MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

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

October 19, 2016 ● 8:30 AM to 4:00 PM

Harvard Faculty Club, Cambridge, Massachusetts

Contents

Executive Summary

In 2014, the Joint Task Force (JTF) for Clinical Trial Competency developed, published and disseminated the Harmonized Core Competencies Framework for the Clinical Research Professional.[1] Since then the uptake and implementation of the core competencies has been rapid, global and broadly impactful. Based on this significant uptake in the relatively short period of time since the framework has been in the field, the JTF leadership decided to convene a workshop to bring together the key stakeholders that have implemented the framework.

This workshop, held on October 19, 2016, assembled 52 participants from academia, government, industry, non-profit organizations, professional associations and others to deliberate:

- the evolution of the Harmonized Core Competencies Framework for the Clinical Research Professional ("the Framework")
- real world applications, exemplified in 15 case studies from five countries and a global survey
- lessons learned and feedback for potential future revisions of the Framework and future projects of the Joint Task Force (JTF) for Clinical Trial Competency

Case studies from academic institutions, professional associations, industry and international settings demonstrated that the Framework has been utilized to develop degree-granting programs, for corporate and governmental workforce development programs, for role responsibility definition and for promotion criteria by the pharmaceutical industry and clinical research organizations.

Key Lessons learned include:

- Confirmation of need for the framework as demonstrated by the widespread implementation: Research is the only field of medicine in which training is not expected before going into practice. A global survey showed that the perception of relevance of core competencies differed by region and function.
- The Framework helped build confidence among stakeholders: The Core Competencies offer an excellent starting point for building a more specific, national model of competency-based metrics. Competency, rather than compliance, made the work more meaningful for clinical researchers.
- The Framework was flexible, adaptable: Most stakeholders modified the framework to meet their need either by creating "tiers" of competencies for various roles or adapting the competencies themselves.
- The Framework had broad applicability: The Framework was utilized across a diverse base of stakeholders for a variety of end uses.

[1] Sonstein, Stephen A., et al. "Moving from compliance to competency: a harmonized core competency framework for the clinical research professional." *Clin Res* 28.3 (2014): 17-23.

- Framework facilitated curriculum development: Aligning current curricula in academic programs to the competencies provided an objective, comprehensive, and structured approach to curriculum development. The framework facilitated review and revision of the curricula/assessments which are subsequently now more aligned with what students were expected to do in the real world.
- Leadership was essential to implement the Competencies framework successfully: The adoption process required leaders to introduce a vision of professionalization grounded in core competencies. The context of the workforce must be considered in applying JTF Core Competencies in concrete situations for successful implementation. It was suggested to engage and communicate with all stakeholders involved in competency-model integration. However, the financial impact of competency integration can be substantial. The competency framework was an investment in time and resources to integrate, but was worth the effort.
- Evaluations are critical after roll-out: Verification of competencies is essential. Tracking individual mastery of competencies and/or periodic tollgates can ensure employee or student progression of mastery. Diagnosis of competency data from JTF should be validated and cross-referenced by regional campaigns.
- Need for training: It was suggested to streamline an on-boarding training curriculum to prioritize critical needs first, and cascade other trainings as appropriate. Allow for customization of training plan by prior experience. Focus on application of knowledge and encourage competency-metric system. Stakeholder input is valuable for training quality to be evaluated and revised.

Suggestions for revisions of the Competency Framework:

Key suggested revisions included: minimize redundancy; conduct validation initiatives; determine if the competencies apply to all members of the team and whether they should be tiered by role; add more explicit requirements for specific roles; and develop metrics to evaluate the competencies.

Specific suggestions for revisions included:

- Further refine competencies: Reduce overlap across domains (e.g., site management and clinical trial operations). Provide additional guidance to clarify definitions of competency statements to minimize differing interpretations. Use objective, measurable language. Define specific skills that need to be mastered for each competency statement. Consider how to include 'soft-skill' measurements.
- Add leveling (or tiers) of competencies for various job descriptions: Consider addressing the leveling of the Competency Statements based on Bloom's Taxonomy for various tiers of job roles and academic programs. Define what depth of knowledge each role is required to understand. Align competencies with job titles and roles. Define learner group(s) and level content accordingly.
- Increase applicability of competencies to all roles in research industry: Consider having competencies tied to certain expertise and level of employment. Distinguish staff versus principal investigator competencies. Include competencies for program management/leadership. Different research roles need different mapping of competencies and competency-standards.

- Add measurement / certification: Add metrics to define success. Define how competencies will be measured. Develop standardized assessment of competencies. Standards must be meaningful, with measurable metrics, developed with multi-stakeholder involvement. Consider independent oversight to ensure integrity, evaluate effectiveness. Track the long-term effects of the competency model.
- Feasibility: Explore the feasibility of core competency implementation in resource-limited regions and apply initiatives accordingly.
- Training: Consider training for all clinical researchers in the international community at the beginning of the trial, to ensure that roles and responsibilities are well-delineated.
- Stakeholder engagement: Broaden the stakeholders participating in the training to comprise all team members including statisticians, data managers, physicians, patient advocates, etc. and tailor the training to their needs.
- 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.
- Job descriptions: Define entry-level position for the clinical research professional.

Overall, the workshop indicated that the competencies have been socialized and enthusiastically implemented widely. There was a consensus that the Framework should be revised in 2017 to ensure the competencies remained relevant and implementable for real-world use and to move "from compliance to competencies to professionalism."

Workshop Summary

Review of the Development of the Joint Task Force for Clinical Trial Competency Framework

Rebecca Li, MRCT Center

Dr. Rebecca Li, Executive Director of the Multi-Regional Clinical Trial Center of Brigham and Women's Hospital and Harvard (MRCT Center) recalled the disparate efforts that were the reason for the MRCT Center to initiate a workgroup in 2012 out of which the Joint Task Force for Clinical Trial Competency (JTF) was launched. The JTF agreed to work toward aligning and harmonizing the many 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. The resulting framework of Harmonized Core Competencies for the Clinical Research Professional has eight domains which are universal. The Framework has been simultaneously issued in several publications in 2014. Since then the implementation over the last two years has been tremendous across stakeholder groups.

