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):
Biannual Global Meeting

Barbara E. Bierer, MD

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Stephen Sonstein, PhD

Co-chair, JTF

Carmen Aldinger, PhD

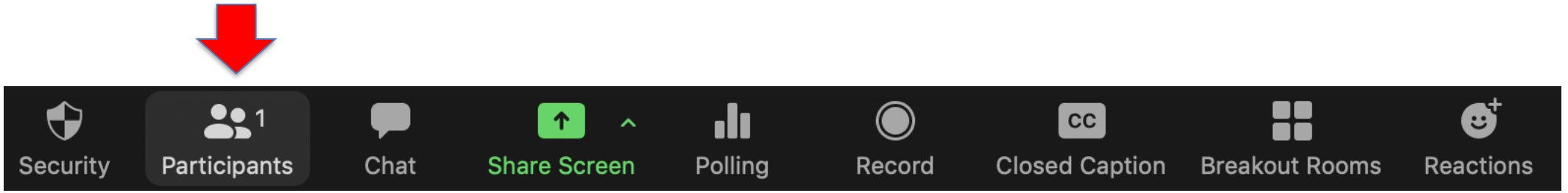
Senior Administrative and Training Manager,
MRCT Center

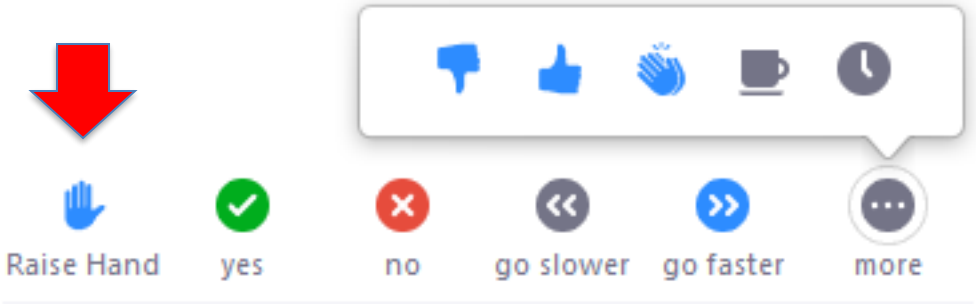
14 November 2023

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

Virtual Meeting

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





This meeting

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

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

Disclaimer:

- The opinions contained herein are those of the presenters and are not intended to represent the position of Brigham and Women's Hospital, Harvard University, or any of the institutions or organizations represented today.
- The MRCT Center is supported by voluntary contributions from foundations, corporations, international organizations, academic institutions and government entities (see www.MRCTCenter.org) and by grants.
- We are committed to autonomy in our research and to transparency in our relationships. The MRCT Center—and its directors—retain responsibility and final control of the content of any products, results and deliverables.
- We have no personal financial conflicts of interests with the content of this presentation.
- Today's meeting will be recorded for internal purposes.

The Multi-Regional Clinical Trials Center (MRCT Center)

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

Our Vision

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

Our Mission

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

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

HARVARD UNIVERSITY

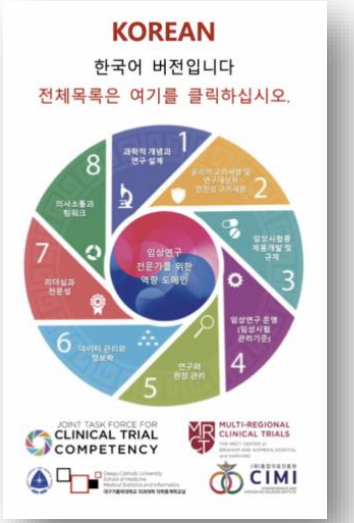
Agenda

Time	Topic	Speaker / Facilitator
9:00-9:15	Introduction Overview	Barbara Bierer, MD Co-Chair, JTF Faculty Director, MRCT Center
JTF Updates and discussion		
9:15-9:30	Data Management Quick Update: Results from Delphi	Manju Bikkanuri, MD, MPH Clinical Research Informatics Specialist University of Texas (UT) Health San Antonio, Long School of Medicine, Department of Population Health Sciences
9:30-9:45	Workforce development for clinical research	Susan Landis, BA Executive Director Association of Clinical Research Professionals (ACRP)
9:45-10:00	Emergency Preparedness: Proposed Rapid Response Appendix	Barbara Bierer, MD Faculty Director MRCT Center
10:00-10:15	Competencies for non-interventional research projects in the Swiss regulatory context	Melanie Glaettli, PhD Scientific Coordinator, Swiss Clinical Trial Organisation (SCTO)
10:15-10:30	Update on the use of the JTF framework in Canada under 3CTN Update on the Arabic translation	Christine Samara, MSc Manager, Quality Assurance and Education, Odette Cancer Center Clinical Research Program, Sunnybrook Research Institute, Toronto, Canada Member on the 3CTN Performance Strategy Sub- Committee, Canadian Cancer Clinical Trial Network (3CTN), Canada Coordinating the Arabic Translation with the Ministry of Health and Prevention, United Arab Emirates
10:30-11:00	Open discussion	Stephen Sonstein, PhD & Barbara Bierer, MD Co-Chairs, JTF

Introduction

JTF dissemination and impact

- Current translations (10):
  - English
  - Spanish
  - French
  - Japanese
  - Thai
  - Bahasa Indonesia
  - Italian
  - Chinese
  - Vietnamese
  - Korean



- Current CIOMS initiative:
  - *International Guidelines for Education in Medicines Development*
  - Working group has met 6 times
  - JTF has helped inform direction of competencies in education

Data Management Update:
Manju Bikkanuri

Quick Update

JTF Data Management Competencies

Meredith Nahm Zozus, PhD
Professor, Div. Chief and Director of Clinical Research Informatics
Joe R. and Teresa Lozano Long School of Medicine
University of Texas Health Science Center San Antonio

Manju Bikkanuri, MD, MS
Clinical Research Informaticist
Joe R. and Teresa Lozano Long School of Medicine
University of Texas Health Science Center San Antonio

Goal:

to update the Data Management and Informatics JTF Competencies.

Competencies are for Clinical Research Professionals such as

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

AKA:

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

Delphi Process Status

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

Round 2: Two-dimensional rating

(1) importance of the competency regardless of the indicated level and

(2) level of agreement with the competency at each indicated level

PLUS comment fields to explain low importance and disagreement

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

Round 4:

If significant disagreement: calls with individual participants to discuss their remaining differences and to perform additional member-checking if needed.

If minor disagreement or group is split on issues: from 1 to 3 group calls

Analysis following Round 4: group vetted draft competencies

Peer-review of results: review of the initial draft by the larger JTF. Early next year.

Resulting Competencies

Data Management, Informatics and Statistics

Data Definition and Generation	Data Collection and Processing	Data Use	Statistical Analysis	Data Re-use

Information System Selection, Application, Use and Evaluation

Delphi Round 1 Results

Draft Competencies for Domain 6: Data Management, Informatics and Statistics:		
Data Definition and Generation • Data definition • Data generation • Data quality • Source data • Form design • Metadata definition	**Data Collection and Processing** • Data flow & Workflow • Data Privacy • Data Processing • Identify & Resolve Data Problems • Change control	**Data Use** • Data Interpretation • Databases • Data Mining and ML • Structured & unstructured data • Handling Bad & Missing Data • Data Surveillance
Statistical Analysis • Descriptive Statistics • Inferential Statistics • Statistical Analysis Plans • Applications to Clinical Trials • DSMB Reports • Evidence Based Medicine and Synthesis	**Data Re-use** • Data sharing • Fitness for use • Research and results Registration • Data Privacy • Data Use Agreements	**Information Systems (ISs)** • Information System use • Information System Development Lifecycle • Information System Security • Automation and decision support • Interoperability

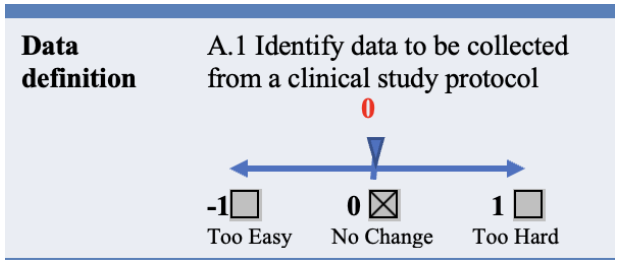
Delphi Round 3

Round 3

Participants receive their results versus aggregate and are free to change their two-dimensional rating.

