Moving from Compliance to Competency for the Clinical Research Professional

Rebecca Li, PhD, Executive Director
Learning Objectives for Today

• How to assess your training needs and gaps based on the core competency framework
• Recognize practical uses for the core competency statements
• Assess the relevance of harmonized clinical research core competencies to your own professional circumstances
Agenda for today

• Current state of clinical research training and unmet needs

• Development of a Harmonized set of Core Competencies

• Educational Needs Assessment using the set of Core Competencies
Collaborating to Improve Multi Regional Clinical Trials

The MRCT Center’s Purpose is... To improve the design, conduct, and oversight of multi-regional clinical trials, especially trials sited in or involving the developing world; to simplify research through the use of best practices; and to foster respect for research participants, efficacy, safety and fairness in transnational, transcultural human subjects research.
Problem statement:

• Many PIs and study staff have little to no formal training in research design, ethics or GCP

• No currently available list of internationally recognized standards or competencies currently exists

Objective:

• Develop a single list of minimum clinical trial training elements that can be endorsed by other groups and utilized for training and site qualification purposes
In 2012 – Initiated a Workgroup for Clinical Research Training to Address:

1. Tremendous variation in skills and experience of PIs and coordinators worldwide

1. Training programs are not typically modified or tailored to suit specific regional (geographic) or cultural requirements.

2. Lack of metrics to establish correlation between PI certification or training and improvements in the quality and efficiency of clinical research.

3. Lack of guidelines for core competencies that must be obtained by investigators prior to conducting clinical research.

Co-chairs:
SHEILA CLAPP (FHI)
SARAH CARTER (Amgen)

Mohanish Anand (Pfizer)
Tracy Blumenthal (Rapidtrials
Ann Claiborne (IOM)
Amy Davis (PRMR)
Kim Havens (PPD)
Anna Ravdel (Synergy)
Jim Thomasell (ACRP)
Jennifer Webb (DIA)
Helmut Wolf (Novartis)
Mark Barnes (MRCT) – ad hoc
Barbara Bierer (MRCT) – ad hoc
Marc Wilenzick (MRCT) – ad hoc
Medicines Development and Clinical Research are among the most highly regulated activities on a global basis

- Governmental regulatory authorities
- ICH – GCPs
- IRB/IEC
- Pharmacovigilance
- Data Safety Monitoring Boards
Personnel who conduct clinical trials

• Very general requirements

• In most countries, anyone with a medical license can serve as a PI ....irrespective of experience or education in clinical research

• Little detail in regulatory authority definitions of criteria required for responsible individuals
ICH 4.1.1 The investigator(s) should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial, should meet all the qualifications specified by the applicable regulatory requirement(s), and should provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB/IEC, and/or the regulatory authority(ies)
New Regulations

- Declaration of Helsinki (Revised 2013)
  "Medical Research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications...."

- FDA Guidance for Investigators, IRBs and Sponsors (2013)
  "The IRB needs to assess the investigator’s training and experience specifically related to the proposed study......and the determination that the investigator is qualified may need a review of the investigator’s previous specific experience....and prior clinical experience"

Gradual realization on the need for leveraged credentials and qualifications through education and training
What are we expecting when we hire a clinical research professional?

- **Principal investigator** – Any licensed physician in US or Europe can serve as a Principal Investigator

- **CRC** – there are no educational requirements

- **CRA** – there are no educational requirements

- **Regulatory Affairs Professional** – there are no educational requirements

• How do we differentiate between an entry level and an advanced level professional?

• What criteria do we use to justify promotion?
Mentoring

Academic Programs

Medical Schools – very little

Pharmatrain – EU

CTSA – oriented toward investigator initiated trials

Graduate/Undergraduate Program in Clinical Research Administration/Regulatory Affairs/Clinical Data Management

Professional organizations

ACRP, DIA, SoCRA, SCDM, RAPS – professional societies
Evolution of Education and Training in Clinical Research

Activity
- Informal training: coaching, tutoring
- Short term courses: how to do it
- Professional bodies (training, support)

Discipline
- Academic involvement: Standards and competencies
- Formal Curriculum: short and long term programs
- National accreditation and certification

Profession
- International Standards/Harmonization of Training/mutual recognition
- International Certification/Specialization?
- Maintenance through Continuing Professional Dev. (CPD)

H. Silva, 2010
Although one can infer that education and training will enhance the level of regulatory compliance, we have been unable to translate this into a measurement of competence.
Systematic harmonization and broad based acceptance of job descriptions and performance outcomes for the many roles that exist in the clinical research enterprise

Standardization and Documentation of education/training and experience in clinical research

Consider required personnel certification
Groups related to the clinical research enterprise have published brought this message to light.