This workshop focused on:

- Discussing the evolution of the Harmonized Core Competencies Framework for the Clinical Research Professional
- Learning about real world applications of the Framework
- Providing feedback to discuss potential future revisions of the Framework
- Discussing potential future projects for the Joint Task Force

Utilization of the JTF Core Competency Framework

Stephen Sonstein, Eastern Michigan University

Dr. Stephen Sonstein, Director, Clinical Research Administration at Eastern Michigan University and Co-Chair Joint Task Force for Clinical Trial Competency, summarized the widespread utilization of the JTF Core Competency Framework ("The Wheel"), its 51 specific core competencies, and its rapid integration into the clinical research enterprise. Since its initial publication in 2014, the Framework has been widely presented at professional meetings globally, adopted by professional organizations, utilized by academic institutions to develop degree-granting programs, served as the basis for corporate and governmental workforce development programs and for role responsibility definition and promotion criteria by the pharmaceutical industry and clinical research organizations. The presentations that follow discuss some of these efforts.

In an effort to further elucidate the status of the Framework within the Enterprise, Dr. Sonstein and a team conducted a Global Survey of Competency, Relevance and Need for Training, which analyzed the

self-perceived competency of 1,584 regional participants from Latin America/Caribbean, USA/Canada, Western Europe, and Asia/Australia for each of the 51 competencies. It showed that Principal Investigators (PI), Research Managers/Program Managers (RM/PM) and Clinical Research Associates (CRA) on average rate themselves as competent in aspects of the eight domains that relate most closely to ICH-GCPs. Data Management Professionals (DM) and Regulatory Affairs Professionals (RA) rate themselves as competent in the Domains that directly relate to their specialty areas, but as less than competent in the GCP-related domains. Quite interestingly, all roles rate themselves as less than competent in the Domains of Scientific Concepts and Research Design (except Principal Investigators) and in Medicines Development and Regulation. One of the study's conclusions is that GCP training alone may not be sufficient to produce a broadly competent clinical research professional. An article describing this study will be published in December 2016 in *Clinical Researcher*.

Session 1: Foundational Initiatives to Integrate the Core Competencies Framework into the Clinical Research Enterprise

This session presented how the Core Competencies Framework has been utilized in four different entities: professional organization, biopharma, academic medical center, and National Center for Advancing Translational Sciences (NCATS) network.

JTF Competency Integration

Terri Hinkley, Association of Clinical Research Professionals

Ms. Terri Hinkley, Workforce Innovation Officer for ACRP, informed the audience how ACRP has been actively aligning their certification and training offerings with the core competencies. ACRP has continued its efforts in workforce development and achieving the goal of an educated, competent workforce using the core competencies as a foundation. By acting as a collaborative member of the Joint Task Force (JTF) for Clinical Trial Competency, ACRP has furthered its advocacy profile for standardized competence in clinical research and leadership in workforce development. Several other ACRP initiatives have begun to develop competence in the workforce, including core competencies required of entry-level and experienced clinical research associates through the multi-stakeholder CRA Workforce Development Task Force. The implementation of these standards will aim to address the difficultly that new and unexperienced CRAs have in obtaining a job and allay concerns for employers about competence and proficiency in their newly hired CRAs.

Key lessons learned:

- Consider how to include 'soft-skill' measurements in certification exams
- Overlap between competency domains made tagging competency-characteristics difficult [most prevalent in (4) Clinical Trial Operations and (5) Study and Site Management]

Suggestions for revisions:

- Reduce overlap across domains
- Bolster competency statements to avoid confusion and increase efficacy
- Increase applicability of competencies to all roles within the research industry
- Consider having competencies tied to certain expertise and level of employment

Applying the Core Competency Framework of the JTF for Clinical Trial Competency to Improve the Overall Training and Career Development of Physicians in Industry Involved with Clinical Trials: A Use Case from a Biopharma Company

Subasree Srinivasan, Alexion

Dr. Subasree Srinivasan, former Therapeutic Lead with Bristol-Myers Squibb (now with Alexion Pharmaceuticals), discussed how the JTF Core Competencies have been used to build training methods, assess performance, and nurture career growth for clinicians involved in the design, execution, and interpretation of clinical trials. A primary concern in industry is holding medical monitors accountable for the data that are reported at the end of the study. Trainings, often guided by the Standard Operating Procedures and/or use of electronic systems, have left monitor-physicians 'trained and compliant' but not always competent to carry out the job requirements in an effective and consistent manner. Bristol-Myers Squibb tasked a cross-disciplinary group of individuals with the formation of teams and sub-teams to map the existing training curriculum for clinicians to the competency framework and to identify gaps in the curriculum. A tool box was developed from these mappings and utilized by clinicians in part of their onboarding and training process. A three bucket approach grouped certain competencies together which led to an overall reduction in the number of training modules for clinicians by about 20% and the identification of key gaps that could be filled with relevant modules or face to face training.

Key lessons learned:

- Streamline on-boarding training curriculum to prioritize critical needs first, and cascade other trainings as appropriate
- Allow for customization of training plan for medical monitors with prior industry experience vs. no experience
- Use of this framework helped build confidence among stakeholders and management of the competency of medical monitors
- Competency, rather than compliance, made the work more meaningful for medical monitors

The Use of Competencies in the Development of Job Classifications and Workforce Development Initiatives

Rebecca Brouwer and Denise Snyder, Duke University

Ms. Rebecca Brouwer, Associate Director of Research Operations (DOCR), and Ms. Denise Snyder, Associate Dean for Clinical Research (DOCR), utilized the JTF Core Competencies to build competency-based job classifications for research professionals at Duke University. Duke organized a Clinical Research Professionals Working Group (CRPWG) comprised of leaders from the clinical research support office, human resources, and individual research units. The CRPWG, along with the Enhancing Clinical Research Professionals' Training and Qualifications (ECRPTQ) workgroup, refined the JTF Core competencies and built them into existing assessments and training opportunities. Through multiple work sessions, involving approximately 75 subject matter experts representing clinical research staff and managers at Duke, 41 relevant competencies were identified and mapped out using language that could be objectively assessed. From there, the competencies were organized into a tiered-level system by CRPWG to develop discrete job descriptions, assess competency, and encourage professional development. By aligning job descriptions to the current market and updating salaries for existing and incoming employees, the Duke Office of Clinical Research (DOCR) anticipates an impact to several areas including: staff trending (hires + attrition), tracking, effort sharing, training, accountability, compliance, performance and improved workforce output. Improvements in these areas should result a significant return on investment (ROI) for Duke and higher quality support for clinical researchers.