- The aggregate score for each leveled sub-competency is calculated taking into consideration the participants comments.
- Each sub-competency at each indicated level is marked with aggregate score along with individual response for review and feedback.

- Next Step: Delphi Round 4 and analysis



Workforce Development for Clinical Research: Susan Landis

LET'S TALK ABOUT THE CLINICAL RESEARCH WORKFORCE

Susan P. Landis
Executive Director
Susan.landis@acrpnet.org
+1.703.723.7924

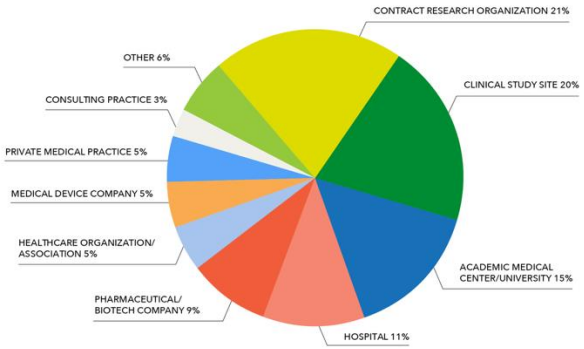
Advancing People Advancing Health™

ACRP is moving the people and practice of clinical research forward™ by:

- Being the Most Passionate Advocate for the Clinical Research Profession
- Providing the Tools Clinical Research Professionals Need to Build Their Own Career Journeys
- Creating Connections through Community
- Giving Employers the Confidence to Know They're Hiring the Best of the Best
- Leading the Way for Workforce Development in Clinical Research

DIVERSE PRACTICE SETTINGS

(of those who answered)



ACRP Advancing People Advancing Health™

SNAPSHOT

16,500+

MEMBERS STRONG

90

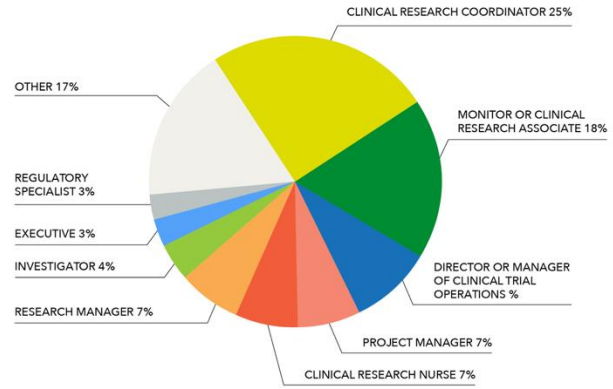
ORGANIZATION MEMBER

"I say with pride I'm honored to be a member of this organization and to be certified for more than 20 years. I also have the opportunity to contribute my voice to changes in the industry and this makes me feel valued."

LUTHERIA HOLLIS, CCRC

DIVERSE ROLES

(of those who answered)



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SNAPSHOT

10,801

ACTIVE ACRP CERTIFIED PROFESSIONALS

3,419

ACRP CHAPTER MEMBERS

46

DISTINGUISHED ACRP FELLOWS

JTF & ACRP Education

			Core Competency Description		Competency Development Methods					Competency Assessment Methods						Self Assmt Progression Rating Scale: 1 = Low Confidence through 5 = High Confidence. ✓ when High Confidence Achieved					Mgr. Assmt	
Priority	Competency Domain	CRC Functional Tasks / Responsibilities	What Foundational Knowledge is Needed?	What Skills / Abilities are Needed?	●	◎	◉	◉	Link to Internal Training Resources	■	◆	✦	❖	▲	Link to Internal Competency Assessment Resources	Pre-Training	Post-Training	After XX Months OTJ	✓	Date Achieved / Completed	✓	Date Achieved / Completed
1-High	1.2	Conduct and document informed consent discussions	Identify and explain the study hypotheses, study objectives and endpoints for a variety of clinical studies.	Explain the study design as it relates to conducting informed consent discussions with subjects	●	◎	◉	◉			◆	✦	❖	▲								
1-High	2.3	Support subject privacy and confidentiality protections	Describe confidentiality and privacy requirements for the institution and protocol and explain site level standard operating procedures (SOPs) for maintaining subject confidentiality and privacy.	Comply with subject privacy and confidentiality guidelines and requirements	●	◎		◉		■	◆		❖									

TALENT ASSESSMENT

ACRP Clinical Research Knowledge Assessment™

FOUNDATIONAL TRAINING

ACRP Early Talent Training Program™

FOUNDATIONAL TRAINING

ACRP CRC Core Competency Foundations™ Training Program

TALENT ASSESSMENT

ACRP Project Management Best Practices™ Training Program

FOUNDATIONAL TRAINING

ACRP Competency-Based Approach to PI Responsibilities™ Training Program

FOUNDATIONAL TRAINING

ACRP CRA Core Competency Foundations™ Training Program

Individuals Provided ACRP Membership through Organization Membership Receive Complimentary Access to the Following Training, Continuing Education, and Certification Exam Preparation Modules

24 Training Modules

1. Good Clinical Practice Simulation
2. Introduction to Decentralized Clinical Trials (DCTs)
3. Informed Consent Simulation
4. ACRP Clinical Research Knowledge Assessment (CRKA)
5. Risk-Based Monitoring: The Essentials
6. Ethics and Human Subject Protection: A Refresher Course
7. Investigator Responsibilities
8. Improving Recruitment, Accrual, and Retention in Clinical Trials
9. Trial Feasibility and Selection: Their Impact on Accrual
10. Implementing a Patient-Centered Informed Consent Process
11. Using Metrics to Improve Subject Recruitment and Retention
12. Introduction to Clinical Trials
13. Site Quality Management Tools: SOPs, Metrics, and Training
14. Inspection Readiness: Best Practices for Managing Clinical Trial Inspections
15. Mastering the Event Reporting Cycle: Understanding Your Impact on Patient Safety
16. Understanding Clinical Trial Protocols: Key Considerations for Effective Development and Feasibility Review
17. Theory to Practice: Operationalize Your Clinical Study Protocol
18. Mastering Budgeting at Your Site: Building and Negotiating Clinical Trial Budgets that Make Sense
19. Key Skills for Ensuring Quality Control through Risk-Based Decision Making
20. Form FDA 1572: Get It Right the First Time
21. Ethics and Human Subject Protection: A Comprehensive Introduction
22. The Drug Development Process: Improving Trial Feasibility and Exploring Your Growth Potential
23. Building Quality Management Systems for Sites and Sponsors: Root Cause and CAPA
24. eResearch: Managing Clinical Trials in an Electronic Environment

200+ Continuing Education Modules

- All Available Live Webinars
- All Available Recorded Webinars
- All Available Recorded Sessions from ACRP Annual Conference
- All Available Home Study Tests

Certification Exam Preparation Resources

- Certification Exam Practice Exercise
- ICH Gap Analysis
- ACRP Certification Exam Preparation eLearning Course

WORKFORCE DEVELOPMENT

The industry has the opportunity to address the workforce issue in a way that it never has looked at it before.

FDA U.S. FOOD & DRUG ADMINISTRATION

"Solve difficult problems with great people."

PARTNERS ADVANCING THE CLINICAL RESEARCH WORKFORCE

PARTNERS ADVANCING THE CLINICAL RESEARCH WORKFORCE

MERCK · Genentech · PPD · CSL Behring · Nationwide Children's · AdventHealth · Biogen · Duke · florence · HCA Healthcare · JAVARA · Health Research BC · North Carolina Biotechnology Center · parexel · RUTGERS · SARAH CANNON · UCDAVIS · Veeva · NIH National Institutes of Health · FDA U.S. FOOD & DRUG ADMINISTRATION · Medical Center of the Americas Foundation

ACRP

WORKFORCE DEVELOPMENT

A glaring disconnect is evident between the visionary discourse on how to revolutionize the clinical research enterprise and the sober recognition that operationalization of any such vision rests on the shoulders of a workforce that's in dire straits."

Just as clinical research is the bedrock of drug and device development, sites are the bedrock of clinical research operations so, when sites cannot perform, the entire industry suffers."

