Joint Task Force for Clinical Trial Competency (JTF):
Updates and Strategic Planning

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Stephen Sonstein, PhD
Co-chair, JTF

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Senior Administrative and Training Manager,
MRCT Center

20 May 2022
https://mrctcenter.org/
Virtual Meeting

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- 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)

- We will call on you to unmute and speak
- Please feel free to continue discussion in the chat as well
- We will turn off slides in a moment to see one another.

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19 May 2022

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This meeting

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- We do wish to post slides and an executive summary of the meeting.
- We will follow up regarding permission to post the slides.
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• We have no personal financial conflicts of interests with the content of this presentation.

• Today’s meeting will be recorded for internal purposes.
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

• Introductions
• Review of JTF accomplishments 2013- present
• Current and future Uses of JTF Core Competency Framework
  – Denise Snyder, Duke University
  – H. Robert Kolb, University of Florida
  – Carolynn Thomas Jones, The Ohio State University
  – Stephen Sonstein, CAAPCR
  – Miwa Sonoda, NCGM
  – Allan Wilsdorf, F-CRIN
• Future Directions for JTF and Open discussion
• Concluding Remarks
Overview of JTF Accomplishments

Stephen Sonstein, PhD
Co-Chair, JTF
The Joint Taskforce for Clinical Trial Competency (JTF) identified the knowledge and skills required for safe, ethical and high-quality clinical research.

We are committed to providing researchers worldwide with guidance and tools to ensure the professional competency of all members of the research team.

[www.mrctcenter.org/clinical-trial-competency](http://www.mrctcenter.org/clinical-trial-competency)
Alignment and Harmonization of Role-based core competencies

1. Identify competency domains
2. Map and define competencies
3. Obtain endorsement

Competency Domains are broad categories of knowledge, skills and attitudes which are necessary to successfully function within a field of expertise.

Competencies are specific knowledge, skills and attitudes which comprise Competency Domains:
- Categorize competencies, learning objectives and statements from published efforts
- Define harmonized competency statements for each category

Early collaborators:

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Evolution of JTF Framework

8 Competency Domains
47 Competency Statements

Core Competency Framework for the Clinical Research Professional, Version 3.1
FUNDAMENTAL, SKILLED and ADVANCED LEVEL

<table>
<thead>
<tr>
<th>Domain 1: Scientific Concepts and Research Design</th>
<th>Encompasses knowledge of scientific concepts related to the design and analysis of Clinical trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 Apply principles of biomedical science to investigational product discovery and development and health-related behavioral interventions</td>
<td></td>
</tr>
<tr>
<td>A1. Recognize the need to apply scientific principles to discovery and development of biomedical investigational products and health-related behavioral interventions</td>
<td></td>
</tr>
<tr>
<td>A2. Explain the basic scientific principles that should be applied during development of biomedical investigational products and health-related behavioral interventions</td>
<td></td>
</tr>
<tr>
<td>B1. Apply scientific principles when implementing a clinical or behavioral study</td>
<td></td>
</tr>
<tr>
<td>B2. Implement data collection according to scientific principles and based on protocol design</td>
<td></td>
</tr>
<tr>
<td>C1. Plan biomedical research according to scientific principles</td>
<td></td>
</tr>
<tr>
<td>C2. Develop a data management plan according to scientific principles</td>
<td></td>
</tr>
</tbody>
</table>

Example: When given a clinical research protocol, researcher differentiates what principles could affect how the data should be collected and implement best practices accordingly.

Example: Given a clinical research protocol and data collected, the researcher evaluates the findings to assess results via a scientific framework.

1.2 Identify scientific questions that are potentially testable clinical research hypotheses

Example: Identifies the following elements in selected study protocols: Study title, key purpose of the study, Why this study is important to be done, Who the specific population for the study is.

Example: When given a study protocol, describes and classifies the objectives and associated safety and efficacy endpoints that will be used to test the hypothesis and identify assessments (clinical, social/behavioral, or economic) that will be used to measure endpoints.

Example: Develops presentations to educate others on the scientific feasibility and conduct of the study to ensure quality collection of endpoints for hypothesis testing.
How can the Competency Framework be utilized?