Key lessons learned:

- Engage and communicate with all stakeholders involved in competency-model integration (e.g., governance, faculty)
- Financial impact of competency integration and resulting employee reclassification can be substantial
- Wording of JTF Core Competencies can be elaborated upon and expanded into levels for implementation benefit
- Not all stakeholders will buy-in to new system, must be able to handle diverse groups with system changes

Suggestions for revisions:

- Include levels of competencies
- Distinguish staff versus PI competencies
- Use objective, measurable language
- Consider program management as an additional competency domain

Education and Training of Clinical & Translational Study Personnel: A Competency-Based Approach

Thomas Perorazio, University of Michigan, and Michelle Wartak, Tufts Clinical and Translational Science Institute

Ms. Michelle Wartak, representing Tufts Clinical and Translational Science Institute, and Mr. Thomas Perorazio, Administrative Program Director at the Michigan Institute for Clinical and Health Research, hypothesized that introducing a competency-metric in a standardized training curriculum would reduce protocol violations in clinical trials and remove redundant training requests. This program was done in order to streamline training curricula and improve health outcomes. The Enhancing Clinical Research Professionals' Training & Qualifications (ECRPTQ) project goal was to move away from an ad hoc training method and to advance towards a competency- based education for standardization and assessment purposes. Using the competencies from the Joint Task Force (JTF) for Harmonized Core Competencies in Clinical Research, domain workgroups refined competency statements and identified training gaps in the current curriculum. The University of Michigan is extending this effort by using a blended learning model and emphasizing hands-on activities that reinforce knowledge through application based case-studies. This program has curriculum and standardized metrics that are available through the University of Michigan. Also, a grant is currently being submitted for funding to continue this curriculum development so that it might be refined and more widely distributed.

Key lessons learned:

- Existing training methods should focus on application of knowledge and encourage competency-metric system
- Competency domains differ, different research roles need different mapping of competencies and competency-standards
- Stakeholder input is valuable for training quality to be evaluated and revised

Suggestions for revisions:

- Refine wording of some domains and competencies (some specific examples were provided)
- Competency framework should be continually updated to follow corresponding advances in science
- Standardized assessment of competence is needed
- Define specific skills that need to be mastered for each competency statement
- Define learner group(s) and level content accordingly

Discussion

The moderated discussion addressed the following issues, in response to questions from audience participants:

Buy-in

Participants raised some concerns over adverse stakeholders and their **buy-in** to the competency model. For example, certain CTSA groups and CROs deemed the GCP and Study & Site related competencies not applicable to medicine development and the scientific concepts. It appeared that some researchers may be viewing the core competencies too narrowly, and therefore not expound upon the principles and

their applicability. To find a balance between broad applicability and specificity, the attendees at the meeting suggested some competencies could be reworded.

Also, adverse stakeholders might need a fundamental change in their approach. Rather than discounting some competency domains immediately, it was suggested that these adverse stakeholders could be coached into seeing where these competencies might apply. Leadership is key to implementation with adverse stakeholders.

Credentialing, Cost, & Efficiency

The JTF Core Competency model was viewed by the group as a stepping-stone towards more deliberate **credentials**. Still, questions arose around how a core administration unit would fold this model into their business model. Establishing credentials seemed to accommodate this task.

The **cost of implementing** the core competencies was raised as a concern: will individual work groups or larger departments pay for restructuring the system? Group members who had successfully integrated the competency model at their respective institution proposed that *workforce engagement* and *building confidence* in the system should be the initial objectives. The financial savings would follow. Subsequently, other departments would feel compelled to follow suit and financially support their own model implementation.

Also, the competency model **drives efficiency**. Tying competency to compensation enabled specialization (e.g., by defining and clarifying job roles and finding the right people to fit those roles), while also challenging the staff to *perform*.

Financial Compensation & Support

There was a question on whether the JTF Core Competency model will **impact derivative funding processes**. For example, will the competency language be integrated into CTSA grants, IRBs for local investigator studies, and projects at academic institutions? Some attendees confirmed that this is already under way.

The competency model has the potential to save institutions financially. Over the long haul, it will also help to apply metrics and to track how each research member is progressing in their career. This will in turn result in greater portfolio transparency.

Education & Dissemination

There was a question of how to bring the **educational theory to practice** and how do we disseminate this material in an effective manner. Employers aim to empower employees by equipping them with competency training. Pedagogical shifts are moving away from lecture-based and rote memorization skills and moving toward an involved and case-study based learning style. The goal is for people to

demonstrate objective competence and move beyond a vague understanding or awareness of the rules, and toward a deeper understanding.

Session 2: Utilization of Competencies for Innovative Workforce Development

This session presented how the Core Competencies Framework has been utilized for workforce development in five different settings.

Re-shaping an Academic Clinical Research Administration (CRA) Graduate Program Through the Application of the Harmonized Core Competencies Framework

Joan Butler and Beth Harper, George Washington University

Dr. Joan Butler, Assistant Professor and Director Academic CRA Programs, and Ms. Beth Harper, Adjunct Assistant Professor at George Washington University and President, Clinical Performance Partners, explained the iterative and interactive approach of how they reshaped their Clinical Research Administration (CRA) Graduate Program by utilizing the Harmonized Core Competencies Framework across courses. In Phase 1, during a faculty retreat in early 2015, existing courses were systematically mapped to domains and competency statements of the Core Competencies Framework. Phase 2 included curriculum alignment and redesign, including a structured process using course templates and competency worksheets to prioritize and cross-reference the domains and core competencies for each course. In Phase 3, courses were launched so that now the majority of graduate CRA courses have been modified. Phase 4, which just started, includes reassessment of program outcomes to ensure competency alignment and student feedback and exploration of student learning outcomes.

