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

Barbara E. Bierer, MD
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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

14 November 2022
https://mrctcenter.org/
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.
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<tr>
<th>Time</th>
<th>Topic</th>
<th>Speaker / Facilitator</th>
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<tbody>
<tr>
<td>9:00-9:10</td>
<td>Introduction Overview</td>
<td>Barbara Bierer, MD</td>
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<td>Co-Chair, JTF</td>
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<td>Faculty Director, MRCT Center</td>
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<td>9:10-9:50</td>
<td>JTF Updates: (3-5 min update each)</td>
<td>Jesús Gómez-Navarro, M.D.</td>
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<td>Distinguished R&amp;D Fellow</td>
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<td>Scientific Advisor, Takeda Physician Scientist Accelerator Program</td>
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<td>Takeda Pharmaceuticals International, Co.</td>
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<td>Integrating JTF Framework into Takeda’s R&amp;D’s Knowledge Development Academy (KDA)</td>
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<td>Update on Translations</td>
<td>Allan Wilsdorf, Engr., MSc</td>
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<td>Head of the Training &amp; Education Unit</td>
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<td>French Clinical Research Infrastructure Network (F-CRIN)</td>
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<td>JTF Competency survey in Low-and Middle Income Countries: Initial Analysis of Results</td>
<td>Miwa Sonoda, RN, MPH, GDip (Clinical Trial), GDip (Global Health)</td>
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<td>Medical Science Liaison</td>
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<td>Department of International Trials, Center for Clinical Sciences</td>
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<td>National Center for Global Health and Medicine (NCGM), Japan</td>
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<td>Clinical Research Core Competencies: an adaptation of the JTF Framework to Switzerland</td>
<td>Melanie Glättli, PhD</td>
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<td>Scientific Coordinator, Swiss Clinical Trial Organisation</td>
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<td>Update from CIOMS (Council for International Organizations of Medical Sciences) meeting</td>
<td>Stephen Sonstein, PhD</td>
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<td>9:50-10:15</td>
<td><strong>Data Management Task Force</strong>&lt;br&gt;10-12 min presentation about proposed data management task force, e.g.,&lt;br&gt;• Motivation, mandate, structure and launch of task force</td>
<td>Meredith Nahm Zozus, PhD&lt;br&gt;Professor, Div. Chief and Director of Clinical Research Informatics&lt;br&gt;University of Texas Health Science Center San Antonio</td>
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<td>10:15-10:45</td>
<td><strong>Assessment of competencies</strong>&lt;br&gt;10-12 min presentation on the assessment of competencies, may include:&lt;br&gt;• Need for objective assessment methods to measure competencies&lt;br&gt;• Need for reliable and valid measures&lt;br&gt;• Proposed process</td>
<td>Elias Samuels, PhD&lt;br&gt;Program Director of Workforce and Evaluation&lt;br&gt;Michigan Institute for Clinical &amp; Health Research&lt;br&gt;University of Michigan</td>
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<td>10:45-11:00</td>
<td><strong>Wrap up and next steps</strong>&lt;br&gt;• Process for making changes to Framework going forward&lt;br&gt;• Plan JTF meetings every 6 months</td>
<td>Barbara Bierer, MD &amp; Stephen Sonstein, PhD</td>
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Integrating the JTF Framework into Takeda R&D’s Knowledge Development Academy (KDA)

JTF Global Strategy Meeting

Jesús Gómez-Navarro, MD

November 14th, 2022
Origins of Takeda R&D’s Knowledge Development Academy

Distinguished R&D Fellows program
launched in 2020

- Focused on contributing to shaping the future of R&D
- Appointment in late 2020 of two fellows (including Jesús Gomez-Navarro)
- Program housed within the Takeda Data Science Institute, led by Anne Heatherington

Takeda’s corporate philosophy incorporates in 2020
lifelong learning and a growth mindset as a priority

- Takeda Learning Team formed with the purpose to defining, implementing and realizing an integrated global learning strategy and transformation plan at Takeda which enables critical business priorities, creates an exceptional people experience and builds a culture of continuous lifelong learning.

