MULTI-REGIONAL
CLINICAL TRIALS

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

Core Competencies in Clinical Research:

Real World Applications, Convergence and Evolution of a Framework

Workshop – October 19, 2016
Briefing Book of Case Studies

Harvard Faculty Club
20 Quincy Street
Cambridge, MA 02138

Joint Task Force for
Clinical Trial Competence

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Introduction

The Joint Task Force (JTF) for Clinical Trial Competency published in 2014 "A Harmonized Core Competency Framework for the Clinical Research Professional" which harmonized clinical trial competencies within eight specific domains (see Appendix). This resulted in a high-level set of standards that could be adopted globally and serve as a framework for defining professional competency throughout the clinical research enterprise.

In the past two years, this framework has been widely distributed and utilized.

This Briefing Book contains a compilation of real world applications of the Core Competency Framework in academic institutions, professional associations, non-profit organizations, and industry. It includes for each case goals and objectives, background, how the framework has been utilized, key stakeholders impacted, impact, lessons learned, suggested revisions, and year the competencies were introduced.

This provides the background for a one-day workshop at Harvard Faculty Club where participants will discuss real world applications of core competencies, gather feedback on potential future revisions of the competency framework, and consider future objectives for the core competency framework and working group.

The planning committee for this workshop included:

- Carmen Aldinger (MRCT Center)
- Barbara Bierer (MRCT Center)
- Esther Daemen (TRIUM)
- Barbara Gladson (CoAPCR and Rutgers Biopharma Educational Initiative)
- Norman Goldfarb (MAGI)
- Terri Hinkley (ACRP)
- Carlton Hornung (CoAPCR)
- Carolynn Jones (OSU)
- Christopher Kabacinski (MRCT Center)
- Greg Koski (ACRES)
- Rebecca Li (MRCT Center)
- Jonathan Seltzer (ACI)
- Honorio Silva (Rutgers, IFAPP)
- Stephen Sonstein (Eastern Michigan, CoAPCR, CoA)

Case Studies
Rebecca Brouwer and Denise Snyder (Duke University)

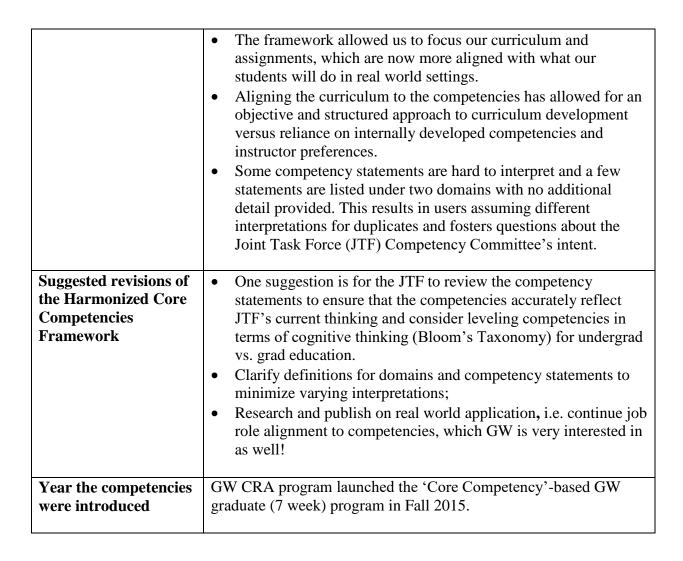|	
Authors / Presenters	Denise Snyder, MS, RD, CSO Rebecca Brouwer, MS
Institution	Duke University
Title of case study	The Use of Competencies in the Development of Job Classifications and Workforce Development Initiatives
Goals and Objectives	There is a need to professionalize the research workforce to continue to produce high quality clinical research. This means that those involved in clinical research must ensure that the roles for staff are 1) well-articulated 2) competency-based 3) appropriately matched to experience and educational level, and 4) described in classifications that are updated frequently to keep up with the shifting landscape.
Background	Duke University undertook a large effort to create competency-based job classifications for research professionals. These new classifications are being applied to incumbent staff in the summer of 2016. In addition, they will form the basis for competency assessments, training programs, and professional development opportunities for the workforce moving forward.
How have you utilized the Harmonized Core Competencies Framework	The work in this initiative was led by Duke's Clinical Research Professionals Working Group (CRPWG), comprised of leaders from our clinical research support office, human resources, and individual research units. Two members of the CRPWG also played a role in CTSA's supplemental award entitled "Enhancing Clinical Research Professionals' Training and Qualifications" (ECRPTQ). Through the work of the ECRPTQ, competencies developed by the Joint Task Force for Clinical Trial Competencies (JTFCTC) were refined. In addition, the project focused on identifying existing assessments and training opportunities that matched the identified competencies. The two members that were a part of the ECRPTQ shared the competencies from the project, which served as the basis for the competencies used in the CRPWG job classification project. Of the 51 competencies resulting from the ECRPTQ work, the committee further revised the competencies to ensure that they were relevant for research staff at Duke, and applied language that could be objectively