- National Center for Advancing Translational Sciences - core competencies for translational research scientists,

- International Federation of Associations of Pharmaceutical Physicians and the Academy of Physicians in Clinical Research - listings of core competencies for pharmaceutical physicians and clinical investigators

- Consortium of Academic Programs in Clinical Research - core competencies for graduates of academic programs to guide curriculum development

- Association of Clinical Research Professionals - career development pathway for CRCs, CRAs and investigators which incorporates competency statements

- Regulatory Affairs Professions Society core competency statements

High quality efforts, but approach of each group has been focused on a specific component of the clinical research enterprise
Agenda for today

• Current state of clinical research training and unmet needs

• Development of a Harmonized set of Core Competencies

• Educational Needs Assessment using the set of Core Competencies
To bring together these disparate, but high quality efforts focused on clinical trial competence …

Meeting of representatives was hosted by the Multi-Regional Clinical Trial Center at Harvard University during Spring, 2013:

• pharmaceutical companies
• contract research organizations
• academic institutions
• clinical research sites
• professional societies

A broad based and widely representative group was formed and named the Joint Task Force for Clinical Trial Competency (JTF).
agreed to work toward aligning and harmonizing the many more focused statements relating to core competency for clinical research professionals into a single, high-level set of standards which could be adopted globally and serve as a framework for defining professional competency throughout the clinical research enterprise
We developed a three step approach to harmonize competencies

1. **Identify competency domains**

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

2. **Map and define competencies**

   **Competencies** are specific knowledge, skills and attitudes which comprise Competency Domains:
   - Categorize competencies, learning objectives and statements from on-going efforts
   - Define competency statements for each category

3. **Obtain endorsement**

   Obtain endorsement from major stakeholders and content providers.
Competency Domains were defined by reviewing and aligning documents of on-going efforts.

**Identify competency domains**

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 Domains are a broad categories of knowledge, skills and attitudes which are necessary to successfully function within a field of expertise.
Competency statements are defined from grouping similar statements from on-going efforts

Map and define competencies

Similar statements are grouped together

- IFAPP
  - Evaluates and applies the regulatory and ethical aspects underpinning clinical development

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

- CTSA
  - Describe cultural and social variation in standards of research integrity

- CONSORT of Academic Programs in Clinical Research
  - 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

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

A Competency to align similar statements is defined
Competency Domains for the Clinical Research Professional

Communication & Teamwork
- The principles and practice of leadership and professionalism in clinical research.

Scientific Concepts and Research Design
- Encompasses knowledge of scientific concepts related to the design and analysis of clinical trials.

Leadership and Professionalism
- Encompasses care of patients, aspects of human subject protection and safety in the conduct of a clinical trial.

Data Management and Informatics
- Covers how data is acquired and managed during a clinical trial, including source data, data entry, queries, quality control, and correction and the concept of a locked database.

Ethical Considerations, Patient Care and Safety
- Covers knowledge of how drugs are developed and regulated.

Study and Site Management
- Includes content required at the site level to run a study (financial and personnel aspects). Includes site and study operations (not encompassing regulatory / GCP’s).

Medicines Development and Regulation
- Covers study management and GCP compliance; safety management (AE identification and reporting, post market surveillance and PV) and handling of investigational product.