Topic “Takeda R&D’s Development Academy: upskilling the R&D organization to meet challenges and opportunities of the future” proposed and endorsed by the R&D Management Committee in March 2022
### Current vs. Future State of Learning

<table>
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<tr>
<th>Current State</th>
<th>Future State</th>
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<tr>
<td>Scientific, clinical and technical knowledge and skills are mainly the territory of individual functions</td>
<td>Clinical Research &amp; Development is an <strong>R&amp;D-wide core capability</strong> supported cross-functionally</td>
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<tr>
<td>Lack of consistency regarding educational or experiential requirements &amp; personnel certification in clinical research</td>
<td>A <strong>harmonized, leveled core competency framework</strong> guides training and accreditation and informs career ladders &amp; trajectories, job descriptions, &amp; performance evaluations</td>
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<td>Available learning is focused on general competencies and processes (SOPs, etc.)</td>
<td>Learning encompasses all knowledge, skills and behaviors necessary for innovative and productive clinical <strong>R&amp;D</strong> (as defined in a competency-based, leveled curriculum)</td>
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<td>Knowledge is hidden, scattered, inaccessible, stale and available in few formats</td>
<td>Knowledge has <strong>unified access</strong>, evolves constantly (users can annotate it) and is available always (on schedule and on demand) and in multiple formats (original documents, audio, video, dynamic visualizations, etc.)</td>
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<td>There is limited ready-access to internally-generated knowledge</td>
<td>Knowledge is <strong>systematically</strong> generated, identified, captured, shared, applied and leveraged, enabling extracting optimal value from it</td>
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<td>Non automatized</td>
<td><strong>AI-supported:</strong> right knowledge at the right time for the right employee</td>
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<td>Focused on personal growth</td>
<td>Adds a focus on <strong>R&amp;D and enterprise productivity and competitive advantage</strong>, as well as risk management</td>
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<td>Functional leaders support learning within their functions</td>
<td><strong>Everyone in R&amp;D is accountable</strong> to contribute to learning and to the knowledge-base</td>
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<td>Learning is mostly done individually at fixed timepoints</td>
<td>Learning is conducted as well as part of a <strong>Community of Learning</strong>, including small cohorts, peers, experiential learning, and “<strong>learning in the flow of work</strong>”, when needed (including micro-formats)</td>
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<td>Learning is focused on compliance</td>
<td>Learning journeys are <strong>individualized</strong>, and tailored to the most needed knowledge, skills and behaviors (competencies)</td>
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<td>Outputs and effectiveness of learning are assessed individually</td>
<td><strong>Feedback</strong> is systematically captured so that new learners benefit from the experience of prior learners and approach to learning is informed by results of prior learning offerings</td>
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<td>Onboarding and exit processes do not systematically capture and transfer “clinical knowledge pearls”</td>
<td>“Clinical knowledge pearls” are <strong>systematically captured and transferred</strong> as part of the employee onboarding &amp; exit processes</td>
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<td>Reluctance to communicate lessons broadly, and time constraints, prevent full engagement in learning</td>
<td><strong>Effective incentives</strong> of knowledge management are embedded into time and performance management and career development processes (promotion requirements)</td>
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Glaveski S. Where companies go wrong with Learning and Development. *HBR*, Oct 2019
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Glaveksi S. Where companies go wrong with Learning and Development. HBR, Oct 2019
Initial **R&D Knowledge Development Academy** Framework

**Pillar 1**  
**Core Clin Dev Curriculum:**  
Foundational curriculum to level-up competencies (knowledge, skills and behaviors) related to clinical development:  
- leveled curricula based on (1) standard curriculum* + (2) items driven by Takeda’s strategy (e.g., digital medicine, Elevate China, cell and gene therapy, etc.)  
- self-assessment  
- study guides

**Pillar 2**  
**Knowledge and learning sharing:**  
Manage knowledge life cycle  
Generate, reflect, capture and exploit learning related to clinical development:  
- structured at program, asset, study level, and business process (R&D Playbook)  
- available on demand  
- multiple formats, leveraging automation and AI

**Pillar 3**  
**Community of Learning:**  
Leverages our culture and leadership behaviors:  
- leaders who model culture, serve as faculty, curate case studies  
- supports growth/adapting mindsets  
- sustains the learning organization  
- ensures broad accountability

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* Multi-Regional Clinical Trial Center’s [Core Competency Framework for clinical research professionals](#)
Enabling a culture of lifelong learning through learning technologies

Integrated learning infrastructure and technology will enable the delivery of relevant, personalized, continuous learning solutions.

