MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

JOINT TASK FORCE FOR CLINICAL TRIAL COMPETENCY

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

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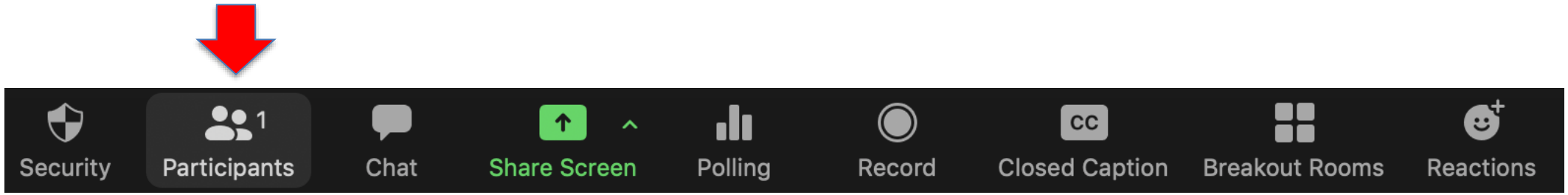
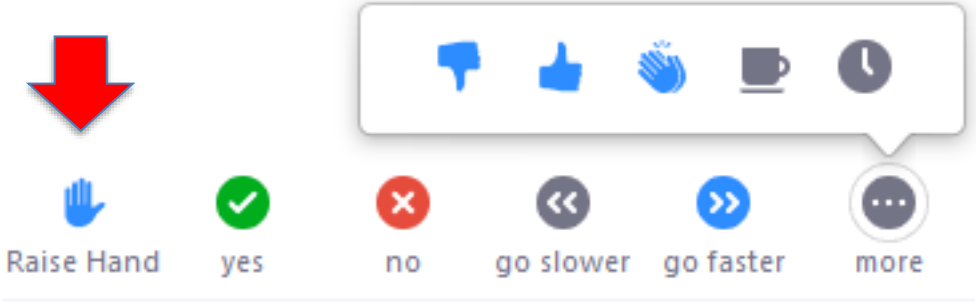
20 May 2022

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)





- 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.

This meeting

- We are recording this meeting for internal purposes of note taking only.
- Recording will not be posted.

- 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.
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- 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.

Brigham and Women's Hospital
Founding Member, Mass General Brigham

HARVARD UNIVERSITY

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

Standards for Clinical Research Professionals

JOINT TASK FORCE FOR CLINICAL TRIAL COMPETENCY

www.mrctcenter.org/clinical-trial-competency

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.

Alignment and Harmonization of Role-based core competencies

1. **Identify competency domains**

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

2. **Map and define competencies**

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

3. **Obtain endorsement**

Obtain endorsement from major stakeholders and content providers

Early collaborators

Evolution of JTF Framework

JOINT TASK FORCE FOR CLINICAL TRIAL COMPETENCY

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Leveled Core Competency Framework for the Clinical Research Professional
Version 3.1 including changes from JTF-Clinical Project Management Workgroup

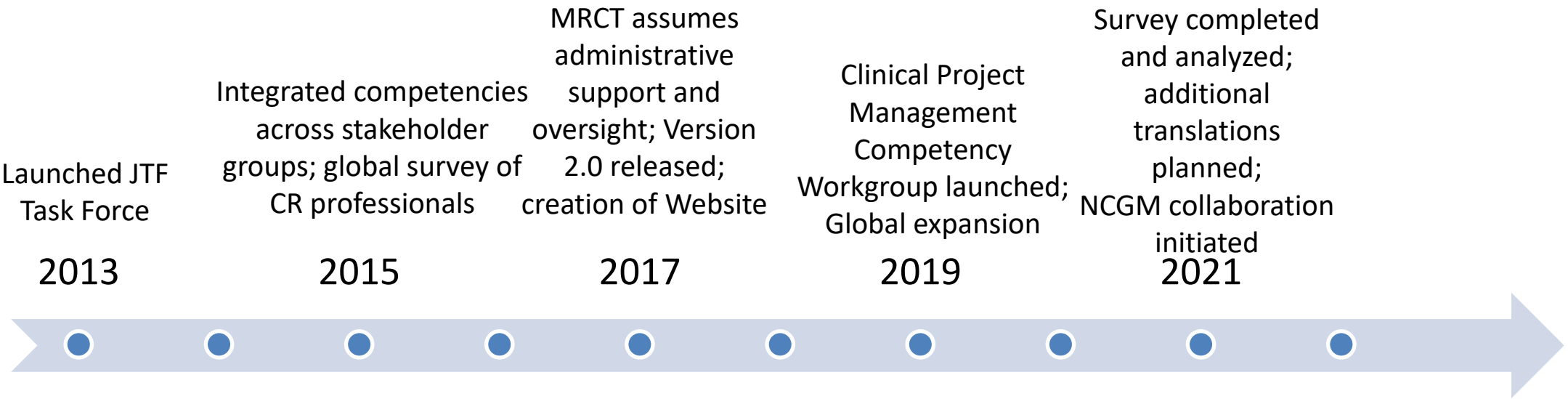
8 Competency Domains
47 Competency Statements

Core Competency Framework for the Clinical Research Professional, Version 3.1 FUNDAMENTAL, SKILLED and ADVANCED LEVEL		
A. Fundamental Level	**B. Skilled Level**	**C. Advanced Level**
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		
A1. **Recognize** the need to apply scientific principles to discovery and development of biomedical investigational products and health-related behavioral interventions A2. **Explain** the basic scientific principles that should be applied during development of biomedical investigational products and health-related behavioral interventions	B1. **Apply** scientific principles when implementing a clinical or behavioral study B2. **Implement** data collection according to scientific principles and based on protocol design	C1. **Plan** biomedical research according to scientific principles C2. **Develop** a data management plan according to scientific principles
Example: When reviewing a clinical research protocol, researcher describes the objective and scientific techniques used to design and implement biomedical research.	**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		
A1. **Articulate** the purpose of the study A2. **Describe** the importance of the study	B1. **Identify** the research hypothesis in a study protocol B2. **Identify** endpoints (primary and secondary) that will be used in data analyses to measure outcomes	C1. **Develop** protocol or source document checklist language that identifies the scientific questions (hypotheses), primary objectives, secondary objectives, and associated endpoints C2. **Align** parameters for collecting data on endpoints with objectives
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



- 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

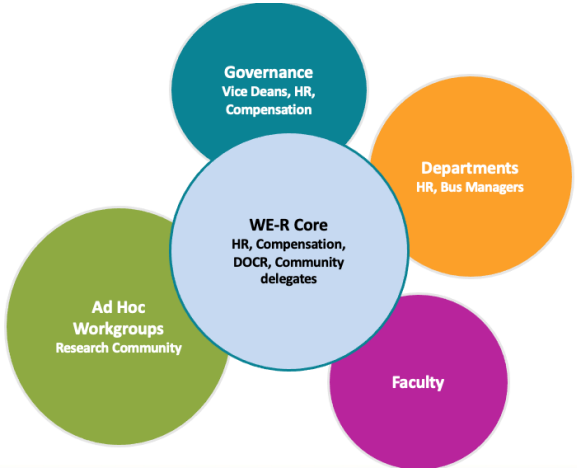
2018

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

2016

- Research Practice Manager
- Research Program Leader, Senior
- Assistant Research Practice Manager
- Research Program Leader
- Regulatory Coordinator, Senior
- Clinical Research Nurse Coordinator, Senior
- Clinical Research Coordinator, Senior
- Regulatory Coordinator
- Clinical Research Nurse Coordinator
- Clinical Research Coordinator
- Clinical Research Specialist, Senior
- Clinical Research Specialist

DUKE-IFYING THE COMPETENCIES

Safety & Ethics

- Adverse Events
- Consent Procedures
- Development of the Informed Consent Documentation and Plan
- Navigating the Ethics Review Process (IRB)
- Sponsor/Regulatory Reporting

Denotes tiered position, which requires competency assessment to advance in tiers

Duke University School of Medicine

THE TITLE PICKER TOOL

Mapping

The Title Picker started with the mapping tool. Developed out of the competencies with levels associated.

