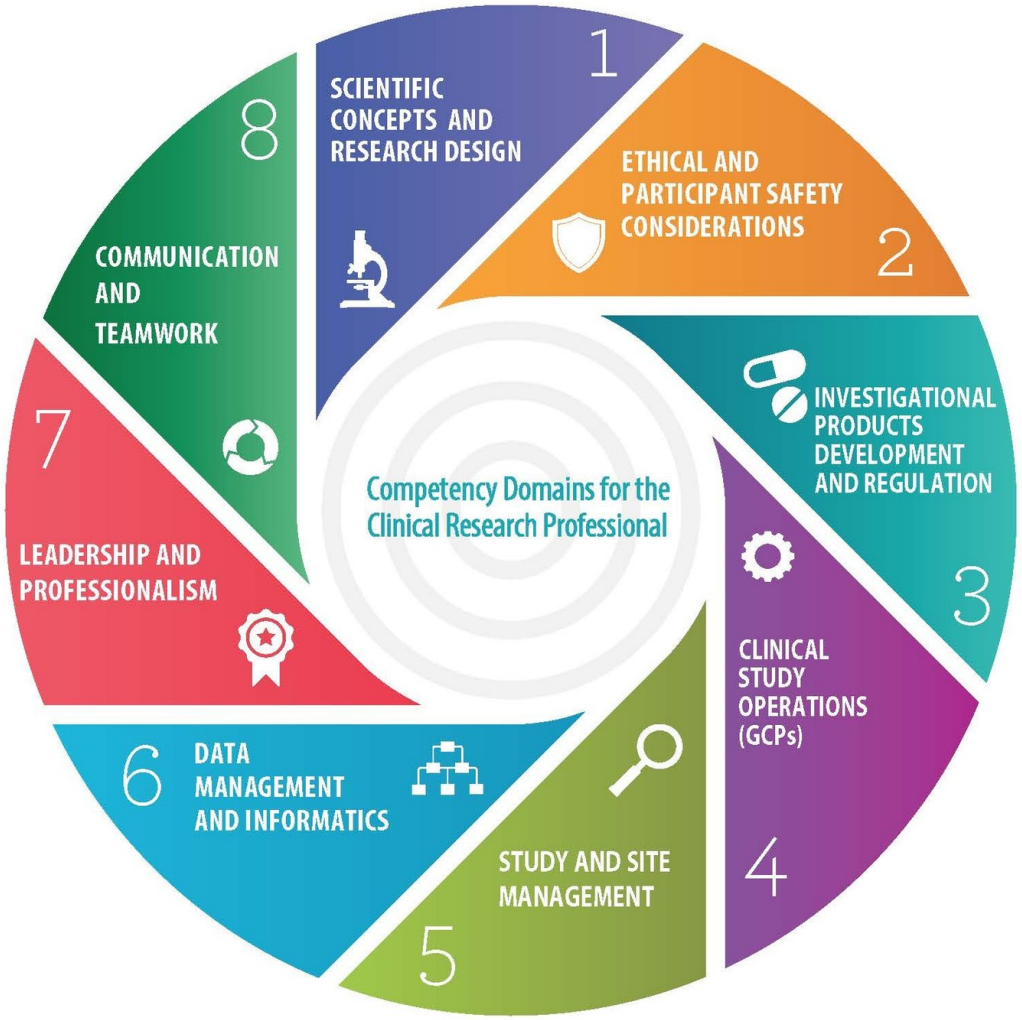
MULTI-REGIONAL CLINICAL TRIALS

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

JTF Core Competency Framework



The Pathway to Professional Workforce Development in Clinical Research

What is Competence?