	assessed. Through multiple work sessions in collaboration with approximately 75 subject matter experts representing clinical research staff and managers at Duke, the committee formulated 41 final competencies applicable for research professionals. While the 41 competencies identified were relevant for research staff, they remained quite broad. Therefore, the CRPWG worked to identify varying levels within the same competency that could be used to develop discrete job descriptions, and assess competency and encourage professional development. For example, the broad competency below was further expanded into multiple levels: **ECRPTQ Competency**: Describe and develop processes for data quality assurance. **CRPWG Revised Competency**: Use data quality assurance systems, guided by standard operating procedures **Levels of CRPWG Competency** • Level 1: Follow SOPs for data QA. • Level 2: Assist with development of SOPs for data QA • Level 3: Develop and follow SOPs for data QA. Monitor QA of study data. • Level 4: Develop QA systems for research data; ensure that QA SOPs are updated and followed by study teams. Implement QA systems across multiple studies, or across entire unit, department or division. reports. Recognize trends; escalate as appropriate. • Level 5: Develop unit/department - wide quality assurance systems for research data; oversee implementation. After the CRPWG articulated levels for each of the competencies, these were matched into appropriate job classifications. The entry-level position, Clinical Research Specialist (CRS), embodied the Level 1 competencies; the CRS, Sr. position included Level 2 competencies; and so on. Ultimately, competency-based discrete job descriptions were created and incumbent employees (~700) were mapped into the new classifications in the summer of 2016.
Key stakeholders impacted by the Core Competencies	• Research professionals involved in operations and implementation at Duke • Research faculty who employ these staff • Departments, centers, and institutes who financially back staffing
Impact	The job classification project itself will have lasting impact on the Duke research staff workforce. Through this process, better defined job descriptions brought about a thorough market analysis, bringing our institution in alignment with the market, and updating salaries, so there is a financial impact to staff and institution.

Lessons learned	- Large-scale change is time consuming, but worth consistency and standardization gained - Engage: 1) stakeholders from various disciplines, 2) governance group, and 3) faculty champions - Messaging: 1) Establish a comprehensive communication plan (town halls and open Q&As for staff were critical); 2) Listen to pushback, see how it can be used to adapt and change process; 3) Living, breathing FAQ document and wiki; 4) Developing a better, more consistently trained and managed workforce was core to our project mission. This is helpful to message throughout, but delivered with slants important to stakeholders. - Workgroup has 1) dedicated effort to commit; 2) paid staff to coordinate - Changes in minimum qualifications (MQs) will raise concerns– be ready to talk with people about education/training options and plans - We had to adopt Health system nursing policy (80% Baccalaureate) to assure staff would be credentialed in health system for ordering activity - All units did not operate the same – exhibit flexibility - HR: 1) Engage recruiters early and often to communicate changes in jobs/MQs, and talk through interim and updated processes; 2) Salary range needs approval before posting new job classifications (our timing was off and this delayed posting by 1 month) - Financial impact can be substantial - We did not make everyone happy, but if 80% feel good about the approach, we believed we were on the right track
Suggested revisions of the Harmonized Core Competencies Framework	- Inclusion of levels of competencies - Distinguish staff versus PI competencies - Objective, measurable language
Year the competencies were introduced	The concept of competencies was introduced to Duke's workforce in 2014 as we began describing the job classification initiative. The initiative related to job classifications began late that year and is ongoing.

Joan Butler and Beth Harper (The George Washington University)

Authors / Presenters	Joan T. Butler, MS, EdD Beth D. Harper, MBA
Institution	The George Washington University
Title of case study	Re-shaping an Academic Clinical Research Administration (CRA) Graduate Program Through the Application of the Harmonized Core Competencies Framework
Goals and Objectives	• Describe an approach for aligning the 'Core Competencies' in GW's CRA graduate program to ensure a competency-based curriculum • Explain an iterative process for mapping 'Core Competencies' to curriculum in order to identify gaps in alignment and opportunities for curriculum re-design • Discuss progress, lessons learned, initial outcomes and next steps
Background	The 'harmonized Core Competency Framework', published in June 2014, provided a framework for competency-based education within academic programs in clinical research. Academic clinical research programs are preparing for future program accreditation and this competency framework will be integral to the accreditation process. GW took the opportunity to utilize the 'published framework' moving forward to replace their current competency framework. In parallel, the GW CRA Program Director took the opportunity to utilize the 'harmonized Core Competency Framework' as the basis for creating the 7-week graduate CRA curriculum, reduced in length from the 15-week semester graduate CRA curriculum.
How have you utilized the Harmonized Core Competencies Framework	**Phase 1 Assessment of Core Competency Alignment of Curriculum:** First step was to convene a 2-day faculty retreat to obtain faculty input on the alignment of CRA graduate curriculum (CRA and Health Sciences (HSCI) coursework) to the 'harmonized Core Competency Framework'. This 'Framework' provided a structure to enable the faculty to critically assess the Master's CRA curriculum. Existing curriculum (objectives, content, and assessments/ assignments) were systematically mapped to the Competency domains and statements. The faculty analyzed the current curriculum and identified 'Core Competency' gaps and where new curriculum was required. The faculty also began to prioritize some competencies for graduate and undergraduate programs.

