JOINT TASK FORCE FOR
CLINICAL TRIAL
COMPETENCY

Stephen A. Sonstein, PhD

MultiRegional Clinical Trial Center of Brigham and Women's Hospital and Harvard University

Cambridge, Massachusetts, USA

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**
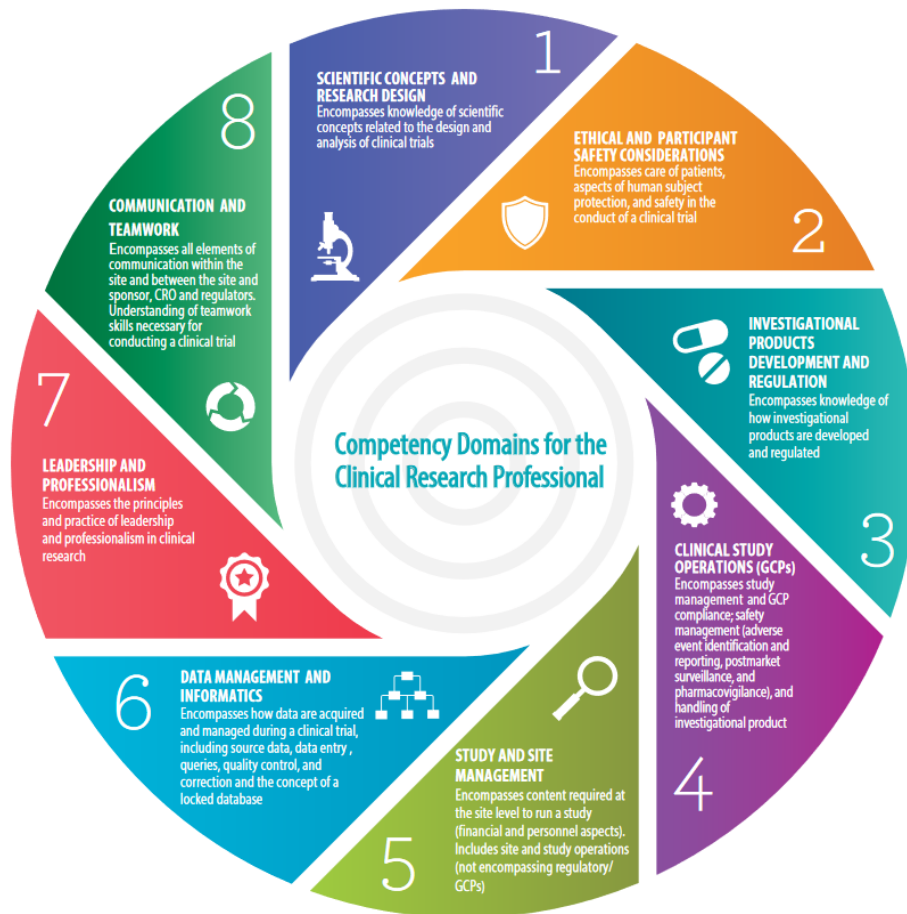
Joint Task Force for Clinical Trial Competency

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

Sonstein, S.A., Seltzer, J., Li, R., Jones, C.T., Silva, H., Daemen, E. (2014, June). **Moving from compliance to competency: A harmonized core competency framework for the clinical research professional**. *Clinical Researcher*. 28(3); 17-23

- *Applied Clinical Trials*. May 28, 2014
- *Journal of Clinical Research Best Practice*s,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 in to 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