Alongside these costly delays, the workforce crisis imperils the quality of clinical research, including compliance with good clinical practice and the integrity of the data generated."

—JOURNAL FOR THE SOCIETY OF CLINICAL TRIALS, JUNE 2023

SHARING OUR VISION FOR THE FUTURE

Increased awareness of the profession, career pathways, and how to get the training and experience needed to advance

Greater collaborations across industry groups (e.g., ACRP, CTTI, CoAPCR, MRCT, SCRC, TransCelerate, etc.) to align efforts, share best practices, develop standards

Globally recognized entry level competencies established with registered site organizations accepting this as their standard

Pipelines between grade schools, high schools, and colleges or training programs; pipelines between colleges and employers; more internships and mentorship

I JUST FELL INTO IT

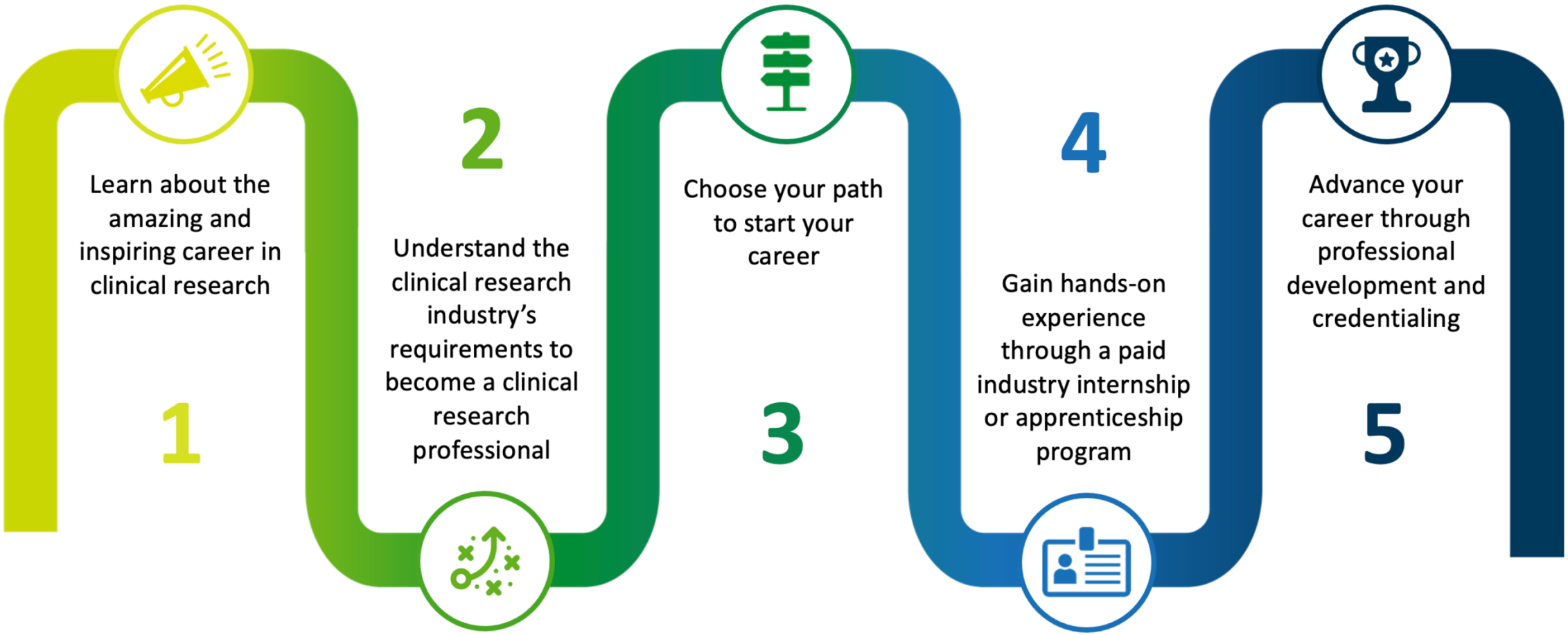
I CHOSE IT

WHO IS FLYING YOUR CLINICAL TRIAL?

HOW TO BECOME A COMMERCIAL PILOT

1. Earn Private Pilot Certificate
2. Add Instrumental Rating
3. Earn Commercial Pilot Certificate
4. Earn Flight Instructor Certificate
5. Add Multi-Engine Rating
6. Gain Experience & Interview
7. Commercial Pilot Job

IT'S TIME TO BUILD A CLEAR PATH FOR A CAREER IN CLINICAL RESEARCH



ACRP

WHO IS A CLINICAL RESEARCH PROFESSIONAL?

- Diverse candidate
- Hired based on skills first vs. years of experience in clinical research
- Competent in clinical research foundational knowledge
- Proven hands-on experience through an internship or apprenticeship
- Seeking an opportunity for mentorship

"I heard about the amazing clinical research profession, and I chose to pursue a career in clinical research. I am confident that I will be hired because I followed the pathway to gain the knowledge that is expected by companies and organizations who hire clinical research professionals."

ACRP

PARTNERS ADVANCING THE CLINICAL RESEARCH WORKFORCE

Ensure a diverse, research-ready and sustainable clinical research workforce essential to advancing therapies that improve global human health

STRATEGIC PRIORITIES

BUILD AN IDENTITY

Build a powerful brand and professional identity for the clinical research profession

CHANGE HOW WE HIRE

Drive Industry-wide adoption of a (competency-based) approach to hiring entry-level clinical research professionals

OPEN DOORS TO A NEW CAREER

Ensure access for all to education, training, and professional development in the clinical research industry

Thank you!

Emergency Preparedness:
Barbara Bierer

MULTI-REGIONAL CLINICAL TRIALS

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

Proposed Rapid Response Appendix to the JTF Framework

Barbara Bierer, MD

Professor of Medicine, HMS
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With special thanks to:

Sarah Evenson, MRCT Center
Jack Ferdman JD, MRCT Center
Sandor Kerpel Fronius, Semmelweis University

14 Nov 2023

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Crisis-Borne Disruptions in Clinical Research Take Many Forms

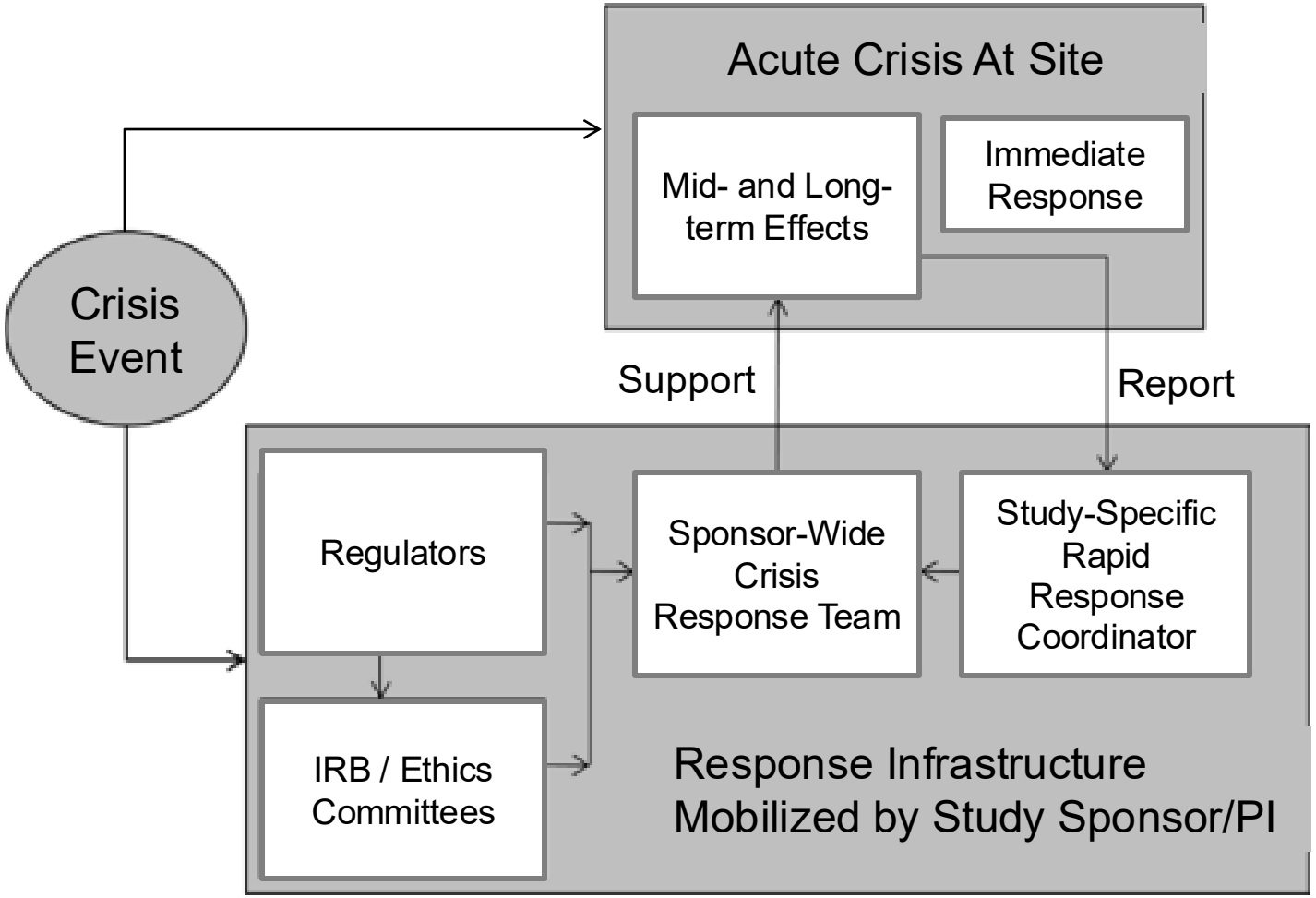
Communicable Diseases	Natural Disasters	Acts of War or Violence
• COVID-19 • Ebola	• Hurricane Katrina	• Russian invasion of Ukraine