- **Education**: Streamlining educational requirements
- **Investigator Selection**: Defining criteria for investigator selection
- **Job Descriptions**: Standardizing job descriptions
- **Development of Accreditation standards**: Defining standards for accreditation
- **Site Qualification**: Defining criteria for site selection and qualification
- **Training Requirements**: Standardizing and streamlining training requirements
Joint Task Force for Clinical Trial Competency (JTF)
Timeline of JTF accomplishments

- **2013**: Launched JTF Task Force
- **2015**: Integrated competencies across stakeholder groups; global survey of CR professionals
- **2017**: MRCT assumes administrative support and oversight; Version 2.0 released; creation of Website
- **2018**: Clinical Project Management Competency Workgroup launched; Global expansion
- **2019**: Developed and published Version 3.0 leveling of JTF Framework (Fundamental, Skilled, Advanced); Translation to Spanish published
- **2020**: PM competencies published; Version 3.1 released; 2nd global survey of CR professionals planned; Translation to Japanese published
- **2021**: Survey completed and analyzed; additional translations planned; NCGM collaboration initiated
- **2022**: Global survey and recommendations published; JTF global meeting

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• Current and future Uses of JTF Core Competency Framework
  – Denise Snyder, Duke University
  – H. Robert Kolb, University of Florida
  – Carolynn Thomas Jones, The Ohio State University
  – Stephen Sonstein, CAAPCR
  – Miwa Sonoda, NCGM
  – Allan Wilsdorf, F-CRIN
Duke’s Workforce Engagement & Resilience (WE-R) Program

Denise Snyder
Associate Dean for Clinical Research
Duke Office of Clinical Research (DOCR)
Creating a Professional Identity

2014
Joint Task Force for Clinical Trial Competency publishes a competency framework with 8 domains. Duke adapts to 12 competency based job classifications for clinical research professionals.

2016
Duke Clinical Research Professionals Working Group (CRPWG) maps Duke CRPs into job classifications and a professional network (RPN) is established.

2018
CRPWG creates and launches an advancement pathway, WE-R is established as a program to maintain CR professional development initiatives.

2019
WE-R begins systematically aligning training with competencies and identifying training gaps.
Workforce Engagement and Resilience (WE-R)

- Standardize competency-based job descriptions for roles and skills
- Create competency-based training programs
- Framework evaluates knowledge and skill gaps within and across individuals
- Self-assessment of competencies to achieve next level of proficiency
- Identification of gaps to prioritize and direct additional training activities
- Improve job portfolio documentation
- Structure for systematic evaluation of proficiency and competencies for performance
Duke Job Ladder Model

DUKE-IFYING THE COMPETENCIES

- Research Operations
- Safety & Ethics
- Data
- Scientific Concepts
- Site & Study Management
- Leadership & Professionalism

Denotes tiered position, which requires competency assessment to advance in tiers
The Title Picker started with the mapping tool. Developed out of the competencies with levels associated. This created consistency across incumbents and new hires. Positions were analyzed by two reviewers to determine title.

Today we use the numbers behind the competencies to provide a suggested title based on numerical calculations and rules.
TIER ADVANCEMENT

Define advancement opportunities, create objective assessments

![Diagram showing tier advancement requirements and progression]

- **Requirements by Tier**
  - **T-1**: < 36 points; default for all new hires
  - **T-2**: Achieve 36-83 points
  - **T-3**: Achieve 84+ points

*Based on level achieved, candidate receives 1, 2, 4, or 8 points for each competency passed.*

*Portfolio for committee review*

*Approval from committee*
INSTITUTIONAL COMPETENCY PROFILE

Research Operations

Safety & Ethics

Data

Sci. Concepts

Site & Study Management

Strengths!

Opportunities!

Strengths!
Comprehensive Onboarding Tools for New CRPs

**INTRODUCE**

**Express Start Online**

**LEARN**

**Onboarding Learning Plan**

**APPLY**

**Engagement Activity Packets**
Impact: Employee Turnover

Attrition rate = \( \frac{\text{# of employees leaving during the period}}{\text{avg # of employees for the same period}} \times 100 \)

FY 2013-2016: 23%
FY 2017-2020: 16%
FY 21: 20%

30% improvement
Hiring vs Attrition @ Duke

Hire vs Attrition

Hiring Freeze

Line graph showing the number of hires and attritions from Q1FY17 to 3QFY22.
Readily available software, package tools for dissemination!

https://medschool.duke.edu/research/research-support/research-support-offices/duke-office-clinical-research-docr
Thank you!

