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

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Co-chair, JTF

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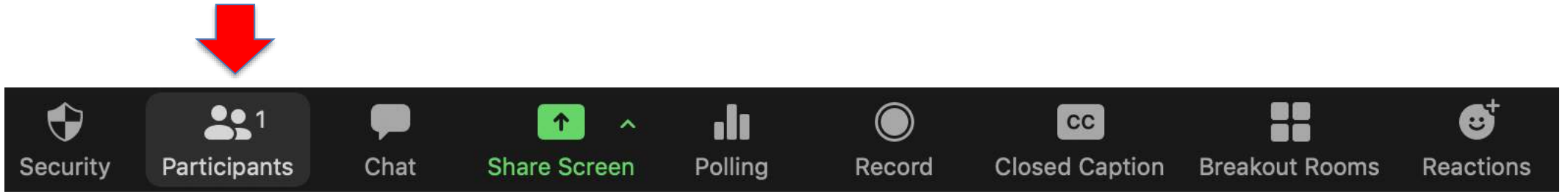
Senior Administrative and Training Manager,
MRCT Center

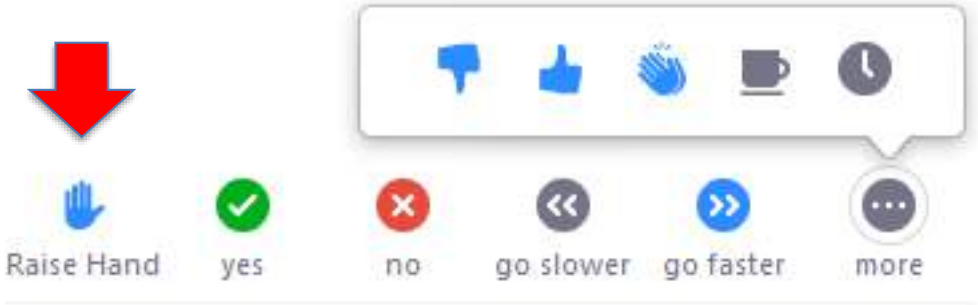
2 May 2023

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

Virtual Meeting

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





This meeting

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

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

Disclaimer:

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

The Multi-Regional Clinical Trials Center (MRCT Center)

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

Our Vision

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

Our Mission

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

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

HARVARD UNIVERSITY

Agenda

Time	Topic	Speaker / Facilitator
9:00-9:10	**Introduction** Overview	**Barbara Bierer, MD** Co-Chair, JTF Faculty Director, MRCT Center
9:10-9:35	**JTF Updates** (5 min each)	
	Use of the JTF Framework in Rutgers MS in CRM Program	**Lisa Palladino Kim, MS** Program Director MS Clinical Research Management Program Rutgers School of Health Professions
	The JTF Framework and Clinical Development Teams in the Biopharmaceutical Industry: Harnessing innovation in data sciences	**Howard Fingert, MD, FACP** Vice President, Medical Oncology ONO Pharmaceuticals Inc, USA
	Integration of the JTF framework as part of the 3CTN's grant objectives and its utilization at the Odette Cancer Centre in Toronto, Canada Updates to the Arabic translation of the JTF Core Competency Framework	**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
	Adapting the JTF framework to non-interventional clinical research	**Melanie Glättli, PhD Life Sciences** SCTO Scientific Coordinator Swiss Clinical Trial Organisation
	Collaboration on Implementing the JTF Framework in China	**Jean Wang** CEO Shanghai Xunyuan Information Technology Co., Ltd **Guo Fuzhen** China's Clinical Trial Development Team Capital Medical University & Beijing Tiantan Hospital
9:35-9:45	**Open Discussion**	**Stephen Sonstein, PhD** Co-Chair, JTF

Agenda cont.

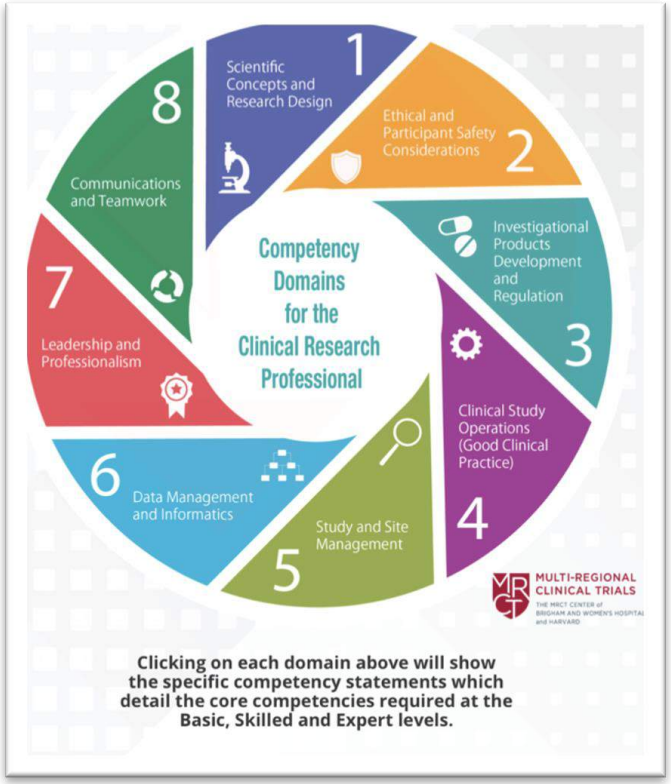
Time	Topic	Speaker / Facilitator
9:45-9:55	**Update: Data Management Task Force**	**Meredith Nahm Zozus, PhD** Professor, Div. Chief and Director of Clinical Research Informatics University of Texas Health Science Center San Antonio
9:55-10:05	Discussion	**Barbara Bierer, MD** Co-Chair, JTF; Faculty Director, MRCT Center
10:05-10:15	**Update: Assessment of competencies**	**Elias Samuels, PhD** Program Director of Workforce and Evaluation Michigan Institute for Clinical & Health Research University of Michigan **Susan Murphy, ScD, OTR** Director, Behavioral Research Innovation and Support Program, Michigan Institute of Clinical and Health Research (MICHR) Professor, Department of Physical Medicine and Rehabilitation, Department of Internal Medicine, Rheumatology Division University of Michigan
10:15-10:25	Discussion	**Stephen Sonstein, PhD** Co-Chair, JTF
10:25-10:40	**Adaptations of the JTF Framework to Emergencies**	**Barbara Bierer, MD** Co-Chair, JTF; Faculty Director, MRCT Center With comments by: **Prof. Sandor Kerpel-Fronius, MD, PhD, DSc** Semmelweis University Department of Pharmacology and Pharmacotherapy Budapest, Hungary
10:40-10:50	Discussion	**Barbara Bierer, MD** Co-Chair, JTF; Faculty Director, MRCT Center
10:50-11:00	**Wrap up and next steps**	**Stephen Sonstein, PhD & Barbara Bierer, MD** Co-Chairs, JTF

Professional competencies:
Joint Task Force Core Competency Framework for Clinical Research Professionals

The JTF Core Competency Framework is made up of

8 Competency Domains, broad categories of knowledge, skills, and attitudes necessary for conducting clinical research

47 Competency Statements, specific skills and abilities related to clinical research



- Identify competency statements
- Align and Harmonize similar concepts
- Reviewing and revision with collaborators

1

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

Fundamental Level	Skilled Level	Advanced Level
A1. Recognize the need to apply scientific principles to discovery and development of biomedical investigational products and health-related behavioral interventions	**B1. Apply** scientific principles when implementing a clinical or behavioral study	**C1. Plan** biomedical research according to scientific principles
A2. Explain the basic scientific principles that should be applied during development of biomedical investigational products and health-related behavioral interventions	**B2. Implement** data collection according to scientific principles and based on protocol design	**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.

Joint Task Force Core Competency Framework for Clinical Research Professionals

English

Spanish

Japanese

French

Thai

Bahasa Indonesia

Italian

Forthcoming Q2-3 2023

- Chinese
- Vietnamese

Portuguese in progress

Open call: Frontiers in Pharmacology special issue

https://www.frontiersin.org/research-topics/53591/building-the-clinical-research-workforce-challenges-capacities-and-competencies?utm_source=F-RTM&utm_medium=TED1&utm_campaign=PRD_TED1_T1_RT-TITLE

Open call: Frontiers in Pharmacology special issue

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

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

  - Clinical research roles and professionalism
  - Clinical research academic education, training and competency development, assessment
  - Clinical research professional employment, retention, progression
  - Diversity of the clinical research workforce
  - Applications and contributions of the JTF Framework
  - Clinical research workforce development in the setting of the evolving clinical research paradigm
  - Clinical research team science, defining research teams, workforce spectrum

JTF Updates

Lisa Palladino Kim

RUTGERS
School of Health Professions

Mapping Professional Competencies in a Clinical Research Management Master's Level Program