Key lessons learned include:

- Aligning the curriculum to the competencies has provided an objective, comprehensive and structured approach to curriculum development versus reliance on internally developed competencies and instructor preferences.
- The framework facilitated review and revision of the curriculum/assessments which are now more aligned with what students will do in the real world.

Two suggestions for revisions were prioritized:

- Provide additional guidance to clarify definitions of competency statements to minimize differing interpretations.
- Consider addressing the leveling of the Competency Statements based on Bloom's Taxonomy for levels of job roles and academic programs.

Developing a Clinical Trials Implementation Program: One Institution's Experience

Penelope Jester, University of Alabama, Birmingham

Ms. Penelope Jester, Program Director of the Clinical Research Support Program (CRSP) / Center for Clinical and Translational Science, presented an implementation case study of how study coordinators and research staff have been trained for clinical trials implementation since 2006 at the University of Alabama at Birmingham (UAB). In 2014, they developed the first phase of a Clinical Investigator Training Program using competencies and Good Clinical Practice (GCPs) as backbone of the curriculum, and began using the Competencies to structure and to document training. For a new employee, there are requirements of which courses and training to take within 2 weeks of employment, within 2 months of employment, within 6 months of employment, and on a continuous basis thereafter. Content of these trainings is driven by Competencies and GCPs.

Lessons learned and challenges include:

- Lacking a mandate
- Costs: convincing institutions it is part of indirect costs
- Difficulty identifying ALL research personnel
- Challenges of incorporating hands-on activities
- Evaluations are critical
- Tracking individual mastery of competencies

Suggestions for revision of competencies:

- Develop certification exam for the competencies
- Minimize or clarify redundancy
- Define what depth of knowledge each role is required to understand
- Define how competencies will be measured
- Align competencies with job titles and roles

Utilization of JTF Framework for CTSI Grant Renewal

H. Robert Kolb, University of Florida

Mr. H. Robert Kolb, Assistant Director of Clinical Research at the Clinical and Translational Science Institute (CTSI) of the University of Florida explained how the Core Competencies Framework has been utilized by the Clinical Research Coordinator Taskforce for grant renewal. Journal articles in 2012 and 2014 called for assessing the training, support and career development requirements of clinical research coordinators. Being introduced in 2014 to the JTF Core Competencies was welcomed in order to act on these recommendations. For a grant application renewal, the Task Force proposed that CTSI education and training initiatives be aligned around a common competency framework to support program organization, integration, and adoption of common assessment and quality measures. Consequently,

the Task Force used the JTF Competencies for Clinical Research Professionals. For two training grants, they mapped the language of the competencies wheel into the language of the grant.

Lessons learned and challenges include:

- Acknowledgement of The Critical Need for Academic Health Centers for such a set of common competencies. This need is not fully acknowledged.
- Requires Champions to introduce a vision of professionalization grounded in core competencies, particularly among supporting coordinators and professionals.
- Steps forward include coordinating directed and strategized communication to catalyze institutional attitudes towards a common core of competencies.

Suggestion:

- Reframing of competencies: Premise #2 "Underscores development of leadership & professionalism as an integral part of clinical/ translational research training, underpinning all other competencies."

Beyond Competency: Building a Professional Clinical Research Workforce for the Future

Greg Koski, Alliance for Clinical Research Excellence and Safety

Dr. Greg Koski, President and CEO of the Alliance for Clinical Research Excellence and Safety, talked about the application of the competencies to build a professional workforce for clinical research. He started with defining professionalism (specialized knowledge and skills, service to others, self-regulation and standard of conducts, honesty and integrity, accountability) and tools of professionalism (standards, certification, and accreditation). Competencies can be utilized to develop global standards of excellence for personnel. The goal is a commitment to excellence by providing sites with standards that can be measured and tools to achieve the standards and then to recognize and reward sites for achievements.

Lessons learned:

- It does not pay off to re-create the wheel
- There is reluctance among the best to be held to standards that somebody else has created
- Research is the only field of medicine in which we do not expect training before going into practice

Challenges and Suggestions:

- Independent oversight: ensure integrity, evaluate effectiveness
- Effective processes: minimize burdens, maximize value, neutral third-party
- Appropriate standards: must be meaningful, measurable metrics, multi-stakeholder

Competency-Based Training for Entry-Level CRAs

Tammi Masters, INC Research

Ms. Tammi Masters, Associate Director, Global Clinical Training, at INC Research presented how they developed an integrated training and management model based on globally accepted monitoring competencies for entry level CRAs to increase productivity and sponsor confidence in ability. In 2014, they partnered with the International Academy of Clinical Research (IAOCR) and mapped entry level CRA training program learning outcomes to IAOCR's globally accepted learning outcome framework for CRAs. They also developed competencies and mapped them to JTF competencies. While it increased sponsor confidence, training competed with project work. They developed a Clinical Training Institute (CTI) that integrates training and development of skills combined with application during a 12-week program. They developed and mapped competencies and developed toll gates to ensure learning progression as well as self-paced training with online lectures and instructor led face-to-face simulation as well as comprehensive assessments to ensure understanding and application of principles taught.

Lessons learned:

- Mapping competencies to learning outcomes creates a robust training program
- Verification of competency is essential
- Periodic tollgates ensures that the employee is progressing
- Protecting training time permits the employee to focus

Key impacts:

- Concentrated time for training coupled with on-site verification of competency prior to project assignment
- Robust training program increased employee confidence
- Provided well documented competency based on tollgates and award of Part I of the IAOCR monitoring credential

Discussion

The moderated discussion addressed the following issues, in response to questions from audience participants:

Access to assessments

Audience member asked if assessments from INC Research will be shared with the audience. Panelist explained that assessments are integrated throughout the program, including self-assessments, exercises, comprehensive essay type assessment, observation. These are proprietary, but will be published soon. IAOCR has accredited the program. Not enough experience has been accumulated for meaningful metrics.