Denise Snyder
denise.snyder@duke.edu

Duke University School of Medicine
CTSA Grant Number UL1TR002553
Community of Practice & JTF Competency Framework: The Research Professionals Network Workshops

Mary-Tara Roth, RN, MSN, MPH
Director, Clinical Research Resources Office, Assistant Director Human Research Protection Program, BU Medical Campus/Boston Medical Center

Kimberly Luebbers, MSHS, RN, BSN, OCN®
Assistant Dean for Clinical Research; Director - Office of Clinical Trials Research; Larner College of Medicine at the University of Vermont

H. Robert Kolb RN, MS, CCRC
Director, Clinical Research Professionals’ Programming; Clinical Translational Science Institute - Workforce Directorate; University of Florida

Diana Lee-Chavarria, MA
Assistant Director for Operations, Translational Science Education and Workforce Development; South Carolina Clinical & Translational Research (SCTR) Institute; Medical University of South Carolina
Research Professionals Network (RPN): CTSA/CTR Inter-institutional Collaborating Teams

- Boston University/ Boston Medical Center
- University of Vermont/ UVM Medical Center
  - Affiliates at Maine Medical Center
- University of Florida
  - Affiliates at Florida State University
- Medical University of South Carolina
  - Affiliates at Clemson University & South Carolina State University
In Line with the Timeline

- **2010**: Original CTSA Regulatory Knowledge KFC–Research Coordinator Taskforce
- **2011**: A CTSA-Sponsored Program for Clinical Research Coordination: Networking, Education, and Mentoring*
- **2014**: Enhancing Clinical Research Professionals Training and Qualifications (ECRPTQ)
- **2016**: Addition of collaborating sites’ affiliates: Maine Medical Center and Florida State University
- **2017**: Addition of 3rd collaborating site, University of Florida
- **2019**: Addition of 4th collaborating site, Medical University of South Carolina
- **2020**: RPN Workshops Started
- **2021**: Joint Task Force Clinical Trial Competencies (JTF)
- **2022–2030**: In Line with the Timeline
RPN Workshops for Clinical Research Professionals

Peer-led Collaborative
2-4 presenters
Inter-institutional
Monthly presentation/workshops – academic year
Zoom platform (pre-registration is required)
Breakout rooms (small group work: cases, activities, problem solving, etc.)
Polling (Zoom polling, Poll Everywhere, Slido, etc.)
Ancillary web-based tools (wordle, Jam board, etc.)

Competency-based
JTF Core Competency Framework for Clinical Research Professionals
Fundamental/ Advanced training levels

- https://mrctcenter.org/clinical-trial-competency/
Inter-institutional Collaborations

• Leadership team
• Presenter teams
• Mentoring
• Workshop activities
  • Peer to peer networking
  • Sharing of best practices
  • New approaches – other institutions doing things differently
  • Affirming current approaches – other institutions doing things the same

It’s about Connecting JTF Competencies to a Community of Practice
Making JTF Competencies the Center of a Community of Practice

- Peer-to-Peer Mentoring
- Intersecting Communities
- External Communities
- Sharing Best Practices
Why is this important?

The new CTSA FOA Priority (PAR-21-293)

CTSA Program Goals

Element C: Training & Outreach

CRPs should...

- ...be provided foundational education and training
- ...learn the collaborative nature of CTS
- ...receive training, education, and mentoring as part of professional development
- ...participate in educational activities, including workshops

6) Create, provide, and disseminate CTS training for clinical research professionals of all disciplines on the research team

PAR-21-293; accessed 2/16/22
Developing Team Science Competencies for Clinical Research Professionals- Expanding and Leveling JTF Domains 7 & 8

Carolynn Jones, DNP, MSPH, RN, CRN-BC, FAAN
Associate Professor of Clinical Nursing, OSU College of Nursing
Director, OSU Master of Clinical Research
Co-Director of Workforce Development, OSU CCTS

Advancing Today’s Discoveries to Improve Health
PROJECT AIM

How do team science competencies develop across the life course?

