MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Update: Joint Task Force for Clinical Trial Competency

Competency Framework 2.0

Competency Levelling Project

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Clinical Research Professional Shortages

- In the last six years, pharmaceutical and biotech companies eliminated 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. Little or no clinical research content in medical school curriculum.
- 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 professionals

Expected Standards in Clinical Research Do not Exist

Entry "Standards"

- Many ways to enter field – "usually who you know not what you know"
- No entry level educational or competency requirements

Tenure does not equate to competency

- Most jobs require 2 or more year's experience but no definition of what experience means
- How do you get the experience without the job?

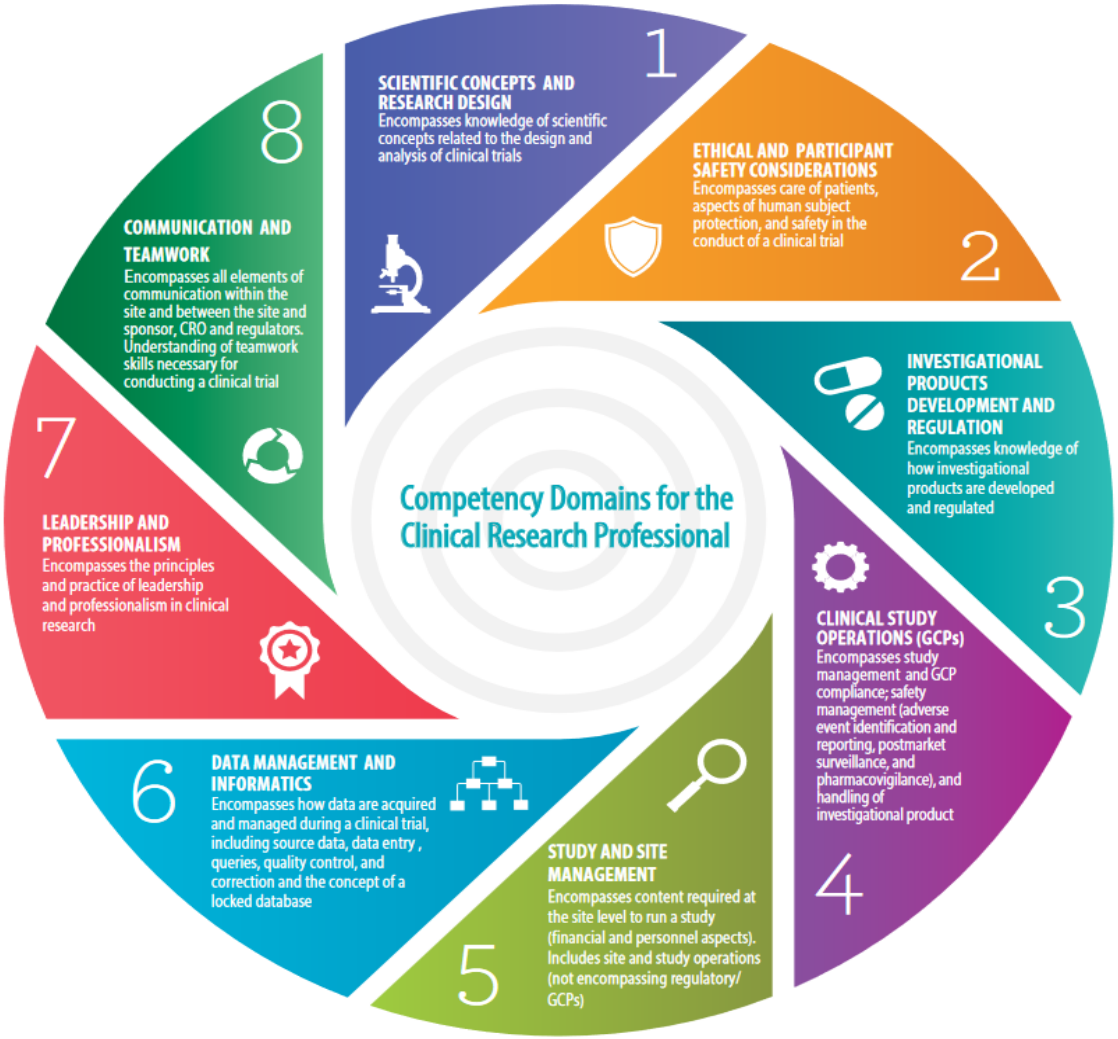
Few obtain certification or degree in clinical research

- No mandatory regulations, standards or licensure requirements for specific job roles within clinical research, nor accreditation requirements for academic programs, nor standards for internal or external training programs

Joint Task Force for Clinical Trial Competency

- Organized under the sponsorship of MRCT at Harvard University (2013)
- Supported by DIA, ACRP, ACRES and MAGI
- Included representatives from industry, academy 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**

Competency Domains for the Clinical Research Professional



Sonstein, S.A., Seltzer, J., Li, R., Jones, C.T., Silva, H., Daemen, E. (2014, June). **Moving form 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 Practices*,10(6); 1-12.
- *CenterWatch Whitepapers*, June, 2014.