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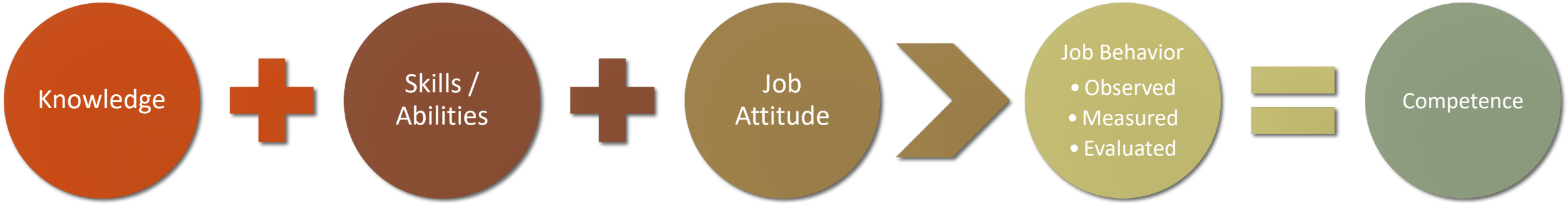

What is Competence?

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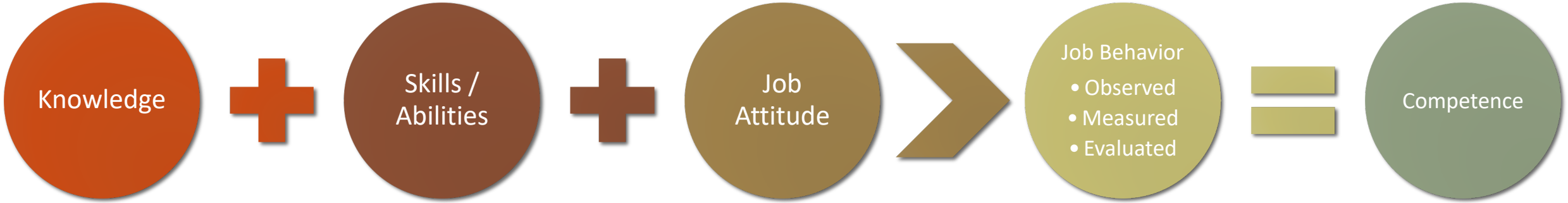
We First Have to Define the Standards and Expectations

Before we can Observe, Measure and Evaluate Behavior



Standards for Clinical Research Professionals

JOINT TASK FORCE FOR CLINICAL TRIAL COMPETENCY

JOINT TASK FORCE FOR CLINICAL TRIAL COMPETENCY

www.mrctcenter.org/clinical-trial-competency

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

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

Published Spring 2014

JOINT TASK FORCE
FOR CLINICAL TRIAL COMPETENCY

Moving from Compliance to Competency: A Harmonized Core Competency Framework for the Clinical Research Professional

PEER REVIEWED | Stephen A. Sonstein, PhD | Jonathan Seltzer, MD, MBA, MA, FACC | Rebecca Li, PhD | Honorio Silva, MD | Carolynn Thomas Jones, DNP, MSPH, RN | Esther Daemen, BSN, PG, PMP, MBA

[DOI: 10.14524/CR-14-00002R1.1]

Medicines development and clinical research are among the most heavily regulated activities on a global basis. As our understanding of pathophysiology and therapeutic intervention has increased, there has been a concomitant increase in the complexity of clinical trial protocol requirements[1] and in the number and complexity of the regulations and guidelines related to the preclinical and clinical testing of new drugs and devices.[2]

Quite curiously, though, only very general requirements and scant detail in the regulatory authority definitions exist for the criteria required of the individuals who are responsible for the conduct of clinical trials with human subjects. Previous versions of the Declaration of Helsinki[3] and the International Conference on Harmonization's Guideline for Good Clinical Practice (ICH GCP) E6[4] list only vague requirements for education and experience.

In most countries, anyone with a medical license can serve as a principal investigator of a clinical trial, regardless of whether he/she has had previous training or experience in clinical research. Certification programs for principal investigators (PIs), clinical research coordinators (CRCs), and clinical research associates (CRAs) are held in high regard, but no formal regulations define the educational or experiential requirements for, or mandate certification in, the conduct of clinical trials.