Reproducibility of training for other stakeholders

Suggestions were made to reproduce successful trainings to a wider range of stakeholders. For instance, the INC Research training could also be applied to data managers.

Utilizing competencies in performance appraisals or merit increases:

Panelists gave examples of job descriptions and pay scales that changed after aligning them with competencies, integrating competencies into assessment systems, and using a systems approach in which competencies will bear on standards.

Incentives for utilizing competencies in academic medical centers:

Panelists acknowledged that clinical research has lower standards than academic research and that there is still a lot of work that needs to be done to bring the standards up to par.

Retaining trained staff and reaching independent sites that are not part of an institution:

Audience members suggested that it is important to retain the people who have been trained (as turnover is very common). It is a **change in paradigm** to put money into the front end of training researchers, rather than into compliance and "clean-up."

Panelists acknowledged that there is a diversity of research sites. A panelist suggested to allow sites of excellence to be established worldwide that would mentor other sites and serve as "models," and to apply the core competencies consistently.

Session 3: International Implementation

This session presented how the Core Competencies Framework has been applied in global settings and research.

The JTF Core Competencies in Latin America: Inter-Regional and Intra-Regional Differences

Honorio Silva, Rutgers University School of Health Professions; International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP), The Netherlands

Dr. Honorio Silva, Adjunct Professor at the BioPharma Educational Initiative, Rutgers University School of Health Related Professions (Newark, NJ) and President-elect for the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP), assessed the differences in the perception of competence, relevance for the job, and additional needs for training among clinical research professionals in a subpopulation who fully completed the JTF questionnaire (n= 852). Through inter-regional comparisons (Latin America vs. Western Europe vs. USA) and intraregional comparison (Mexico vs. rest of Latin America), Dr. Silva analyzed the attitudes amongst Principal Investigators (PI), Clinical Research Coordinators, Clinical Research Associates, and Clinical Research Managers with respect to the competency framework. Results showed that the relevance of competencies and needs for training varied from region to region and between functions. These preliminary findings suggest the need for further validation (focus groups, additional surveys, etc.) amongst clinical research professionals, particularly PIs from Latin America, taking into consideration its large sample size as compared to other regions. Dr. Silva encouraged the involvement of regional stakeholders to leveraging efficacy and uptake of the competency model.

Key lessons learned:

- Regional/country context should be considered in the validation of competencies and assessment of training/education programs
- Perception of relevance of core competencies differed by region and function

Suggestions for revisions:

- Explore feasibility of core competency implementation in resource-limited regions and apply initiatives accordingly

Competence-Based Certification in Clinical Research in Mexico — A Proposal

Matilde Damian and Jose Viramontes, Association of Professional Specialists in Clinical Research, Mexico

Dr. Matilde Damian and Mr. Jose Viramontes, representatives from the Association of Professional Specialists in Clinical Research (APEIC), Mexico, reported the need for a common competency platform

in the Certification of Clinical Research Professionals in Mexico. They highlighted the JTF's survey of Competences in Clinical Research conducted in 2015 that referenced main stakeholders and provided an ample sample size to be used as the basis for a Mexican Profile definition. APEIC has in place a three-step project plan that involves confirmation of JTF competency diagnosis of Mexico (Phase 1), content development and vocational training for tutors/mentors (Phase 2), and the implementation and evaluation of a competency model (Phase 3). By the final phase, APEIC plans to present the standardized competency model and metrics to the Regulatory Authority for use as a mandatory certification amongst the academia and the pharma industry members in Mexico. A competence-based certification program is expected to have a positive impact on Mexico´s participation in international clinical trials, as well as in the local productivity and consistency of these trials.

Key lessons learned:

- Competency diagnosis using the JTF guidelines should be validated and cross-referenced by regional campaigns

Suggestions for revisions:

- Mapping out skills and behaviors associated with each competency might have a cultural dimension
- Involving stakeholders in competency-model discussions is important for traction and model uptake in local regions

The Acceptance and Application of the Competencies in the EU

Esther Daemen, TRIUM Clinical Research Consultancy, Belgium

Ms. Esther Daemen, Clinical Research Professional at TRIUM Clinical Research Consultancy, Belgium, shared how the JTF Core Competencies are accepted and applied in the EU, while also sharing her own experiences in consulting pharma companies from a competency-based model. In her case-based presentation, Ms. Daemen utilized the JTF core competencies as a baseline to identify gaps in client performance, developing training measures to meet these gaps, and then correcting client Human Resource departments to develop a consistent approach and ensure staff buy-in. In addition, Ms. Daemen showed that competency data can help explain situational or systematic issues to stakeholders in an organized and efficacious manner. If cultural differences are taken into account when presenting the competency model, Ms. Daemen observed little difference in model uptake between the US and EU.

Key lessons learned:

- Competency framework takes time to explain to clients, is worth it in the end
- Some competencies overlap, making it difficult to attach metrics for standardization and assessment

Suggestions for revisions:

- More role-specific guidelines are needed for company alignment
- More evidence of performance increases from competency framework integration needed across different platforms (e.g., industry, academia, non-profit)

Using the Harmonized Core Competencies to Inform the Development of an Integrated Workforce Framework in the UK

Fiona O'Neill, NIHR Clinical Research Network, United Kingdom

Ms. Fiona O'Neill, Head of Workforce and Learning at the NIHR Clinical Research Network, United Kingdom, shared how the JTF Harmonized Core Competencies have been used by the NIHR to develop research capacity and capability in the English National Health Service (NHS). Currently there is a growing number of clinical professionals without registration or nationally agreed standards of practice. Known as the Integrated Workforce Framework, the NIHR is spearheading this initiative to develop overarching role descriptors for the workforce and provide a more coherent approach to knowledge and skills development. This national project will also provide more visibility for research career pathways for the UK graduate workforce by articulating professional identities and making connection pathways. Participants at an initial workshop with key stakeholders in the research arena agreed that the competency domains are helpful, but conversations will need to continue to discover and unpack the full potential of these competencies in the UK region. The NIHR is committed to taking a responsive, evidence-based approach to integration of the JTF Core Competencies and remains open to learning from international colleagues in developing a national competency standard system.

