

Moving from Compliance to Competency: A Harmonized Core Competency Framework for the Clinical Research Professional²

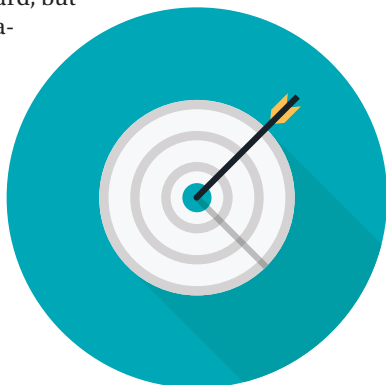
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[DOI: 10.14524/CR-14-00002R1.1]

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 requirements¹ 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 Helsinki³ and the International Conference on Harmonization's Guideline for Good Clinical Practice (ICH GCP) E6⁴ 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.”³ 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

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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

Joint Task Force for Clinical Trial Competency Contributors and Collaborators

Academy of Physicians in Clinical Research

Association of Clinical Research Professionals

Amgen

Alliance for Clinical Research Excellence and Safety

Clinical & Translational Science Awards

Clinical Trials Transformation Initiative

Collaborative Institutional Training Initiative

Consortium of Academic Programs in Clinical Research

Deloitte

Drug Information Association

Global Health Network

Inter-American Foundation for Clinical Research

International Academy of Clinical Research

International Federation of Associations of Pharmaceutical Physicians

Korea National Enterprise for Clinical Trials

MAGI

Multi-Regional Clinical Trial Center

Pfizer

PharmaTrain

TransCelerate Biopharma, Inc.

UK Clinical Research Collaboration

As the concept of competency-based education and training has spread to the medicines development industry, many groups have produced a list of knowledge, skills, and attitudes defining the core competencies required of the clinical research professional. For the most part, the approach of each group has been focused on a specific component of the clinical research enterprise. Some examples are:

- The National Center for Advancing Translational Sciences (part of the National Institutes of Health) in the U.S., which has developed listings of core competencies for translational research scientists;¹¹
- The International Federation of Associations of Pharmaceutical Physicians and the Academy of Physicians in Clinical Research (APCR), which have developed listings of core competencies for pharmaceutical physicians and clinical investigators;^{12,13}
- The Consortium of Academic Programs in Clinical Research, which has developed core competencies for graduates of academic programs and to guide curriculum development;⁷
- The Association of Clinical Research Professionals (ACRP), which has defined a career development pathway for CRCs, CRAs, and PIs incorporating competency statements;¹⁴ and
- The Regulatory Affairs Professionals Society, which has adopted core competency statements that relate to regulatory affairs professionals.¹⁵

Furthermore, professional nursing in the U.S. and United Kingdom has contributed to this effort through a variety of clinical research role delineation studies and competency-defining publications.¹⁶⁻²⁰ These combined efforts have begun the process of moving the clinical research enterprise from a focus on regulatory compliance to a focus on professional competency.