Turning of the Tide

The tide is beginning to turn, however. The latest version of the Declaration of Helsinki, dated October 2013, now states that "medical research must be conducted by individuals with appropriate training and qualifications in clinical research."[5] India has mandated certification for clinical investigators, but it is uncertain what competencies such certification will require. Also, many professional organizations have developed training programs for individuals who conduct clinical trials, and some clinical institutions require clinical research training as a prerequisite for participation on research teams.[5]

During the last decade, academic institutions have developed programs that award advanced degrees in clinical research, clinical trial management, and regulatory affairs.[6] Although one can infer that education and training will enhance the level of regulatory compliance, we have been unable to translate this into a measurement of competence. This is perhaps because there is no systematic harmonization of job descriptions and performance outcomes for the many roles that exist in the clinical research enterprise. Recently, several professional groups related to the clinical research enterprise published articles and white papers or presented content at professional meetings to bring this message to light.[7-10]

HS

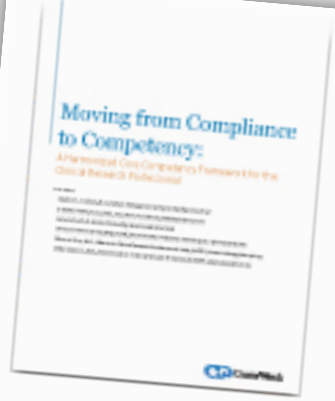
LEARNING OBJECTIVE
After reading this article, participants should be able to explain the value of developing a harmonized framework of core competencies required for the conduct of high-quality, safe, and ethical clinical research.

DISCLOSURES
Stephen A. Sonstein, PhD; Jonathan Seltzer, MD, MBA, MA, FACC; Rebecca Li, PhD; Honorio Silva, MD; Carolynn Thomas Jones, DNP, MSPH, RN: Nothing to Disclose
Esther Daemen, BSN, PG, PMP, MBA: Employee of ACRP

JOURNAL OF CLINICAL RESEARCH BEST PRACTICES
Vol. 10, No. 6, June 2014
"Happy Trials to You"

Moving From Compliance to Competency: A Harmonized Core Competency Framework for the Clinical Research Professional

By Stephen A. Sonstein, Jonathan Seltzer, Rebecca Li, Honorio Silva, Carolynn Thomas Jones, and Esther Daemen



By CenterWatch
Published: June 2014

The 8 JTF Competency Domains

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Scientific Concepts and Research Design

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

Ethical & Participant Safety Considerations

Encompasses care of patients, aspects of human subject protection, and safety in the conduct of a clinical trial.

Medicines Development and Regulation

Encompasses knowledge of how drugs, devices, and biologicals are developed and regulated

Clinical Trials Operations (GCPs)

Encompasses study management and GCP compliance; safety management and handling of investigational product

Study and Site Management

Encompasses content required at the site level to run a study including site and study operations.

Data Management and Informatics

Encompasses how data isacquired and managed during a clinical trial, including source data, data entry, queries, etc.

Leadership and Professionalism

Encompasses the principles and practice of leadership and professionalism in clinical research

Communication and Teamwork

Encompasses all elements of communication within the site and between site, sponsor, & CRO

Each domain includes specific competency statements

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For example:

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
+ 1.2 Identify Scientific Questions that are Potentially Testable Clinical Research Hypotheses
+ 1.3 Identify the Elements and Explain the principles and Processes of Designing a Clinical Study
+ 1.4 Maintain awareness of new technologies, methodologies and techniques which enhance the conduct, safety and validity of the clinical study
+ 1.5 Critically analyze clinical study results

Each competency is expressed at a Basic, Skilled and Advanced level with an example of implementation

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1

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.

How can the Competency Framework be utilized?

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Education	Streamlining educational requirements
Investigator Selection	Defining criteria for investigator selection
Job Descriptions	Standardizing job descriptions
Development of Accreditation standards	Defining standards for accreditation
Site Qualification	Defining criteria for site selection and qualification
Training Requirements	Standardizing and streamlining training requirements

Example A: Develop Job Classifications

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DUKE

Duke University built competency-based job classifications for their research professionals

- Refined and incorporated the JFT Core Competencies into existing assessments and training programs
- Developed discrete, tiered-leveled job descriptions
- Assessed current competency of employees
- Encouraged professional development

Current employees (approx. 700) mapped into new classifications

Aligned job descriptions to the current market and updated salaries of existing and incoming employees

Reference: Proceedings Core Competencies in Clinical Research: Real World Applications, Convergences and Evolution of a Framework. http://mrctcenter.org/wp-content/uploads/2016/12/2016-10-19-Core-Competencies-Briefing-Book.pdf Published October 19, 2016.