- Character
- Timing: Onset, Length, Resolution
- Intensity

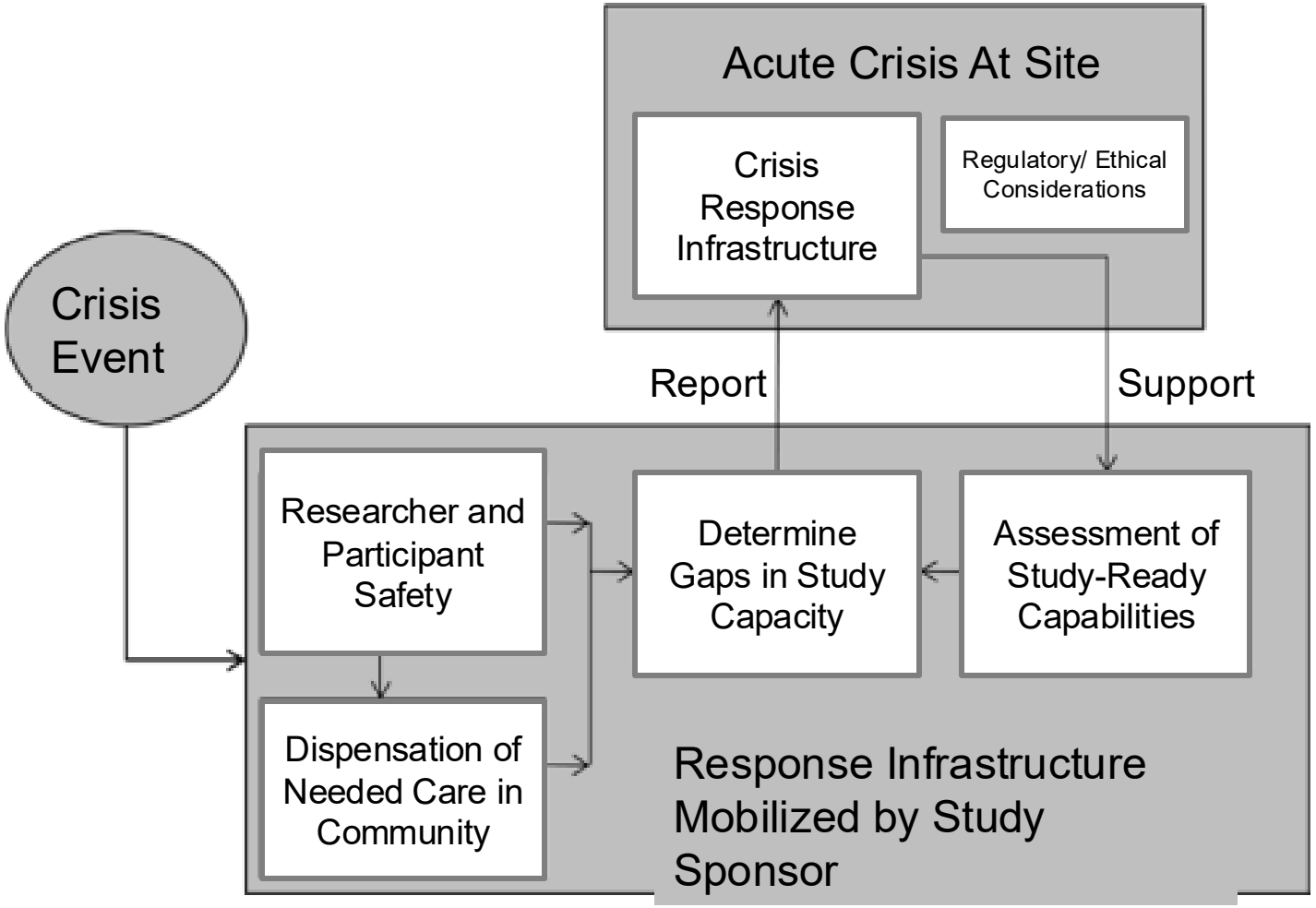
- Impact on Research
  - Ongoing (e.g., modified, paused, discontinued)
  - New research on disruption itself

Crisis-borne disruptions may implicate all JTF Core Competencies but may do so differently depending on type, location, and severity of disruption

Effective Crisis Responses Require Crisis Capacity Building at Sponsor Level



Effective Responses Require Skilled Dynamic Assessment at Site Level



Matrix of Competencies and Concerns: Sponsor Level

Core Competency	Sponsor Level Implication
Scientific Concepts and Research Design	Are protocol deviations warranted to maintain scientific rigor?
Ethical and Participant Safety Considerations	Is study question still in equipoise following crisis disruption?
Medicines Development and Regulation	Can study treatments be safely received and samples for further study safely shipped out from distal site?
Clinical Trials Operations and Good Clinical Practice	Are pre-crisis records accessible and post-crisis records able to comport with GCP requirements?
Study and Site Management	Can researchers and participants relocate outside of crisis area?
Data Management and Informatics	Are cloud-based record redundancies built into study protocols complete?
Leadership and Professionalism	Have study sponsors built response training into staff onboarding and participant recruitment processes?
Communication and Teamwork	Do crisis response teams have clearly established chains of command and information cascades to enable rapid crisis responses?

Matrix of Competencies and Concerns: Site Level

Core Competency	Site Level Implication
Scientific Concepts and Research Design	Has crisis compromised scientific rigor in sample collection or storage?
Ethical and Participant Safety Considerations	Medical professionals duty-bound to deliver care as needed in crisis situation
Medicines Development and Regulation	Can study treatments be adequately stored and safely dispensed?
Clinical Trials Operations and Good Clinical Practice	Has the integrity of site-based clinics been compromised?
Study and Site Management	Can researchers and participants safely access study sites?
Data Management and Informatics	If internet access disrupted, when were records last backed up?
Leadership and Professionalism	Site-level leaders need access to well established crisis response plan even with no power and/or internet access
Communication and Teamwork	Do participants and lower-level staff understand where and how to access study-specific crisis information and support?

In our assessment, there are specific questions that arise, and specific roles and responsibilities that must be defined, but it is unclear whether any of these represent new competencies requiring a revision of the JTF Framework itself.