Clinical Trials Operations (GCP’s)
- PLEASE TAKE A HANDOUT
Core Competencies

Table 1: Harmonized Core Competencies for the Clinical Research Professional

<table>
<thead>
<tr>
<th>Scientific Concepts and Research Design</th>
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<tbody>
<tr>
<td>• Demonstrate knowledge of clinical research, biostatistics, pharmacology, and toxicology related to medicines, devices, and biologics.</td>
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<tr>
<td>• Identify clinically important questions that are potentially testable through clinical research hypotheses, through review of the professional literature.</td>
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<tr>
<td>• Explain the elements (clinical, epidemiological, and operational) of clinical and translational study design.</td>
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<tr>
<td>• Design a clinical trial.</td>
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<tr>
<td>• Critically analyze study results with an understanding of the impact on comparative effectiveness.</td>
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<table>
<thead>
<tr>
<th>Clinical Trials Operations (GCPs)</th>
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<tbody>
<tr>
<td>• Evaluate the conduct and management of clinical trials within the context of GCPs and the Clinical Development Plan.</td>
</tr>
<tr>
<td>• Describe the key roles and responsibilities of the clinical investigator (investigator, site principal investigator) and describe the role of the regulatory body in the conduct of clinical trials.</td>
</tr>
<tr>
<td>• Describe appropriate data management and storage, and dispensing of investigational products.</td>
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<tr>
<td>• Differentiate the types of adverse events (AEs) that occur during clinical trials, understand the identification process for AEs, and describe the reporting requirements to institutional review boards/international ethics committees [IRB/IEC], sponsors, and regulatory authorities.</td>
</tr>
<tr>
<td>• Describe how global clinical operations and guidelines are monitored to ensure subject protection and efficacy during the conduct of clinical trials.</td>
</tr>
<tr>
<td>• Describe the reporting requirements of global regulatory bodies relating to clinical trial conduct.</td>
</tr>
<tr>
<td>• Describe the role and process for monitoring of clinical studies.</td>
</tr>
<tr>
<td>• Describe the data and documentation requirements of regulatory agencies (both pre- and postapproval).</td>
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<tr>
<td>• Describe the various methods by which safety issues are identified and managed during the development and postmarketing phases of research.</td>
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<tr>
<th>Data Management and Informatics</th>
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<tr>
<td>• Describe the role that biostatistics and informatics serve in biomedical and public health research.</td>
</tr>
<tr>
<td>• Describe the logical flow of data through a clinical trial.</td>
</tr>
<tr>
<td>• Summarize the process of electronic data capture and the importance of information technology in data collection, storage, and management.</td>
</tr>
<tr>
<td>• Describe the CHIRP requirements for data correction and queries.</td>
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<tr>
<td>• Describe the significance of electronic data capture systems and how standard operating procedures are used to guide these processes.</td>
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<table>
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<tr>
<th>Ethical and Participant Safety Considerations</th>
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<tbody>
<tr>
<td>• Compare and contrast clinical care and clinical management of research participants.</td>
</tr>
<tr>
<td>• Define the concepts of “clinical equipoise” and “therapeutic misconception” as related to the conduct of a clinical trial.</td>
</tr>
<tr>
<td>• Compare the requirements for human subject protections and privacy under different national and international regulations and their implementation throughout all phases of a clinical study.</td>
</tr>
<tr>
<td>• Evaluate the evolution of the requirement for informed consent from research participants and the principles and content of the key documents ensuring the protection of human participants in clinical research.</td>
</tr>
<tr>
<td>• Describe the ethical issues involved when dealing with vulnerable populations and the need for additional safeguards.</td>
</tr>
<tr>
<td>• Evaluate and understand the importance of the ethical and current ethical issues, subtitles, and alternative aspects to the medicines development process.</td>
</tr>
<tr>
<td>• Explain how inclusion and exclusion criteria are included in clinical trials to assure human subject protection.</td>
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<tr>
<td>• Summarize the principles and methods of distributing and balancing risk and benefit through selection and management of clinical trial participants.</td>
</tr>
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<tr>
<th>Medicines Development and Regulation</th>
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<tbody>
<tr>
<td>• Describe the clinical trial events that are associated with regulatory medicine development and regulatory submission processes.</td>
</tr>
<tr>
<td>• Describe the roles and responsibilities of the various institutions participating in the medicines development process.</td>
</tr>
<tr>
<td>• Discuss the ways in which the data generated are interpreted and used to support regulatory submissions.</td>
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<tbody>
<tr>
<td>• Describe the methods utilized to determine whether or not to sponsor, supervise, or participate in a clinical trial.</td>
</tr>
<tr>
<td>• Develop and analyze the financial, ethical, and regulatory aspects of the trial.</td>
</tr>
<tr>
<td>• Conduct the clinical trial.</td>
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<tr>
<td>• Analyze the trial data.</td>
</tr>
<tr>
<td>• Develop and validate the trial conclusions.</td>
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<tr>
<th>Study and Site Management</th>
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</thead>
<tbody>
<tr>
<td>• Conduct the study and site management.</td>
</tr>
<tr>
<td>• Identify the key responsibilities, tasks, liabilities, and accountabilities that are associated with the conduct of a clinical trial.</td>
</tr>
<tr>
<td>• Identify and explain the specific procedures, documentation, and data requirements of the IRB, sponsors, contract research organizations (CROs), and regulatory authorities related to the conduct of a clinical trial.</td>
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<th>Leadership and Professionalism</th>
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<tbody>
<tr>
<td>• Describe the principles and ethics of leadership, management, and mentorship, and apply them within the working environment.</td>
</tr>
<tr>
<td>• Identify and implement procedures for the prevention and management of the ethical and professional conflicts that are associated with the conduct of clinical research.</td>
</tr>
<tr>
<td>• Identify and adhere to the ethical and professional standards that are applied to the conduct of clinical research.</td>
</tr>
<tr>
<td>• Describe the ethical issues of cultural diversity and the need for cultural competency in the design and conduct of clinical research.</td>
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</tbody>
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<tr>
<th>Communication and Teamwork</th>
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</thead>
<tbody>
<tr>
<td>• Discuss the role and appropriate communication between sponsor, CRO, and clinical research site.</td>
</tr>
<tr>
<td>• Describe the components of an international scientific publication.</td>
</tr>
<tr>
<td>• Effectively communicate the content and relevance of clinical research findings to colleagues, advocacy groups, and the scientific community.</td>
</tr>
<tr>
<td>• Conduct the research through interdisciplinary and interprofessional research teams.</td>
</tr>
</tbody>
</table>
Agenda for today