Coalescing on Competency

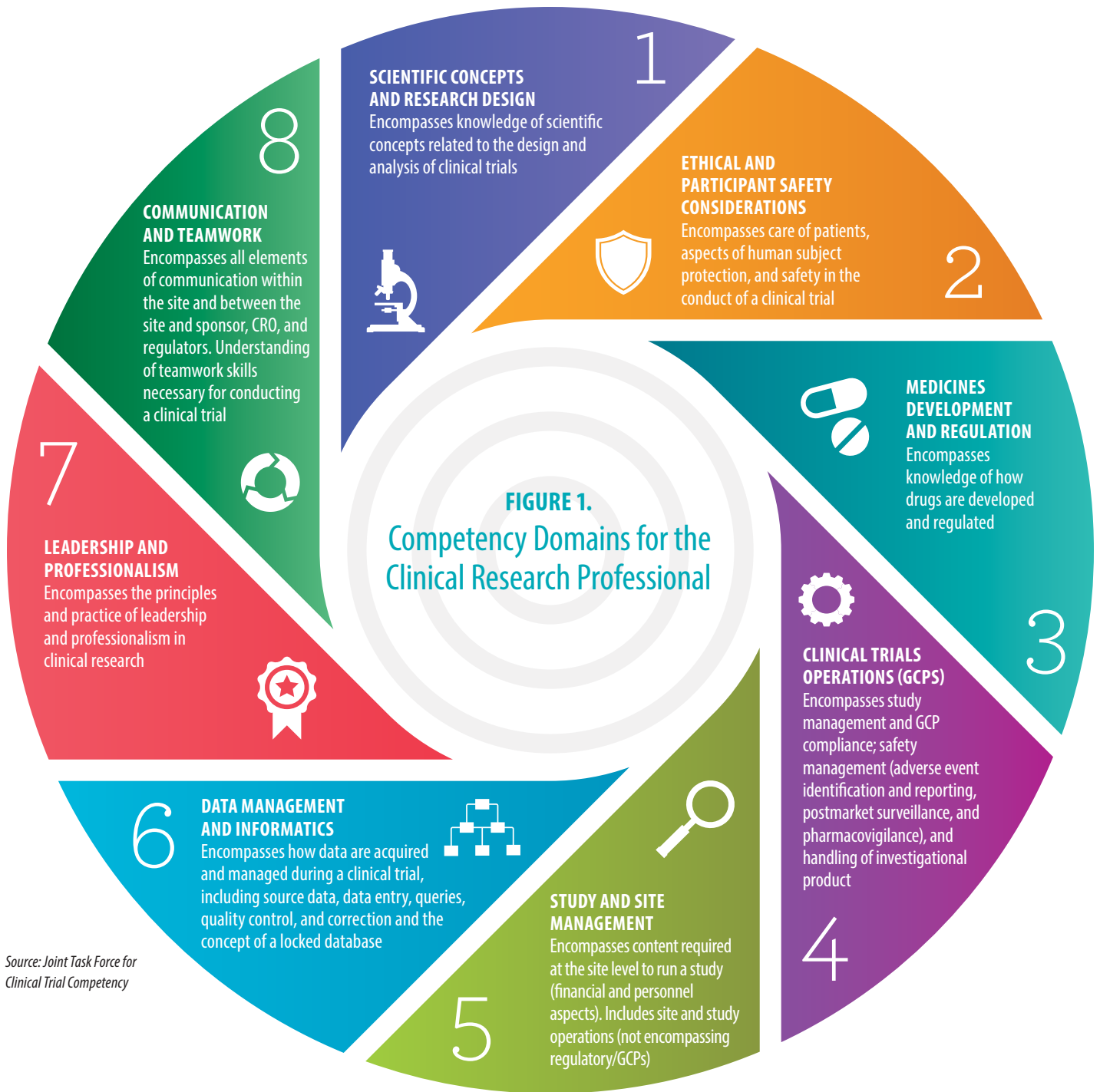
In an attempt to bring together these disparate, but high-quality efforts focused on clinical trial competence, a meeting of representatives from pharmaceutical companies, contract research organizations, academic institutions, clinical research sites, and professional societies was hosted by the Multi-Regional Clinical Trial (MRCT) Center at Harvard University during spring 2013. A broad-based and widely representative group was formed and named the Joint Task Force (JTF) for Clinical Trial Competency.

The members of the JTF agreed to work toward aligning and harmonizing the many focused statements relating to core competency for clinical research professionals into a single, high-level set of standards, which could be adopted globally and serve as a framework for defining professional competency throughout the clinical research enterprise. The JTF had a second face-to-face meeting in June 2013, which included participants from an even broader representation of the clinical research community.

A listing of the JTF's collaborating organizations is found in the sidebar. The JTF then worked through the summer of 2013 and presented its final report in October of that year.

The process used by the JTF was designed to acknowledge and incorporate the inputs from the many participating organizations. It required a review of the many different competency statements and identification of competency domains, or broad categories of the knowledge, skills, and attitudes necessary to function within the field of clinical research. It determined that all of the competency statements could be aligned within the eight competency domains listed in Figure 1.

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Source: Joint Task Force for Clinical Trial Competency

The next step required focusing on the individual statements of knowledge, skill, and attitude (KSA) learning objectives from each of the many publications and presentations and aligning them within the appropriate competency domain. The final step involved reviewing all of the KSA learning objective statements within each competency domain and harmonizing them, so that the wording of the final KSA statements was inclusive and represented each individual organization's priorities, but was not redundant or repetitive.

The JTF decided that the harmonized competency statements at this level should

reflect primarily cognitive skills, and that the performance or attitudinal aspects of learning objectives were best defined at a more granular level by groups that would use the statements as a Core Competency Framework to further develop focused expressions for specific components of the enterprise (e.g., job descriptions, accreditation criteria, training requirements). The JTF and collaborating organizations then systematically reviewed the proposed competencies and domains, integrating comments and suggestions into the final product, which is presented in Table 1.