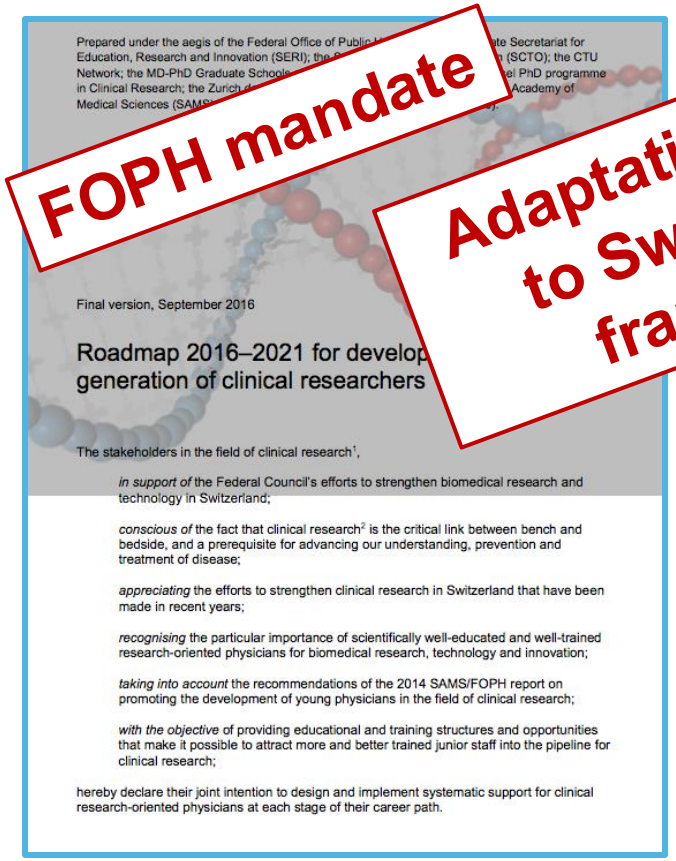
An appendix could annotate the application of competencies to an emergency response.

Thoughts?
Questions and Discussion

Competencies for non-interventional clinical research projects in the Swiss regulatory context

JTF Strategic Global Meeting, November 14, 2023
Melanie Glaettli, Swiss Clinical Trial Organisation (SCTO)

FOPH mandate

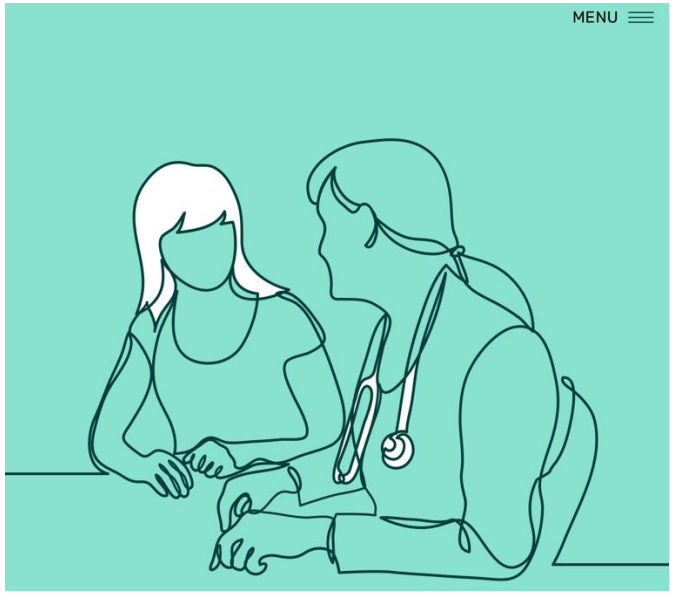


Clinical Research Core Competencies Framework
for clinical trials

Implemented on cr-careers.ch

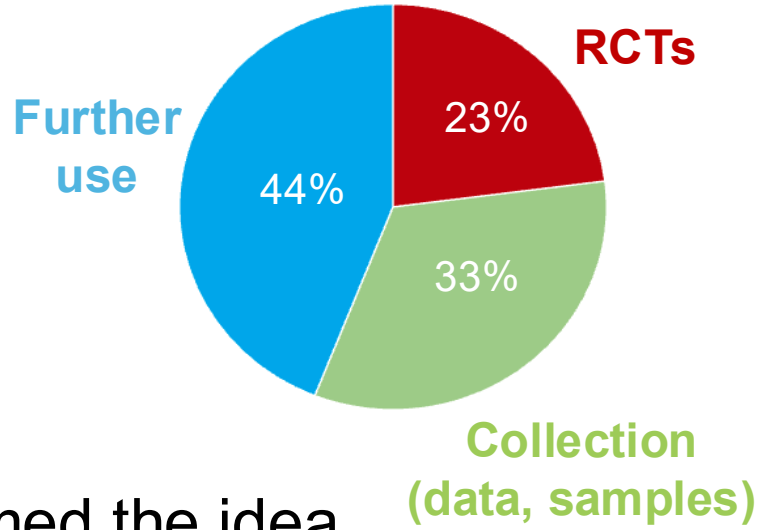
Clinical Research Careers

Core competencies



Why is an adaptation to non-interventional research projects interesting?

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



Raise the awareness of developing the competencies necessary to conduct non-interventional research projects

Swiss legal framework for human research

Human Research Act (HRA)

with human beings | without human beings

Clinical Trials Ordinance (ClinO)

- Medicinal products
- Other clinical trials
- Transplant products, transplantation
- Gene therapies

Ordinance on Clinical Trials with Medical Devices (ClinO-MD)

Medical devices

Ordinance on Human Research with Exception of Clinical Trials (HRO)

- Collection of data and/or biological material (chap. 2)
- Further use of data and/or biological material (chap. 3)

SCTO PLATFORMS

How did we adapt the Framework?

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

- 8 JTF domains
- shorter competency statements (some needed to be removed, e.g., referring to clinical equipoise, investigational product, etc.)
- no reference to GCP (not mandatory for HRO projects in CH)
- no proficiency levels
- 2 columns to differentiate between

Collection of data and/or biological material
(HRO, chapter 2)

Further use data and/or biological material
(HRO, chapter 3)

3.1 Historical context for the development of regulatory processes

Collection of data and/or samples (HRO, chapter 2)	**Further use of data and/or samples** (HRO, chapter 3)
1. Identify and understand historical and current events that have influenced national and international guidelines and regulatory processes concerning human research. 2. Be able to apply and explain contents of national and international guidelines. Example: Researcher understands why informed consent is necessary for research projects (e.g. non-information scandal of Tuskegee study) and develops a protocol which is compliant with the Swiss regulations on research projects (Human Research Act (HRA) and Human Research Ordinance (HRO)).	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects.*

4.7 Monitoring and audits

Collection of data and/or samples (HRO, chapter 2)	**Further use of data and/or samples** (HRO, chapter 3)
1. Consider whether monitoring, quality check, and audits may be of added value for the research project. 2. Develop policies and SOPs in response to monitoring and audit findings. Example: Given an audit report, researcher creates a comprehensive CAPA plan to respond to audits and develops appropriate SOPs.	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects. Even data quality checks can be relevant in large reuse of data and biological material research projects (e.g. registry projects).*

4.5 Safety reporting requirements

Collection of data and/or samples (HRO, chapter 2)	**Further use of data and/or samples** (HRO, chapter 3)
5 statements and 1 examples	*Statements for HRO chapter 2 projects are **not applicable** for HRO chapter 3. Safety is not applicable in further use of data and biological material research projects.*

SCTO PLATFORMS

2.4 Evolution of Requirements for Informed Consent Form

Collection of data and/or samples (HRO, chapter 2)	**Further use of data and/or samples** (HRO, chapter 3)
1. Identify the historical events and key documents, which have led to the development of the current informed consent regulations. 2. Recognise the critical nature of communicating the potential risks or hazards as well as the benefits of a research project using terminology and a manner that is understandable by potential participants during the informed consent process. 3. Apply knowledge of the current national and international regulations, especially concerning data protection measures, when drafting an ICF for a research project. 4. Implement processes and control measures to ensure participant protection regulations' requirements are met. **Example**: Researcher composes and evaluates the ICF in relationship to the protocol to assure that it not only meets current regulations and guidelines but also provides the information needed for a potential participant to make an informed decision.	*Statements for HRO chapter 2 also apply to HRO chapter 3 research projects. Further statements need to be considered:* 1. Investigate whether sites to be included in the research project have implemented the General Consent (GC) allowing the further use of health-related data and biological material already collected during standard of care for research purposes. 2. Develop an appropriate information form (and/or consent form) according to the type of data (genetic versus non-genetic and coded versus uncoded) to be reused in the project (HRO, Art. 28-32). 3. Assess surrogate consent by the ethics committee (HRA Art. 34) allowing exceptional further use of data without consent by participants. **Example**: Researcher contacts person in charge of the institutional General Consent (GC) to assess whether further use project can be carried out with the use of GC.