• Current state of clinical research training and unmet needs

• Development of a Harmonized set of Core Competencies

• Educational Needs Assessment using the set of Core Competencies
An example of application

**Ethical Considerations, Patient Care and Safety**
Encompasses care of patients, aspects of human subject protection and safety in the conduct of a clinical trial.

- **Sponsor – clinical researcher**
- **IRB member**
- **PI or study coordinator**

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

Each competency should be interpreted based on your current role.
## Competencies by Role

<table>
<thead>
<tr>
<th>Clinical Trial Operations Domain</th>
<th>PI</th>
<th>Clinical Research Coordinator (CRC)</th>
<th>Monitor (CRA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluate the conduct and management of clinical trials within the context of a Clinical Development Plan</td>
<td>Required</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td>Describe the roles and responsibilities of the clinical investigation team as defined by Good Clinical Practice Guidelines</td>
<td>Required</td>
<td>Optional</td>
<td>Required</td>
</tr>
<tr>
<td>Evaluate the design conduct and documentation of clinical trials as required for compliance with Good Clinical Practice Guidelines</td>
<td>Required</td>
<td>Optional</td>
<td>Required</td>
</tr>
</tbody>
</table>

*PLEASE TAKE HANDOUT*
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
52 specific competencies within the 8 domains derived from the published and presented efforts of specific groups

Based upon cognitive parameters

Not expected that each member of the clinical research enterprise is competent in all

Still need to be leveled as Expert, Competent, Novice

Hope is that Harmonized Core Competencies will be utilized as a basic framework to produce the more granular and specific competency statements which include knowledge, skills and attitudes which define the many roles which exist in the clinical research enterprise
New approaches to professional development

The questions for Life Long Learning

What competences do I need for my work and what are the gaps?

What learning opportunities can help me?

How can I consolidate the learning and become “competent”?

31
Simultaneous Publication of the Framework

Moving From Compliance to Competency: A Harmonized Core Competency Framework for the Clinical Research Professional

Published: May 28, 2014

By: Stephen A. Sonstein, PhD, Jonathan Seltzer, MD, MBA, MA, Rebeca Li, PhD, Carolynn Thomas Jones, DNP, MSPH, RN, Honorio Silva, MD, Esther Daemen, MBA, RN

Source: Applied Clinical Trials
http://www.appliedclinicaltrials.com/appliedclinicaltrials/article/articleDetail.jsp?id=844359

Editor's Note: This article originally appeared as a peer-reviewed article in the June 2014 issue of ACRP's Clinical Researcher. http://www.acrnnet.org/MainMenu/Cateocry/Resources/ClinicalResearcher.aspx

Harmonized Core Competencies for the Clinical Research Professional:
The Joint Task Force, 2014

Journal of Clinical Research Best Practices
Vol. 10, No. 6, June 2014

Moving From Compliance to Competency: A Harmonized Core Competency Framework for the Clinical Research Professional