Who are the main stakeholders making up clinical and translational science teams?
The Project

Team Science Competencies in Translational Teams

(Lotrecchiano et al. 2021)

3 Constituencies:
• Trainees and Faculty
• Clinical Research Professionals
• Community Partners
5 Translational Team Science Competency Domains

- Facilitating Team Affect (Bonding)
- Team Communication
- Managing Team Research
- Collaborative Problem Solving
- Team Leadership

(Lotrecchiano et al., 2021)
Team Science Competencies - Individual

• Self-awareness
• Facilitating awareness and exchange
• Cognitive openness
• Interdisciplinary research management
• Passion, perseverance

(Lotrecchiano et al, 2021)
Team Science Competencies - Team

- Team roles
- Team-based communication
- Shared visioning
- Understanding complexity
- Team learning, adaptive behaviors
- Meeting management
- Interdisciplinary collaboration
- Building Trust

(Lotrecchiano et al, 2021)
Clinical Research Professionals (CRP)

Team Includes: 14 members from 7 CTSA Hubs (and Expanding)

Carolynn Thomas Jones, DNP, MSPH, RN, CRN-BC, FAAN (Co-chair) Director, Master of Clinical Research, College of Nursing The Ohio State University

Angela Mendell, MS, CCRP (Co-chair) Program Manager University of Cincinnati

H. Robert Kolb, RN, MS, CCRC Director, Clinical Research Professionals Programming University of Florida

Bernadett “Candy” Capili, PhD, NP-C Director, Heilbrunn Family Center for Research Nursing Rockefeller University

Laura Hildreth Program Director University of Cincinnati

Jessica Fritter, MACRP, ACRP-CP Clinical Research Administration Manager Nationwide Children’s Hospital

Elizabeth J. Kopras Sr. Research Associate University of Cincinnati

Nicole Exe Training Specialist Senior University of Michigan

Karen Carter The Ohio State University

Nicole Summerside University of Washington

Jen Sprecher University of Washington

Nop Thanthaeng Harvard University

Ty Salana The Ohio State University

David Aslaner The Ohio State University
Define the diverse CRP Network

• Coordinators
• Data Managers
• Regulatory Affairs Coordinators
• IRB Analysts
• Business/Financial
• Grants/Contracts
• Laboratory
• Research Pharmacy
Defining the Lifespan of Clinical Research Professionals

- **Fundamental** - can perform, have knowledge of, with assistance
- **Skilled** - perform independently, consistency, moderate level of expertise
- **Advanced** - advanced KSAs, coach, mentor, supervises, critical thinking
Creating Leveled Smart Skills for Each Individual and Team Competencies (13)

What does facilitating awareness and exchange look like—across the lifespan (fundamental, skilled, advanced levels)?

<table>
<thead>
<tr>
<th>Translational Team Science Competencies (Individual Competencies)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Facilitating Awareness and Exchange</td>
</tr>
<tr>
<td>Defined as: Emotional bonds between team members that are grounded in expressions of genuine care and concern for the welfare of others including empathy, affiliation, and rapport on the basis of shared regard for others</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SMART SKILLS</th>
<th>FUNDAMENTAL (Examples)</th>
<th>SKILLED (Examples)</th>
<th>ADVANCED (Examples)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employ active listening</td>
<td>Can describe the purpose of and demonstrate active listening behaviors during a training session, begins to show a developing skill using active listening.</td>
<td>Consistently uses active listening with co-workers, internal and external teams, and study participants to gain clarity of exchanged messages; modeling the behavior to others.</td>
<td>Models active listening by helping train staff to perform study activities (e.g., active listening used to assess adverse events experienced by participants) and during supervisory sessions.</td>
</tr>
<tr>
<td>Use introductions to welcome and build team membership</td>
<td>Introduces self at meetings, welcomes new team members</td>
<td>Welcomes new team members, introduces team members</td>
<td>Includes all team members, creates an atmosphere whereby team members are free to speak up, highlights strengths of team members during meetings</td>
</tr>
</tbody>
</table>

What training toolkits can be tapped into to help develop individual and team competencies?
## Individual Competency

**Defining Facilitating Awareness and Exchange in CRPs**

<table>
<thead>
<tr>
<th>Employ Active Listening</th>
<th>Fundamental</th>
<th>Demonstrates active listening behaviors during a training session, begins to show a developing skill using active listening.</th>
<th>Skilled</th>
<th>Consistently uses active listening with co-workers, internal and external teams, and study participants to gain clarity of exchanged messages.</th>
<th>Advanced</th>
<th>Models active listening by helping train staff to perform study activities and during supervisory sessions.</th>
</tr>
</thead>
</table>