The Core Competency Framework can be used in many ways toward improving the quality and safety of the clinical research enterprise.

TABLE 1. Harmonized Core Competencies for the Clinical Research Professional

SCIENTIFIC CONCEPTS AND RESEARCH DESIGN

- Demonstrate knowledge of pathophysiology, pharmacology, and toxicology as related to medicines discovery and development
- Identify clinically important questions that are potentially testable clinical research hypotheses, 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

ETHICAL AND PARTICIPANT SAFETY CONSIDERATIONS

- Compare and contrast clinical care and clinical management of research participants
- Define the concepts of “clinical equipoise” and “therapeutic misconception” as related to the conduct of a clinical trial
- Compare the requirements for human subject protections and privacy under different national and international regulations and ensure their implementation throughout all phases of a clinical study
- Explain the evolution of the requirement for informed consent from research participants and the principles and content of the key documents ensuring the protection of human participants in clinical research
- Describe the ethical issues involved when dealing with vulnerable populations and the need for additional safeguards
- Evaluate and apply an understanding of the past and current ethical issues, cultural variations, and commercial aspects to the medicines development process
- Explain how inclusion and exclusion criteria are included in a clinical protocol to assure human subject protection
- Summarize the principles and methods of distributing and balancing risk and benefit through selection and management of clinical trial subjects

MEDICINES DEVELOPMENT AND REGULATION

- Discuss the historical events that precipitated the development of governmental regulatory processes for drugs, devices, and biologics
- Describe the roles and responsibilities of the various institutions participating in the medicines development process
- Explain the medicines development process and the activities that integrate commercial realities into the life cycle management of medical products
- Summarize the legislative and regulatory framework that supports the development and registration of medicines, devices, and biologics and ensures their safety, efficacy, and quality

- Describe the specific processes and phases that must be followed in order for the regulatory authority to approve the marketing authorization for a medical product
- Describe the safety reporting requirements of regulatory agencies both pre- and post-approval
- Appraise the issues generated and the effects of global expansion on the approval and regulation of medical products

CLINICAL TRIALS OPERATIONS (GCPS)

- Evaluate the conduct and management of clinical trials within the context of a Clinical Development Plan
- Describe the roles and responsibilities of the clinical investigation team as defined by GCP guidelines
- Evaluate the design conduct and documentation of clinical trials as required for compliance with GCP guidelines
- Compare and contrast the regulations and guidelines of global regulatory bodies relating to the conduct of clinical trials
- Describe appropriate control, storage, and dispensing of investigational products
- Differentiate the types of adverse events (AEs) that occur during clinical trials, understand the identification process for AEs, and describe the reporting requirements to institutional review boards/independent ethics committees (IRBs/IECs), sponsors, and regulatory authorities
- Describe how global regulations and guidelines assure human subject protection and privacy during the conduct of clinical trials
- Describe the reporting requirements of global regulatory bodies relating to clinical trial conduct
- Describe the role and process for monitoring of the study
- Describe the roles and purpose of clinical trial audits
- Describe the safety reporting requirements of regulatory agencies both pre- and post-approval
- Describe the various methods by which safety issues are identified and managed during the development and postmarketing phases of clinical research

STUDY AND SITE MANAGEMENT

- Describe the methods utilized to determine whether or not to sponsor, supervise, or participate in a clinical trial
- Develop and manage the financial, timeline, and cross-disciplinary personnel resources necessary to conduct a clinical or translational research study
- Apply management concepts and effective training methods to manage risk and improve quality in the conduct of a clinical research study
- Utilize elements of project management related to organization of the study site to manage patient recruitment, complete procedures, and track progress

- Identify the legal responsibilities, issues, liabilities, and accountabilities that are involved in the conduct of a clinical trial
- Identify and explain the specific procedural, documentation, and oversight requirements of PIs, sponsors, contract research organizations (CROs), and regulatory authorities related to the conduct of a clinical trial

DATA MANAGEMENT AND INFORMATICS

- Describe the role that biostatistics and informatics serve in biomedical and public health research
- Describe the typical flow of data throughout a clinical trial
- Summarize the process of electronic data capture and the importance of information technology in data collection, capture, and management
- Describe the ICH GCP requirements for data correction and queries
- Describe the significance of data quality assurance systems and how standard operating procedures are used to guide these processes