SCTO PLATFORMS

Next steps

- Review performed with several stakeholders

- **Review by JTF biannual global meeting participants**

  → ANY COMMENT?

- Implementation on cr-careers.ch and further dissemination via newsletters, publication, etc.

Thank you for your attention


Melanie Glaettli


Laura Di Petto


Aurélie Fayet


Caecilia Schmid


Andreja Vujicic Zagar


Verena Küppers


Claudia Fila


Simone Kälin


Antoine Poncet


Sven Trelle

Update on the use of the JTF Framework in Canada under 3CTN &
Update on the Arabic Translation:
Christine Samara

Canadian
Cancer Clinical
Trials Network

3CTN Objectives

Christine Samara, 3CTN PSC member
Performance Strategy Sub-Committee (PSC)

November 2023

Overview of 3CTN

The Canadian Cancer Clinical Trials Network (3CTN) is a pan-Canadian initiative to improve recruitment, efficiency and quality of academic clinical trials

Member Cancer Centres	• Contribute to/access the 3CTN Academic Cancer Trial Portfolio, report on Portfolio trials' performance and accrual. • Collaborate on common initiatives and share best practices via the innovative Network structure
Patient and Public Involvement (PPI)	• Patient Representatives, Patient Groups, Advisory Committees • Contribute a crucial perspective to clinical trials by providing feedback, insight, expertise and support towards trial activities and initiatives
Governance and Scientific Oversight	• Scientific Advisory Board and Directors ensure the appropriateness and optimal impact of the Network strategic plan and activities • Governance Committees provide oversight for 3CTN management and support key functions: The trials Portfolio, Performance, PPI
Coordinating Centre	• Central support for operations, project management, strategic planning & governance and communications

Cancer Centre Site – Research Core Competencies

Improving the performance and quality of academic, multi-centre trials on the 3CTN Portfolio is a shared priority for the current business period, 2022-2027

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

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

- Promote the capacity for high-quality cancer clinical research
- Highlight identified core competency gaps – both locally and shared, and
- Link to available, best-practice training and education resources by core competency domain/sub-domain

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

Canadian Cancer Clinical Trials Network

Joint Task Force Core Competency Framework

JTF Core Competency framework defines core knowledge and skills necessary for conducting clinical research.

- *Support onboarding, orientation and core training of staff*
- *Inform role descriptions, performance evaluations, career ladders*

Canadian Cancer Clinical Trials Network

Network Approach to Core Competency

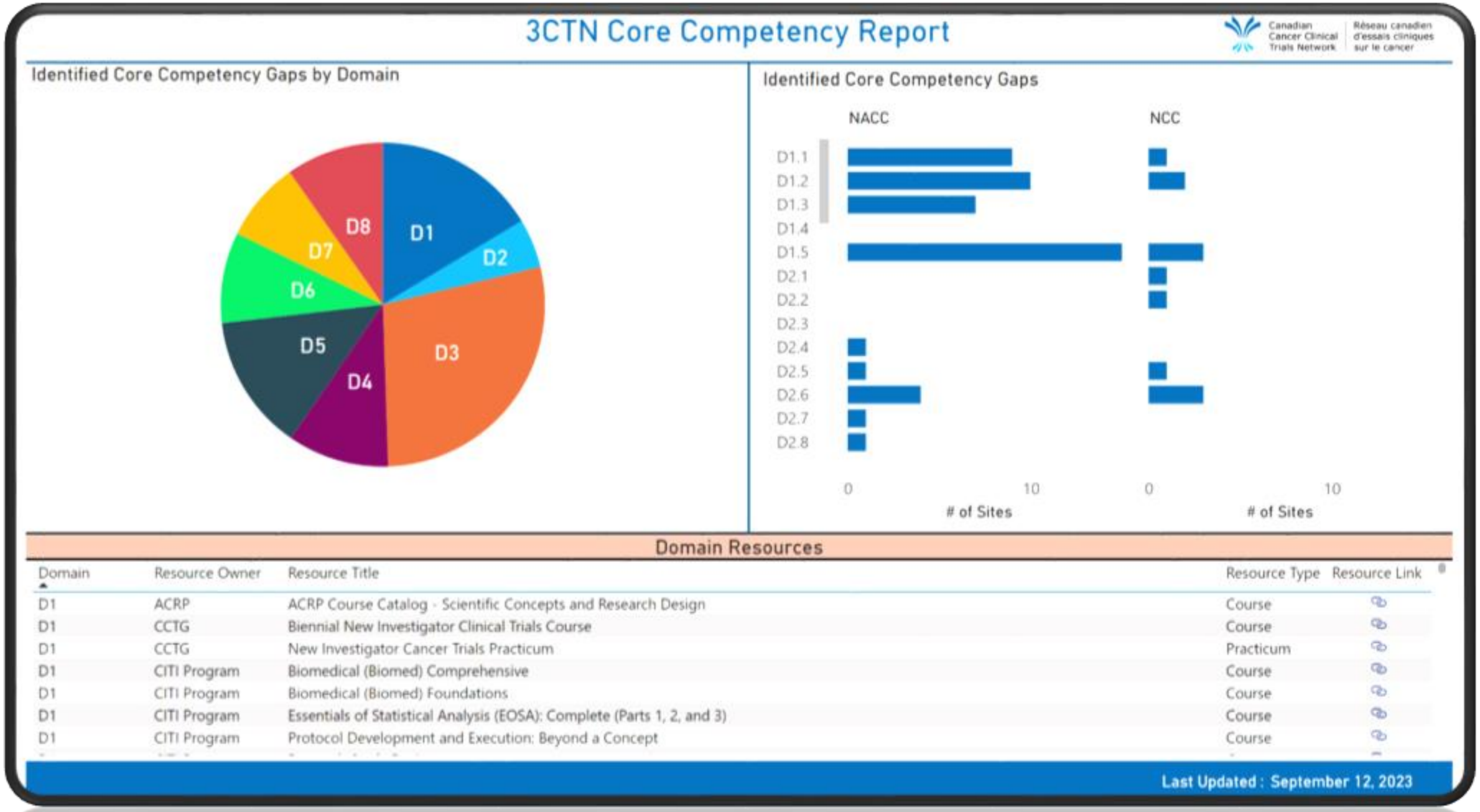
On a Global scale:

Support for validation and proof-reading of JTF's French translation to enable use by CRPs in jurisdictions where it would be of value

National progress to date:

- Identified overall Network priorities to address reported gaps
- Facilitated sharing of best practice learning and training resources, expertise across the Network
- Created the 3CTN Core Competency Report to enable:
  - Direct links to learning resources associated with each sub-domain into a single tool
  - Visualization of Network-wide, regional, or site-specific strengths and gaps
  - Trial unit management in highlighting support needs for individual/team development

Canadian
Cancer Clinical
Trials Network



Canadian Cancer Clinical Trials Network

Future Directions

- Manuscript pending for publication
- Support training targeted to address priority core competency domains
- Develop evaluation framework:
  - # of sites that have used framework in staff development plans
  - Track overall changes for competency statement gap areas from 2022 survey and identify emerging gaps
  - Capture a measure of competency levels within each statement
  - Assess effectiveness of initiatives to support Network learning objectives

Integration of the JTF as a 3CTN Objective and its utilization at the Odette Cancer Center in Toronto, Canada.