A unified, learner-friendly interface which can connect learning solutions and people systems/data is foundational to sparking one’s interest and excitement about learning.
And we gave it a name
Our Learning Experience Platform, Bloom, provides content for everyone

**Strategic Learning Initiatives for All Employees:** Learning Channels for All Employees based on key learning initiatives

**Core Enterprise Learning for All Employees:** Our Takeda, My Development & My Productivity

**My BU/F:** Learning Channels for Specific BU/F Learning Experiences

**My Roles:** Learning Channels for Specific Roles (i.e., People Managers, E&C Professionals, etc.)

**Featured Content Providers:** Enterprise Content Providers (for all Takeda employees)
Bloom’s CONTENT ARCHITECTURE

Overview

**CONTENT ASSETS**
- **SMARTCARDS**
  - It is the basic unit of content, such as video, link, article, etc.
- **PATHWAYS**
  - It is a collection of Smartcards.
- **JOURNEYS**
  - It is a structured collection of Pathways or SmartCards.

**CONTENT CONTAINERS**
- **CHANNELS**
  - It is a collection of content from multiple sources related to a topic.

| ~Songs | ~Albums | ~Boxed Set | ~Radio Station |
Next steps for Takeda R&D’s Knowledge Development Academy

Enhance the digital medicine offering: a digital curriculum?

In addition to the foundational curriculum (JTF), we envisioned having a Takeda-specific component of the curriculum for clinical research professionals that aligns directly with Takeda's corporate philosophy and strategy. "Data, digital, and technology" is a new, central element of the strategy.

- We partnered with the Digital Medicine Society to develop and offer a Digital Medicine Fundamentals for Pharma course.
- Jenifer Goldsack, DiMe's CEO, recently announced its completion and availability.

There is a need and an opportunity to start building a curriculum for that specific aspect of the work of clinical research professionals at Takeda, given the anticipated scale-up within Takeda and across the ecosystem.

Build a knowledge management platform that links with the curriculum/competency framework

Engage the recently created Takeda R&D Learning Community of Practice to support the KDA (governance, employee participation, sustainability plan)
Deploying the JTF framework across the world – Translations and applications

Allan WILSDORF, F-CRIN/CRIGH

JTF – Strategic Global Meeting
November 14th 2022
Publication of the French Translation

To be proofread by the Canadian Cancer Clinical Trials Network (3CTN)
Finalisation of the Italian Translation

Currently being proofread by the CTU in Lugano (SCTO – Switzerland)
New Translations

- Assist the **Thai**, **Indonesian** and **Vietnamese** translations within ARISE (ARO Alliance for ASEAN & East Asia) led by NCGM (Japan)
- Several on-going contacts for the setup of an **Arabic** translation group (Saudi Arabia and Dubai)
- On-going contact for the setup of a **Dutch** translation group
Work on original English version

Objectives of the critical reading of the original English version

- Mapping of the differences between the original framework and the Swiss adaptation (SCTO)
  - Shows what has been kept “untouched”, what has been discarded and what has been added

- Wording analysis of the Swiss adaptation
  - Highlights the work which has been conducted by SCTO on the homogeneisation of the wording

- Wording homogeneisation
- Global meaningfulness
- Additional topics
Applications
Following the survey set up in France (297 answers collected between January and July 2021)

- Work with Tech4Health’s Training Working Group (French Investigation Network specialised in medical devices)
- Identification of specific competency families for clinical research professionals working with medical devices (to be used for the second survey targeting clinical research professionals of the private sector)

Talks with Inserm (French National Institute of Health and Medical Research) for the use of the framework in the design of a training program specific to project managers
JTF Competency survey in Low-and Middle Income Countries: Initial Analysis of Results

Miwa SONODA  RN, MPH, GDip(Clinical Trial), GDip(Global Health)

Deputy Director General of ARISE Secretariat

Medical Science Liaison
Department of International Trials
Center for Clinical Sciences
National Center for Global Health and Medicine
## Team Members