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

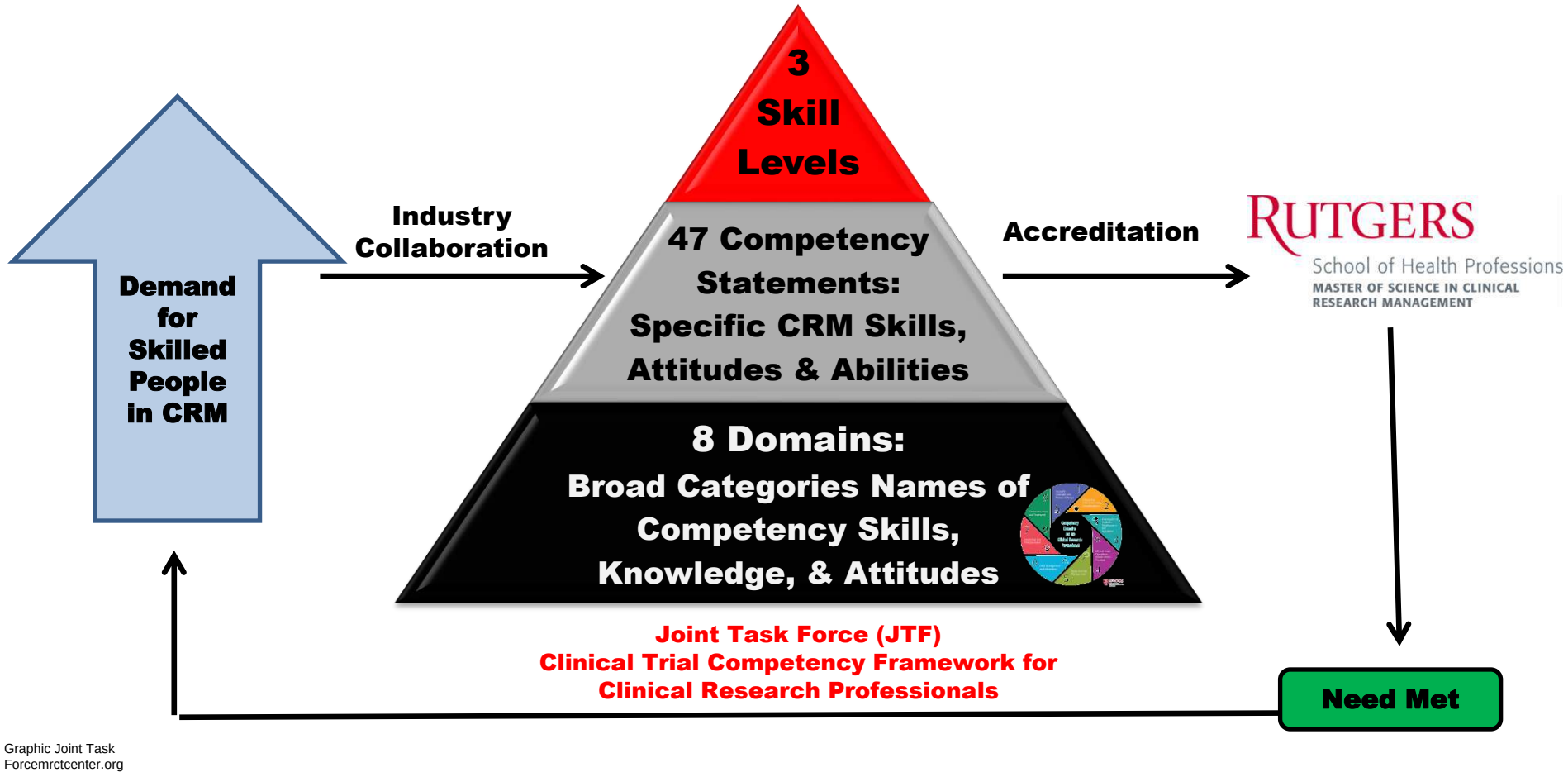
Lisa Palladino Kim, MS
Program Director
Rutgers SHP MS in CRM Program
Presented to JTF Biannual Global Mtg on May 2, 2023

Student Intern
Lauren M. Castelli, MS, MBA
MS CRM Student 2022
Rutgers SHP MS in CRM

MS CRM Program Website

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

Introduction



Graphic Joint Task
Forcemrctcenter.org

Methods

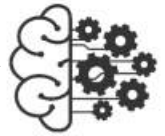
RUTGERS School of Health Professions
MASTER OF SCIENCE IN CLINICAL RESEARCH MANAGEMENT

CRM Courses Fall 2020

Regulatory & Ethics

Research Design

Clinical Operations

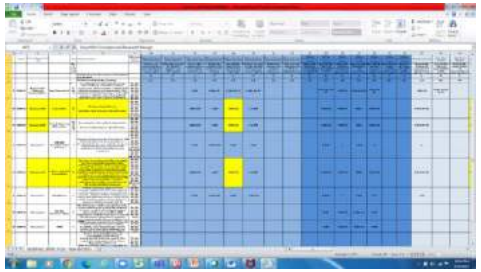


Learning Outcome Assessments

+

canvas

Online Course Program



Build Excel Database

Map Assignments to Joint Task Force Domains, Competencies and Levels

Review and Finalize Course Maps with Professor(s)

Graphics from BioRender

Domain Gap Analysis

Gap:
Effectively communicate the content and relevance of clinical research findings to colleagues, advocacy groups and the non-scientist community

Gap:
Describe the component parts of a traditional scientific publication

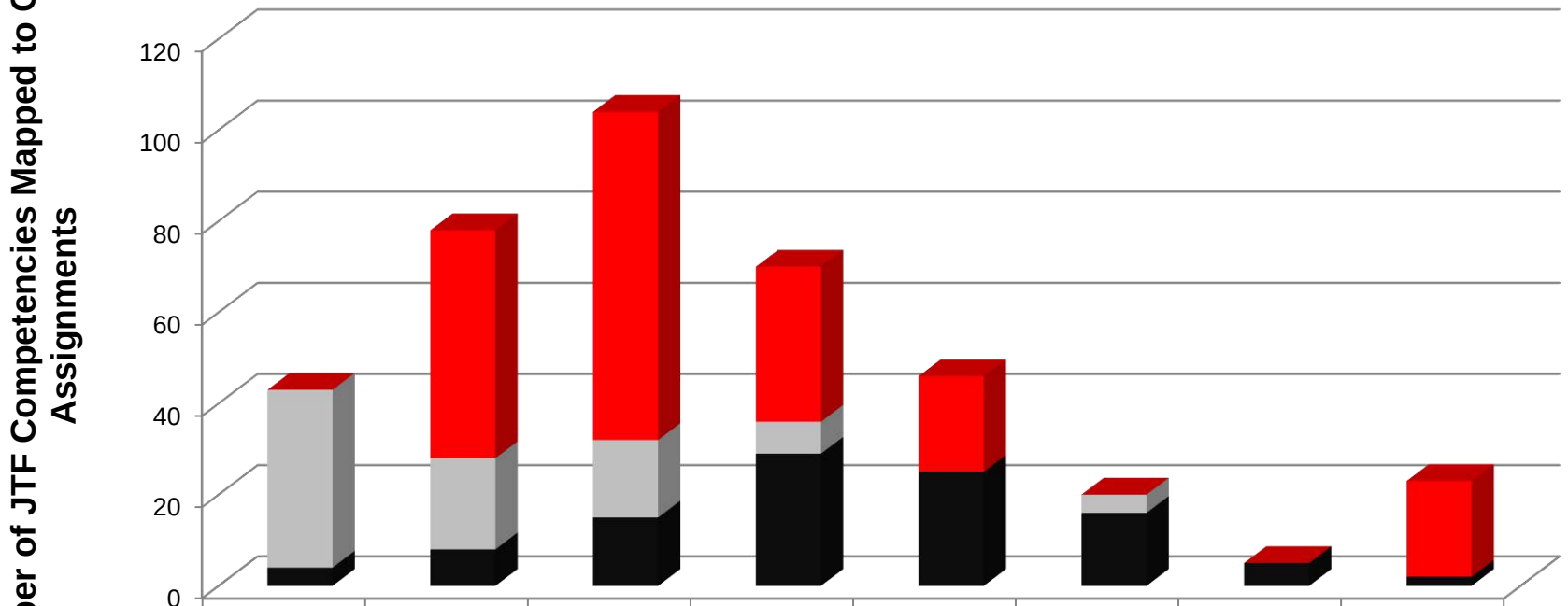
Gap:
Describe the safety reporting requirements of regulatory agencies both pre and post approval

Gap:
Develop and manage the financial, timeline and cross-disciplinary personnel resources necessary to conduct a clinical or translational research study

Gap:
Describe the roles and purpose of clinical trial audits

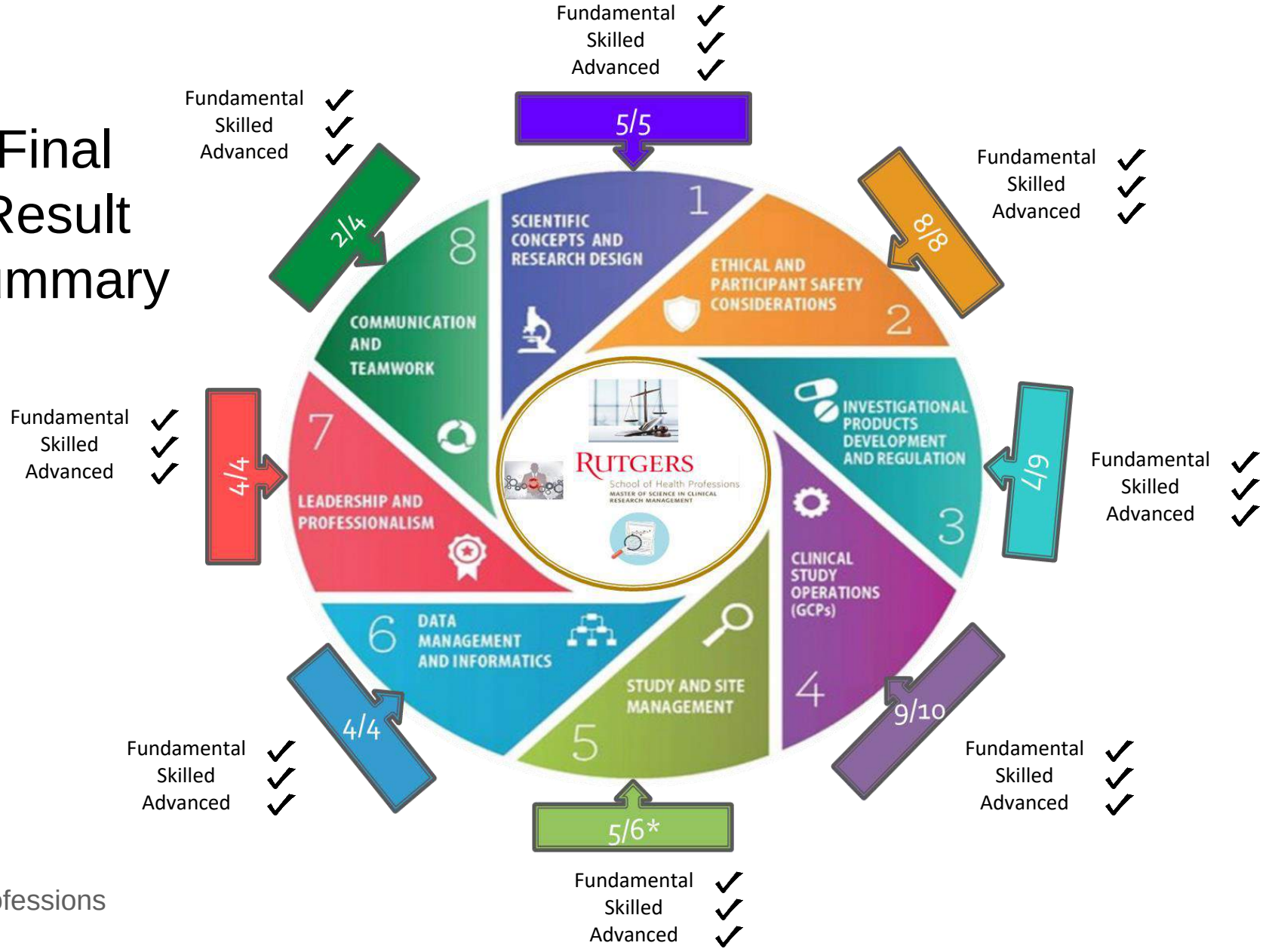
*There is a new competency 5.7 that was not included in the Accreditation Appendix B version and therefore was not counted as a gap in this exercise.