Sunnybrook Research Institute
Sunnybrook Health Science Center

Christine Samara
Manager, Quality Assurance and Education
Odette Cancer Centre Clinical Research Program

November 2023

Tertiary Hospital
Toronto, Ontario. Canada

- Internationally recognized health science center
- Affiliated with University of Toronto (U of T)
- Leading research institute

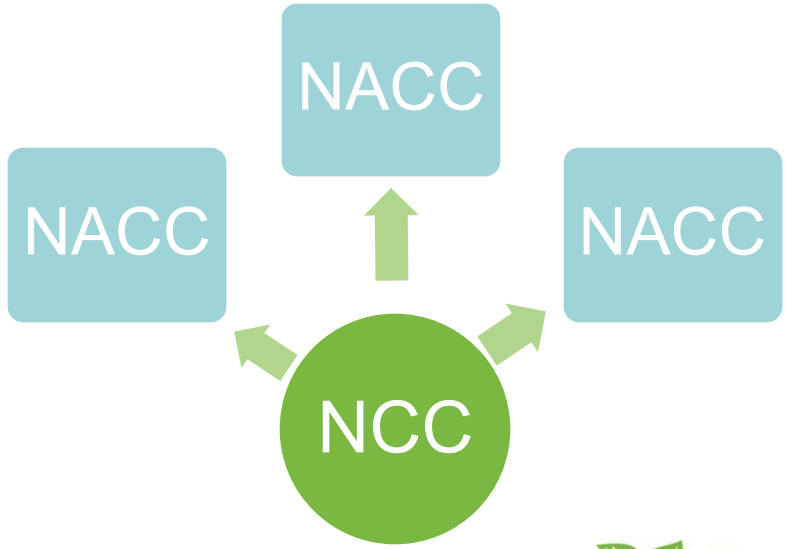
Sunnybrook as a NCC (3CTN)

The Odette Cancer Center (OCC) is one of the 3CTN Network Cancer Centers (NCC) with 2 affiliate sites as Network Affiliate Cancer Centers (NACCs) & 1 in the pipeline.

NCCs are larger centres with capabilities to recruit cancer patients to a broad portfolio of trials, and to work with Network Affiliated Cancer Centres (NACCs) to ensure broader patient access to trials.

OCC Clinical Research Program

- Around 55 staff
- Largest research group within the hospital



New Training Initiative Focused on the JTF Core competencies for CRP @ SRI OCC CR

- SRI OCC CR implemented the JTF in July 2021 as part of the onboarding of new staff

- 3CTN Grant Cycle (2022-2027): Ongoing efforts to improve the efficiency and effectiveness of clinical trial sites across the Network
  - Diagnostic tool for sites to assess areas of competency and deficiency within their clinical trial staff
  - Promote a competency framework for clinical research professionals
  - Identify area (s) of potential improvement for their trial unit

November 2023

CRP and CR Workforce

- BandAid' solutions
- Unlike PIs, CRPs are generally overlooked as key stakeholders in the clinical research ecosystem
- Most CRPs find their way into the profession by chance
- Increase in the number and complexities in clinical trials
- Few institutional oversight mechanism

Table 1. Key areas for workforce regeneration.

Imperatives
• Prioritize the creation of a strong and clear identity for the clinical research professional and promote visibility, recognition, and value of CRPs in interprofessional collaboration
• Establish a baseline global standard of excellence in training and qualification for CRPs
• Elevate and standardize clinical research roles across all the enterprise to support salary equity and ensure funding keeps pace with workforce growth
• Raise awareness of the clinical research profession as a distinct career goal for both future generations and professional lateral movers
• Establish universal, competency-based definitions of clinical research roles to support equitable assessment of workforce readiness among entry-level applicants and professional advancement throughout clinical research careers
• Ensure a diverse workforce by providing access and advancement in training for historically underserved communities

CRP: clinical research professionals.

The JTF Core Competency Framework—a matrix of competency domains that objectively define the knowledge, skills, and attitudes necessary for conducting safe, ethical, and high-quality clinical research

Ibrahim, S. (2022). Adapting the Joint Task Force Core Competency Framework for Clinical Research Professionals: A Canadian Paediatric Research Perspective, SRAI. https://www.srainternational.org/blogs/srai-jra2/2022/10/14/adapting-the-joint-task-force-core-competency-fram

Freel SA, Snyder DC, Bastarache K, et al. Now is the time to fix the clinical research workforce crisis. Clinical Trials. 2023;20(5):457-462. doi:10.1177/17407745231177885 https://journals.sagepub.com/doi/10.1177/17407745231177885

November 2023

Define Professional Roles

Revised Job Titles and Job Description

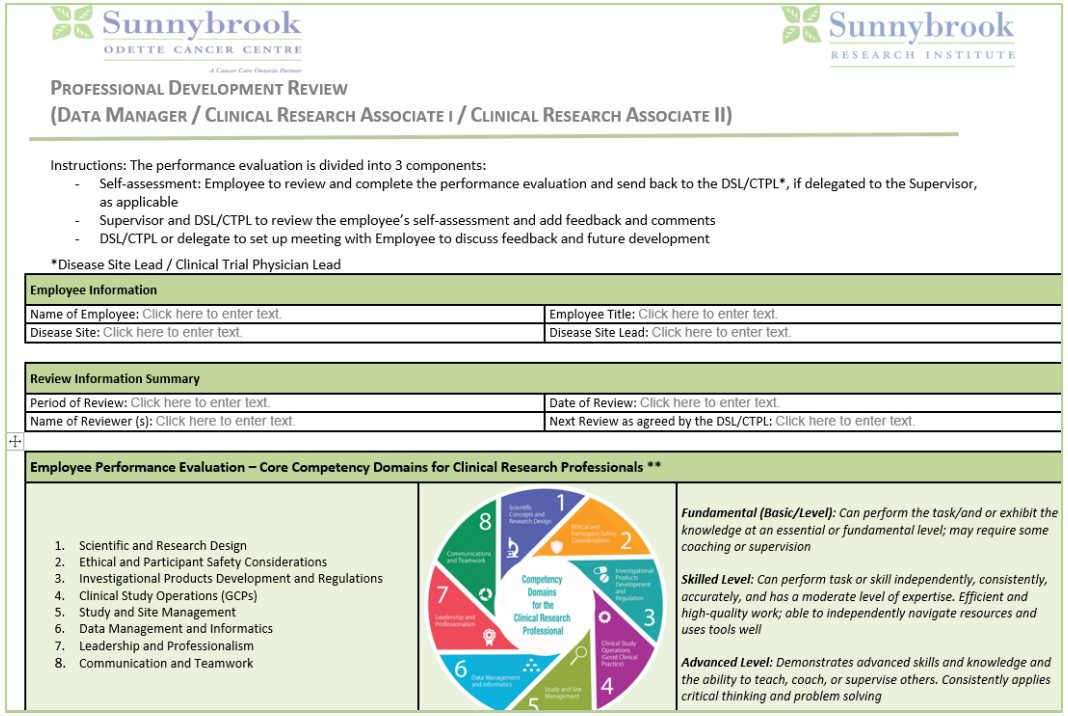
- Created a mechanism for growth

Data Manager	CRA I *	CRA II *
Supervisor *		

*Protocol Activator

Professional Development Review

- Initiated draft in Summer 2022
- Pilot conducted in Q2 2023
- Revisions being made following the pilot phase – Q3 2023



Sunnybrook ODETTE CANCER CENTRE

Sunnybrook RESEARCH INSTITUTE

PROFESSIONAL DEVELOPMENT REVIEW
(DATA MANAGER / CLINICAL RESEARCH ASSOCIATE I / CLINICAL RESEARCH ASSOCIATE II)

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

*Disease Site Lead / Clinical Trial Physician Lead

Employee Information	
Name of Employee: Click here to enter text.	Employee Title: Click here to enter text.
Disease Site: Click here to enter text.	Disease Site Lead: Click here to enter text.

Review Information Summary	
Period of Review: Click here to enter text.	Date of Review: Click here to enter text.
Name of Reviewer (s): Click here to enter text.	Next Review as agreed by the DSL/CTPL: Click here to enter text.