Title Picker

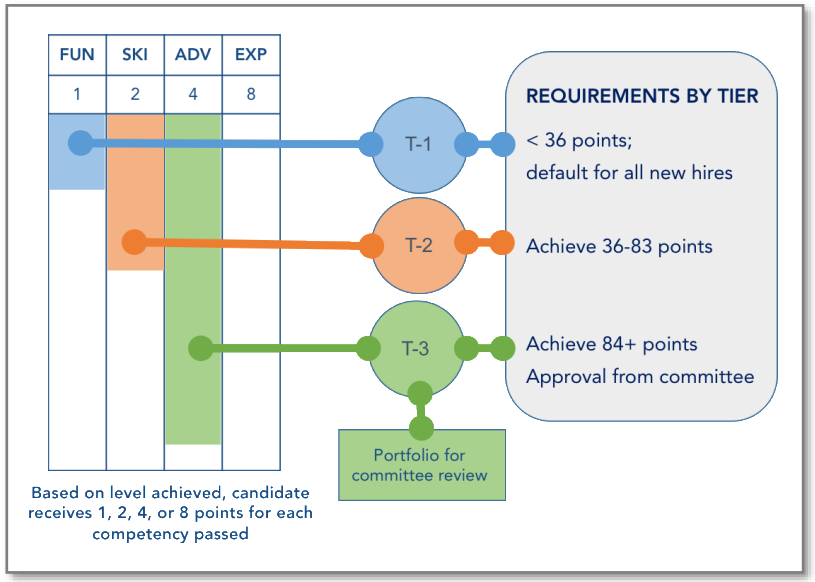
The Title Picker was generated out of the mapping competencies and levels. This created consistency across incumbents and new hires. Positions were analyzed by two reviewers to determine title.

Automated Title Picker

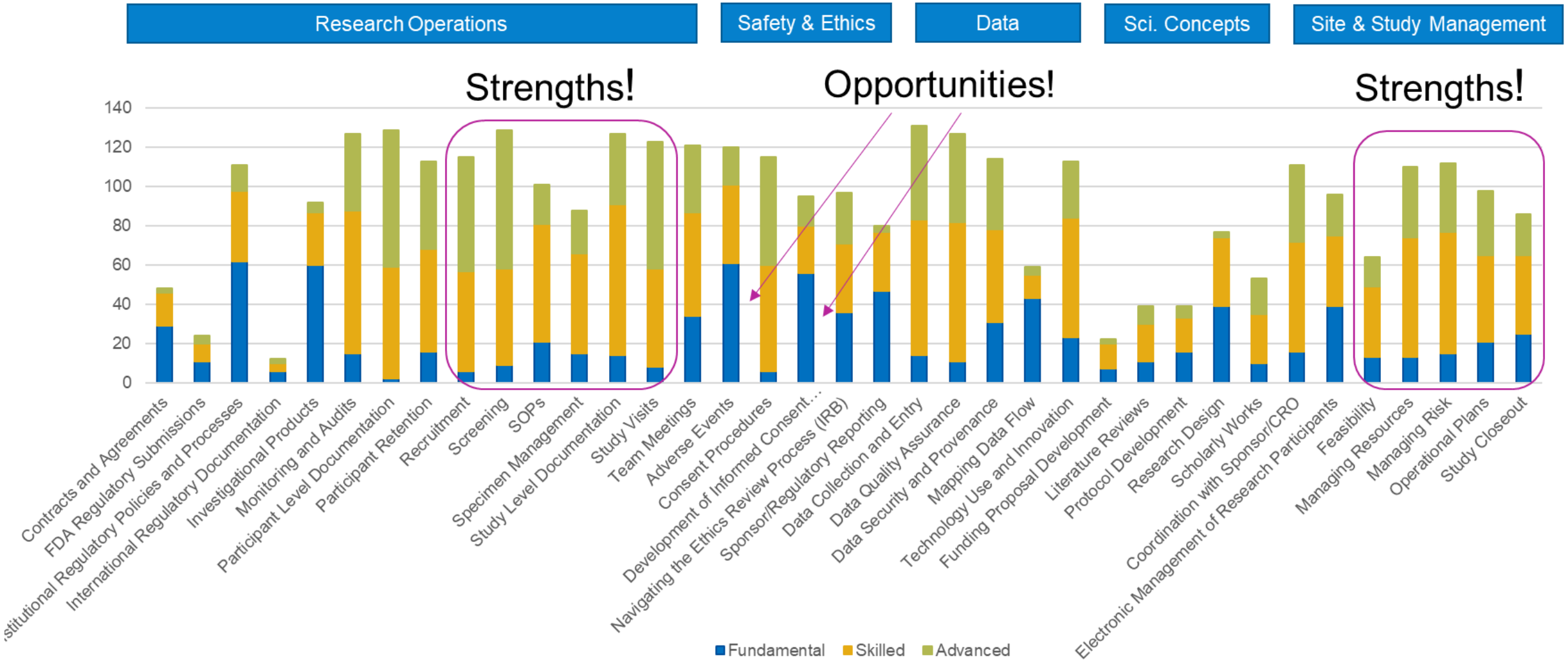
Today we use the numbers behind the competencies to provide a suggested title based on numerical calculations and rules.

