JOINT TASK FORCE FOR CLINICAL TRIAL COMPETENCY

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Disclosure of Conflict of Interest (COI)

- The author has no Conflict of Interest (COI) with regard to the presentation.
Clinical Research Professional Shortages

• In the last six years, pharmaceutical and biotech companies removed roughly 150,000 jobs from their workforce as they shifted more R&D activities to CROs. - Centerwatch, 2015

• At least 10,000 open CRA Positions in the US as of June, 2015 – DIA, 2015

• Number of physicians doing research has declined 5.5% since 2003 and the number in their 60’s and 70’s exceeds the number in their 50’s and below – NIH, 2012

• Many nurses would like to move into Clinical Research Coordinator positions, but salaries are lower and they really do not have CR training in nursing school

• As number of clinical trials increases and number of sites per trial increases there is a tremendous shortage of competent clinical research coordinators
Status of the pipeline of new personnel?

- Still primarily on-the-job training focused on specific role requirements as opposed to defined core competencies
- Supplemented by recurring GCP training with little understanding of the underlying science of medicines development or regulatory perspectives – JTF, 2017
- The current “on the job” training system in place to train and mentor CRAs and CRC’s is inadequate to meet a growing demand for new skills and talents – ACRP, 2016
- No requirement for academic preparation or professional certification
- Graduates of academic programs in clinical research have difficulty obtaining position due to arbitrary experiential requirement.
JTF origin

- Organized under the sponsorship of MRCT/ACRES at Harvard University conference (2013)
- Supported by DIA, ACRP and MAGI
- Included representatives from industry, academia and nonprofit organizations
- Agreed to work toward aligning and harmonizing the many more focused statements relating to core competencies for clinical research professionals into a single, high-level set of standards which could be adopted globally

- serve as a framework for defining professional competence throughout the clinical research enterprise
Joint Task Force for Clinical Trial Competency

Representatives met in person or via TC during the period October 2013-June 2015
JTF Coordinators: S. Sonstein and R. Li
JTF Framework – Competency Domains for the Clinical Research Professional


- Applied Clinical Trials. May 28, 2014
- Journal of Clinical Research Best Practices, 10(6); 1-12.
- CenterWatch Whitepapers, June, 2014.
Examples of Utilization of JTF Framework

- **ACRP** – organized annual meeting tracks and professional certification examination based on JTF Framework
- **Duke University** – restructured research job classifications based on competencies. Went from over hundred to fewer than 20. Restructured promotion criteria
- **Takeda Pharmaceuticals** – reorganized internal training programs based on competency framework
- **CTSA** adopted core competency framework as basis for clinical investigator training program
- **CAAHEP** sponsored accreditation of academic programs in clinical research. Standards based on JTF framework
- **The UK National Institute for Health Research (NIHR) Clinical Research Network (CRN)** has used the JTF Framework in a clinical research workforce development initiative called the Integrated Workforce Framework (IWF).
Current and Future JTF activities

• JTF website – http://clinicaltrialcompetency.org
  • Broaden the stakeholders utilizing competencies to comprise all team members including statisticians, data managers, physicians, patient advocates

• JTF Framework 2.0
  • Reduced overlap across domains. Uses objective, measurable language. Gives examples of specific skills that need to be mastered for each competency statement.

• Add leveling (or tiers) of competencies
  • Obviously there are entry, mid and expert levels of competency

• Personal competency portfolios
  • Individuals can apply for employment or promotion based on documented competencies instead of “length of time of employment”

• Development of Metrics to show impact of integration of competency framework into the clinical research enterprise
JTF Vision

• To develop a universally applicable, globally relevant harmonized competency framework for clinical research professionals
• To align competency-based efforts (e.g., education, training, and workforce development) across the clinical research enterprise
• To identify knowledge, skills, and attitudes that are essential for the successful, ethical, and safe conduct of clinical trials
• To build a framework that can adapt to meet the needs of clinical researchers as the discipline evolves and advances
• To facilitate the success and development of current and aspiring clinical research professionals
• To align stakeholders across the clinical research enterprise—including academia, industry, government, non-profits and professional societies