Example B: Improve Training and Career Development of Physician

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Bristol-Myers Squibb

Bristol-Myers Squibb mapped existing training curriculum for clinicians to framework and identified gaps

- Grouped certain competencies which reduced overall number of training modules by 20%
- Key gaps filled with relevant modules or face to face trainings
- Streamlined on-boarding – prioritized critical needs first
- Customized training plan with prior industry experience vs. no experience

Reference: Proceedings Core Competencies in Clinical Research: Real World Applications, Convergences and Evolution of a Framework. http://mrctcenter.org/wp-content/uploads/2016/12/2016-10-19-Core-Competencies-Briefing-Book.pdf Published October 19, 2016.

Key Lessons Learned After 15 Case Studies Implemented

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Confirmed framework was beneficial

- Helped build confidence among stakeholders
- Was flexible and adaptable
- Had broad application
- Facilitated curriculum development
- Required leadership to successfully implement
- Required roll-out evaluations to validate framework
- Used to streamline on-boarding training curriculum

JTF Leveled Core Competency Framework

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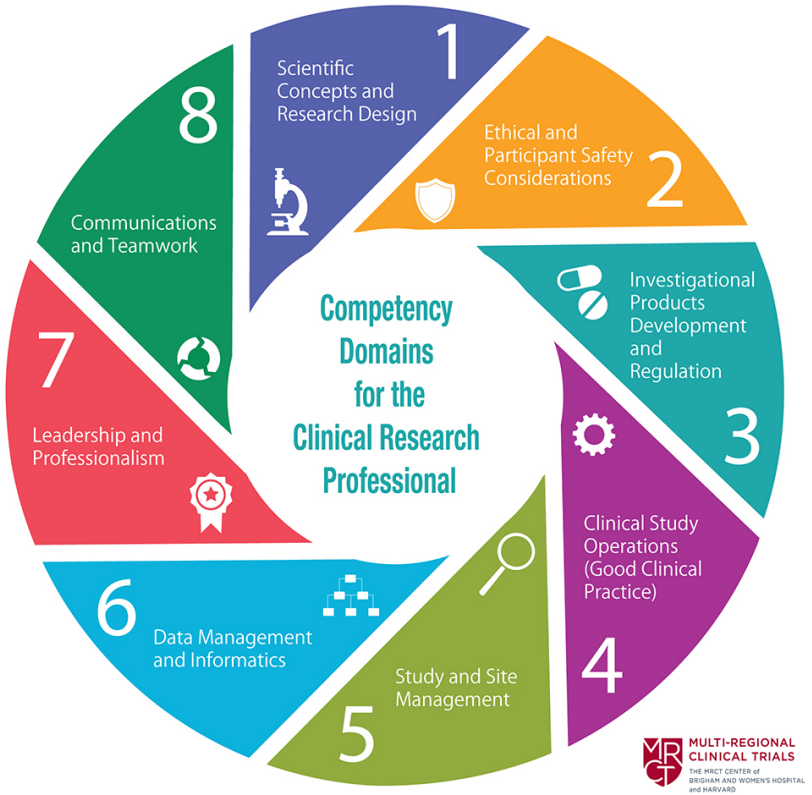

To download the entire Framework of domains, leveled competency statements and examples of how each competency may be implemented in a clinical research environment go to:

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

JTF Continuing Activities

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- Update the Core Competency Framework based upon regulatory and technological innovation
- Expand the adoption and utilization of the Core Competency Framework within the Clinical Research Enterprise
- Provide support to individuals and organizations wishing to implement the Core Competency Framework
- Integrate the JTF activities with the other activities of the Multi-Regional Clinical Trials Center.