Advancing Today’s Discoveries to Improve Health
# Team Competency

## Defining Trust in CRPs

<table>
<thead>
<tr>
<th>Actively Include Team Members</th>
<th>Fundamental</th>
<th>Demonstrates listening to others’ ideas and solutions.</th>
<th>Skilled</th>
<th>Consistently engages members to share thoughts and opinions.</th>
<th>Advanced</th>
<th>Models shared decision-making for how best to accomplish team goals.</th>
</tr>
</thead>
</table>

*The Ohio State University Center for Clinical and Translational Science*

*Advancing Today’s Discoveries to Improve Health*
JTF Clinical Trial Competency Framework

(McCormack and Kolb, UFL, 2017)
Acknowledgements

This project was supported by the National Center for Advancing Translational Sciences of the National Institutes of Health under the following grant numbers: UL1 TR002535 (University of Colorado/Colorado State University), UL1TR001450 (Medical University of South Carolina), UL1TR001427 (University of Florida), UL1TR001449 (University of New Mexico), 2UL1TR001425-05A1 (University of Cincinnati), UL1TR002733 (The Ohio State University).

The content of this presentation is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.
Accreditation of Academic Programs in Clinical Research

Stephen Sonstein, PhD
Chair, Committee on Accreditation of Academic Programs in Clinical Research (https://www.caahep.org/CAAPCR.aspx)
Evolution of Education and Training in Clinical Research

**Activity**
- Informal training: coaching, tutoring
- Short term courses: how to do it
- Professional bodies (training, support)

**Discipline**
- Academic involvement: Standards and competencies
- Formal Curriculum: short and long term programs
- National accreditation and certification

**Profession**
- International Standards/Harmonization of Training/mutual recognition
- International Certification/Specialization?
- Maintenance through CPD
Consortium of Academic Programs in Clinical Research
(www.coapcr.org)

Founded in 2003 - Mission
• To provide a medium for communication among educators of clinical research professionals.
• To encourage and support the development and maintenance of academically based clinical research educational programs to meet the needs of the clinical research community.
• To foster inter-institutional articulation among educational institutions, clinical institutions, professional associations, and industry.
• To initiate and/or support research and studies relating to the educational, manpower and service needs of clinical research professionals.

Currently over 100 academic programs globally that educate clinical research professionals

One of the founding priorities of COAPCR was the development of an accreditation process for academic programs in clinical research
2013, COAPCR sponsored the creation of a Committee on Accreditation of Academic Programs in Clinical Research (CAAPCR).

The Commission on Accreditation of Allied Health Education Programs (CAAHEP) was chosen as the umbrella accreditation body to house CAAPCR.

Standards and Guidelines for the accreditation process were based on the JTF Core Competency Framework and approved by CAAHEP in April, 2017.

In order to become accredited a program must have at least one learning objective which maps to each of the 8 JTF Core Competency Domains.

Currently 4 academic programs are accredited and 8 additional programs are in process.
How we can develop competent clinical research professionals in LMICs? :

Promotion of the JTF Core Competency Framework in Asia and Africa.

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

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

May 20, 2022
ARO Alliance for ASEAN & East Asia (ARISE)

**ARISE Chief Representative**

**ARISE Secretariat**

**Cooperation with global clinical research networks**

**Accelerate in Asia**

- Investigator-Initiated Trials
- Research Strategy
- Capacity Development
- PAPPs
- Regulatory Consultation
- Quality Management
- Health Diplomacy

**Research collaboration with Asian countries**

**Establishment of NCGM offices in Asia**

- Indonesia office, University of Indonesia
- Vietnam office, Bach Mai Hospital
- Philippine office, University of Philippines Manila
- Thai office, Faculty of Medicine Siriraj Hospital, Mahidol University

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### Ongoing activities: Competency Survey and Competency Translation in ARISE network countries

