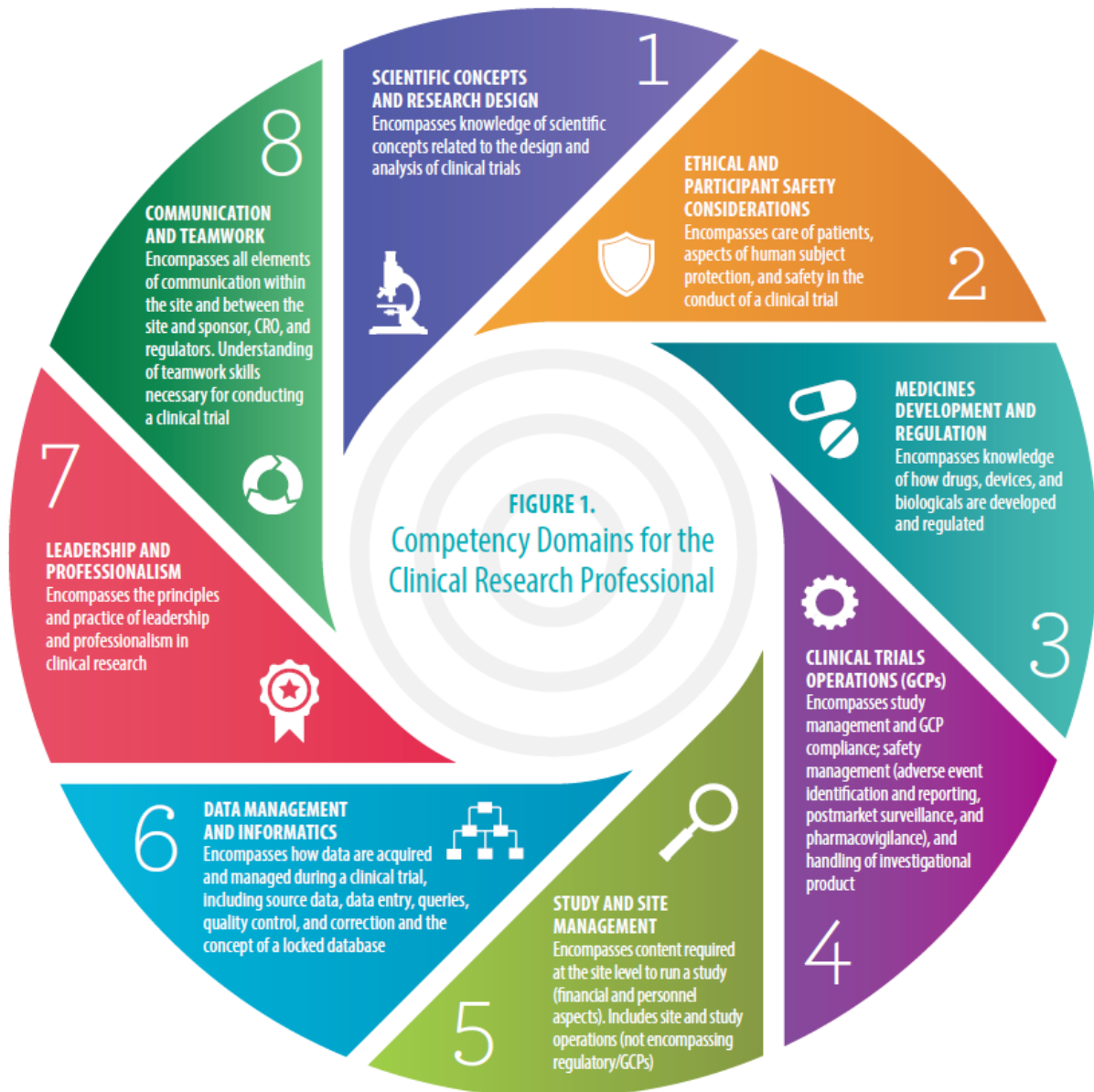


Joint Task Force on Clinical Trial Competency: Major Progress

By Norman M. Goldfarb

The Joint Task Force on Clinical Trial Competency (JTF) provided a progress report at ACRP’s 2015 Global Conference & Exhibition. The JTF has made significant strides over the past year in creating a harmonized competency framework for clinical research professionals (Figure 1). See: http://firstclinical.com/journal/2014/1406_Competency.pdf.