TIER ADVANCEMENT

Define advancement opportunities, create objective assessments

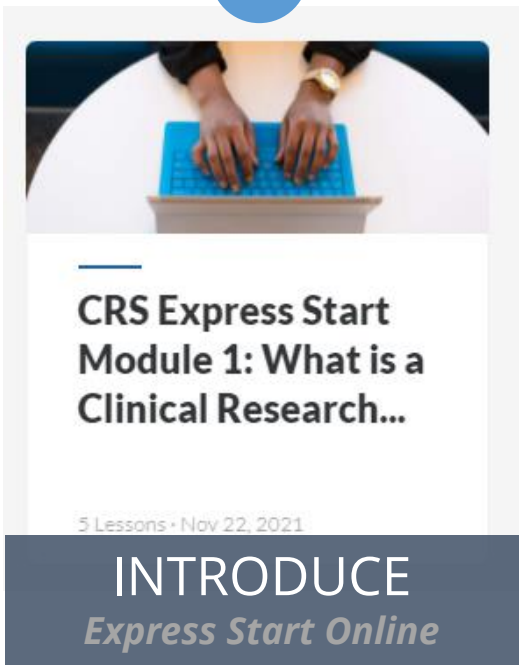


INSTITUTIONAL COMPETENCY PROFILE



Comprehensive Onboarding Tools for New CRPs

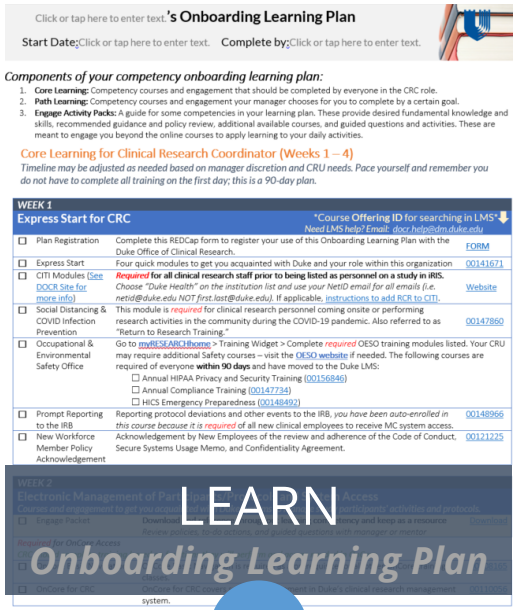
1



INTRODUCE

Express Start Online

2



LEARN

Onboarding Learning Plan

3

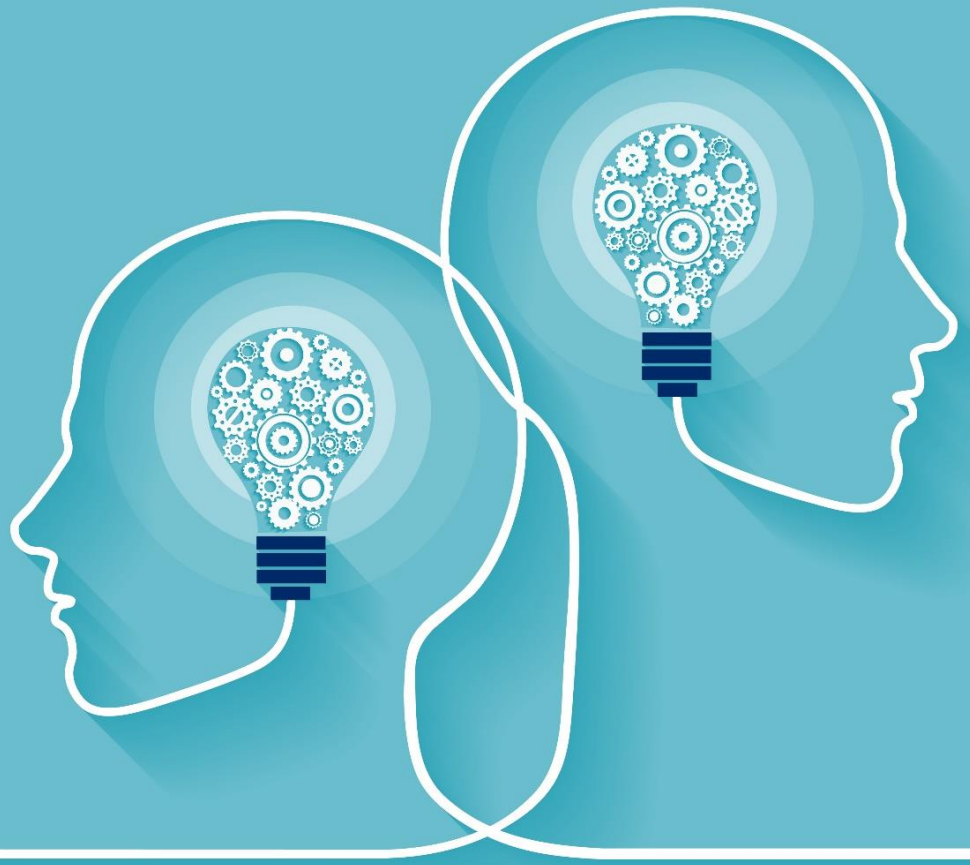
APPLY

Engagement Activity Packets

4

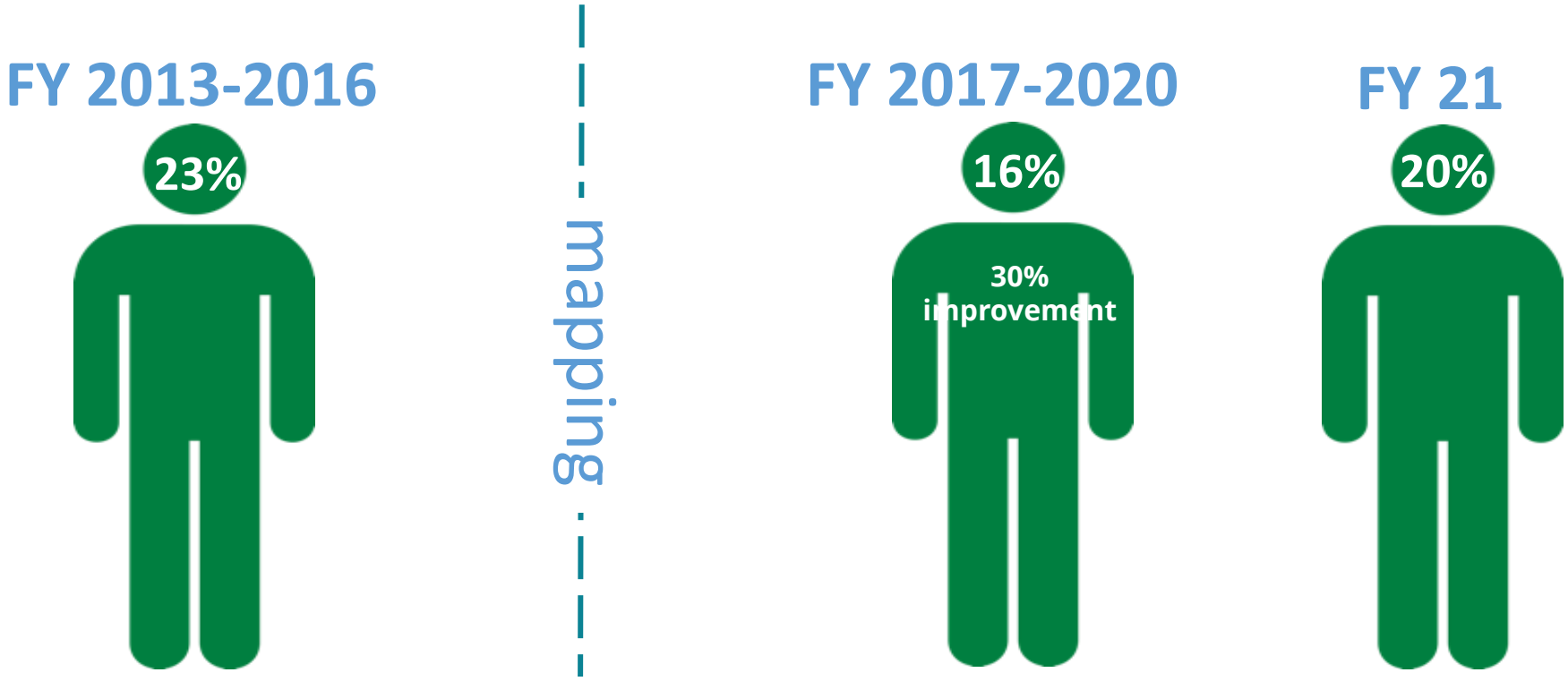
BUILD RELATIONSHIPS

Research Professionals Network +



Impact

Impact: Employee Turnover

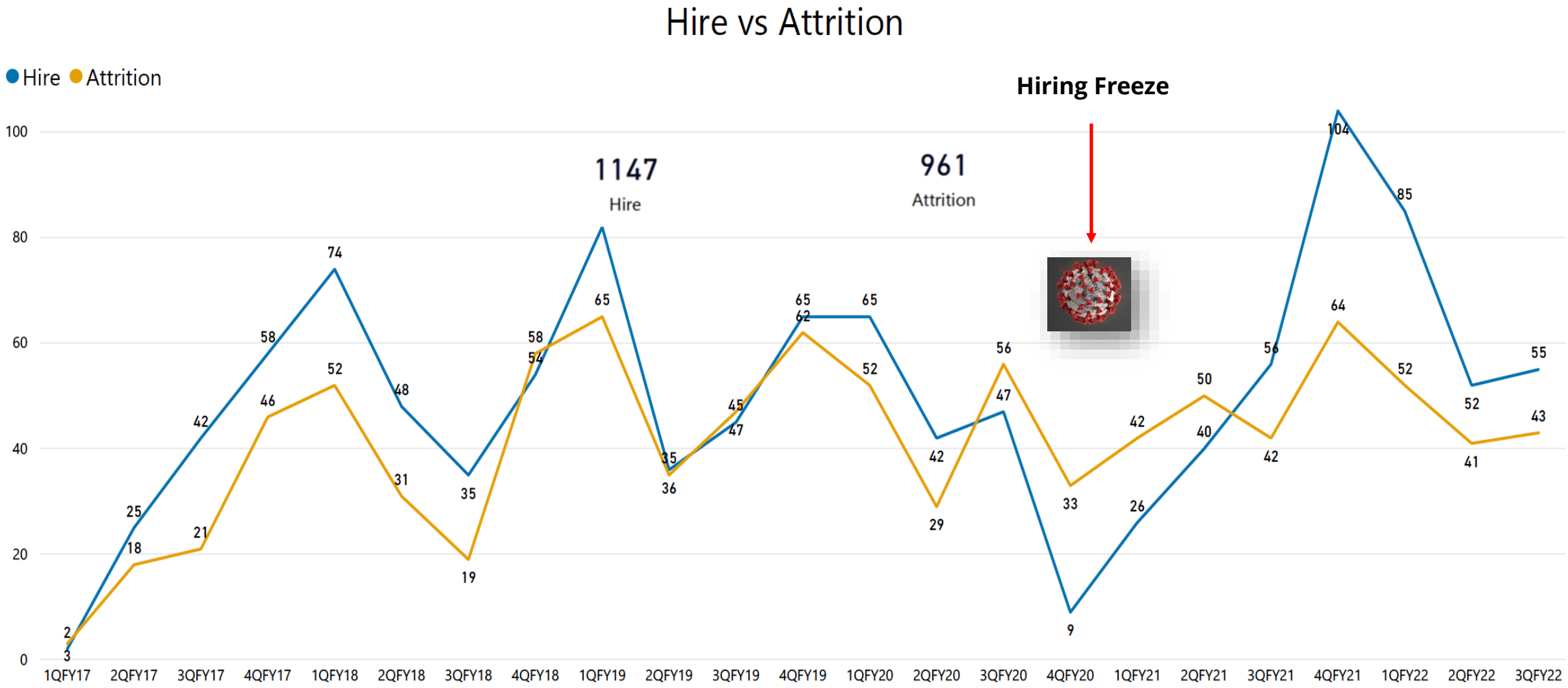


Attrition rate = <u># of employees leaving during the period X 100</u>
avg # of employees for the same period

Stroo M., Asfaw K., Deeter C., Freel S., Brouwer R., Hames B., ***Snyder D.C.***
Journal of Clinical and Translational Science 2020 April; 1-5.

