Harmonized Core Competencies for the Clinical Research Professional

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The Joint Task Force for Clinical Trial Competency seeks to integrate and harmonize efforts to produce a single list of core competencies

Multiple groups identifying clinical trials competencies creates an opportunity for harmonization

- Investigators and support professionals require an appropriate knowledge, skills and attitudes to carry out clinical duties
- Interested groups have varying approaches to develop core competencies for investigators and support professionals

The Joint Task Force for Clinical Trial Competency was created to integrate efforts

- Responsible for integrating efforts and aligning competencies
- Responsible for developing harmonization strategy

**Core Team**

- **Rebecca Li**
  Harvard Multi-Regional Clinical Trials Center (MRCT)
- **Sarah Carter**
  Amgen
- **Esther Daemen**
  Association of Clinical Research Professionals (ACRP)
- **Honorio Silva**
  Alliance for Clinical Research Excellence and Safety (ACRES)
- **Stephen Sonstein**
  Consortium of Academic Programs in Clinical Research (CoAPCR)
- **Sheila Clapp**
  FHI360
- **Jason Nyrop**
  Deloitte Consulting
Harmonized competencies can be used as the basis for various end-uses

- **Education**: Streamlining educational requirements
- **Job Descriptions**: Standardizing job descriptions
- **Investigator Selection**: Defining criteria for investigator selection
- **Site Qualification**: Defining criteria for site selection and qualification
- **Development of Accreditation Standards**: Defining standards for accreditation
- **Training Requirements**: Standardizing and streamlining training requirements
The Joint Task Force builds upon previous work

Many efforts have identified investigator competencies and learning objectives

The Joint Task Force is positioned to integrate on-going efforts

Diverse representation
- The Joint Task Force brings together Harvard Multi-Regional Clinical Trials Center and Consortium of Academic Programs in Clinical Research to guide and lead the effort

Process oriented
- The Joint Task Force has developed a process to harmonize competencies

Focused on output
- The Joint Task Force is committed to the output of competency domains and core competencies to enable various end-uses
We developed a three step approach to harmonize competencies

1. **Identify competency domains**

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

2. **Map and define competencies**

   **Competencies** are specific knowledge, skills and attitudes which comprise Competency Domains
   - Categorize competencies, learning objectives and statements from on-going efforts
   - Define competency statements for each category

3. **Obtain endorsement**

   Obtain endorsement from major stakeholders and content providers
Competency Domains were defined by reviewing and aligning documents of on-going efforts

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

Documents were reviewed from on-going efforts...

- Academy of Physicians in Clinical Research
- Association of Clinical Research Professions
- Clinical & Translational Science Awards
- Collaborative Institutional Training Initiative
- Consortium of Academic Programs in Clinical Research
- Global Health Network
- Inter-American Foundation for Clinical Research
- International Academy of Clinical Research
- International Federation of Associations of Pharmaceutical Physicians
- Multi-Regional Clinical Trials
- TransCelerate
- UK Clinical Research Collaboration

...and eight Competency Domains were defined:

- Scientific Concepts and Research Design
- Study and Site Management
- Ethical Considerations, Patient Care and Safety
- Data Management and Informatics
- Medicines Development and Regulation
- Leadership and Professionalism
- Clinical Trial Operations
- Communication & Teamwork
Competency statements are defined from grouping similar statements from on-going efforts

**Competencies** are specific knowledge, skills and attitudes which comprise Competency Domains.

Similar statements are grouped together:

- Evaluates and applies the regulatory and ethical aspects underpinning clinical development
- Describe the historical development of regulations associated with the protection of human subjects
- Describe cultural and social variation in standards of research integrity
- Develop a personal statement on professional ethics and behavior as a clinical research

The Competency Statement is mapped to a Competency Domain:

- Ethical Considerations, Patient Care and Safety

Describe the ethical issues involved when dealing with vulnerable populations and the need for additional safeguards

A Competency to align similar statements is defined.
Eight domains of the Harmonized Core Competencies for the Clinical Research Professional

- **Communication & Teamwork**: Encompasses all elements of communication within the site and between the site and sponsor, CRO and regulators. Understanding of teamwork skills necessary for conducting a clinical trial.

- **Leadership and Professionalism**: The principles and practice of leadership and professionalism in clinical research.

- **Data Management and Informatics**: Covers how data is acquired and managed during a clinical trial, including source data, data entry, queries, quality control, and correction and the concept of a locked database.

- **Scientific Concepts and Research Design**: Encompasses knowledge of scientific concepts related to the design and analysis of clinical trials.

- **Ethical Considerations, Patient Care and Safety**: Encompasses care of patients, aspects of human subject protection and safety in the conduct of a clinical trial.

- **Study and Site Management**: Covers content required at the site level to run a study (financial and personnel aspects). Includes site and study operations (not encompassing regulatory / GCPs).

- **Medicines Development and Regulation**: Covers knowledge of how drugs are developed and regulated.

- **Clinical Trials Operations (GCP’s)**: Covers study management and GCP compliance; safety management (AE identification and reporting, post market surveillance and PV) and handling of investigational product.
Scientific Concepts and Research Design

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

- Demonstrate knowledge of pathophysiology, pharmacology and toxicology as they relate to medicines discovery and development
- Identify clinically important questions that are potentially testable clinical research hypothesis, through review of the professional literature
- Explain the elements (statistical, epidemiological and operational) of clinical and translational study design
- Design a clinical trial
- Critically analyze study results with an understanding of therapeutic and comparative effectiveness