Figure 1. Competency Domains For the Clinical Research Professional



Uses & Benefits

The framework will have many uses, including, for example:

- Developing job requirements
- Assessing job candidates
- Matching employees/contractors with assignments
- Planning training to support career paths
- Assessing investigator qualifications
- Designing conference agendas and training programs
- Choosing training and education events to attend

At an educational session during the ACRP conference, about 150 audience members unanimously agreed that the JTF's competency framework would help them plan their own training and education programs.

Membership & Governance

The JTF operates as an informal collaboration, with no corporate entity or memberships fees. Numerous organizations, including those in Table 1, have been involved.

The original JTF core team members have asked ACRP to serve as the "custodian" of the competency framework, with Terri Hinkley, ACRP's Interim Executive Director, leading the group. ACRP is currently evaluating the appropriate governance structure. JTF participation and benefits will not be limited to ACRP members.

Continuing Work

A team of JTF members, led by Stephen Sonstein, of the Consortium of Academic Programs in Clinical Research, is currently analyzing data from a comprehensive self-assessment survey of competency, relevance and training needs. The results will help validate which of the 51 core competencies are relevant to which positions and where training and education is most needed.

ACRP has mapped its new training program (<http://www.acrpnet.org/training>) to the JTF competencies and provides information on how each training links to specific JTF competencies. MAGI also plans to map its conference programs to the competencies to ensure that content addresses training and education needs.

The Commission on Accreditation (CoA), sponsored by CoAPCR, has adopted the JTF framework in conjunction with its previously endorsed Core Competencies in Clinical Research. Currently, a committee of the CoA is working on self-study documents for clinical

Table 1. Organizations Involved

- Association of Clinical Research Professionals (ACRP) / Academy of Physicians in Clinical Research (APCR)
- Alliance for Clinical Research Excellence and Safety (ACRES)
- Clinical & Translational Science Awards (CTSA)
- Clinical Trials Transformation Initiative (CTTI)
- Collaborative Institutional Training Initiative (CITI)
- Consortium of Academic Programs in Clinical Research (CoAPCR)
- Drug Information Association (DIA)
- Global Health Technologies Coalition (GHTC)
- Innovative Medicines Initiative / PharmaTrain
- Inter-American Foundation for Clinical Research (IAFCR)
- International Federation of Associations of Pharmaceutical Physicians (IFAPP)
- Model Agreements & Guidelines International (MAGI)
- Multi-Regional Clinical Trial Center (MRCT)
- TransCelerate Biopharma

research academic program accreditation that utilize the JTF Framework. The CoA will begin accrediting clinical research academic programs in 2016 as an organizational member of the Commission on Accreditation of Allied Health Education Programs (CAAHEP). CAAHEP is recognized as an accrediting body by the Council for Higher Education Accreditation and formally recognized the clinical research profession in 2013.

The United Kingdom National Health Service (NHS) has conferred with the JTF and plans future discussions with ECRTPTQ and the JTF for a similar core competency mapping exercise as they vision forward to strengthen clinical research workforce.

The Clinical & Translational Science Awards (CTSA) program includes a new competency initiative led by Thomas Shanley, MD (University of Michigan) and Richard Barohn (University of Kansas) called "Enhancing Clinical Research Professionals' Training & Qualifications" (ECRTPTQ). After reviewing the available competency frameworks, ECRTPTQ determined that the JTF framework can serve as a structure for defining standards for research workforce training for principal investigators and study coordinators. In consultation with the JTF and CoAPCR, ECRTPTQ has identified a number of promising improvements, including aligning each competency to learning outcomes for PIs and CRCs. The JTF, CoAPCR and ECRTPTQ will now collaborate to refine the framework to support CTSA's training standards.

The JTF invites other input, especially from industry, with the goal of updating the framework by the end of 2015.

Longer-Term Objectives

ACRP intends to submit the competency framework, when ready, for recognition as a standard by American National Standards Institute (ANSI) and International Organization of Standards (ISO). The standardization process will further validate the framework, and recognition as an ANSI and ISO standard will lend it weight.

The JTF's competency framework does not specify the level (e.g., basic, intermediate, advanced or none) of competency required to perform a particular role. Nor does it specify the constituent parts of each competency or the relevance of those parts to specific roles like principal investigator, study coordinator, or clinical research associate. Such information will be required to create a method for objectively assessing competencies. However, the core competency framework is a solid first step. Much of the future work will consist of individual organizations using the framework and related principles to develop job requirements, training programs, etc., that address their particular needs and philosophies.

If you are interested in staying informed about the JTF, expressing support, or contributing time, please contact the author, who is a member of JTF's governing board.

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