JTF Domains Met in CRM Core Courses
Fundamental Skill Level



	Scientific Concepts and Research Design	Ethical and Participant Safety Considerations	Medicines Development and Regulation	Clinical Trial Operations	Study and Site Management	Data Management and Informatics	Leadership and Professionalism	Communication and Teamwork
Reg and Ethics	0	50	72	34	21	0	0	21
Research and Design	39	20	17	7	0	4	0	0
Clin Ops	4	8	15	29	25	16	5	2

Final Result Summary



RUTGERS
School of Health Professions

Any additional questions,
please contact:

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

E-mail crmprogram@shp.rutgers.edu

Howard Fingert

Howard Fingert, MD, FACP

Vice President Medical Oncology, ONO Pharmaceuticals, USA

Brief BIO:

Global Clinical Development of Heme-Lymphoma and Solid Tumor Therapies

Academic experiences:

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

Industry career:

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

CONVERGENCE OF CORE COMPETENCIES BY CLINICAL RESEARCH TEAMS

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

The JFT Framework, updated document, and domains reflect:

- Teams build on multi-disciplines, structure, constructive interaction
- Updates needed to manage the changing research landscape
- Deep learning builds on interfacing internal and external environments

To make progress we must embrace deep thinking & data sciences

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

Dr. Tachi Yamada inspires focused, deep, data-driven R&D decisions

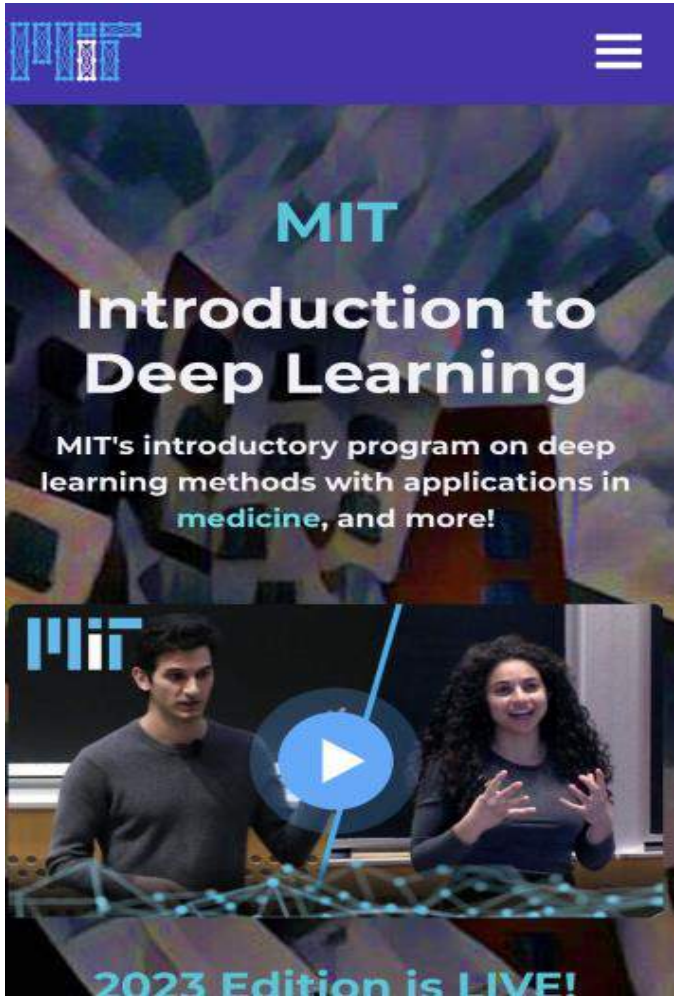
Dr. Tachi Yamada transitioned between academia - Industry former leader at U. Michigan GSK, Takeda, Gates Foundation:

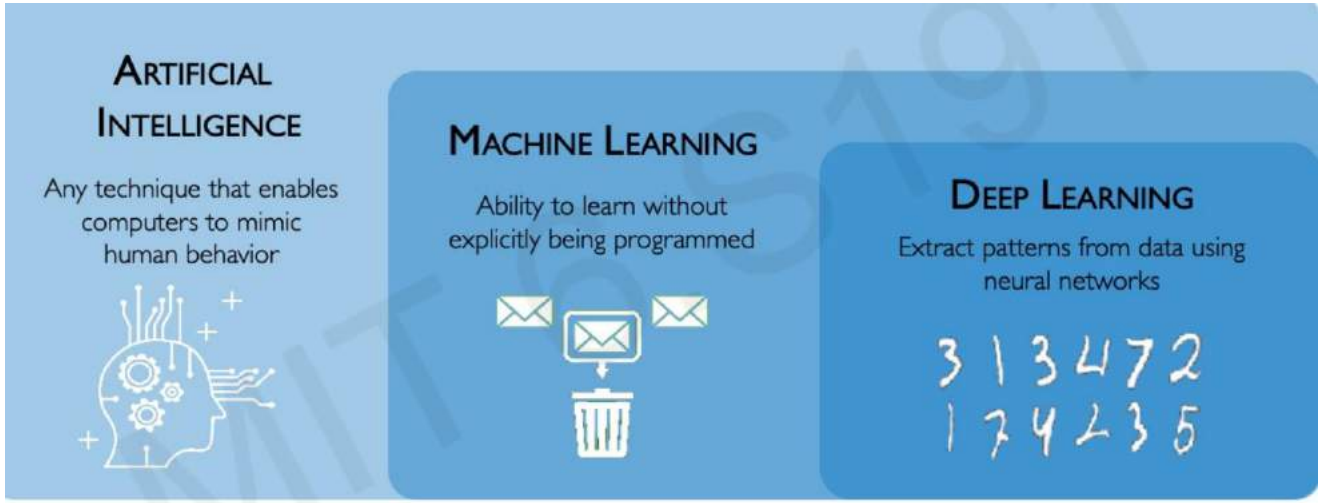
"Beware of being a mile wide…but an inch deep."

DATA SCIENCES, DEEP LEARNING IN ACADEMIA

Advancing multi-regional opportunities in medical research & care

Excerpts from on-line MIT course about Deep Learning and relevant informatics.





Teaching computers how to **learn a task** directly from **raw data**

DATA-SHARING, HARDWARE- SHARING, DEEP LEARNING

Advancing multi-regional opportunities to accelerate progress in medical research & care

Why Now?

Neural Networks date back decades, so why the resurgence?

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

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

3. Software
- Improved Techniques
- New Models
- Toolboxes

MULTI-REGIONAL HARDWARE-SHARING BY TOKYO-1 SUPERCOMPUTER

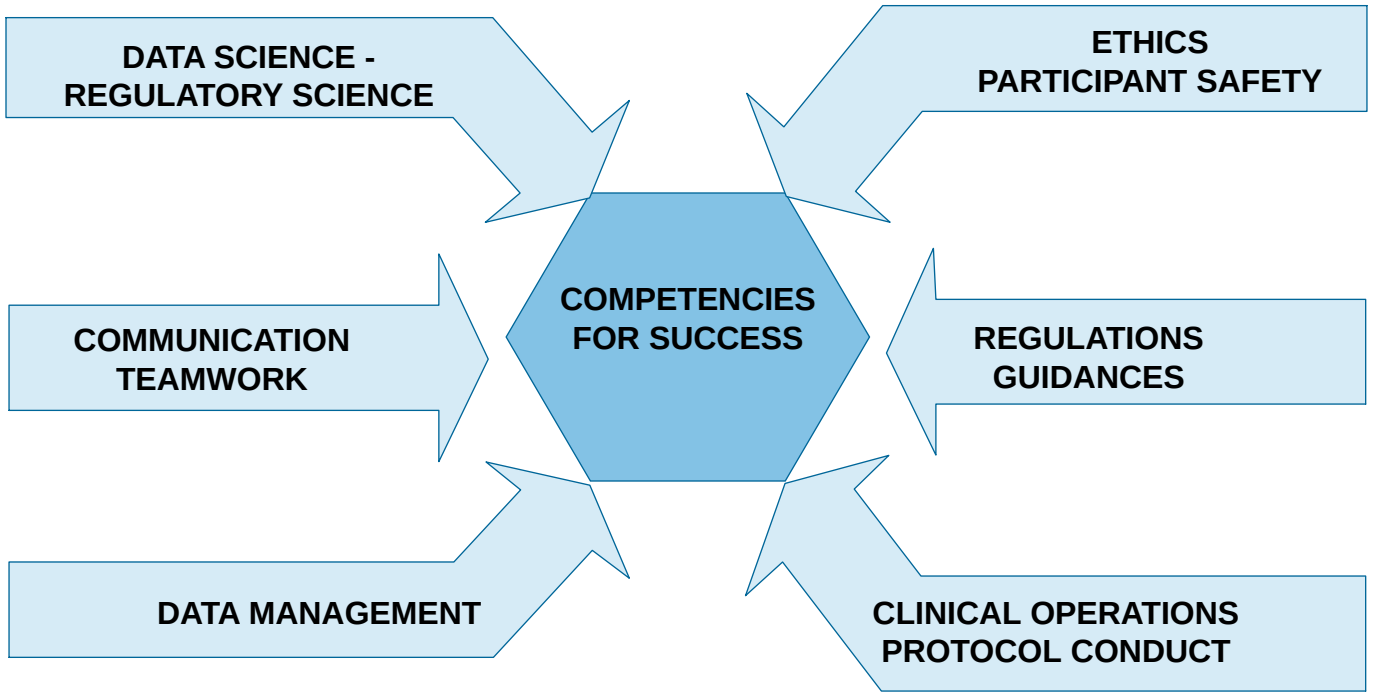
Planned access for artificial intelligence (AI) and other applications