Duke University School of Medicine

Hiring vs Attrition @ Duke



Workforce Engagement and Resilience

To achieve the vision of advancing health and executing a coordinated strategy in clinical research to evolve the model of care outcomes.

The Workforce Engagement and Resilience group utilized the work of the Joint Task Force for Clinical Trials Competency (JTFCTC), which had recently developed draft competencies for research professionals, to create a framework for clinical research jobs at Duke. The competencies are used as the foundation to help managers select titles for new positions, and provide professional development and career advancement opportunities. School of Medicine leadership truly believes that a strong workforce of clinical research professionals will enable higher quality research and ultimately lead to better patient care and health outcomes.

+ ACRP Blogs

Sharable Tools

+ Mapping Tool

+ Title Picker Tool

Readily available software, package tools for dissemination!

REDCap
Research Electronic Data Capture

Office

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

Thank you!

Denise Snyder
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Duke University School of Medicine
CTSA Grant Number UL1TR002553

Community of Practice & JTF Competency Framework: The Research Professionals Network Workshops

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BU Medical Campus/Boston Medical Center

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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

UF Clinical and Translational Science Institute
UNIVERSITY of FLORIDA

The University of Vermont
LARNER COLLEGE OF MEDICINE

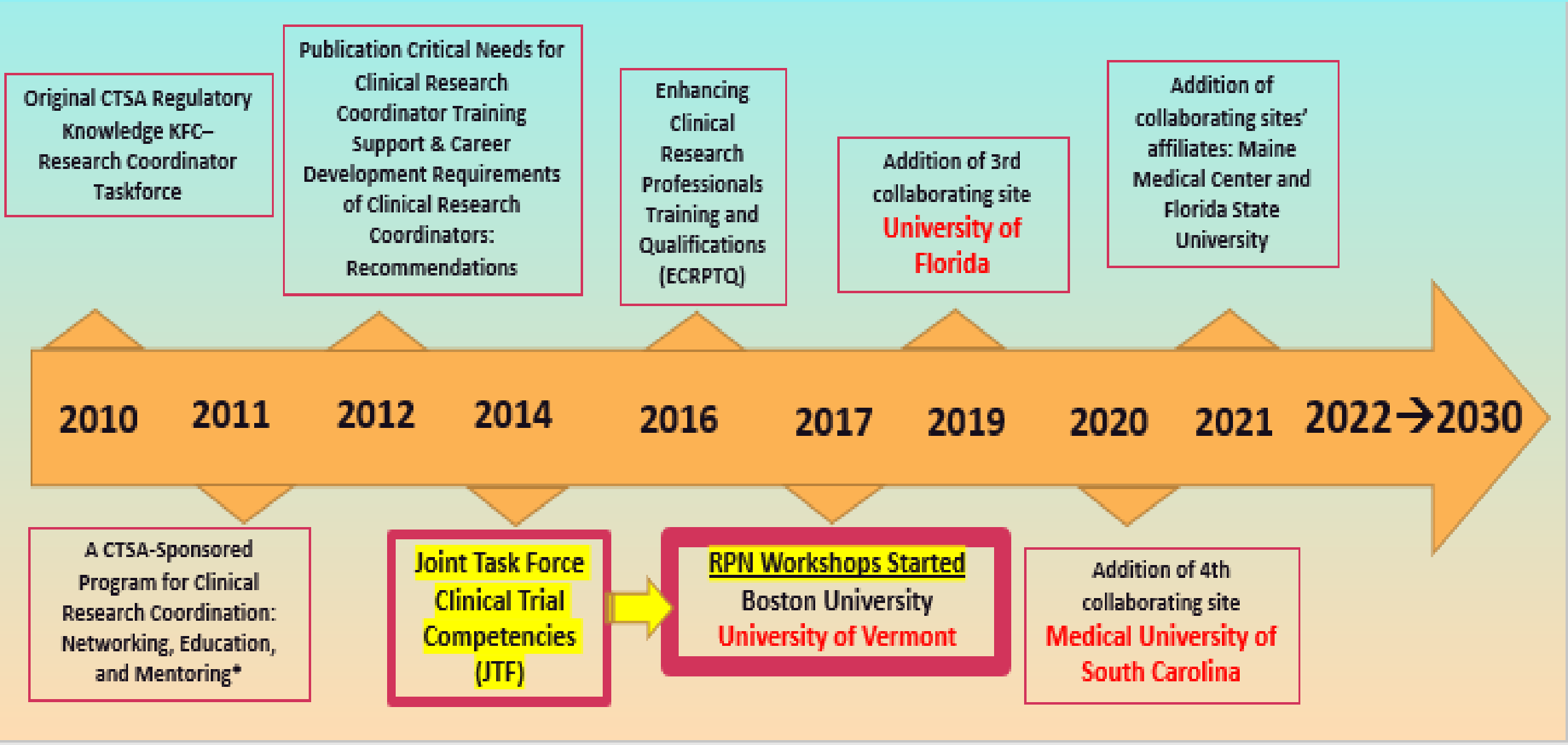
THE University of Vermont MEDICAL CENTER

BOSTON MEDICAL CENTER
EXCEPTIONAL CARE. WITHOUT EXCEPTION.

BU Clinical & Translational Science Institute

MUSC Medical University of South Carolina
South Carolina Clinical & Translational Research Institute

In Line with the Timeline



RPN Workshops for Clinical Research Professionals

Joint Task Force Competency Framework

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.)