Key lessons learned:

- JTF Core Competencies offer an excellent starting point for building a more specific, national model of competency-based metrics
- Context of workforce must be considered in applying abstract principles of JTF Core Competencies into concrete solutions
- Use the motivation of 'opportunity and improvement' to create team engagement and policy uptake
- Integration of the JTF Core Competencies takes time, but it is well worth it

Suggestions for revisions:

- Questions around regulation and assurance of competency practices for research professionals who enter the workforce without a clinical qualification still need to be answered
- Explore certification and accreditation implications of implementation

Research Essentials — Developing Excellence in Research Design and Practice. An Australian Story

Ian Kerridge, PRAXIS Australia and University of Sydney, Australia

Prof. Ian Kerridge, Director of PRAXIS Australia Ltd and Professor of Bioethics and Medicine at the Centre for Values, Ethics and the Law in Medicine (VELiM) at the University of Sydney, Australia, reported the influential work PRAXIS Australia has done in developing excellence in research design and practice. PRAXIS Australia has used the JTF Core Competency outline as the basis for a purpose-built, modular learning program for all those working in the research sector – irrespective of their professional role or disciplinary focus.. Drawing upon resources of two of Australia's leading tertiary Universities and Australia's largest independent Ethics Committee (IRB), PRAXIS Australia provides a "Research Essentials" package that is flexible and specialized to different research work groups. Training modules can be built to meet certain competency requirements for different professional roles, as well as provide optional or advanced training for greater ascension. Programs that integrate the JTF Core Competencies, like PRAXIS Australia, have encouraged clinical research professionals to maintain, expand, and develop the skills needed to enter the workforce.

Key lessons learned:

- Current JTF Core Competency model does not account for non-clinical trial researchers (e.g., public health, social sciences, etc.)
- More time is needed to determine the efficacy of competency-model in industry and academic settings
- JTF Core Competencies allow for specificity but not flexibility amongst roles and competency application

Discussion

The moderated discussion addressed the following issues, in response to questions from audience participants:

Global Standard

The group imagined a **global standard** of competencies, which could improve consistency and efficacy across multi-disciplinary platforms and encourage global awareness of deficiencies in research. A standardized set of competencies that align with current national models would streamline the implementation process. There was some confusion over definition of certification, accreditation, and licensure. It was apparent that definitions must be clarified.

Accreditation, Certification, & Scalability

Audience members inquired who will grant **accreditation and certification** of core competency standards in different countries. Given the cost parameters, there was a question whether the **scalability** was feasible. It was suggested that local universities be the primary sponsor. Involvement from these universities would be a matter of acquiescence rather than leadership, because many stakeholders believed these competency certifications should be affordable and accessible to everyone. A dissenting opinion insisted that the profession should be responsible for certification, not the universities.

However, even with regulatory and institutional support, it will be difficult to demand accreditation from every research workforce member. Many **practical hurdles** such as financial costs and stakeholder buy-in seem to be the main obstacles for competency integration into current systems.

Pushback against the competency model has been from groups that are already profiting off a poor standard and minimal expectations for clinical trial professionals. Market resistance was overcome by a network of facilitators willing to make a change; variable for different countries and markets.

Session 4: Panel Discussion of Impacts

The panel was comprised of: **Robert O'Neill**, FDA; **Howard Fingert**, Takeda; **Rick Sax**, Quintiles; **Kathryn Mileham**, ASCO; **Dirk de Naeyer**, Janssen; **Margaret McCabe**, IACRN; and **Thy Pham**, Gates Foundation, moderated by Rebecca Li, MRCT Center.

Panel members shared the impact of the core competencies framework for their domain or organization and then discussed questions from the moderator and audience. Discussion points included:

Competency Training

Panel members and audience members agreed on the need for **competency training** which would lead to more successful clinical trials. With defined roles and responsibilities, the research team would understand the cost implications and monitor the sources of variability more closely. Even with training of all clinical research staff, the principal investigator should take a central role in implementing the competency model in his/her team. Also, warning signs and safety signals would be more easily detected with competency training.

Participants suggested that training and competency levels be as broad and applicable as possible to ensure adoption. Also, the international expansion of the JTF competency model should leverage existing networks in different countries for more accrual. This would grant greater access to qualified sites.

Regulatory Science

A panel member suggested that the emerging concept of regulatory science needs to be taught. This would include how to look for quality data and to interpret data analysis and how to deal with conflicting evidence and heterogeneity if results of multi-regional clinical trials differ among the regions.

Stakeholder Engagement

Participants suggested that all clinical trial **stakeholders** should be a part of the deliberation process. A balance would need to be found for patient safety and quality care for research participants with fidelity to the research protocol and the quality of the data and outcomes of the research. Certification could help find this subtle equilibrium. Competencies would allow for synergy between research and patient quality control.

Participants suggested that it would help to collaborate, share, and harmonize trial knowledge. Learning would increase with 'open access' information systems. However, it can be expected that a paradigm change will be met with some level of resistance.

Measurement & Metrics

The group began to define some competency **metrics and measurements**. Competency success should include, but not be solely determined by, easy access to clinical trial enrollment, the retention of well-trained staff, and a conceivable "end game" (as there are consequences for not having a defined end point). The "quality by design" concept should be continually revisited to make certain the regulatory authority will eventually adopt the competency model.

Panel members suggested the following **next steps** with revision of the competency framework:

- Make it a "living document" in which competencies evolve as issues emerge
- Add areas of research as they emerge
- Harmonize how each group applies the framework
- Include the voice of study participants
- Clarify who **monitors** the evolution of the framework: It was suggested that a dedicated group of stakeholders do so
- Focus on changes that really matter rather than wordsmithing and tinkering with details
- Put together a comprehensive text (textbook), with case studies
- Address gaps: guidance on measurement, project management/discipline, risk-based management

Other suggestions:

- Provide incentives to operationalize and implement what is available, rather than doing "rescue work" afterwards
- Proactively find ways to address missing data
- Use analytics to quickly find trends in data
- Approach FDA to raise the bar in complexity
- Ensure to employ competencies in order to obtain high quality clinical trials data
- Make tools and resources available via Global Health Network at Oxford University

There was a sense that risk-based data management will be here to stay, which affirms the need for competencies and to translate them into a monitoring plan. This is an opportunity for the Joint Task Force to change the landscape of regulators, sponsors, and sites.