Director Drug Discovery at a global biopharma company was quoted:

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

EXPANDING SKILLS FOR BIOPHARMACEUTICAL CLINICAL DEVELOPMENT

DATA SCIENCES ENABLE NEW R&D METHODS AND COMMERCIAL OPPORTUNITIES



Moderna 2nd-Generation mRNA Cancer Vaccine Shows Promising but Modest Clinical Benefit

← AACR Annual Meeting 2023 Itinerary Planner Home

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Session CTPL01 - Harnessing the Immune System in the Clinic

CT001 - A personalized cancer vaccine, mRNA-4157, combined with pembrolizumab versus pembrolizumab in patients with resected high-risk melanoma: Efficacy and safety results from the randomized, open-label Phase 2 mRNA-4157-P201/Keynote-942 trial

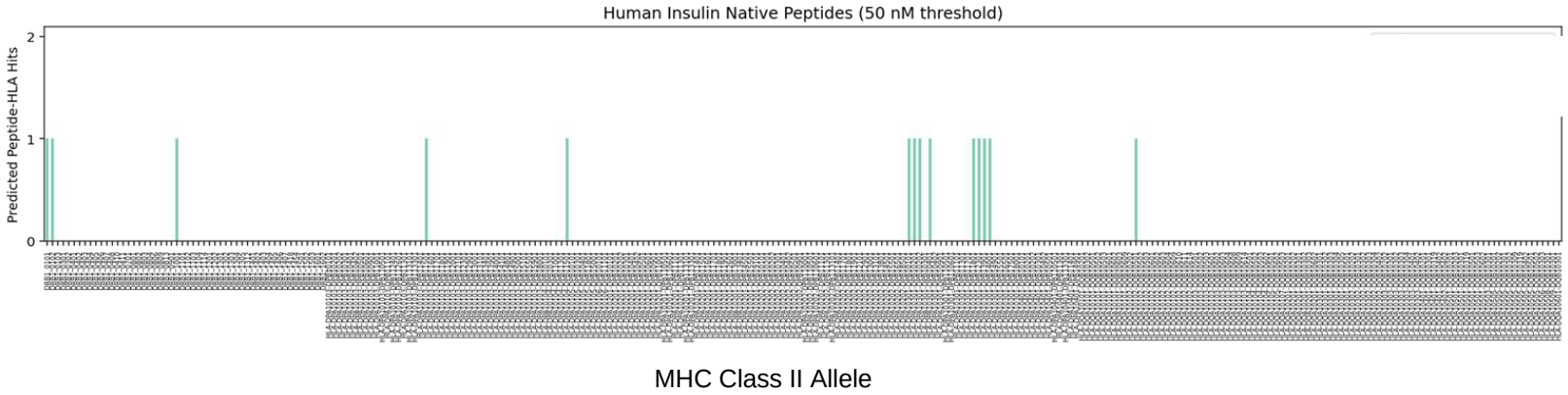
Abstract from American Assn. Cancer Research, April, 2023

- Full journal publication in press
- Phase 3 registration trial planned

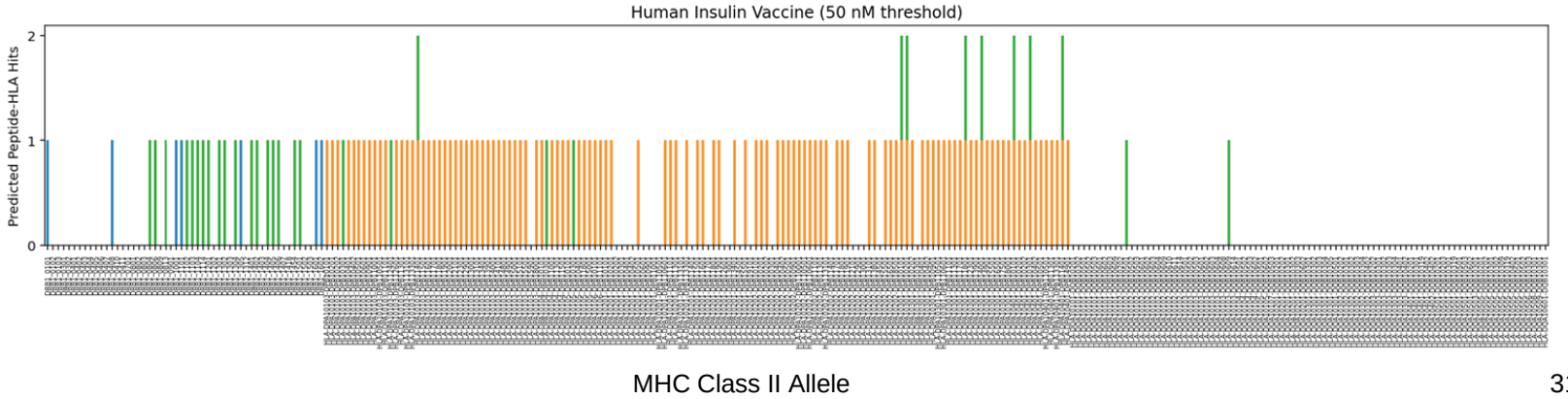
EXAMPLE: *ACTIONABLE* MODERN DATA SCIENCES

Updated AI, Analytics, and Cloud Supercomputer Lead to patented 3rd-Generation, off-the-shelf mRNA Vaccines

Older designs 15.5% population coverage



New Vaccine - 99.9% population coverage



Lower figure illustrates 3rd-Generation, broad coverage & practical 'off the shelf' mRNA vaccine without the burdens from 2nd generation, that required >1 month for surgery; biopsy processing; vaccine manufacture

Navigating
the Stepstones

What sources and competencies are needed to …
- **reduce risks**
- **gain efficiencies**
- **navigate to accelerate progress?**

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

2. Publications in news articles and blogs

3. Publications in peer-reviewed journals

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

5. Collaborating TEAMS, structured to include updated biomedical, regulatory & data sciences

Core Competencies

CONCLUSION

What sources and competencies are needed to …
- **reduce risks, gain efficiencies**
- **accelerate progress?**

Best answer:
Collaborating TEAMS, working together to apply updated biomedical, regulatory & data sciences

Core Competencies

Christine Samara

Canadian
Cancer Clinical
Trials Network

3CTN Objectives

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

Canadian Cancer Clinical Trials Network

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

Canadian Cancer Clinical Trials Network

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

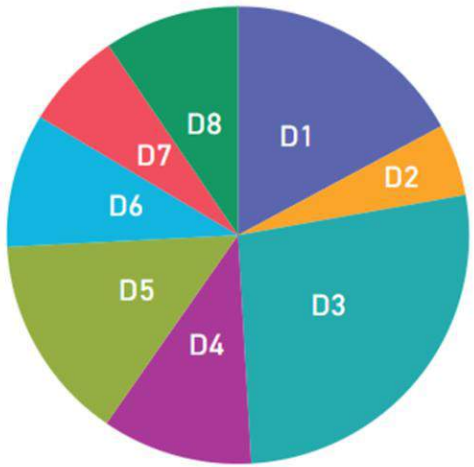
- Promote the capacity for high-quality cancer clinical research
- Highlight identified core competency gaps – both locally and shared, and
- Link to available, best-practice training and education resources by core competency domain/sub-domain

Canadian
Cancer Clinical
Trials Network

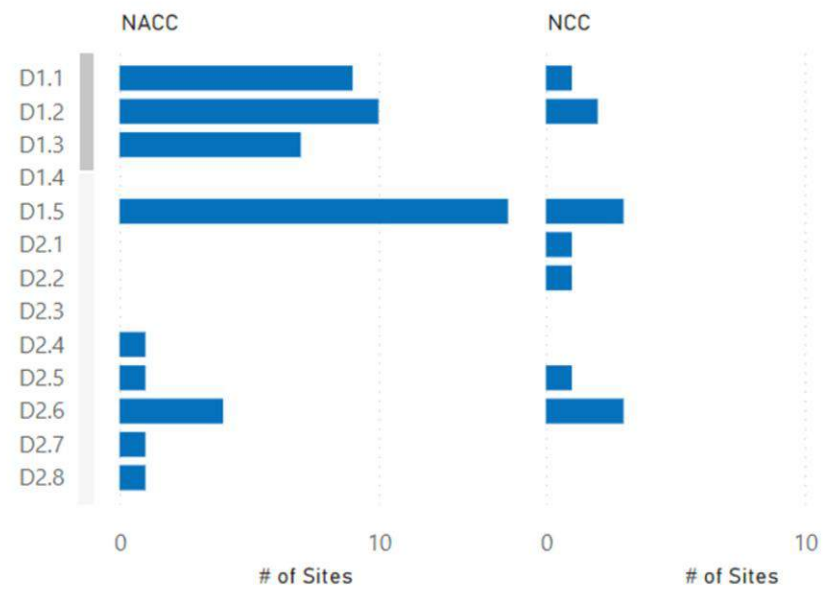
Core Competency Report

Canadian Cancer Clinical Trials Network | Réseau canadien d'essais cliniques sur le cancer

dentified Core Competency Gaps by Domain



Identified Core Competency Gaps



Domain Resources

Domain	Resource Owner	Resource Title	Resource Type	Resource Link
D1	CITI Program	Biomedical (Biomed) Comprehensive	Course	
D1	CITI Program	Biomedical (Biomed) Foundations	Course	
D1	CITI Program	Essentials of Statistical Analysis (EOSA): Complete (Parts 1, 2, and 3)	Course	
D1	CITI Program	Protocol Development and Execution: Beyond a Concept	Course	
D1	CITI Program	Research Study Design	Course	
D1	ACRP	ACRP Course Catalog - Scientific Concepts and Research Design	Course	
D1	Duke Office of Clinical	Duke Office of Clinical Research (DOCR) - Scientific Concepts	Course	