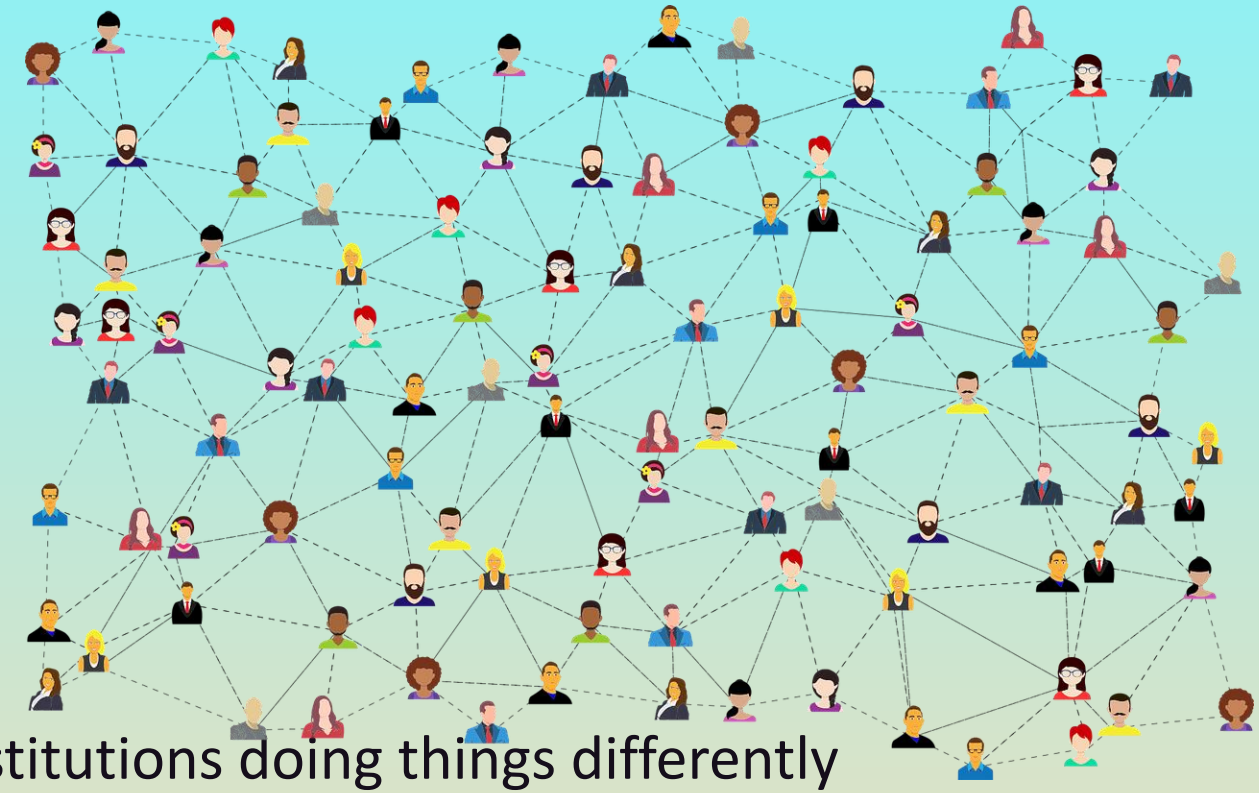
Competency-based

- 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

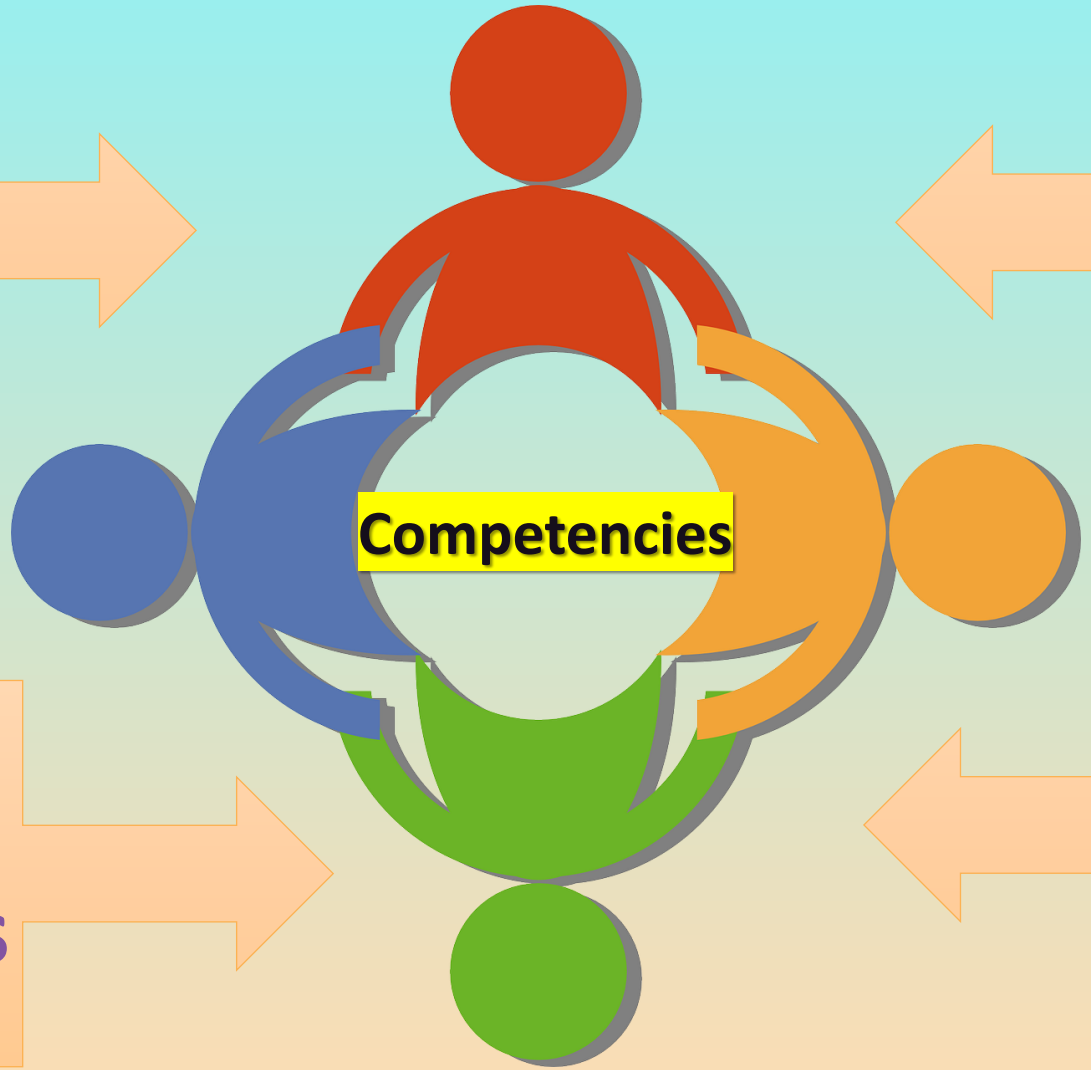


It’s about Connecting JTF Competencies to a Community of Practice

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

NCATS amended the CTSA Program goals in response to the recent feedback and the maturation of the existing CTSA Program and will use a variety of mechanisms to achieve these goals, including this UM1 FOA and other training and research opportunities.

1. Advance CTS: develop, demonstrate, and disseminate scientific and operational innovations that improve the efficiency and effectiveness of clinical translation from identification to first-in-human studies to medical practice implementation to community health dissemination
2. Promote partnerships and collaborations to facilitate and accelerate translational research projects locally, regionally, and nationally
3. Create, provide, and disseminate innovative research programs and partnerships across institutions and communities to address health disparities and deliver the benefits of translational science to all
4. Create and implement scientific and operational innovations that increase the quality, safety, efficiency, effectiveness, and informativeness
5. Provide a national resource for the rapid response to urgent public health needs
6. Create, provide, and disseminate CTS training programs for clinical research professionals of all disciplines on the research team
7. Create, provide, and disseminate CTS training and career support programs for translational scientists
8. Foster the development of the emerging field of translational science

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

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**

PAR-21-293; accessed 2/16/22

Developing Team Science Competencies for Clinical Research Professionals- Expanding and Leveling JTF Domains 7 & 8

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Director, OSU Master of Clinical Research

Co-Director of Workforce Development, OSU CCTS

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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

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Journal of Clinical and Translational Science

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Education Brief Report

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Individual and team competencies in translational teams

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Abstract

Translational scientists create, advance, and translate knowledge as a result of research, learning, and application. Translational teams are composed of dynamic and diverse interprofessional and cross-disciplinary members that generate new knowledge to address a shared translational objective. The objective involves advancing an interventional product, behavioral intervention, or evidence-based approach to improve human health. This paper focuses on identifying individual and team competencies using a modified Delphi method to reach a consensus on the competencies needed by translational teams (TTs).

Introduction

With the increasing emphasis on research programs to address complex health and societal problems, a grass-roots revolution in interprofessional and cross-disciplinary team approaches is occurring in the scientific community [1]. This research revolution is driven by a number of factors, including increasing depth of research disciplines, focus on real-world applications, enhanced productivity, and utilization of research projects [2]. An abundance of social science research from disciplines such as organizational psychology, social psychology, sociology, philosophy, leadership studies, and communications has focused on team effectiveness and can be used to inform our understanding of translational teams (TTs). With the increased emphasis on enhancing team outcomes, substantial effort has been invested in comprehensive reviews and meta-analyses that have resulted in the identification of competencies (i.e., knowledge, skills, abilities, and attitudes) that are needed to advance team performance [3–5].

Previous studies have indicated that appropriately applied team training substantially impacts team performance and innovation [6, 7]. In particular, training efforts focusing on knowledge, skills, and abilities that are content-appropriate can result in substantial transfer and positive outcomes [8]. It is important to consider the context in which teams function. TTs, typically located in academic institutions, operate in a complex organization that has unique characteristics and implications for training. Because these training activities are most impactful when tailored to the team context, a great need arises to identify evidence-informed competencies most relevant to TTs with the goal of enabling trainees to successfully participate in TTs, enhance the productivity of TTs that they participate in, and derive satisfaction from participating in research as teams.

A TT, in line with the formal definition of a team [9], is composed of diverse members who interact, adapt, and evolve using established norms and defined roles to address a shared translational objective. Diverse members involve multiple perspectives, professions, career stages, stakeholders (patients, communities), and other voices appropriate for its developmental stage. The objective of a TT involves advancing a product (device/drug/diagnostic), behavioral intervention, or evidence-based approach to sustainable improvements in human health. A TT may work in one or more phases of translation, including preclinical, clinical, implementation,

ACTS
ASSOCIATION FOR CLINICAL AND TRANSLATIONAL SCIENCE

Clinical Research FORUM
Analysis. Advocacy. Action.