Use of competencies

- Standardized role descriptions
- Competency-based training/education
- Level of competency vs level of job
  - Promotion and upward mobility
- Self-assessment & competence
  - Personal portfolio of competencies
- Competence & career development
  - Academic program accreditation
- Continuous process (competence not static, jobs change, gaps appear); lifelong learning

Core Competencies in Clinical Research: Real World Applications, Convergence and Evolution of a Framework

- October 19, 2016, MRCT at Harvard Faculty Club
  - 52 participants from academia, government, industry, non-profit organizations, professional associations and others
  - Discussed evolution of the Harmonized Core Competency Framework for the Clinical Research Professional
  - Presented real world applications exemplified in 15 case studies from five countries and a global survey
  - Proceedings available on MRCT website

Suggestions from Workshop for Revision of Framework and future JTF efforts

- **Continue publicizing Framework and broaden stakeholder engagement**
  - Create JTF website
  - Broaden the stakeholders participating in the training to comprise all team members including statisticians, data managers, physicians, patient advocates
- **Further refine competencies**
  - Reduce overlap across domains. Use objective, measurable language. Give examples of specific skills that need to be mastered for each competency statement. Consider how to include 'soft-skill' measurements.
- **Add leveling (or tiers) of competencies**
  - Obviously there are entry, mid and expert levels of competency
- **Add measurement/certification**
  - Develop standardized assessment of competencies. Integrate into professional certification
- **Regulatory science**
  - The emerging concept of regulatory science should be added to the curriculum including an understanding of data quality and data analysis. Consider whether this should be a new domain.

JTF Update: 2016-17

- Clinicaltrialcompetency.org
- Competency Framework 2.0
  - Requested comments and suggestions from pharma, CROs, regulators, sites, academicians
  - Revisions workgroup (30 participants) reviewed
  - Released September, 2017
- Levelling of Framework 2.0
  - Fundamental, Skilled, Advanced levels with examples
  - 5 Workgroup Chairs, 27 participants, international representation
  - In final stages of development (see handout)

Example of Levelled Competency Statement

1.3 Identify and explain the elements, principles and processes of designing a clinical study

Fundamental Level	Skilled Level	Advanced Level
Researcher can: 1. Identify the key elements of a clinical study protocol. 2. Able to describe the general process of clinical study protocol development. 3. Recognize the basic differences between the various types of clinical studies.	Researcher meets the fundamental level AND: 1. Is able to apply the basic principles of study design in authoring a draft (non-complex) clinical study. 2. Can review a clinical study protocol ensure all needed elements are included. 3. Can compare and contrast potential study designs. 4. Is able to apply and align all applicable regulations and international guidelines to the design of a clinical study.	Researcher meets the skilled level AND: 1. Can evaluate the process of clinical study design ensuring all regulatory and international guidelines are followed, make adjustments to the processes as needed. 2. Can develop protocols as applicable to the therapeutic area. 3. Can evaluate strengths and weakness of study designs and explain these to others.
Example	Example	Example
When given a clinical study protocol the researcher can identify the key elements required for a protocol and understands the basic process involved in protocol development	The researcher understands the concepts of clinical study design, can differentiate between study designs, and apply applicable international and local regulatory laws and guidelines to the design of a study protocol	When presented with a protocol the researcher can not only evaluate the strengths and weaknesses of the study designs, but can explain these to others. The researcher also has an understanding of what protocol designs align with specific therapeutic areas.

Examples of utilization of levelled Competency Framework

- **Rebecca Brouwer – Duke University**
  - Using levelled competencies for job classifications and workforce development
- **H. Robert Kolb – University of Florida**
  - Using levelled competencies for training of clinical research coordinators
- **William Gluck – Durham Technical College**
  - Utilization of levelled competencies by pharma and CRO's
- **Carolynn Thomas-Jones – Ohio State University**
  - Using levelled competencies to create professional portfolios
- **Stephen Sonstein – Eastern Michigan University/MRCT**
  - Using levelled competencies to create an accreditation process for academic programs

Questions, Comments, Suggestions

Panel Discussion

Rebecca Brouwer (Duke University)

H. Robert Kolb (University of Florida)

William Gluck (Durham Technical Community College)

Carolynn Thomas-Jones (Ohio State University)

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