JTF Core Competency Framework

The Pathway to Professional Workforce Development in Clinical Research
What is Competence?

Knowledge + Skills / Abilities + Job Attitude = Job Behavior
- Observed
- Measured
- Evaluated

= Competence
What is Competence?

We First Have to Define the Standards and Expectations

Knowledge + Skills / Abilities + Job Attitude = Competence

Before we can Observe, Measure and Evaluate Behavior

Job Behavior
- Observed
- Measured
- Evaluated
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.
Moving from Compliance to Competency: A Harmonized Core Competency Framework for the Clinical Research Professional

By Stephan A. Sonstein, Jonathan Seltzer, Rebecca L., Hanorio Silva, Carolyn Thomas Jones, and Esther Baemen

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The 8 JTF Competency Domains

- **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 biologics 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 is acquired 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

For example:

**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.

### 1.1 Apply Principles of biomedical science to investigational product – discovery and development and health-related behavioral interventions

<table>
<thead>
<tr>
<th>Fundamental Level</th>
<th>Skilled Level</th>
<th>Advanced Level</th>
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<tbody>
<tr>
<td><strong>A1. Recognize</strong> the need to apply scientific principles to discovery and development of biomedical investigational products and health-related behavioral interventions</td>
<td><strong>B1. Apply</strong> scientific principles when implementing a clinical or behavioral study</td>
<td><strong>C1. Plan</strong> biomedical research according to scientific principles</td>
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<tr>
<td><strong>A2. Explain</strong> the basic scientific principles that should be applied during development of biomedical investigational products and health-related behavioral interventions</td>
<td><strong>B2. Implement</strong> data collection according to scientific principles and based on protocol design</td>
<td><strong>C2. Develop</strong> a data management plan according to scientific principles.</td>
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**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?

- **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

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

Example B: Improve Training and Career Development of Physician

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

Key Lessons Learned After 15 Case Studies Implemented

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
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

- 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

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.

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。
• 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/