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

(Lotrecchiano et al, 2021)

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

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

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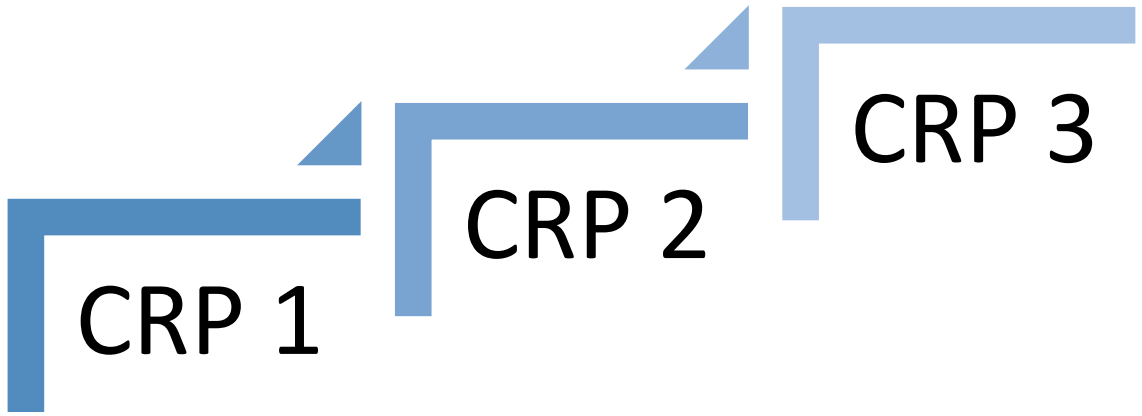
Advancing Today's Discoveries to Improve Health

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)?

Translational Team Science Competencies (Individual Competencies)	Roles 1. CRC 2. RA 3. DM 4. Lab 5. QA Monitoring 6. Admin	LEVELING: 1) **Fundamental** ("Can perform task/and or exhibit knowledge of an essential or fundamental level); 2) **Skilled** ("can perform task or skill independently, consistently, accurately and has a moderate level of expertise. Efficient and high quality work; able to independetnly navigate resoures and uses tools well"); 3) **Advanced** ("demonstrates advanced KSAs to teach, coach, mentor or supervise others. Consistently applies critial thinking and problem solving." (Sonstein et al, 2018) (Duke University Role Progression Readiness Tool, 2017).		
1. Facilitating Awareness and Exchange				
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				
SMART SKILLS:		**FUNDAMENTAL**	**SKILLED**	**ADVANCED**
		(Examples)	*(Examples)*	*(Examples)*
Employ active listening	all	*Can describe the purpose of and demonstrate active listening behaviors during a training session, begins to show a developing skill using active listening.*	*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.*	*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.*
Use introductions to welcome and build team membership	all	*Introduces self at meetings, welcomes new team members*	*Welcomes new team members, introduces team members*	*Includes all team members, creates an atmosphere whereby team members are free to speak up, highlights strengths of team members during meetings*

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

Individual Competency

Defining Facilitating Awareness and Exchange in CRPs

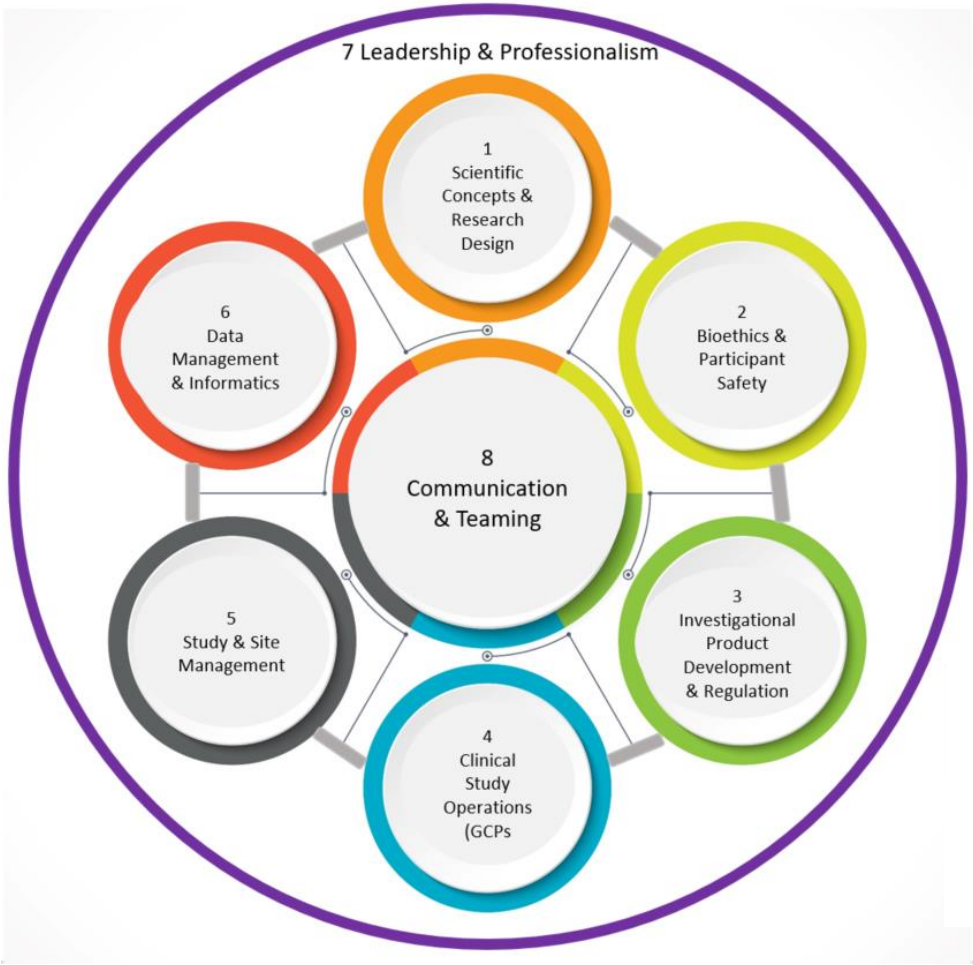
Employ Active Listening	**Fundamental**	**Demonstrates** active listening behaviors during a training session, begins to show a developing skill using active listening.	**Skilled**	**Consistently uses** active listening with co-workers, internal and external teams, and study participants to gain clarity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

Team Competency

Defining Trust in CRPs

Actively Include Team Members	**Fundamental**	**Demonstrates** listening to others' ideas and solutions.	**Skilled**	**Consistently** engages members to share thoughts and opinions.	**Advanced**	**Models** shared decision-making for how best to accomplish team goals.

JTF Clinical Trial Competency Framework



(McCormack and Kolb, UFL, 2017)

THE OHIO STATE UNIVERSITY
CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

Acknowledgements

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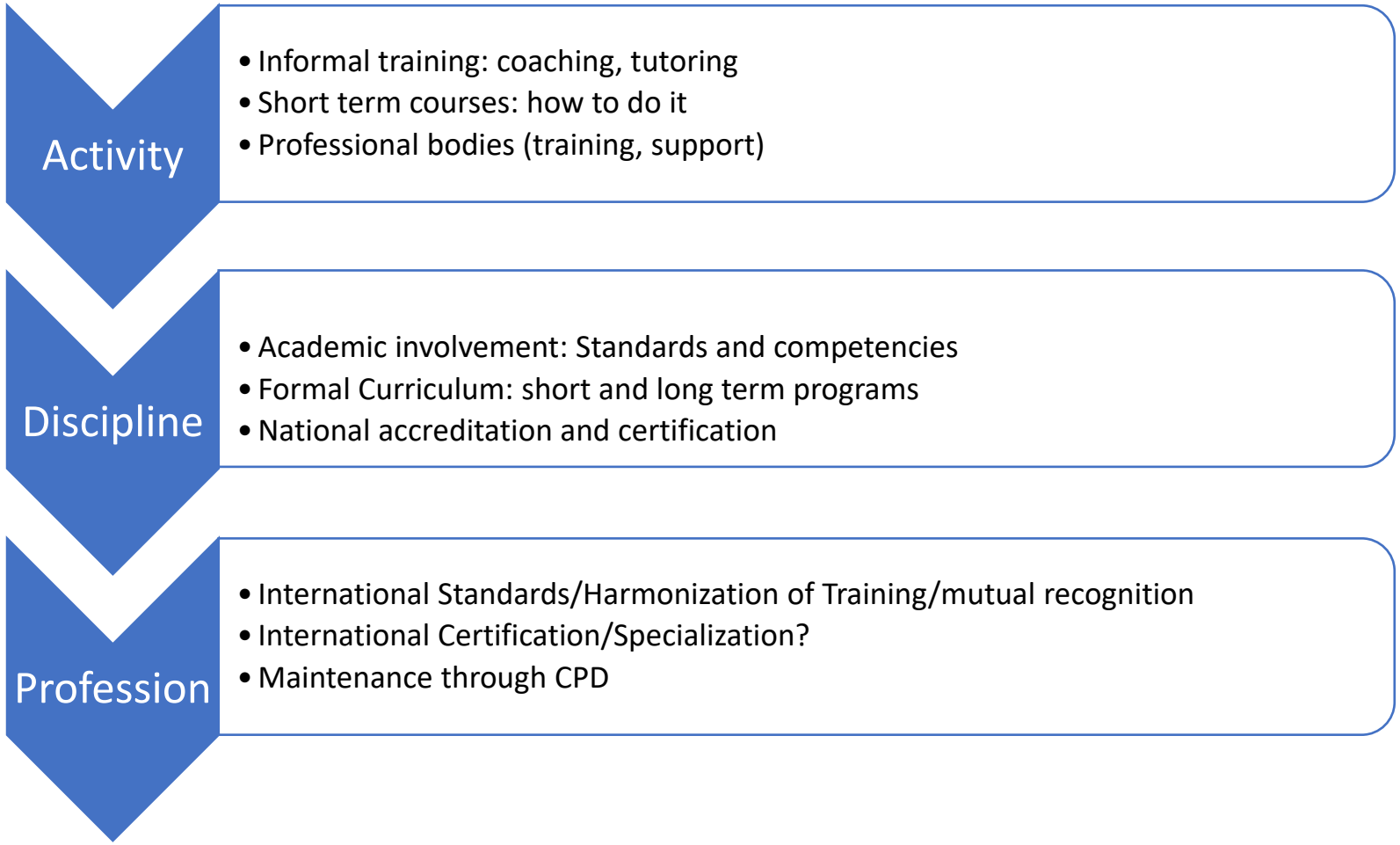
The content of this presentation is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