<table>
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<tr>
<th>Name of Institute</th>
<th>Project Participants</th>
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<tr>
<td>National Center for Global Health and Medicine (NCGM)</td>
<td>Dr. Sifa Muchanga, Dr. Nattha Kerdsakundee, Dr. Umano Maria Ruriko, Ms. Marlinang Diarta Siburian, Dr. Tastuo Iiyama</td>
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<tr>
<td>Osaka Electro-Communication University</td>
<td>Dr. Masahiko Sakaguchi</td>
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<td>University of Indonesia</td>
<td>Dr. Wawaimuli Arozal, Dr. Anggi Gayatri, Dr. Melva Louisa</td>
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<td>Philippines University of Philippines Manila</td>
<td>Dr. Ian Cabulana, Dr. Edwin C Ruamero</td>
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<tr>
<td>Thailand, Mahidol University</td>
<td>Dr. Kulkanya Chokephaibulkit, Ms. Pornsuda Nipathakosol</td>
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<tr>
<td>Vietnam, Bach Mai Hospital</td>
<td>Ms. Ngueyn Thi Thu Ha, Ms. Phuong Doan, Ms. Huong Nguyen</td>
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<tr>
<td>DRC, The University of Kinshasa</td>
<td>Dr. Tona Lutete Gaston, Dr. Yve Lula Ntamba</td>
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Competency Translation

Plan: Make available in 2022 on the website at each country, NCGM & the MRCT Center

Japanese

[Website](https://mrctcenter.org/clinical-trial-competency/framework/translations/japanese/)

Thai (Done)

Indonesian

Vietnamese
Survey: Self-Assessment of Clinical Research Competence

- **Study objective:**
  To investigate
  - the competency level of clinical research professionals
  - the relationship between each competency and job function
  - the training needs of each competency.

- **Participating country:** Indonesia, DRC, Philippines, Thai, Vietnam

- **e-Survey:**
The questionnaire developed by the MRCT center was applied and translated into the local languages.

- **Data collection Period:** From March to June 2022

- **Study Population**
  - The study population is a non-random, purposeful samples.
  - The minimum number of participants is 150 in each country

- **Respondents:** 843/1020 (Respondents rate 82.6% )
Clinical Research Core Competencies (CRCC):
an adaptation of the JTF Framework to Switzerland

JTF Strategic Global Meeting, November 14, 2022
Melanie Glaettli, Swiss Clinical Trial Organisation (SCTO)
- National and decentralised clinical research infrastructure since 2009.
- Network of **7 CTUs**, including all 5 Swiss university hospitals
- Since 2017, setup of **8 thematic platforms**

http://www.scto.ch/
Each thematic platform includes persons from each CTU
We develop **freely available tools and resources**

www.sctoplatforms.ch
Roadmap of national relevance

- support research-oriented physicians at each stage of their career path

- Two mandates for the SCTO Education Platform
  - Standards for clinical research skills
  - Clinical Research Education Centre
Clinical Research Competencies: what we did

- Review of existing frameworks
- Adaptation to Swiss context
- Implementation on career development website

Glaettli et al. 2022. Swiss Medical Weekly
Clinical Research Competencies: what we did

- Review of existing frameworks
- Adaptation to Swiss context
- Implementation on career development website
- Link to training opportunities of our CTU network
- Acknowledgement of stakeholders
- Consultation of physician-scientists running clinical trials

Glaettli et al. 2022. Swiss Medical Weekly
Become a clinical researcher

Are you a medical student or a resident interested in a clinical research career in Switzerland? or a senior registrar aiming to run high-quality clinical research projects?

This website provides you a clear overview of career support and funding opportunities, available training options and mentoring programmes. Use it to explore typical career tracks and plan your academic career.

MORE ON CAREER TRACKS

http://www.cr-careers.ch/
Become a clinical researcher

Are you a medical student or a resident interested in a clinical research career in Switzerland? Or a senior registrar aiming to run high-quality clinical research projects?

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MORE ON CAREER TRACKS

http://www.cr-careers.ch/
Core competencies

Explore each of the 8 competency domains below to identify the knowledge, skills, and attitudes necessary for the effective, ethical, and safe conduct of clinical trials. The domains are based on the internationally recognised Joint Task Force for Clinical Trial Competency (JTF) framework and have been adapted to Swiss legislation on human research.

Fundamental, skilled, and advanced levels correspond to sub-investigator, investigator and sponsor-investigator roles respectively, as defined by ICH-GCP guidelines and Swiss legislation on human research.
### Core Competencies Framework

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<tr>
<th></th>
<th>Scientific concepts and research design</th>
<th>Ethics and participant rights</th>
<th>Healthcare intervention development and regulation</th>
<th>Clinical research operations (Good Clinical Practice)</th>
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### 1 — Scientific concepts and research design

Encompasses the knowledge of scientific concepts related to the design and analysis of clinical trials

- Have health-related knowledge and practical experience in the medical area
- Apply scientific principles to the discovery and development of interventions
- Identify scientific questions, clinical research hypotheses, and objectives of clinical trials
Identify the elements and explain the principles and processes of a clinical trial; understand clinical research methodology

**Fundamental level**
A1. Recognise the basic differences between the various types of clinical trials
A2. Identify the key elements of a clinical trial protocol
A3. Adhere to a clinical trial protocol to ensure validity of the trial
**Example:** When given a clinical trial protocol, researcher identifies the trial type and key elements of the protocol and can adhere to them.