By Stephen A. Sonstein, Jonathan Seltzer, Rebeca Li, Honorio Silva, Carolynn Thomas Jones, and Esther Daemen

Medicines development and clinical research are among the most heavily regulated activities on a global basis. As our understanding of pathophysiology and therapeutic intervention has increased, there has been a concomitant increase in the complexity of clinical trial protocol requirements and in the number and complexity of the regulations and guidelines related
Job/Role Specific Professional Development Pathways
Professional Pathways

- Competencies in Action – A real life example
- ACRP Professional Development Pathways
Competencies in Action – A real life example

- ACRP Professional Development Pathways
  - Incorporated in and aligned with the eight (8) global levels of competency as identified by the taskforce
  - Next step -> Three pathways - Job/ role specific!
    - CRA, CRC and PI
  - What?
    - Identifies the knowledge/skills the CRA, CRC and PI need and when
    - A roadmap for professional development (training)
### Professional Pathways

- Mastery Levels

<table>
<thead>
<tr>
<th>Mastery Level</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unnecessary (NA)</td>
<td>Not Required</td>
</tr>
<tr>
<td>Exposure (E)</td>
<td>Sufficiently aware of the knowledge to be able to look up relevant information</td>
</tr>
<tr>
<td>Comprehension/Application (C/A)</td>
<td>Able to interpret and/or discuss concepts</td>
</tr>
<tr>
<td></td>
<td>Able to use knowledge to solve simple problems based on application of concepts in new settings</td>
</tr>
<tr>
<td>Mastery (M)</td>
<td>Able to apply the knowledge to complex problems, integrate information, and create, synthesize and evaluate solutions</td>
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</table>
### INSTRUCTIONAL LEVELS (FIGURE 2)

<table>
<thead>
<tr>
<th>Instructional Level</th>
<th>Experience</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic</td>
<td>2 years (CRCs, CRAs, PIs)</td>
<td>Individuals, without knowledge or skills, who require understanding or basic ability</td>
</tr>
<tr>
<td>Intermediate</td>
<td>2-5 years (CRCs, CRAs); 2-6 years (PIs)</td>
<td>Individuals, with core knowledge or basic skills, who want to expand knowledge or skills but will not make decisions that require expertise</td>
</tr>
<tr>
<td>Advanced</td>
<td>5+ years (CRCs, CRAs); 6 years (PIs)</td>
<td>Individuals who seek to specialize in the area or are current specialists and seek updates/interactions with peers</td>
</tr>
</tbody>
</table>
### Professional Pathways

- Example CRC Pathway/Regulatory and Ethics

<table>
<thead>
<tr>
<th>REGULATORY KNOWLEDGE &amp; ETHICS</th>
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<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Knowledge and understanding of the regulations and guidelines governing clinical trials.</td>
<td>Subject Privacy Regulations</td>
<td>C/A</td>
<td>M</td>
</tr>
<tr>
<td></td>
<td>Regulatory Requirements</td>
<td>C/A</td>
<td>M</td>
</tr>
<tr>
<td></td>
<td>Ethics GCP/Ethical Codes</td>
<td>C/A</td>
<td>M</td>
</tr>
<tr>
<td></td>
<td>Research Misconduct (Falsification, Fabrication, Plagiarism)</td>
<td>C/A</td>
<td>M</td>
</tr>
<tr>
<td></td>
<td>Conflict of Interest</td>
<td>C/A</td>
<td>M</td>
</tr>
</tbody>
</table>
mission of this JTF initiative has been to bridge the gap between “what to do” and “how to do it

a universally applicable, globally relevant framework now exists which identifies the Competency Domains and the associated cognitive skills necessary to conduct a high quality, ethical and safe clinical trial.

eventually to approach the regulatory bodies of the world for recognition and acknowledgment of the Core Competency Framework and to ultimately house the document and its future evolutions within the International Conference on Harmonization as a guideline similar to the E6 Guideline for Good Clinical Practice.
Summary – How can you use the framework?

- Explain how the eight levels of competency as identified by the Taskforce can be applied to your specific job and roles
- Consider the advantage of having (role specific) competencies as a standard to set up certification exams
- Consider how the framework may be used to standardize job descriptions for your department
- Standardize training requirements for your team
Thank you!

REBECCA LI, PHD

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