Last Updated : October 17, 2022

Canadian Cancer Clinical Trials Network

Core Competency Priorities – Network Survey Results

Domain/ Sub-Domain	Domain Category	Core Competency Statement	# Sites Reporting	Impact	Effort	Ranked Priority
D4 - 4.1	Clinical Study Operations (GCP)	Explain how the design, purpose, and conduct of individual clinical studies fit into the goal of developing a new intervention	3	High	Low	5
D4 – 4.7	Clinical Study Operations (GCP)	Describe how global regulations and guidelines assure human subject protection and privacy during the conduct of clinical studies	6	High	Low	4
D4 – 4.8	Clinical Study Operations (GCP)	Describe the role and process of monitoring a clinical study	**3**	High	Low	**3**
D5 – 5.5	Study and Site Management	Identify the legal responsibilities, liabilities and accountabilities that are involved in the conduct of clinical studies	**11**	High	Low	**2**
D6 – 6.1	Data Management & Informatics	Describe the role and importance of statistics and informatics in clinical studies	6	High	Low	6
D6 – 6.3	Data Management and Informatics	Describe best practices and resources required for standardizing data collection, capture, management, analysis, and reporting	**10**	High	Low	**1**

Canadian Cancer Clinical Trials Network

Performance Strategy Sub-Committee (PSC)

*Proposed **3CTN Priority Initiatives***

Rank	Initiative	Description
1	Training/education	Provide training opportunities for clinical research professionals
2	Share job description/salary ranges	Provide platform to share job description, salary ranges
3	Mentorship	Connect requests for mentors with targeted expertise
4	Role-specific Development Pathway	Role specific framework for professional growth and development

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

Sunnybrook Research Institute
Sunnybrook Health Science Center

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

Tertiary Hospital
Toronto, Ontario. Canada

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

New Training Initiative Focus
JTF Core competencies for CRP @ SRI OCC CR

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

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

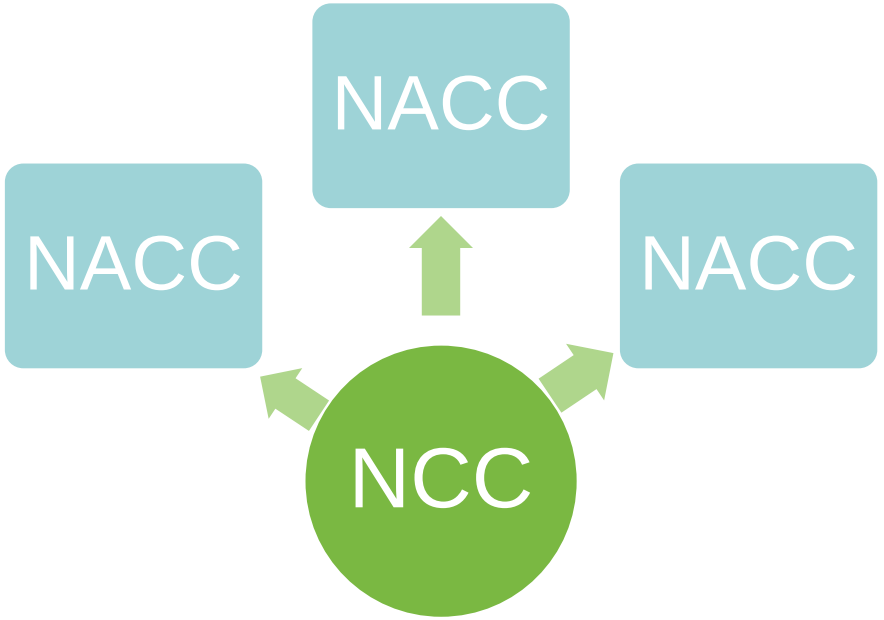
  Ongoing efforts to improve the efficiency and effectiveness of clinical trial sites across the Network

  - *Diagnostic tool for sites to assess areas of competency and deficiency within their clinical trial staff*
  - *Promote a competency framework for clinical research professionals*
  - *Identify area (s) of potential improvement for their trial unit*

Under 3CTN Objective

NCC – Network Cancer Center / NACC – Network Affiliate Cancer Centers

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



Sunnybrook
HEALTH SCIENCES CENTRE

SRI – OCC
Use of the JTF Core Competency Framework

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

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Data Manager	CRA I *	CRA II *
Supervisor		

*Protocol Activator

SRI – OCC
Use of the JTF Core Competency Framework

2. Identify training and educational requirements

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- Revamped the onboarding plan
- N2 Source, CRF and Good Data Management
- CITI Clinical Research Coordinator
- Increased time spent on shadowing various tasks
- Therapeutic Area Training
- Overview on different study designs

SRI – OCC
Use of the JTF Core Competency Framework

3. Outline continuing professional development

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- Customize training, mentoring and coaching for various new tasks and job responsibilities
- Solicit feedback from staff on training needs
- Share new training platforms and initiatives as needed

4. Interdisciplinary Collaboration

- Build bridges across departments and various stakeholders
- Enhance communication
- Share knowledge, experience and best practices

SRI – OCC
Use of the JTF Core Competency Framework

5. Focus

- Interpersonal skills (negotiating, influencing, resolving conflict, etc.)
- Effective and efficient communication and teamwork
- Professional communication practices in written and verbal interactions

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SRI – OCC
Use of the JTF Core Competency Framework

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

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Sunnybrook ODETTE CANCER CENTRE

Sunnybrook RESEARCH INSTITUTE

EMPLOYEE PERFORMANCE REVIEW (DATA MANAGER / CLINICAL RESEARCH ASSOCIATE I / CLINICAL RESEARCH ASSOCIATE II)

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

*Disease Site Lead / Clinical Trial Physician Lead

mployee Information	
lame of Employee: Click here to enter text.	Employee Title: Click here to enter text.
isease Site: Click here to enter text.	Disease Site Lead: Click here to enter text.
eriod of Review: Click here to enter text.	Date of Review: Click here to enter text.
lame of Reviewer: Click here to enter text.	Next Review: Click here to enter text.

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

Sunnybrook HEALTH SCIENCES CENTRE

Employee Performance 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

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

Deploying the JTF framework across the world

Arabic Translation

Christine Samara

UNITED ARAB EMIRATES
MINISTRY OF HEALTH & PREVENTION

الإمارات العربية المتحدة
وزارة الصحة ووقاية المجتمع

Arabic translation of the MRCT JTF Core Competency Framework is

- Coordinated by Christine Samara

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

- ✓ Identified the organization for collaboration - Initial contact and agreement November – December 2022 with Dr. Khalil Qayed
- ✓ Initiated translation – February 2023, led by Dr. Ahmed Alosi
- ✓ Discussed the plan for document translation and progress on April 11, 2023 *(Received preliminary draft of 3 domains)*
- ✓ Finalize the initial complete draft for all domains: anticipated June 2023
- ✓ Start the revision and validation: expected July 2023

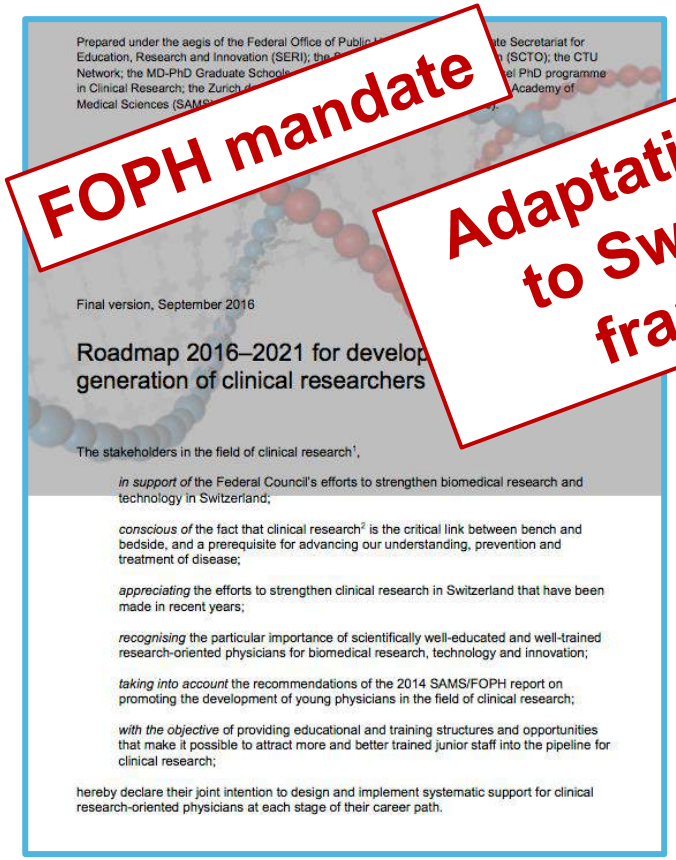
Melanie Glättli

Adapting the JTF framework to non-interventional clinical research

Core Competencies for HRO research projects

JTF Strategic Global Meeting, May 2, 2023
Melanie Glaettli, Swiss Clinical Trial Organisation (SCTO)

Competency framework – mandate and adaptation


Prepared under the aegis of the Federal Office of Public
te Secretariat for
Education, Research and Innovation (SERI); the
n (SCTO); the CTU
Network; the MD-PhD Graduate Schools
el PhD programme
in Clinical Research; the Zurich
Academy of
Medical Sciences (SAMS

Final version, September 2016

Roadmap 2016–2021 for develop
generation of clinical researchers

The stakeholders in the field of clinical research[1],

in support of the Federal Council's efforts to strengthen biomedical research and technology in Switzerland;

conscious of the fact that clinical research[2] is the critical link between bench and bedside, and a prerequisite for advancing our understanding, prevention and treatment of disease;

appreciating the efforts to strengthen clinical research in Switzerland that have been made in recent years;

recognising the particular importance of scientifically well-educated and well-trained research-oriented physicians for biomedical research, technology and innovation;

taking into account the recommendations of the 2014 SAMS/FOPH report on promoting the development of young physicians in the field of clinical research;

with the objective of providing educational and training structures and opportunities that make it possible to attract more and better trained junior staff into the pipeline for clinical research;

hereby declare their joint intention to design and implement systematic support for clinical research-oriented physicians at each stage of their career path.