**Skilled level**
B1. Review a clinical trial protocol to ensure all needed elements are included
B2. Understand (design) aspects of a clinical trial that are critical to answer the scientific question(s)
B3. Evaluate strengths and weaknesses of trial designs and explain these to others
B4. Understand the importance of and methods for accessing, critiquing and synthesising literature appropriately
**Example:** When given a clinical trial protocol, researcher identifies missing, incomplete, or inappropriate features and aspects that are of relevance for conducting the trial and are critical for the objectives.

**Advanced level**
C1. Evaluate the clinical trial design and communicate it to others
**Example:** When given a clinical trial protocol that has misalignment between the measures and objectives, researcher appropriately modifies the protocol.

VIEW TRAINING OPTIONS
Raising awareness and further work

Clinical Research Core Competencies Framework for clinical trials

Making the framework more visible

Adapting the framework to “research projects” (not clinical trials: observational and/or further use of health data & samples)

- 80% of projects submitted to ECs
- Make it more accessible to young researchers

SMW publication

in progress
Thank you for your attention
Update from CIOMS
• The Council for International Organizations of Medical Sciences (CIOMS) is an international, non-governmental, non-profit organization established jointly by WHO and UNESCO in 1949.

• CIOMS mission is to advance public health through guidance on health research and policy including ethics, medical product development and safety.

• April, 2021: Based on JTF leadership, Barbara and Stephen asked to join international group developing:
  “Recommended Standards of Education and Training for Health Professionals Participating in Medicines Development”
• Motivation for formation of workgroup was:
  – General lack of understanding by health professionals of the process of medicines development
    • Primarily due to lack of content on subject in educational programs
  – Controversies relating to medicines development and regulation during COVID pandemic
  – Increasing global medicines development activity and need for all levels of health professionals to understand process at varying levels

• Workgroup met online multiple times during 2021 and 2022 and developed Table of Contents, Background and Objectives
• Workgroup met face to face in Geneva, Switzerland on 9/6-7, 2022
  – Refined table of contents
  – Developed proposed text for Chapter 1: Background and Objectives
    • Much of proposed content designed around JTF Core Competency Framework, IFAPP Framework and PharmaTrain
  – Assigned subgroups to develop content for remaining chapters:
    • Principles of Working Group and Intended Benefits
    • Educational and Training Landscape
    • Syllabus Proposals
    • Good Education Practice Principles
• Workgroup planning another face to face meeting in February or March, 2023
  – Plan is to have final document by late Summer, 2023.
Discussion
Data Management Task Force
Discussion
Assessment of Competencies
Questions on Assessment of Competencies: Personal answers & examples

Presentation to the Joint Task Force for Clinical Trial Competency (JTF)

- November 14, 2022

Elias M. Samuels
University Michigan
Michigan Institute for Clinical and Heath Research
Q1: Why should competency be assessed?
A: To evaluate & enable learning.

Q2: What competencies should be assessed?
A: Subjective & objective measures of comprehension or skill.

Q3: When should competency be assessed?
A: Pre- & post-program, or at every milestone.

Q4: Whose competency should be assessed?
A: All members of the workforce, including students, teachers, & staff.

Q5: How should competency be assessed?
A: Using rigorous evaluation plans & appropriate validation methods.
Why should competency be assessed?

Assessing competency is essential for measuring what & if;

- information is understood.
- capacities are possessed.
- competency changes over time.

Assessing competency is essential for enabling learning by;

- disseminating formative & summative evaluations.
- informing the content & design of new training programs.
- educating the next generation of teachers & investigators.
Why should competency be assessed?

What competencies should be assessed?

Subjective measures of comprehension & skill, including;

• 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, including;

• knowledge checks & competency-based tests.
• ‘See One, Do One, Teach One’.
• programmatic benchmarks & milestones.
What competencies should be assessed?

When should competency be assessed?

Pre- & post-program, including assessments conducted;

• at the point of application.
• when needed for formative evaluation.
• as need to measure long-term programmatic outcomes.

