

A collaboration for the harmonization of education and training requirements for clinical research professionals

Harmonized Core Competencies for the Clinical Research Professional

January 31, 2014

Rebecca Li

Disclaimer

The views and opinions expressed in this presentation are those of the individual presenter and do not necessarily reflect the views of the Clinical Trials Transformation Initiative

Content providers and collaborators

Content Providers



Academy of Physicians in Clinical Research



Association of Clinical Research Professions



Clinical & Translational Science Awards



Collaborative Institutional Training Initiative



Consortium of Academic Programs in Clinical Research



Global Health Network



Inter-American Foundation for Clinical Research



International Academy of Clinical Research



International Federation of Associations of Pharmaceutical Physicians



Multi-Regional Clinical Trials



TransCelerate



UK Clinical Research Collaboration

Collaborators



Alliance for Clinical Excellence and Safety



Clinical Trials Transformation Initiative



Amgen



Deloitte



Drug Information Association



MAGI



Pfizer



PharmaTrain



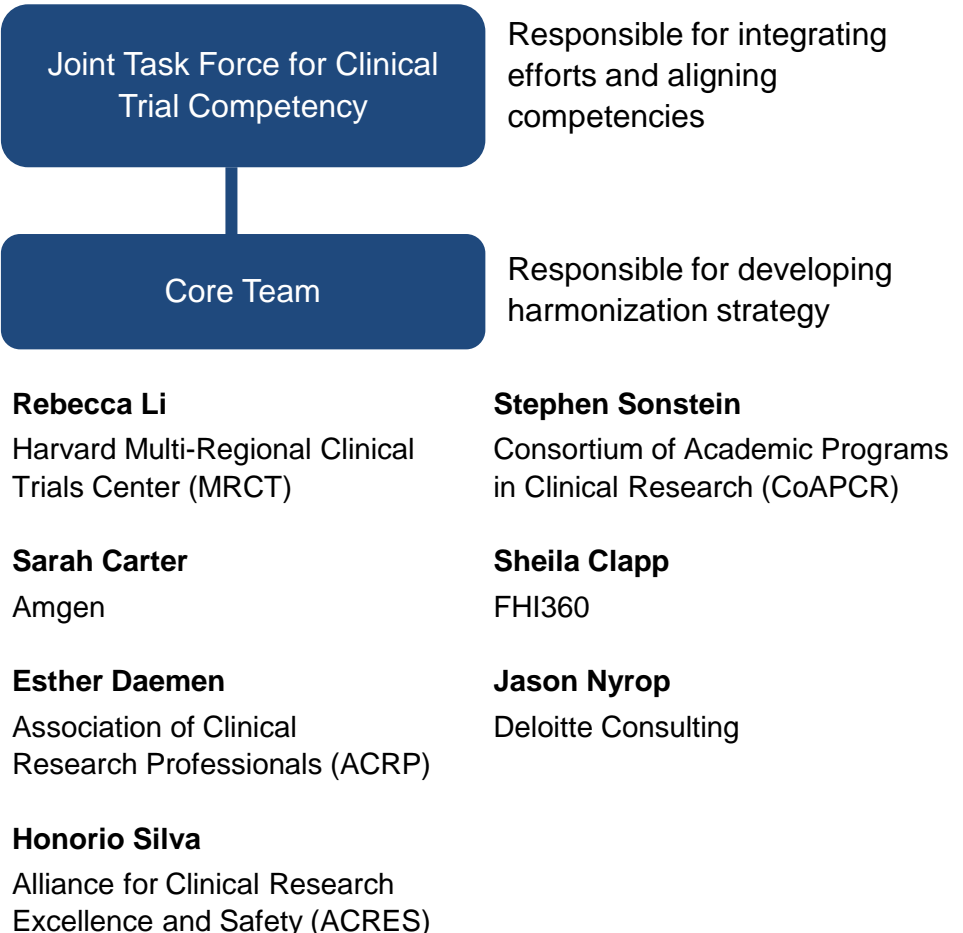
Korea National Enterprise for Clinical Trials

The Joint Task Force for Clinical Trial Competency seeks to integrate and harmonize efforts to produce a single list of core competencies

Multiple groups identifying clinical trials competencies creates an opportunity for harmonization

- Investigators and support professionals require an appropriate knowledge, skills and attitudes to carry out clinical duties
- Interested groups have varying approaches to develop core competencies for investigators and support professionals

The Joint Task Force for Clinical Trial Competency was created to integrate efforts



Harmonized competencies can be used as the basis for various end-uses

Education

Streamlining educational requirements

Investigator Selection

Defining criteria for investigator selection

Job Descriptions

Standardizing job descriptions

Development of Accreditation standards

Defining standards for accreditation

Site Qualification

Defining criteria for site selection and qualification

Training Requirements

Standardizing and streamlining training requirements

The Joint Task Force builds upon previous work

Many efforts have identified investigator competencies and learning objectives



The Joint Task Force is positioned to integrate on-going efforts

Diverse representation

- The Joint Task Force brings together Harvard Multi-Regional Clinical Trials Center and Consortium of Academic Programs in Clinical Research to guide and lead the effort

