the Elements and Explain the principles and Processes of Designing a Clinical Study
- 1.4 Maintain awareness of new technologies, methodologies and techniques which enhance the conduct, safety and validity of the clinical study
- 1.5 Critically analyze clinical study results

Emergency preparedness competency or considerations
Discussion
Wrap-Up and Next Steps
Questions, Comments, Suggestions

Questions and discussion

Carmen Aldinger, PhD
caldinger@bwh.Harvard.edu

Barbara E. Bierer, MD
bbierer@bwh.Harvard.edu

Stephen Sonstein, PhD
ssonstein@gmail.com