LEADERSHIP AND PROFESSIONALISM

- Describe the principles and practices of leadership, management, and mentorship, and apply them within the working environment
- Identify and implement procedures for the prevention or management of the ethical and professional conflicts that are associated with the conduct of clinical research
- Identify and apply the professional guidelines and codes of ethics that apply to the conduct of clinical research
- Describe the effect of cultural diversity and the need for cultural competency in the design and conduct of clinical research

COMMUNICATION AND TEAMWORK

- Discuss the relationship and appropriate communication between sponsor, CRO, and clinical research site
- Describe the component parts of a traditional scientific publication
- Effectively communicate the content and relevance of clinical research findings to colleagues, advocacy groups, and the nonscientist community
- Describe methods necessary to work effectively with multidisciplinary and inter-professional research teams

Implementing the Core Competency Framework

The Core Competency Framework can be used in many ways toward improving the quality and safety of the clinical research enterprise, such as to define certification criteria used by personnel or site certifying agencies. The framework also could be used to formulate accreditation standards for academic programs, both to standardize curricula and to ensure that programs are sufficiently comprehensive.

Ultimately though, the most effective method to improve clinical trials would be to ensure that those responsible for the various aspects of the clinical trial bring the appropriate competence at the appropriate time. The greater challenge is implementation of this conceptual framework into an operational model, and a good place to start could be the clinical research design, whereby a look at competencies across two different types of studies can reveal variability in requirements.

For instance, comparing an investigator-initiated, observational trial to an industry-sponsored, premarket interventional trial illustrates how this framework might be used to qualify a PI. As depicted in Table 2, the competencies for the Study and Site Management Domain are identical in the two different styles of trial, but not so for the Scientific and Research Design Domain. This does not imply that a less competent investigator can perform an observational study, but that a lower level of competency is required for that study method. Furthermore, the level of competency might be quite different for other clinical research team roles, such as CRC, CRA, data manager, or regulatory affairs coordinator.

Once the necessary competency is defined, the PI, study sponsor, and interested regulatory authority must ensure that the study team member possesses the necessary competencies to carry out the selected, protocol-defined tasks. If additional knowledge or skills are needed, this would be the proper place to integrate with training programs that have training materials and processes that are harmonized to the protocol-specific competency requirements.

As a second example, Table 3 illustrates how one could use the Core Competency Framework to define the ICH GCP knowledge requirements for an interventional clinical trial based on the functional roles of a PI, CRC, or CRA.

TABLE 2. Competencies and Study Methods

DOMAIN	STUDY METHOD	
	Observational	Interventional
Scientific and Research Design		
Demonstrate knowledge of pathophysiology, pharmacology, and toxicology as they relate to medicines discovery and development	Optional	Required
Identify clinically important questions that are potentially testable clinical research hypotheses, through review of the professional literature	Required	Optional
Explain the elements (statistical, epidemiological, and operational) of clinical and translational study design	Required	Required
Design a clinical trial	Required	Optional
Critically analyze study results with an understanding of therapeutic and comparative effectiveness	Optional	Optional
Study and Site Management		
Describe the methods used to determine whether or not to sponsor, supervise, or participate in a clinical trial	Required	Required
Develop and manage the financial, timeline, and cross-disciplinary personnel resources necessary to conduct a clinical or translational research study	Required	Required
Describe the reporting requirements of global regulatory bodies relating to clinical trial conduct		
Apply management concepts and effective training methods to manage risk and improve quality in the conduct of a clinical research study	Required	Required
Use elements of project management related to organization of the study site to manage patient recruitment, complete procedures, and track progress	Required	Required
Identify the legal responsibilities, issues, liabilities, and accountability that are involved in the conduct of a clinical trial	Required	Required
Identify and explain the specific procedural, documentation, and oversight requirements of PIs, sponsors, CROs, and regulatory authorities that relate to the conduct of a clinical trial	Optional	Required

Not all members of the clinical research team require the highest level competency in all of the areas listed, but these harmonized core competencies can provide a basis for development of specific statements of knowledge, skills, and attitudes required by clinical research professionals in focused environments.