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

1. Scientific and Research Design
2. Ethical and Participant Safety Considerations
3. Investigational Products Development and Regulations
4. Clinical Study Operations (GCPs)
5. Study and Site Management
6. Data Management and Informatics
7. Leadership and Professionalism
8. Communication and Teamwork

Fundamental (Basic/Level): *Can perform the task/and or exhibit the knowledge at an essential or fundamental level; may require some coaching or supervision*

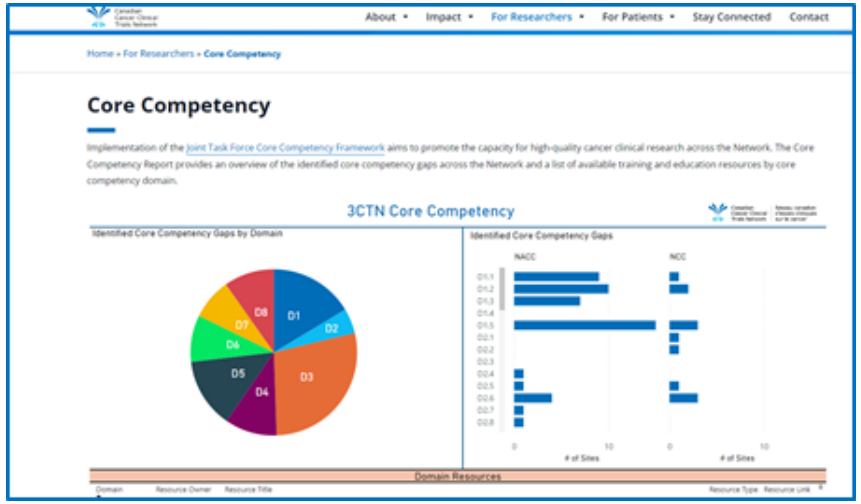
Skilled Level: *Can perform task or skill independently, consistently, accurately, and has a moderate level of expertise. Efficient and high-quality work; able to independently navigate resources and uses tools well*

Advanced Level: *Demonstrates advanced skills and knowledge and the ability to teach, coach, or supervise others. Consistently applies critical thinking and problem solving*

November 2023

Professional Development Review

- Changed from “Employee Performance” to “Professional Development”
- Added guidance for the staff with examples for self assessment
- Minor edits to the content in terms of applicability to the different job roles
- Added ink to the 3CTN Core Competency Report for training resources



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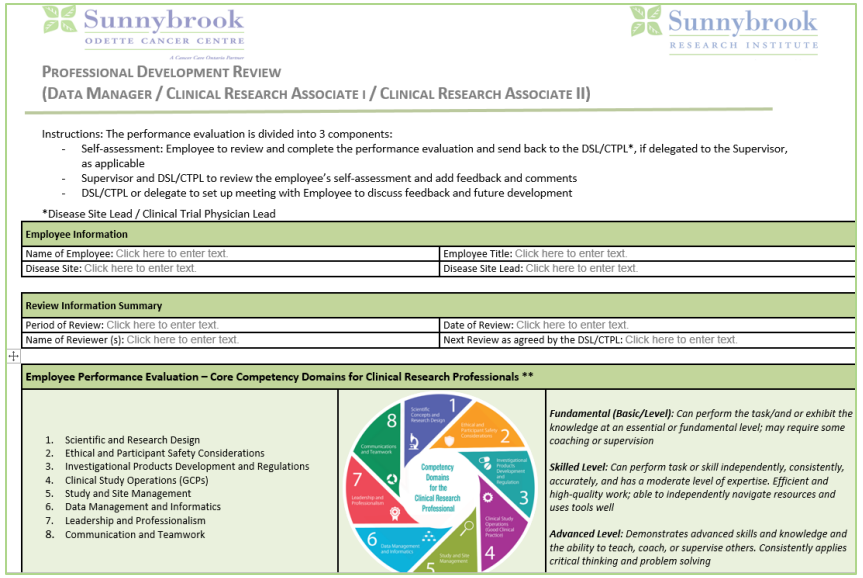
Professional Development Review

- Implement across the Odette Cancer Centre Clinical Research Program – Q4 2023



Sunnybrook ODETTE CANCER CENTRE

Sunnybrook RESEARCH INSTITUTE

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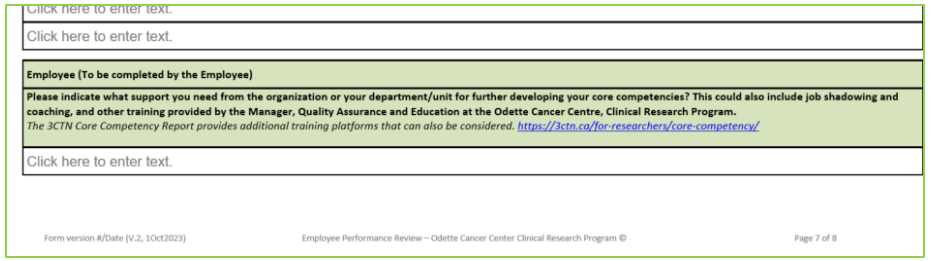

Click here to enter text.

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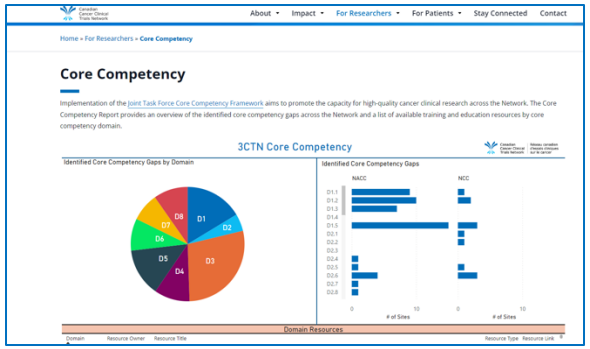
Employee (To be completed by the Employee)

Please indicate what support you need from the organization or your department/unit for further developing your core competencies? This could also include job shadowing and coaching, and other training provided by the Manager, Quality Assurance and Education at the Odette Cancer Centre, Clinical Research Program.
The 3CTN Core Competency Report provides additional training platforms that can also be considered. https://3ctn.ca/for-researchers/core-competency/

Click here to enter text.

Form version #/Date (V.2, 1Oct2023) Employee Performance Review – Odette Cancer Center Clinical Research Program © Page 7 of 8



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Sunnybrook HEALTH SCIENCES CENTRE

Professional Development Review

Two level review

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

Self assessment	Reviewers
✓ Honest assessment ✓ Self reflect / consider strengths and areas of improvement ✓ Personal growth ✓ Self awareness ✓ Opportunity to list goals and objectives for the upcoming year	✓ Feedback from employee ✓ How employee see themselves (team and organization) ✓ Motivation (beyond salary) ✓ Achievements ✓ Growth

Next Steps

- Institution
  - Implement the Performance Evaluation across the Odette Cancer Centre Clinical Research Program – Q4 2023 & Q1 2024

- 3CTN network sites
  - Collaborate with leading research sites to assess training needs and create training material for CRPs

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Deploying the JTF framework across the world

Arabic Translation

Christine Samara

November 2023

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

UNITED ARAB EMIRATES
MINISTRY OF HEALTH & PREVENTION

الإمارات العربية المتحدة
وزارة الصحة ووقاية المجتمع

Arabic translation of the MRCT JTF Core Competency Framework

- Coordinated by Christine Samara

- Translation has been conducted by the UAE Ministry of Health and Prevention
  - Dr. Khalil Qayed, Director National Center for Health Research
  - Dr. Ahmed Radeef Ibrahim Alosi, Research Consultant

November 2023

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

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MINISTRY OF HEALTH & PREVENTION

الإمارات العربية المتحدة
وزارة الصحة ووقاية المجتمع

Identified the organization for collaboration

Initial contact & agreement with Dr. Khalil Qayed.

November – December 2022

Translation Plan

Discussed the plan for document translation & progress with Dr. Qayed and Dr. Alosi.

Received preliminary draft of 3 domains.

February – April 2023

Translation Phase

Completed the initial draft for all domains.

Initial contacts made validation phase.

May – September 2023

Validation / Proof reading Phase

Ongoing validation / Proof reading Phase

October – December 2023

November 2023

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وزارة الصحة ووقاية المجتمع

- **Validation expected to be finalized by December 2023**
- **Target to publish the Arabic Translation Q1 2024**
- **Organizations / Institutions involved in the Validation / Proof reading Phase**

Country	Organization / Institution	Contributors
Gulf, Levant and North Africa	Phoenix Clinical Research	Georges Labaki Racha Aaraj
Lebanon	Lebanese American University	Dr. Joseph Stephan Karmen Baroudy
Levant and Iraq	Sanofi	Dr. Marie-Therese Sawaya

November 2023

Open Discussion

Discussion

- Further comments and questions on presentations
- Emerging issues
- Future issues that the JTF might address

Questions, Comments, Suggestions

Questions and discussion

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Stephen Sonstein, PhD
ssonstein@gmail.com