FOPH mandate

Adaptation of JTF to Swiss legal framework

Clinical Research Core Competencies Framework
for clinical trials

Implemented on cr-careers.ch

Making the framework more visible

Adapting the framework to non-interventional research projects

Swiss Medical Weekly publication

Swiss legal framework for human research

Human Research Act (HRA)

with human beings | without human beings

Clinical Trials Ordinance (ClinO)

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

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

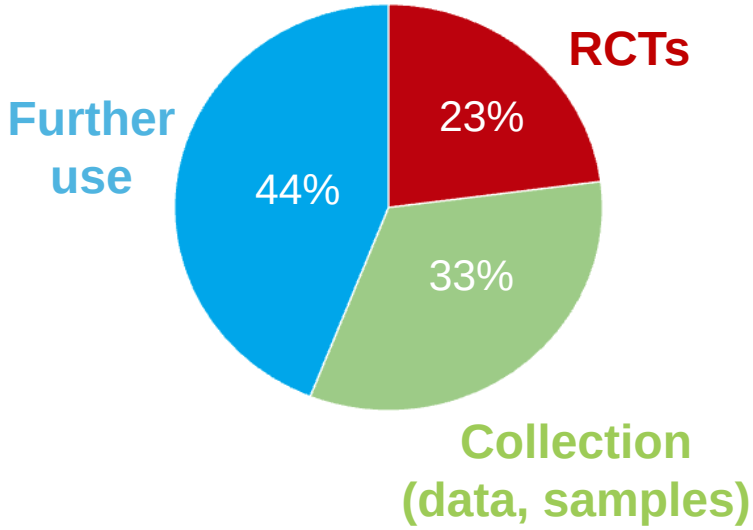
Medical devices

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)

An adaptation to HRO projects, why?

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



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

SCTO PLATFORMS

How are we adapting the Framework?

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

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

Next steps

- Review & have it approved by other Platforms (RA, PM) and stakeholders
- Implement it on cr-careers.ch and further disseminate via NL, Tools & Resources website, etc.

SCTO PLATFORMS

Concret example

2 — Ethics and participant rights

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

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

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.

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

Jean Wang &
Guo Fuzhen

Collaboration on Implementing the JTF Framework in China

Bejing Tiantan Hospital,Capital Medical University
&
XunYuan Information Technology Co., Ltd.]

巽沅 XUNYUAN

首都医科大学附属北京天坛医院 BEIJING TIANTAN HOSPITAL, CAPITAL MEDICAL UNIVERSITY

首都医科大学 公共卫生学院 School of Public Health, Capital Medical University

Content

- Introduction of XunYuan and Beijing Tiantan Hospital
- Implementing Plan of JTF Framework in China

巽沅 XUNYUAN

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首都医科大学 公共卫生学院 School of Public Health, Capital Medical University

About Xunyuan

巽沅
XUNYUAN

- Establised in 2015
- Partner of competence development for 20+ sponsors, CROs and hospitals in China
- Pioneer in Independent/Freelancing Clinical Research Market in CHINA.
- Independent Quality Assurance and Inspection Readiness Services

Jean Wang

Funder & Principal Trainer

- 8+ years experience of the clincial research training
- Speech content sharpener, "Ma Xujun New Year's Speech" content partner;
- The situational leadership II ® II certified trainer

首都医科大学附属北京天坛医院
BEIJING TIANTAN HOSPITAL, CAPITAL MEDICAL UNIVERSITY

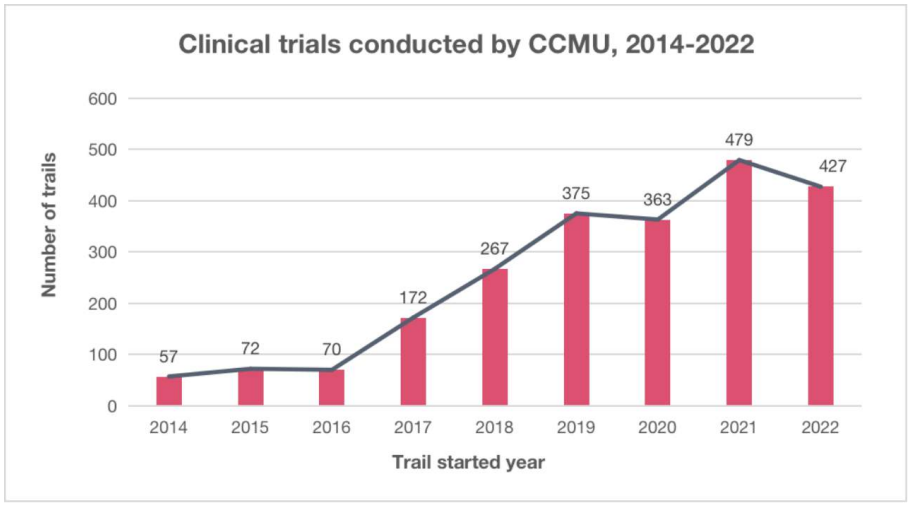
首都医科大学 公共卫生学院
School of Public Health, Capital Medical University

首都医科大学
临床流行病学与临床试验学系
Department of Clinical Epidemiology and Clinical Trial, Capital Medical University

国家神经系统疾病临床医学研究中心
China National Clinical Research Center for Neurological Diseases

China's Clinical Trial Development Team of Beijing Tiantan Hospital & Capital Medical University

Capital Medical University（CCMU）



- **The largest affiliated hospital cluster in China**
- **The highest number of clinical trial institutions**
- **Five National Medical Centers**
- **Six National Clinical Medical Research Centers**

国家神经系统疾病临床医学研究中心
China National Clinical Research Center for Neurological Diseases

首都医科大学附属北京友谊医院
国家消化系统疾病临床医学研究中心
NATIONAL CLINICAL RESEARCH CENTER FOR DIGESTIVE DISEASES

国家老年疾病临床医学研究中心(宣武医院)
National Center Research Center Of Geriatric Diseases
(Xuanwu Hospital)

国家心血管疾病临床医学研究中心
NATIONAL CLINICAL RESEARCH CENTER FOR CARDIOVASCULAR DISEASES

国家呼吸系统疾病临床医学研究中心
National Clinical Resrarch Center for Respiratory Disease
首都医科大学附属北京儿童医院

国家精神心理疾病临床医学研究中心
National Clinical Reserach Centre for Mental Disorders

首都医科大学附属北京天坛医院
BEIJING TIANTAN HOSPITAL, CAPITAL MEDICAL UNIVERSITY

首都医科大学公共卫生学院
School of Public Health, Capital Medical University

首都医科大学
临床流行病学与临床试验学系
Department of Clinical Epidemiology and Clinical Trial, Capital Medical University

国家神经系统疾病临床医学研究中心
China National Clinical Research Center for Neurological Diseases

Beijing Tiantan Hospital & NCRC-ND

Beijing Tiantan Hospital

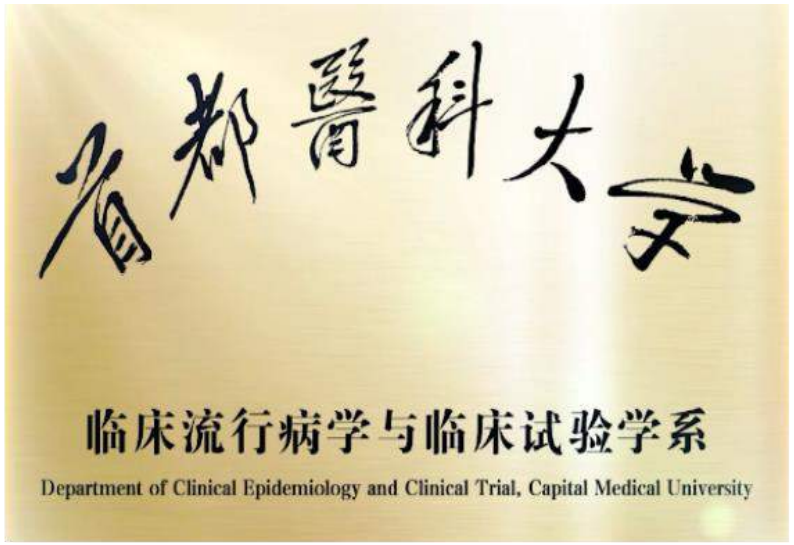
- A **Grade-3 Class-A hospital** with a neurosurgery unit and a leading characteristic neuroscience cluster
- “Noble Medical Ethics, Persistent Excellence, Rigorousness and Practicality, Diligence and Honesty”
- Awards: Highest Science and Technology Award and First-Class / Second-Class Prizes for the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

China National Clinical Research Center for Neurological Diseases

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

Establishment, Positioning & Targets

- The Department of Clinical Epidemiology and Clinical Trials of Capital Medical University was formally established on May 20, 2020.
- It serves as a university-wide resource integration platform for clinical epidemiology and clinical trials, aiming at cultivating high-level clinical scientists and creating a more pleasant research atmosphere, thus promoting the development of clinical research in China.