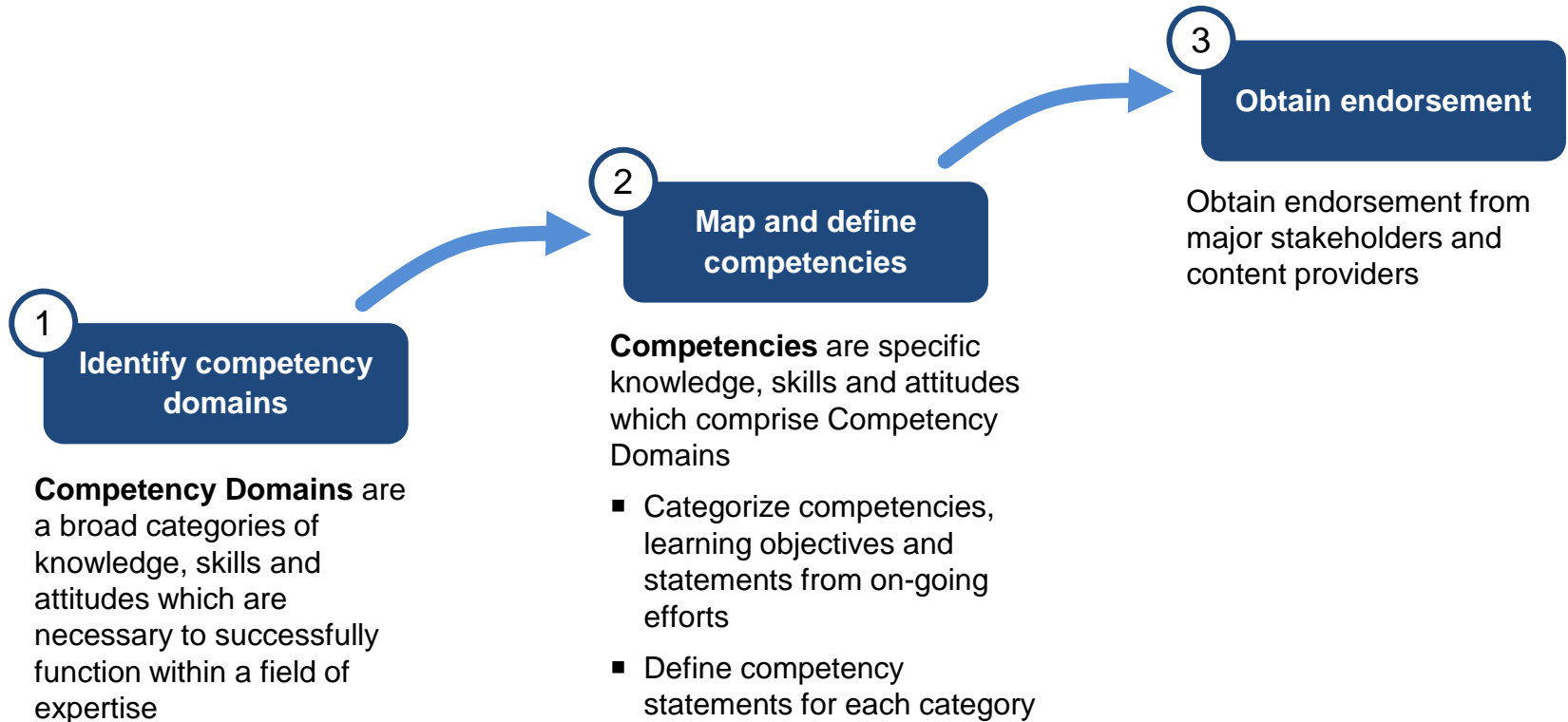
Process oriented

- The Joint Task Force has developed a process to harmonize competencies

Focused on output

- The Joint Task Force is committed to the output of competency domains and core competencies to enable various end-uses

We developed a three step approach to harmonize competencies



Competency Domains were defined by reviewing and aligning documents of on-going efforts

1

Identify competency domains

Competency Domains are a broad categories of knowledge, skills and attitudes which are necessary to successfully function within a field of expertise

Documents were reviewed from on-going efforts...