<table>
<thead>
<tr>
<th>ARISE/ NCGM</th>
<th>1. Competency assessment survey</th>
<th>2. Language of Competency Translation</th>
<th>Cooperative organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>2021～2022</td>
<td>Thai</td>
<td>Thai</td>
<td>Mahidol University, Faculty of Medicine Siriraj Hospital</td>
</tr>
<tr>
<td></td>
<td>Indonesia</td>
<td>Indonesian</td>
<td>The University of Indonesia, Department of Pharmacology and Therapeutic Pre-Clinic</td>
</tr>
<tr>
<td></td>
<td>Vietnam</td>
<td>Vietnamese</td>
<td>Bach Mai Hospital</td>
</tr>
<tr>
<td></td>
<td>The Philippines</td>
<td>(English)</td>
<td>The University of Philippine Manila, National Institute of Health</td>
</tr>
<tr>
<td></td>
<td>DRC</td>
<td>(French)</td>
<td>The University of Kinshasa, faculties of Medicines and Pharmaceutical Science</td>
</tr>
</tbody>
</table>

#### CRIGH Project 2 (2016～)

- Leader: Mr. Allan Wirsdorf of F-CRIN
- Global Survey was done by Harvard MRCT Center (2016. 2020)

<table>
<thead>
<tr>
<th>Language</th>
<th>Draft Translation</th>
<th>Proofreading</th>
</tr>
</thead>
<tbody>
<tr>
<td>Japanese</td>
<td>published in 2019</td>
<td>NCGM, Osaka University, NCC</td>
</tr>
<tr>
<td>French</td>
<td>draft translation by F-CRIN (France) – Proofread by KCE (Belgium), LIH (Luxembourg), SCTO (Switzerland) and IRESSEF (Senegal) - Contacts currently being identified for proofreading by Morocco and Canada</td>
<td></td>
</tr>
<tr>
<td>Portuguese</td>
<td>draft translation by PtCRIN (Portugal) – Proofread by Fiocruz (Brasil) – To be proofread by CISM (Mozambique) and Angolan contact currently being identified</td>
<td></td>
</tr>
<tr>
<td>Italian</td>
<td>draft translation by Mario Negri and ISS (Italy) – Proofread by IFO - Regina Elena and San Gallicano Research Institutes (Italy) – To be proofread by SCTO (Switzerland – Lugano CTU)</td>
<td></td>
</tr>
<tr>
<td>Spanish</td>
<td>translation by APEIC (Mexico) of v3.0 already available (APEIC contacted for complementary v3.1 translation) – To be proofread by Spanish professionals</td>
<td></td>
</tr>
<tr>
<td>German</td>
<td>translation team currently being set up (Austria, Germany, Luxembourg and Switzerland (the last two having agreed to participate))</td>
<td></td>
</tr>
<tr>
<td>Russian</td>
<td>draft translation by ACTO (Russia) / Proofreading ongoing</td>
<td></td>
</tr>
<tr>
<td>Korean</td>
<td>contacts currently being identified (KoNECT)</td>
<td></td>
</tr>
</tbody>
</table>
Study Flow

**Step 1: Questionnaire translation (and Competency Translation)**
- Forward Translation into local languages by each country’s translation team.
- Back Translation from local languages into English by a professional translator other than the translation team.
- Discrepancies will be discussed and addressed among each country’s translation team.

**Step 2: Pilot-test**
- Pilot-testing will be conducted to assess the clarity of the competency and questionnaire for at least 10 staffs in each country.
- Cognitive interview will be conducted to assess their understanding of the competency and questionnaire.
- Respondents feedback will be considered to modify the wording by each country’s translation team.

**Step 3: Competency Survey using translated questionnaire**
- Participant Recruitment (Announcement from a main sites to network sites in the country).
- Obtaining informed consent.
- E-Survey (at least 150 staffs in each country).
- Data Analysis:
  - Self- perceived competence level
  - Self- perceived relevance to positions across each of the competency
  - Self-reported learning needs across each of the each of the competency
Survey: Self-Assessment of Clinical Research Competence

Study objective:
To investigate
- the competency level of clinical research professionals (Applied the questionnaire developed by MRCT Center)
- the relationship between each competency and job function
- the training needs of each competency.