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



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

Commission on Accreditation of Allied Health Education Programs

- 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 NCGM

ARISE Secretariat Department of International Trials

European Clinical Research Infrastructure Network (ECRIN)

ecrin

Cooperation with global clinical research networks

Clinical Research Initiative for Global Health (CRIGH)

CRIGH

Cooperation with Japanese organizations

AMED

Pmda

JICA

JPMA

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

ARISE

Accelerate in Asia

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

Research collaboration with Asian countries

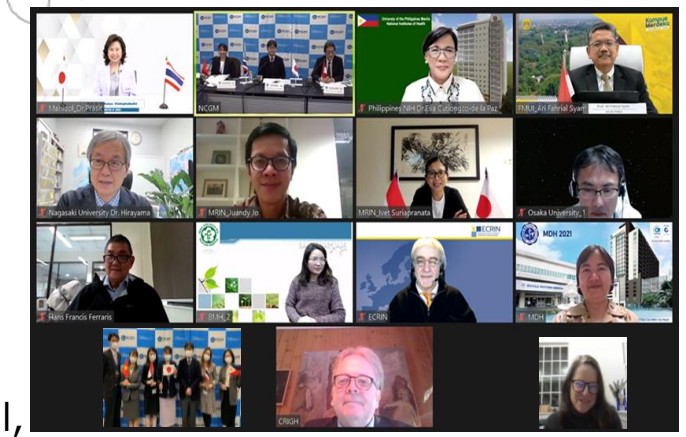
Establishment of NCGM offices in Asia

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



ARISE Members

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

	1.Competency assessment survey	2. Language of Competency Translation	Cooperative organization
ARISE/ NCGM 2021～2022	Thai	Thai	Mahidol University, Faculty of Medicine Siriraj Hospital
	Indonesia	Indonesia	The University of Indonesia, Department of Pharmacology and Therapeutic Pre-Clinic
	Vietnam	Vietnamese	Bach Mai Hospital
	The Philippines	(English)	The University of Philippine Manila, National Institute of Health
	DRC	(French)	The University of Kinshasa, faculties of Medicines and Pharmaceutical Science
CRIGH Project 2 （2016～） • Leader: Mr. Allan Wirsdorf of F-CRIN • Global Survey was done by Harvard MRCT Center （2016、2020）		Japanese (published in 2019)	NCGM, Osaka University, NCC
		French	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
		Portuguese	draft translation by PtCRIN (Portugal) – Proofread by Fiocruz (Brasil) – To be proofread by CISM (Mozambique) and Angolan contact currently being identified
		Italian	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)
		Spanish	translation by APEIC (Mexico) of v3.0 already available (APEIC contacted for complementary v3.1 translation) – To be proofread by Spanish professionals
		German	translation team currently being set up (Austria, Germany, Luxembourg and Switzerland (the last two having agreed to participate))
		Russian	draft translation by ACTO (Russia) / Proofreading ongoing
		Korean	contacts currently being identified (KoNECT)

Study Flow

Step1: 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.

Step2: 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

Step3: 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.

https://www.surveymonkey.com/r/FKUI?lang=id

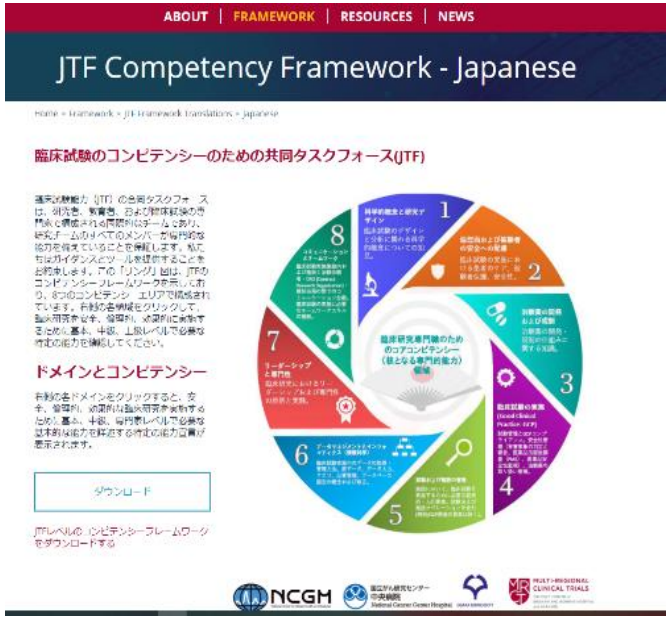
Numbers of survey responses As of 14th May

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

Competency Translation

Japanese Version

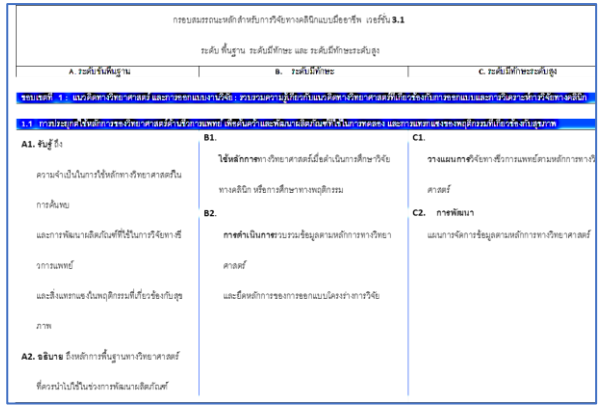
websitehttps://mrctcenter.org/clinical-trial-competency/framework/translations/japanese/