- Academy of Physicians in Clinical Research
- Association of Clinical Research Professions
- Clinical & Translational Science Awards
- Collaborative Institutional Training Initiative
- Consortium of Academic Programs in Clinical Research
- Global Health Network
- Inter-American Foundation for Clinical Research
- International Academy of Clinical Research
- International Federation of Associations of Pharmaceutical Physicians
- Multi-Regional Clinical Trials
- TransCelerate
- UK Clinical Research Collaboration

... and eight Competency Domains were defined

Scientific Concepts
and Research Design

Study and Site
Management

Ethical
Considerations,
Patient Care and
Safety

Data Management
and Informatics

Medicines
Development and
Regulation

Leadership and
Professionalism

Clinical Trial
Operations

Communication &
Teamwork

Competency statements are defined from grouping similar statements from on-going efforts

2

Map and define competencies

Competencies are specific knowledge, skills and attitudes which comprise Competency Domains

ILLUSTRATIVE

Similar statements are grouped together



Evaluates and applies the regulatory and ethical aspects underpinning clinical development



Describe the historical development of regulations associated with the protection of human subjects



Describe cultural and social variation in standards of research integrity



Develop a personal statement on professional ethics and behavior as a clinical research

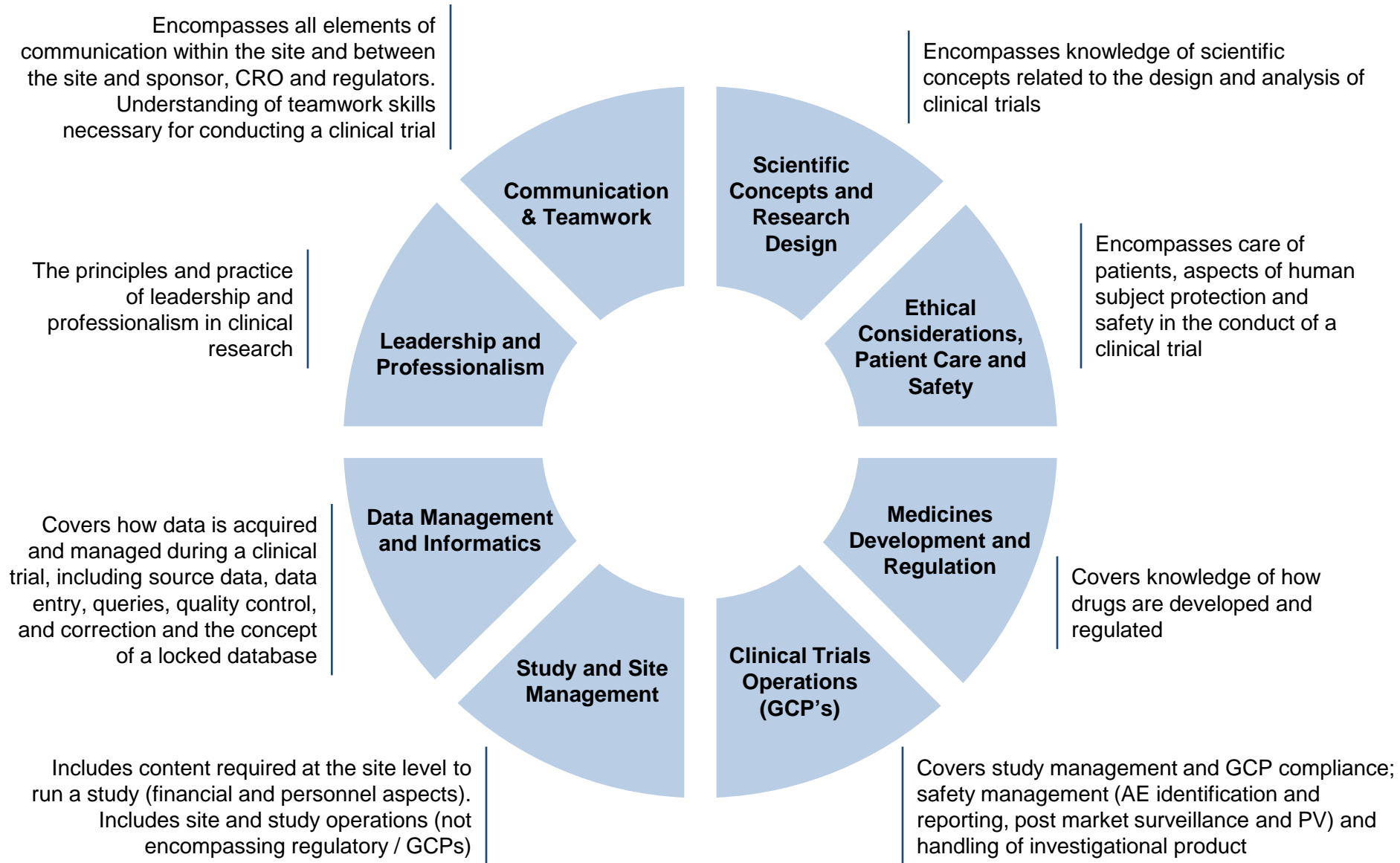
Ethical Considerations, Patient Care and Safety

The Competency Statement is mapped to a Competency Domain

Describe the ethical issues involved when dealing with vulnerable populations and the need for additional safeguards

A Competency to align similar statements is defined

Eight domains of the Harmonized Core Competencies for the Clinical Research Professional



Scientific Concepts and Research Design



Scientific Concepts and Research Design

Encompasses knowledge of scientific concepts related to the design and analysis of clinical trials

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