Compositions of Department

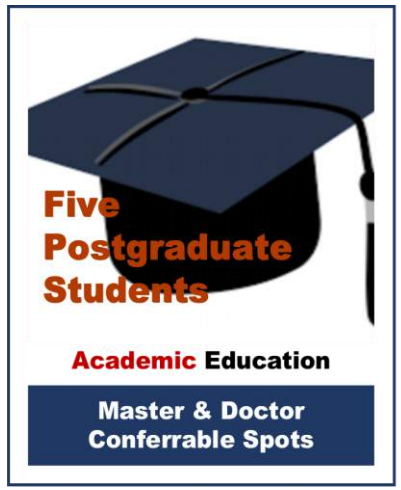
- **Affiliated to Beijing Tiantan Hospital**
- **Consisting 32 Clinical medical schools, Affiliated hospitals, Teaching hospitals & Schools**

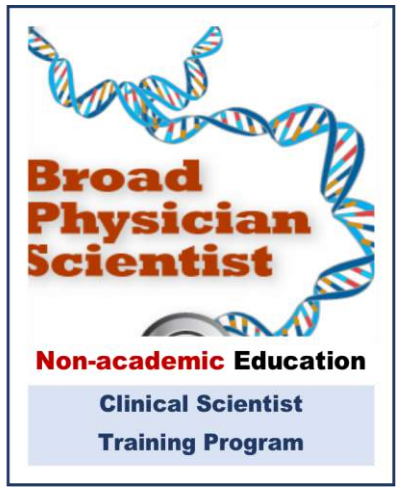
  Beijing Tiantan Hospital, Xuanwu Hospital, Beijing Friendship Hospital, Beijing Chaoyang Hospital, Beijing Tongren Hospital, Beijing Anzhen Hospital, Fuxing Hospital, Beijing Youan Hospital, Beijing Chest Hospital, Sanbo Brain Hospital, Beijing Children's Hospital, Beijing Stomatological Hospital, Beijing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

- **Plays an important role in clinical teaching for the whole university**

Education & Training Programs

Education Types





Public Training Program

More Professional Research Teams

More Experienced Clinical Scientists

Better Clinical Research Atmosphere

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Department of Clinical Epidemiology and Clinical Trial, Capital Medical University

国家神经系统疾病临床医学研究中心
China National Clinical Research Center for Neurological Diseases

Implementing Plan of JTF Framework in China

Step 1: Translate the JTF Framework into Chinese

April				May		Jun		
		The 1st Translation						
				The 1st Round Discussion				
					Translation Revision			
						Internal Team Review		
							JTF Team Review and Finalization	

巽沅 XUNYUAN

首都医科大学附属北京天坛医院 BEIJING TIANTAN HOSPITAL, CAPITAL MEDICAL UNIVERSITY

首都医科大学 公共卫生学院 School of Public Health, Capital Medical University

Implementing Plan of JTF Framework in China

Step 2: Moving Forward with a Clear Strategy

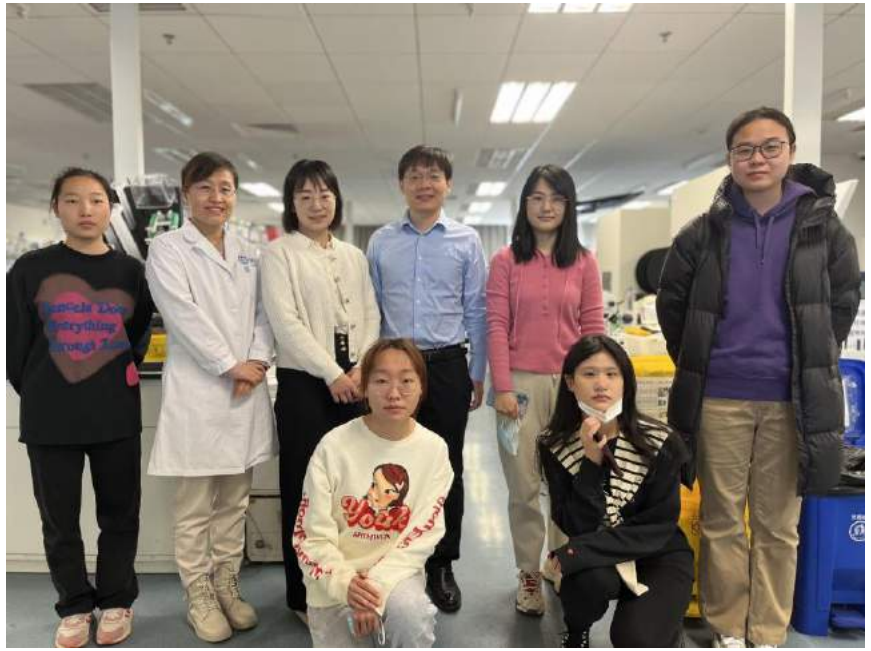
- Use JTF core competency assessment to evaluate the competence level and role relevance of Chinese clinical trial personnel.
- Understand the competency requirements of Chinese clinical trial personnel and develop training plans based on the JTF core competency framework.
- Develop graduate courses and assessment standards that are consistent with the 8 domains of JTF.
- Develop training program to professionals working in phamacuitical company and CROs.
- Integrate JTF into the professional qualification certification of Chinese clinical trials.

巽沅 XUNYUAN

首都医科大学附属北京天坛医院 BEIJING TIANTAN HOSPITAL, CAPITAL MEDICAL UNIVERSITY

首都医科大学公共卫生学院 School of Public Health, Capital Medical University

Let's Work Together



For a Better Future of Clinical Research

巽沅 XUNYUAN

首都医科大学附属北京天坛医院 BEIJING TIANTAN HOSPITAL, CAPITAL MEDICAL UNIVERSITY

首都医科大学 公共卫生学院 School of Public Health, Capital Medical University

Discussion

Update: Data Management Task Force: Meredith Zozus

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

Status

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

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

- Plan: draft report to JTF for an internal peer review late summer.

Delphi Process

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

Round 2: Two-dimensional rating

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

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

PLUS comment fields to explain low importance and disagreement

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

Round 4:

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

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

Analysis following Round 4: group vetted draft competencies

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

Group Members

- Philippe Andry, p.andry@accelsiors.com
  VP Data Mgt. and Data Integration, Accelsiors, significant experience in Europe
- Kaye Fendt, MS, Kaye_Fendt@msn.com
  Former FDA and NIH, Statistics and Data Mgt.
- Susan Fenton, PhD, Susan.H.Fenton@uth.tmc.edu
  Assoc. Professor and Assoc. Dean for Academic and Curricular Affairs, UT Health Science Center Houston
- Susan Howard, Susan.Howard@adaptimmune.com
  Adaptimune, Small Biotech, Data Management
- Rick Ittenbach, PhD, Richard.Ittenbach@cchmc.org
  Cincinnati Children's Hospital, Statistics and Data Mgt.; Academia
- Yiannis Karageorgos, yiannis.karageorgos@gmail.com
  Former BMS, Current IQVIA (CRO), Data Management, Europe
- Michelle Kelly, Michelle.Kelly@ppdi.com
  Senior Director, Clinical Data Systems at PPD/ThermoFisher, CRO, Data Mgt.
- Muayad Maallah, MD, maallah@uthscsa.edu
  Research Informatics, Univ. of Texas Health Science Center San Antonio, significant experience in Middle East
- Blandina T Mmbaga, MD,. blaymt@gmail.com
  Kilimanjaro Clinical Research Institute (KCRI)
- Steve Wilson, DrPH, stephen.wilson@fda.hhs.gov
  FDA, Statistics
- Meredith Zozus, PhD, Zozus@uthscsa.edu
  Univ. of Texas Health Science Center San Antonio, Clinical Research Informatics and Data Mgt.

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

Delphi Leader
Manju Bikkanuri, MD
bikkanuri@uthscsa.edu

Discussion

Update: Assessment of Competencies:
Elias Samuels & Susan Murphy

Updating Assessments of JTF Competencies

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

Elias M. Samuels, PhD

Director of Evaluation & Quality improvement

UM Michigan Institute for Clinical and Heath Research

Susan Murphy, ScD, OTR

Professor, Department of Physical Medicine and Rehabilitation, Internal Medicine,