Open Discussion with Audience

Dr. Barbara Bierer provided a summary of what we heard today, to move "from compliance to competencies to professionalism:"

- Competencies: need to clarify definitions; need competencies for project leadership, data management and IT, and other emerging competencies; core vs additional competencies; cultural appropriateness
- Training: challenge of appropriate educational resources to address project management, drug and medicines development, leadership, "soft" skills, etc.; e-learning; face-to face and/or hands-on learning; role of mentoring; gamification (reinforcement)
- Job descriptions: aligning competencies with job titles and roles; tiers of levels of competencies
- Evaluation and metrics: how and how often competencies will be measured; evaluation/tracking of individual mastery of competencies, "toll gates";

The moderated discussion with the audience included the following issues:

- Certification standards: define a minimum bottom line, and consider developing a registry of individuals who are interested and who have achieved
- Job descriptions: define entry level position for clinical research professional and present it to regulatory body
- Buy-in: get buy-in by working "inside-out" or "bottom-up", start with various stakeholders rather than with regulators
- Accountability: realize that the only regulatory body in the world that looks at data is FDA, and this does not include checking quality of data and conduct of trial
- Additional stakeholders: engage additional stakeholders (i.e., industry, global partners, professional organizations worldwide, non-profit organizations, clinical research organizations, regulators, participant advocates, other) and additional team members (i.e. statisticians, data management, IT team, data management committee members, regulators, CHW/CHV, other)

Next Steps

This workshop made it clear as the competencies have been socialized and utilized. There is a need to revise and ensure they remain relevant and implementable for real-world use.

Top suggested revisions include:

- minimize redundancy
- conduct validation initiatives
- determine if the competencies apply to all members of the team and whether they should be tiered by role
- add more explicit requirements for specific roles
- develop metrics to evaluate the competencies.

As an immediate follow-up, the MRCT Center sent out slides from this meeting the following day and asked participants if they wanted to be involved in one of two workgroups: Revisions Workgroup and/or Leveling Workgroup. The JTF will also set up a mechanism for formal endorsement of the competencies and will reach out to additional stakeholders.

In a subsequent Debriefing meeting, the JTF decided on the following next steps:

- 2016 – Alignment on next steps, agreement on process forward
- 2017 – Phase 0: Update website
- 2017 – Phase 1: Start two workgroups: Revisions and Levelling; communication and dissemination, endorsement of competencies across stakeholder groups
- 2018-2019: Phase 2: Work on metrics and evaluations; and job descriptions (or competency portfolios) for roles
- 2018-2019: Phase 3: Training and educational resources

Appendices

Appendix 1: Workshop Agenda

CORE COMPETENCIES IN CLINICAL RESEARCH:
REAL WORLD APPLICATIONS, CONVERGENCE AND EVOLUTION OF A FRAMEWORK

OCTOBER 19, 2016
8:00 AM – 4:00 PM
HARVARD FACULTY CLUB
READING ROOM
20 QUINCY STREET, CAMBRIDGE, MA 02138

TIME	TOPIC	PRESENTER
8:00 – 8:30	**REGISTRATION & BREAKFAST**	
8:30 – 8:50	**REVIEW OF THE DEVELOPMENT OF THE JOINT TASK FORCE FOR CLINICAL TRIAL COMPETENCY FRAMEWORK**	**Rebecca Li** *MRCT Center*
8:50 – 9:00	**UTILIZATION OF THE FRAMEWORK — RESULTS OF GLOBAL SURVEY; COMMITTEE ON ACCREDITATION OF ACADEMIC PROGRAMS IN CLINICAL RESEARCH (COAPCR); INTRODUCTION TO CASE STUDIES**	**Stephen Sonstein** *Eastern Michigan University, CoAPCR, Commission on Accreditation (CoA)*
9:00 – 10:40	**SESSION 1: FOUNDATIONAL INITIATIVES TO INTEGRATE THE CORE COMPETENCIES FRAMEWORK INTO THE CLINICAL RESEARCH ENTERPRISE**	**Moderator: Stephen Sonstein** *Eastern Michigan University, CoAPCR, CoA*
	Mission Achievement through Competence Development	**Terri Hinkley** *Association of Clinical Research Professionals (ACRP)*
	Applying the Core Competency Framework of the JTF for Clinical Trial Competency to Improve the Overall Training and Career Development of Physicians in Industry Involved with Clinical Trials: A Use Case from a Biopharma Company	**Subasree Srinivasan** *Alexion; formerly Bristol-Myers-Squibb*

	The Use of Competencies in the Development of Job Classifications and Workforce Development Initiatives	**Rebecca Brouwer** *Duke University* **Denise Snyder** *Duke University*
	Education and Training of Clinical & Translational Study Personnel: A Competency-Based Approach	**Thomas Perorazio** *University of Michigan* **Michelle Wartak** *Tufts Clinical and Translational Science Institute*
	Moderated Discussion (20 Min.)	
10:40 – 10:50	Break	
10:50 – 12:00	**SESSION 2: UTILIZATION OF COMPETENCIES FOR INNOVATIVE WORKFORCE DEVELOPMENT**	**Moderator: Rebecca Li** *MRCT Center*
	Re-shaping an Academic Clinical Research Administration (CRA) Graduate Program Through the Application of the Harmonized Core Competencies Framework	**Joan Butler** *George Washington University* **Beth Harper** *George Washington University*
	Developing a Clinical Trials Implementation Program: One Institution's Experience	**Penelope Jester** *University of Alabama, Birmingham*
	Utilization of JTF Framework for CTSI Grant Renewal	**Robert Kolb** *University of Florida*
	Beyond Competency: Building a Professional Clinical Research Workforce for the Future	**Greg Koski** *Alliance for Clinical Research Excellence and Safety (ACRES)*
	Competency-Based Training for Entry-Level CRAs	**Tammi Masters** *INC Research*
	Moderated Discussion (20 Min.)	
12:00 – 12:30	Lunch	
12:30 – 1:40	**SESSION 3: INTERNATIONAL IMPLEMENTATION**	**Moderator: Barbara Bierer** *MRCT Center*