TABLE 3. Competencies by PI, CRC, and CRA Roles

DOMAIN	PI Role	CRC Role	CRA Role
Clinical Trial Operations			
Evaluate the conduct and management of clinical trials within the context of a Clinical Development Plan	Required	Optional	Optional
Describe the roles and responsibilities of the clinical investigation team as defined by GCP guidelines	Required	Required	Required
Evaluate the design conduct and documentation of clinical trials as required for compliance with GCP guidelines	Required	Optional	Required
Compare and contrast the regulations and guidelines of global regulatory bodies relating to the conduct of clinical trials	Required	Optional	Required
Describe appropriate control, storage, and dispensing of investigational products	Required	Required	Required
Differentiate the types of AEs that occur during clinical trials, understand the identification process for AEs, and describe the reporting requirements to IRBs/IECs, sponsors, and regulatory authorities	Required	Required	Required
Describe how global regulations and guidelines assure human subject protection and privacy during the conduct of clinical trials	Required	Optional	Optional
Describe the reporting requirements of global regulatory bodies relating to clinical trial conduct	Required	Optional	Optional
Describe the reporting requirements of global regulatory bodies relating to clinical trial conduct	Required	Optional	Optional
Describe the role and process for monitoring of the study	Required	Optional	Required
Describe the roles and purpose of clinical trial audits	Required	Optional	Required
Describe the safety reporting requirements of regulatory agencies both pre- and post-approval	Required	Required	Required
Describe the various methods by which safety issues are identified and managed during the development and post-marketing phases of clinical research	Optional	Optional	Optional
Study and Site Management			
Describe the methods used to determine whether or not to sponsor, supervise, or participate in a clinical trial	Required	Optional	Optional
Develop and manage the financial, timeline, and cross-disciplinary personnel resources necessary to conduct a clinical or translational research study	Required	Optional	Optional
Apply management concepts and effective training methods to manage risk and improve quality in the conduct of a clinical research study	Required	Optional	Optional
Use elements of project management related to organization of the study site to manage patient recruitment, complete procedures, and track progress	Required	Required	Optional
Identify the legal responsibilities, issues, liabilities, and accountabilities that are involved in the conduct of a clinical trial	Required	Required	Required
Identify and explain the specific procedural, documentation, and oversight requirements of PIs, sponsors, CROs, and regulatory authorities related to the conduct of a clinical trial	Required	Optional	Required

Summary

The mission of this JTF initiative has been to bridge the gap between “what to do” and “how to do it.” For the first time, a universally applicable, globally relevant framework exists that identifies the competency domains and the associated cognitive skills necessary to conduct a high-quality, ethical, and safe clinical trial.

Not all members of the clinical research team require the highest level competency in all of the areas listed, but these harmonized core competencies can provide a basis for development of specific statements of knowledge, skills, and attitudes required by clinical research professionals in focused environments. The leveling of competencies from novice to expert—or by professional role—can be a next step in this endeavor.

Competency-based curricula or job descriptions can lead to standardization and elimination of redundancy in training requirements, standardization and accreditation of educational programs, and definition of career tracks and performance evaluations. The sidebar lists several of the possible uses and outcomes that can result from the adoption and use of the Core Competency Framework by the clinical research enterprise and global regulatory authorities.

The JTF aims to approach the regulatory bodies of the world for recognition and acknowledgment of the Core Competency Framework, and ultimately to house the document and its future evolutions within the ICH as a guideline similar to ICH GCP E6.⁴

Acknowledgments

The authors would like to acknowledge Jason Nyrop (Deloitte, Inc.) for his expertise in production of the graphics and tables included; Norman Goldfarb (MAGI, Inc.), Jim Thomasell (ACRP), and Jennifer Webb (Drug Information Association) for their support in facilitating the meetings of the JTF; and Jacquelyn Murphy of the MRCT Center at Harvard for her administrative support.



Potential Uses and Outcomes of a Harmonized Core Competency Framework, for Standardizing and Streamlining

- Curriculum development
- Training initiatives
- Basic training requirements
- Investigator approvals
- Guidance for IRB approvals
- Site approvals and selection
- Study coordinator delegation
- Study monitor roles
- Defining clinical research career ladders and levels
- Job descriptions and performance evaluations
- Policy development
- Regulatory compliance
- Quality improvement
- Academic program and site accreditation
- Academic requirements for clinical research roles
- Professional certification
- Bridging gaps in innovation exchange
- Infusing improved performance outcomes into the global clinical research enterprise workforce

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