Numbers of survey responses As of 14th May

<table>
<thead>
<tr>
<th>Country</th>
<th>Local Primary Investigator</th>
<th>No. of Survey response Completed all/Provided Consent (Completion rate %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indonesia</td>
<td>Dr. Wawaimuli Arozal, University of Indonesia</td>
<td>832/1015 (81.9%)</td>
</tr>
<tr>
<td>Philippines</td>
<td>Dr. Ian Cabulana, University of Philippines Manila</td>
<td></td>
</tr>
<tr>
<td>Thailand</td>
<td>Dr. Kulkanya Chokephaibulkit, Mahidol University</td>
<td></td>
</tr>
<tr>
<td>Vietnam</td>
<td>Dr. Dao Xuan Co, Bach Mai Hospital</td>
<td></td>
</tr>
<tr>
<td>DRC</td>
<td>Dr. Tona Lutete Gaston, The University of Kinshasa</td>
<td></td>
</tr>
</tbody>
</table>
Competency Translation

Japanese Version

Vietnamese Version

Indonesian Version

Thai Version

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

Good points..

• Our activities are well organized, based on the existing research network in Asia and Africa.
• Technical supports by the MRCT Center and JTF members is highly beneficial to proceed the activity in LMICs.
• Being a part of global coordinated work motivates us, and it helps to expand new collaborative works.

Toward next steps...

• To promote the dissemination of translated competencies in each country.
• To utilize the survey results in planning trainings programs in the future.
Deploying the JTF framework across the world – Translations and applications

Allan WILSDORF, F-CRIN/CRIGH

JTF – Strategic Global Meeting
May 20th 2022
Translations
Additional translations considered

• Finalise the setup of the German translation group:
  o Agreement of LIH (Luxembourg) to participate to the translation
  o Agreement of SCTO (Switzerland) to participate to the proofreading
  o Austrian and German contacts currently being identified

• Setup of a Korean translation group

• Setup of a Chinese translation group

• Assist the Thai, Indonesian and Vietnamese translations within ARISE (ARO Alliance for ASEAN & East Asia) led by NCGM (Japan)
Perspectives for 2022

• Publication of the French translation before the summer (finalised in May 2022)
• Finalisation and publication of the Portuguese and Italian translations by the end of the year
• Support on-going translations and translation group setups
Applications
Example of a survey set up in France

• Targeted to clinical research professionals based in French hospitals
• Questionnaire based on the JTF framework:

• 297 answers collected between January and July 2021
Lessons learned

1. The answers collected enabled to highlight, for each function (investigator, clinical research assistant,...), the three domains of strongest interest among the eight domains of the framework

2. It was noticed that certain functions shared common or even identical areas of interest. From these shared interests, it was possible to form six function groups

3. For each domain, the competency statements of strongest interest (top 3) are, overall, independent of the level of interest of the participant for the domain

4. It was noticed that certain function groups showed some specificities regarding the competency statements of strongest interest

   D2-2.1 “Differentiate between standard of care and clinical study activities” for the group comprised of the study nurses and clinical study technicians
JTF: Envisioning the Future

Barbara Bierer, MD
Stephen Sonstein, PhD
Co-Chairs, JTF
JTF Core Competency Framework for Clinical Research Professionals

- Future updates and JTF development
- Professional Development
- Further translations
- Training and education assets and resources
- Governance and organization

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JTF Core Competency Framework for Clinical Research Professionals

• Future updates and JTF development
  ➢ Given translations, need to manage and limit updates to only major changes

• Topics to consider
  ➢ Diversity, inclusion, and equity
  ➢ Cultural considerations
  ➢ Privacy and confidentiality
  ➢ Participant and community engagement
  ➢ Vulnerable populations considerations
  ➢ Novel technologies and changes in research
  ➢ Data security, storage, and transfer
  ➢ Transparency

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JTF Core Competency Framework for Clinical Research Professionals

- Professional Development
  - Career pathways
  - Portfolio template
  - Job Description templates
  - Mapping of competencies to role and responsibilities on team
  - Self-evaluation tool
  - Performance evaluation template

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Translations: *In progress*
- French
- Italian
- Portuguese
- Russian

Translations: *to consider*
- Arabic
- German
- Chinese
- Hindi
- Other?

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JTF: Training and education

JTF Core Competency Framework for Clinical Research Professionals

• Training and education assets and resources
  ➢ Need for curation of any training assets
  ➢ Significant effort to develop roadmap for curriculum
  ➢ Translation
  ➢ Utility

• Potential role of educational institutions, accreditation organizations, and professional certification bodies, among others

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JTF: Governance and organization

JTF Core Competency Framework for Clinical Research Professionals

• Governance and organization
  ➢ Organization
  ➢ Representation
  ➢ Coordination
  ➢ Communication

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04 March 2022
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