Director, Behavioral Research Innovation and Support Program

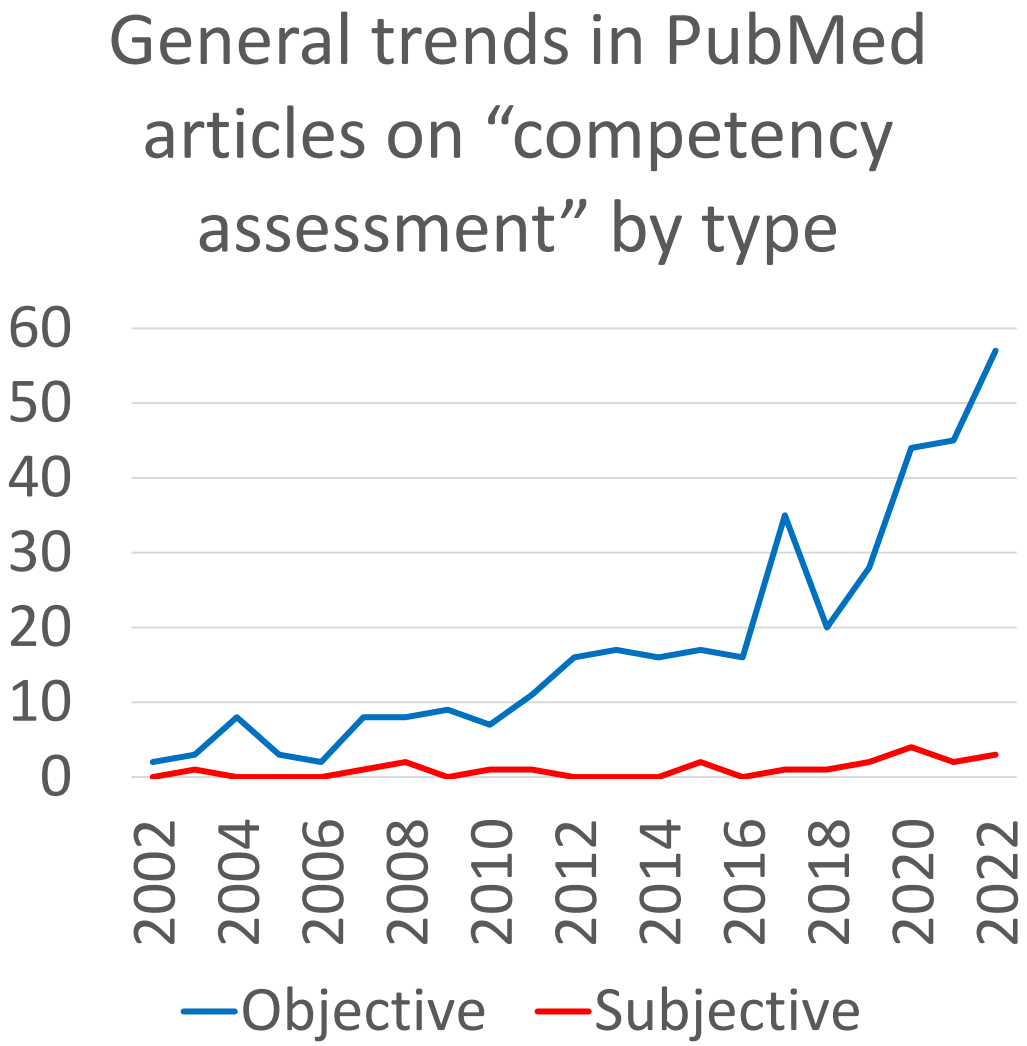
UM Michigan Institute for Clinical and Heath Research

MICHR MICHIGAN INSTITUTE FOR CLINICAL & HEALTH RESEARCH UNIVERSITY OF MICHIGAN

Presentation Outline

- Need for objective competency assessments
- Methods for validating objective assessments
- Applying JTF Competency Framework to BSSR
- Potential next steps
- Challenges

Objective assessments of CTR competence are needed



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

CTR is lagging this trend.

Of the 28 publications listed on the JTF website, the need for objective assessments is widely noted & most of the validated competency assessments published are subjective.

Subjective vs objective assessments of competence

Subjective measures of comprehension & skill include

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

Objective measures of comprehension & skill include

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

Objective assessments of CTR competency, …

are comparatively difficult to design, administer and validate, yet

Jones, C.T., Jester, P., Croker, J.A., Fritter, J., Roche, C., Wallace, B., Westfall, A.O., Redden, D.T. and Willig, J., 2020. Creating and testing a GCP game in an asynchronous course environment: The game and future plans. *Journal of Clinical and Translational Science, 4*(1), pp.36-42.

Ianni, P.A., Eakin, B.L., Samuels, E.M., Champagne, E. and Ellingrod, V.L., 2021. The Research Objective Structured Clinical Exam (R-OSCE): an innovative tool to assess clinical and translational research competencies. *MedEdPublish, 10*(143), p.143.

are needed for more rigorous evaluation & quality improvement

Samuels, E., Ianni, P.A., Chung, H., Eakin, B., Martina, C., Murphy, S.L. and Jones, C., 2020. Guidelines for evaluating clinical research training using competency assessments. *MedEdPublish, 8*(202), p.202.

Sonstein, S.A., Samuels, E., Aldinger, C., White, S.A. and Bierer, B.E., 2022. Self-assessed competencies of clinical research professionals and recommendations for further education and training. *Therapeutic Innovation & Regulatory Science*, 56(4), pp.607-615.

Objective competency assessments should be validated using complimentary theoretical models

The Content-Criterion Model

Validate assessments can predict related measures and outcomes

The Construct Model

Validate that assessments measure coherent and comprehensive constructs

The Unified Construct Model

Validate that assessments have theoretically sound construct and content validity

The Argument-Based Approach to Validation

Validate that assessments produce evidence of practical value for specific applications

Kane, M.T., 2021. Articulating a validity argument. In *The Routledge handbook of language testing* (pp. 32-47). Routledge.

Kane, M.T., 2013. Validating the interpretations and uses of test scores. *Journal of Educational Measurement*, *50*(1), pp.1-73.

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

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

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

Clinical Study Operations - BSSR Nuances

GCP – ICH principles

FDA-regulated trials
drug, device, biologic trials

Research Best Practices

BSSR trials

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

Murphy SL, Byks-Jazayeri C, Calvin-Naylor N, Divecha V, Anderson E, Eakin B, Fair A, Denton L. Best practices in social and behavioral research: report from the Enhancing Clinical Research Professional's Training and Qualifications project. J Clin Trans Sci 2017; 1: 26-32.

Potential Next Steps for Assessment

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

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

3. **Identify models & methods for validity testing**

Challenges to using objective assessments

- Evaluating impact at the person level or study level?
  - Existing assessments are not validated for all CT researchers
- Study level – Auditing – can be problematic
  - Adverse Event Conundrum – are more AEs a sign of better or worse quality of study?
  - What should measurable trends in outcomes be compared to?
- New study at UMich
  - Examining research compliance issues in BSSR trials
    - Partnership of MICHR with research compliance office
  - Help identify strategies to improve competencies
  - Can lead to an objective assessment strategy

Thank you
for your time & interest

CONTACT INFORMATION:

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

Susan Murphy, ScD, OTR (sumurphy@med.umich.edu)

Discussion

Adaptation of the JTF Framework to Emergencies: Sandor Kerpel-Fronius & Barbara Bierer

Recommendation for developing a practical guidance for managing clinical trials in times of crisis

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

Vulnerable patients who already entered clinical trials

Vulnerable patients due to war and destruction

Vulnerable patients due to economic sanctions

Main ethical conclusion and recommendation of the IFAPP Ethics Working Group

- According to International Ethical Guidelines for Health-related Research Involving Humans [Prepared by the Council for International Organizations of Medical Sciences **(CIOMS)** in collaboration with the World Health Organization **(WHO)** (2016)]
  - ***"the judgment that groups are vulnerable is context dependent and requires empirical evidence to document the need for special protections."***
- Based on this principle the IFAPP Ethics Working Group postulated that seriously ill participants enrolled already into clinical trials performed in countries involved in armed conflicts, economic sanctions hitting healthcare or natural disasters should be considered belonging to a ***vulnerable patient population***
- The investigational treatment might be the last chance for these patients to obtain therapeutic benefit for their disease

Phases of trial management in times of war The experience in Ukraine

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

Emergency trial management during the initial „chaotic” phase of a developing disaster

DEVELOPING DISASTER

Investigator site	Sponsor
• Unfolding disaster, extent unknown • Contact with the sponsor either non-existent or sporadic and inadequate	• Unfolding disaster, extent unknown • Contact with investigator site either non-existent or sporadic and inadequate
Evaluation of the effects of the disaster on the staff, healthcare facilities and social infrastructure	Information gathering concerning the effects of the disaster on the staff, healthcare facilities and social infrastructure
Ethically motivated emergency clinical decisions • Clinical activities impossible • Stopping clinical trials and providing best treatment outside the trials • ***Continuation of already initiated trial treatments if possible*** • Modified GCP level documentation of trials	Ethical and scientific evaluation of possible management changes without destroying the scientific value of the study • Closing the trial if trial treatment is impossible • Provide guidance for GCP conform trial management under altered circumstances • Organize transfer of participants to alternate research sites

Primary recommendation for ongoing clinical trials in times of emergency

- The continuation of already initiated trial treatments for the benefit of the patients is the primary ethical obligation of clinical investigators in case of war, economic sanctions or natural catastrophes

Suggested cooperation with CIOMS Developing a guidance for the conduct of clinical trials in crisis situations

- **February 20, 2023. Recommendation for a CIOMS-hosted Working Group to Develop Guidance for Health-related Research in Times of Crisis**
  - Joint recommendation by IFAPP, UCRSI and MRCT
- **March 31. 2023.** ***Further clarification of the goals of the suggested Guidance for Health-related Research in Times of Crisis Contact with Dr. Lembit Rägo, Secretary General of CIOMS***
- ***Concerns:***
  - Most of the participants of the CIOMS Executive Board considered that the present ethical guidance's provide adequate background for correctly performing clinical trials even under crisis situation.
  - They were concerned that our intention is to develop a specific "crisis related additional ethical guidance".

Suggested cooperation with CIOMS Developing a guidance for the conduct of clinical trials in crisis situations

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

Answers:

- According to our opinion, a list of detailed practical recommendation how to overcome difficulties created by external circumstances ***in agreement with the spirit of the accepted ethical guidelines*** could be very useful for ethics committee members, investigators and sponsors
- Such guidance would be especially needed in times when a crisis develops and rapid actions are required to keep trials going in a modified but still GCP conform way.
- The experience obtained in Ukraine showed convincingly the outstanding importance of rapidly communicated practical, GCP conform suggestions to the investigators by the local regulatory authorities.
- A joint TC with the CIOMS Executive Board is planned to discuss pros and cons concerning our proposal.

Adapting the JTF Framework to Emergencies

- Not all emergencies are the same
  - Variably variable in type
    - Natural disasters (e.g., earthquakes, hurricanes, floods)
    - War, conflict
    - Public health crises (e.g., pandemics, epidemics)
    - Other disruptive events (e.g., 9/11)
- Emergencies occur at different scales
  - Variable in intensity, from catastrophic (e.g., Covid-19, war in Ukraine) to relatively minor
- Responses should reflect the type and extent of the emergency
- Preparedness is necessary as disruption is unpredictable

Are different competencies necessary?

Adapting the JTF Framework to Emergencies

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

Discussion

Wrap-Up and Next Steps

Questions, Comments, Suggestions

Questions and discussion

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