Vietnamese Version

Indonesian Version

Thai Version



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

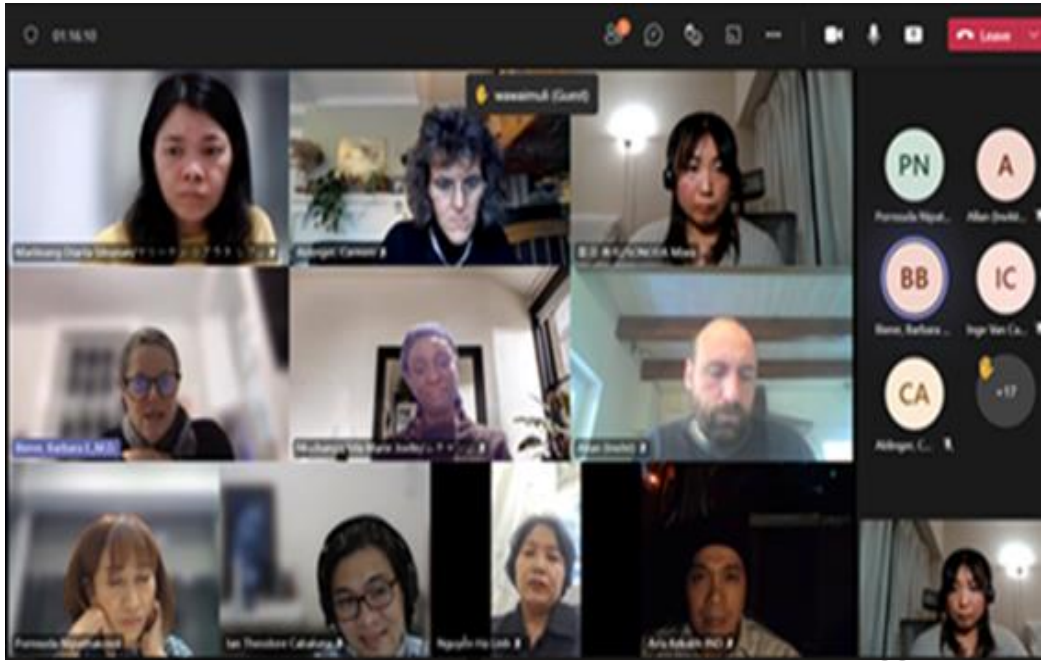
Summary

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

CRIGH

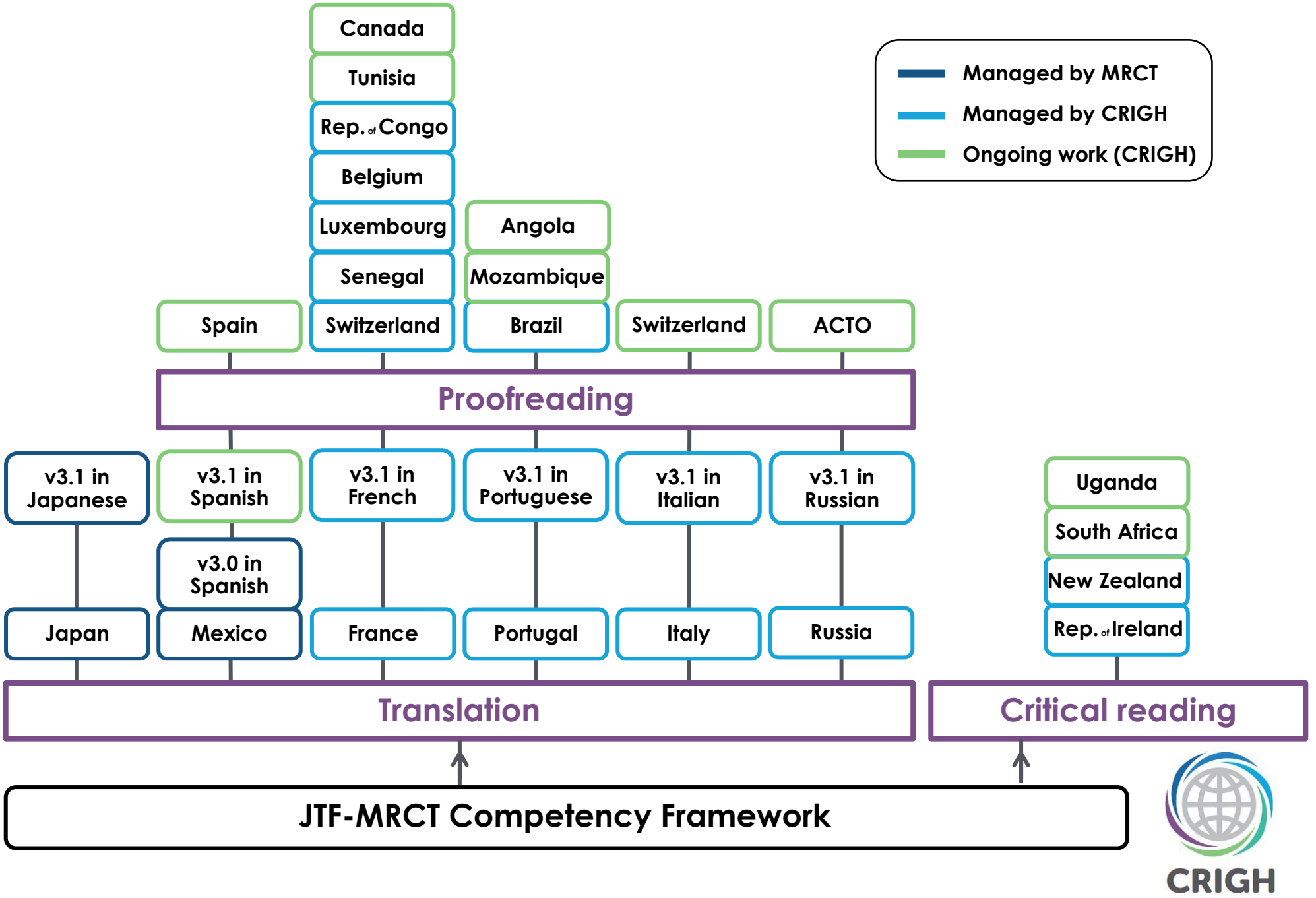
Translations

20th May, 2022

CRIGH

Translation versions

20th May, 2022



Additional translations considered

- Finalise the setup of the **German** translation group:
  - Agreement of LIH (Luxembourg) to participate to the translation
  - Agreement of SCTO (Switzerland) to participate to the proofreading
  - Austrian and German contacts currently being identified
- Setup of a **Korean** translation group
- Setup of a **Chinese** translation group
- Assist the **Thaï**, **Indonesian** and **Vietnamese** translations within ARISE (ARO Alliance for ASEAN & East Asia) led by NCGM (Japan)

CRIGH

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

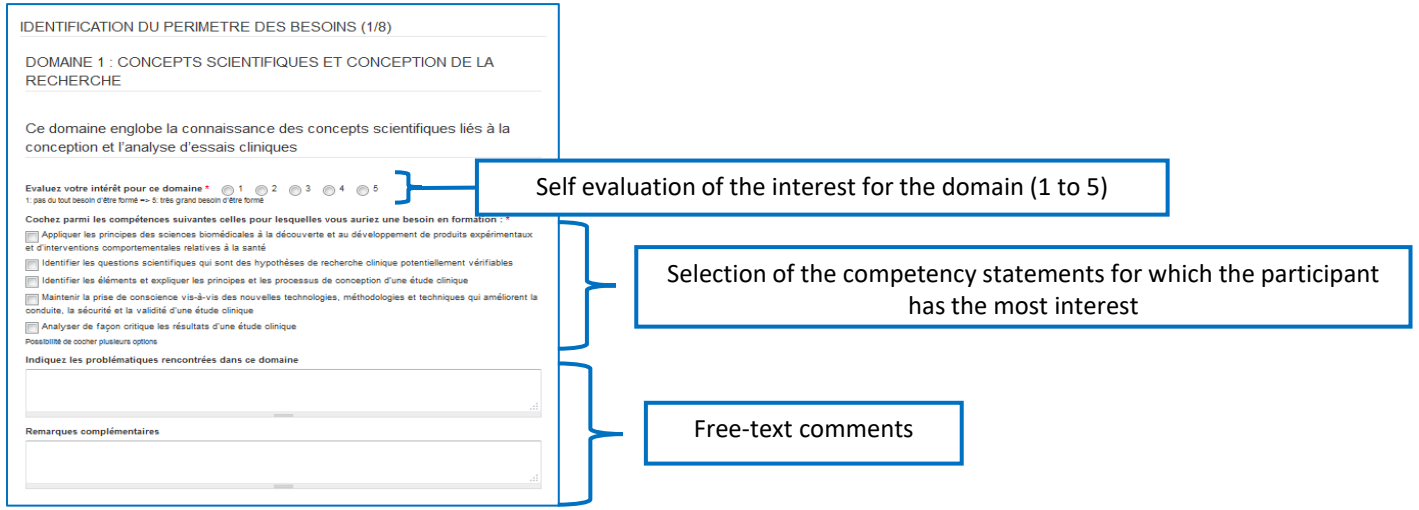
CRIGH

Applications

CRIGH

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

CRIGH

JTF: Envisioning the Future

Barbara Bierer, MD

Stephen Sonstein, PhD

Co-Chairs, JTF

JTF: Future Plans

Clicking on each domain above will show the specific competency statements which detail the core competencies required at the Basic, Skilled and Expert levels.

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

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

JTF: Future updates and JTF development

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

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

JTF: Professional Development

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

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

JTF: Translation

JTF Core Competency Framework for Clinical Research Professionals

Translations: *In progress*

- French
- Italian
- Portuguese
- Russian
- Thai
- Vietnamese
- Indonesian

Translations: *to consider*

- Arabic
- German
- Chinese
- Hindi
- Other?

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

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

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

JTF: Governance and organization

JTF Core Competency Framework for Clinical Research Professionals

- Governance and organization
  - Organization
  - Representation
  - Coordination
  - Communication

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

Questions, Comments, Suggestions

Questions and discussion

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