Established program milestones could include participants’;

• matriculation & completion the program.
• demonstration of key competencies in practice.
• meeting programmatic benchmarks.
• advancing programmatically or professionally.
When should competency be assessed?


![A Quasiexperimental Evaluation of a Clinical Research Training Program](image)

**FIGURE 2:** Sankey diagram of the paths U-M K awardees took to an R01 award (2005–2015).

*Note: Diagram was created using SankeyMATIC*
Whose competency should be assessed?

Assess those involved in training programs, including;

• faculty, investigators & program directors.
• scholars, trainees, fellows & students.
• staff, contractors, volunteers & mentors.

Assess professionals constituting the workforce, including;

• workers in all contributing roles, units and partnerships.
• workers advancing or onboarding into new roles.
• interns, apprentices & others in probationary statuses.
Whose competency should be assessed?


<table>
<thead>
<tr>
<th>Role</th>
<th>Number of respondents</th>
<th>Scientific Concepts &amp; Research Design</th>
<th>Ethical and Safety Considerations</th>
<th>Development and Regulation</th>
<th>Investigational Product Development and Operations</th>
<th>Clinical Study Operations</th>
<th>Study and Site Mgt</th>
<th>Data Mgmt and Informatics</th>
<th>Leadership and Professionalism</th>
<th>Communications and Teamwork</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Research Associate/Monitor</td>
<td>52</td>
<td>6.9</td>
<td>7.4</td>
<td>7.3</td>
<td>7.9</td>
<td>7.7</td>
<td>7.3</td>
<td>7.9</td>
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<td>7.5</td>
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<tr>
<td>Clinical Research Coordinator/Nurse</td>
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<td>7.5</td>
<td>6.1</td>
<td>7.6</td>
<td>6.9</td>
<td>7.1</td>
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<td>Educator/Trainer</td>
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<td>8.4</td>
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<td>8.5</td>
<td>8.3</td>
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<tr>
<td>Principal Investigator/Co-Investigator</td>
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<td>6.9</td>
<td>7.7</td>
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<td>6.8</td>
<td>8.0</td>
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<tr>
<td>Project Manager/Research Manager</td>
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<td>8.2</td>
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<tr>
<td>Regulatory Affairs Professional (49)</td>
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<td>8.3</td>
<td>7.5</td>
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<td>6.6</td>
<td>8.1</td>
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<tr>
<td>Average of All Roles</td>
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<td>7.1</td>
<td>8.0</td>
<td>7.6</td>
<td>7.6</td>
</tr>
</tbody>
</table>
How should competency be assessed?

Competency assessments benefit from evaluations of;

- differences across domains of comprehensive frameworks.
- appropriate comparisons between & within groups.
- changes in competency over time.

Apply statistical techniques to validate assessments by;

- generalizing assessments to valid study populations.
- analyzing the factor structure of valid assessments.
- demonstrating assessments are predictive of outcomes.
How should competency be assessed?


Assessments of Research Competencies for Clinical Investigators: A Systematic Review

Phillip A. Ianni1, Elias M. Samuels1, Brenda L. Eakin1, Thomas E. Perorazio1, and Vicki L. Ellingrod1,2

Abstract
Although there is extensive research literature on clinical skill competencies and the use of competency-based frameworks for clinical research, the appropriate methods to assess these competencies are not as well understood. Our goal in this systematic literature review is to identify, compare, and critique assessments of clinical research competencies. Articles were included in this review if they examined clinical investigators or clinical investigators in training, focused on research-based skills, and included some form of assessment of research-based competencies. A total of 76 articles were identified as part of the initial search; 16 met the criteria for inclusion. Two types of assessments of clinical research competence were identified: subjective self-assessments (n = 13) and objective tests (n = 6). These assessments covered a wide range of competencies, but there were no competency domains common to all. Most assessments had limited validation. Training was consistently associated with self-assessed com-
Thank You
Co-authors &
Joint Task Force for Clinical Trial Competency (JTF)

Elias M. Samuels
University Michigan
Michigan Institute for Clinical and Heath Research

November 14, 2022
Discussion
Wrap Up and Next Steps
New JTF Initiatives

- Update of Data Management and Informatics (Domain 6) competencies
- Issues relating to Assessment of Competency
Wrap Up and Next Steps

• New initiatives

• Process for making changes to JTF Framework going forward
  – Issues related to future changes and modification of translations

• Next Meeting of JTF
Questions and discussion

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