	The JTF Core Competencies in Latin America: Inter-Regional and Intra-Regional Differences	**Honorio Silva** *Rutgers University*
	Competence-Based Certification in Clinical Research in Mexico — A Proposal	**Matilde Damian** **Jose Viramontes** *Association of Professionals Specialists in Clinical Research (APEIC), Mexico*
	The Acceptance and Application of the Competencies in the EU	**Esther Daemen** *TRIUM Clinical Research Consultancy*
	Using the Harmonized Core Competencies to Inform the Development of an Integrated Workforce Framework in the UK	**Fiona O'Neill** *NIHR Clinical Research Network, UK*
	Research Essentials — Developing Excellence in Research Design and Practice. An Australian Story.	**Ian Kerridge** *PRAXIS Australia Ltd* and *University of Sydney*
	Moderated Discussion (20 Min.)	
1:40 – 3:00	**SESSION 4: PANEL DISCUSSION OF IMPACTS** • Sponsors • Professional Associations • Regulatory Authorities • Nonprofit Organizations • Clinical Research Organizations Moderated Discussion	**Moderator: Rebecca Li** *MRCT Center* Dirk De Naeyer (Janssen) Howard Fingert (Takeda) Margaret McCabe (IACRN) Kathryn Finch Mileham (ASCO) Robert O'Neill (FDA) Thy Pham (Gates Foundation) Rick Sax (Quintiles)
3:00 – 3:50	**OPEN DISCUSSION WITH AUDIENCE**	**Moderator: Barbara Bierer**
3:50 – 4:00	**NEXT STEPS**	**Rebecca Li** *MRCT Center* **Stephen Sonstein** *Eastern Michigan University, CoAPCR, CoA*

Appendix 2: Workshop Participants

First Name:	Last Name:	Institution:	Job Title:
Carmen	Aldinger	MRCT Center	Program Manager
Mark	Arquiza	Ocular Therapeutix	Manager, Field Clinical Monitoring
Liza	Behrens	Rockefeller University	Consultant, Research Training and Education
Barbara	Bierer	MRCT Center	Faculty Co-Director
Rebecca	Brouwer	Duke Office of Research Informatics (ORI) / DOCR	Product Manager
Joan	Butler	George Washington University	Assistant Prof. & Dir. Clinical Research programs
Joan	Chambers	CenterWatch	COO
Michelle	Culp	NCATS, NIH	Director, Clinical Operations
Esther	Daemen	Trium Clinical Research Consultancy	Clinical Research Professional
Matilde	Damian	APEIC	Vice-President
Karla	Damus	BUSM CRRO	Education and Regulatory Manager
Dirk	De Naeyer	Johnson & Johnson	Vice President Global Clinical Operations
Scott	Evans	Harvard University and Society for Clinical Trials	Board of Directors
Howard	Fingert	Takeda	Senior Medical Director
Barbara	Gladson	Rutgers School of Health Professions	Associate Dean
Catherine	Griffith	Massachusetts General Hospital	Clinical Research Nurse
Kathleen	Grinke	Massachusetts General Hospital	Clinical Research Nurse
Beth	Harper	Clinical Performance Partners, Inc. / GWU	President / Adjunct Professor
Terri	Hinkley	Association of Clinical Research Professionals	Workforce Innovation Officer
Carolyn	Hoban	None	VP research
Lorraine	Hodsdon	Great Ormond Street Children's Hospital London, UK	Head of Nursing Clinical Research
Penelope	Jester	University of Alabama at Birmingham	Program Director
Christopher	Kabacinski	MRCT Center	Program Coordinator
Jared	Kerr	University of North Carolina Wilmington	Assistant Professor, Clinical Research
Ian	Kerridge	Praxis Australia and University of Sydney	Director, Praxis Australia
H. Robert	Kolb	University of Florida	Assistant Director Clinical Research - RSA

Greg	Koski	ACRES	President and CEO
Rebecca	Li	MRCT Center	Exec director
Doreen	Lechner	Rutgers University	Program Director
Erich	Lukas	Society of Clinical Research Associates	Executive Director
Dylan	Marashi	MRCT Center	Volunteer
Nicole	Masen	Northwestern University	Senior Program Administrator
Tammi	Masters	INC Research	Associate Director, Global Clinical Training
Margaret	McCabe	Boston Children's Hospital	Director Nursing Research, Medicine Patient Service
Juli	Merhaut	Halloran Consulting Group	Consultant
Kathryn	Mileham	Levine Cancer Institute	Chief, Section of Thoracic Medical Oncology
Fiona	O'Neill	National Institute For Health Research	Head of Workforce and Learning
Robert	O'Neill	FDA	Senior Statistical Advisory
Thomas	Perorazio	University of Michigan - MICHR	Administrative Program Director
Thy	Pham	The Bill & Melinda Gates Foundation	Program Officer
Regina	Ponder, J.D.	PRA Health Sciences	Research Associate
Mary-Tara	Roth	Boston University Medical Campus	Director, Clinical Research Resources Office
Rick	Sax	Quintiles	Senior VP, Quintiles Advisory Services
Caroline	Schenkel	ASCO	Program Coordinator, Research & Analysis
Honorio	Silva	IFAPP-Pharmaceutical Medicine	President
Denise	Snyder	Duke Office of Clinical Research (DOCR)	Associate Dean for Clinical Research
Stephen	Sonstein	Eastern Michigan University	Director, Clinical Research Administration
Subasree	Srinivasan	Alexion Pharmaceuticals (formerly Bristol Myers Squibb)	Senior director
Emily	Traw	Northwestern University	Assistant Director, NUCATS Institute
Jose Luis	Viramontes-Madrid	PPD	Director
Michelle	Wartak	The Broad Institute of MIT and Harvard	Learning Architect
Liz	Wool	Barnett International Inc.	Global Head of Training