The following translations are currently available:

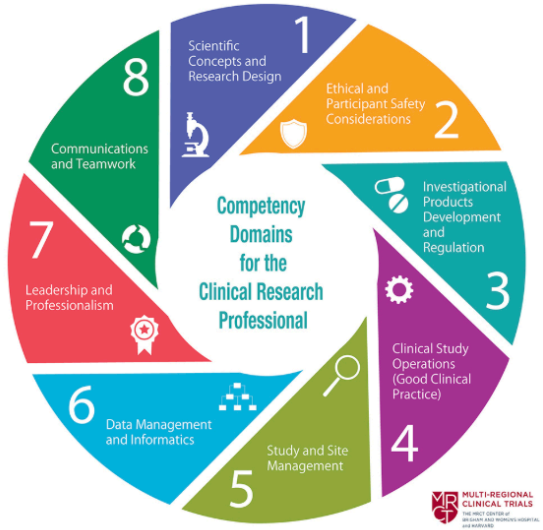
French and Portuguese translations available soon and additional translations in process

JOINT TASK FORCE FOR CLINICAL TRIAL COMPETENCY

ENGLISH

View the English version

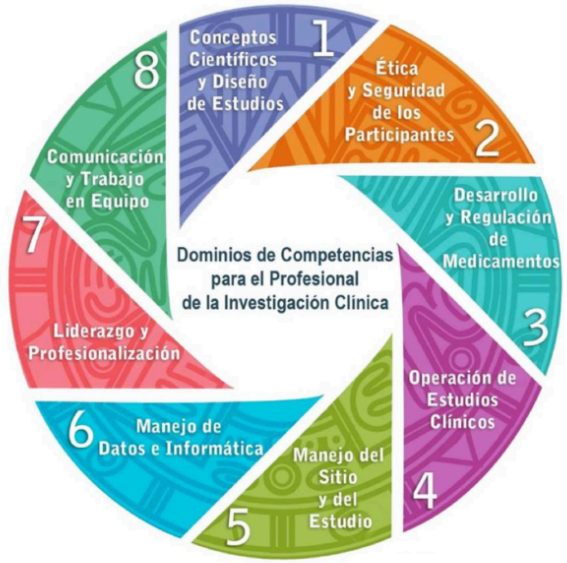
Find a full list of domains here.



SPANISH

Vea la traducción al español.

Encuentre una lista completa de dominios aquí.



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www.clinicaltrialcompetency.org

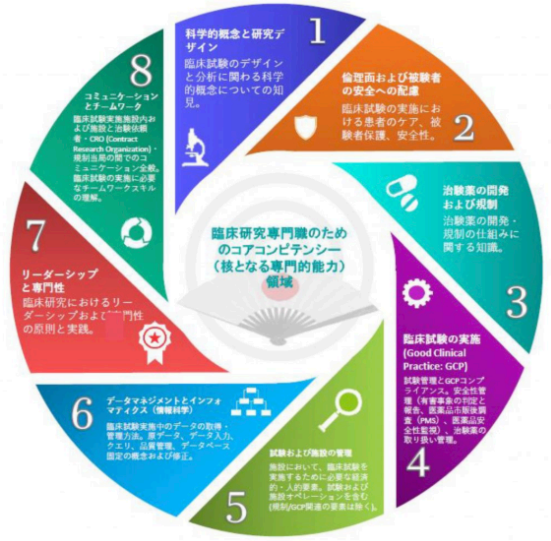
MULTI-REGIONAL CLINICAL TRIALS

APEIC
www.apeic.org

JAPANESE

日本語の翻訳を表示します。

ここでドメインの完全なリストを検索してください。



NCGM
国立がん研究センター 中央病院 National Cancer Center Hospital
OSAKA UNIVERSITY
MULTI-REGIONAL CLINICAL TRIALS

- Interested in learning more about the Joint Task Force for Clinical Trial Competency?
- Will you share how you have utilized the Framework?
- Do you have feedback, questions, or ideas?
- Do you want to get involved with our work?

Let Us Know:

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