	Phase 2 Redesign Process for GW CRA Curriculum: Post-retreat, the authors reflected on the aligned 'harmonized Core Competencies' already identified and identified additional competencies to be aligned across GW's CRA curriculum. For each CRA course**,** the authors listed the 'Core Competencies' that must align with the assessments (case studies, written papers, MS PowerPoint slide deck with Voice Thread, Senior Management written proposals, Discussion Boards, Quizzes, etc.). Course templates plus competency worksheets were created to structure the preparation and assessment of the curricular changes required to prepare the GW CRA graduate competency-based curriculum. Based on the level of change, course changes were reviewed and approved by our curriculum committee and university. **Phase 3 Launch of Core Competency-based Curriculum:** The majority of graduate courses in the CRA program have been re-designed based on our process of "Core Competency' alignment. Several competency-aligned courses are already being offered as of Fall 2015. Additional course revisions are ongoing. **Phase 4 Assessment of Competency-based Curriculum:** Once the competency-based curriculum changes are completed, program outcomes will be re-assessed and an updated curriculum map will be prepared. Future research areas of interest are exploring student-learning outcomes demonstrated through CRA competency-based educational programming.
Key stakeholders impacted by the Core Competencies	• GW CRA Faculty, Students, and university • Academic Clinical Research programs • Employers of and employees who are Clinical Research Professionals • Clinical Research related certification and training programs
Impact	• GW CRA graduate program is now aligned with 'Core Competencies' • Faculty challenged to think more strategically and differently about some concepts and got their buy-in that this is an improvement! (Anecdotal) • Competency aligned curriculum has been received favorably by our faculty and students (Anecdotal)
Lessons learned	• Gaining consensus on terminology/ interpretations of 'Core Competencies' across all faculty members has taken time and is an iterative process.

	• The framework allowed us to focus our curriculum and assignments, which are now more aligned with what our students will do in real world settings. • Aligning the curriculum to the competencies has allowed for an objective and structured approach to curriculum development versus reliance on internally developed competencies and instructor preferences. • Some competency statements are hard to interpret and a few statements are listed under two domains with no additional detail provided. This results in users assuming different interpretations for duplicates and fosters questions about the Joint Task Force (JTF) Competency Committee's intent.
Suggested revisions of the Harmonized Core Competencies Framework	• One suggestion is for the JTF to review the competency statements to ensure that the competencies accurately reflect JTF's current thinking and consider leveling competencies in terms of cognitive thinking (Bloom's Taxonomy) for undergrad vs. grad education. • Clarify definitions for domains and competency statements to minimize varying interpretations; • Research and publish on real world application, i.e. continue job role alignment to competencies, which GW is very interested in as well!
Year the competencies were introduced	GW CRA program launched the 'Core Competency'-based GW graduate (7 week) program in Fall 2015.

Esther Daemen (TRIUM Clinical Consulting)

Author / Presenter	Esther Daemen, BSN, MBA
Institution	TRIUM Clinical Consulting
Title of case study	The Acceptance and Application of the Competencies in the EU
Goals and Objectives	Goal: To ensure the audience understands how the competencies are accepted and applied in the EU Objectives: • Describe how the EU differs from the US and other regions • Describe an example of the use of the competencies in the EU with pharma clients • List lessons learned from the introduction of the competencies to pharma clients
Background	**Case 1:** Setting up our TRIUM internal training strategy using the competencies as a starting point. The competencies were used as baseline. Staff was listed per role and competencies per role were identified based on the 8 domains. It showed current knowledge/skills levels and helped identify gaps in training for current and future clients. Priority of training was identified quickly and a training plan was set up knowing we were tackling the highest needs first. **Case 2**: Investigator-Initiated Research (IIR). Site that becomes sponsor for IIR trials. What competencies are we missing? The competencies were used as baseline. The sponsor related competencies were identified and training needs and procedures not in place were identified. Helped save time and ensure an efficient use of training resources went to the real needs. **Case 3**: Pharma and device clients in the EU: assessing performance issues using the competencies to assess training gaps. The competencies were used as baseline. Overall performance issues were identified through a RCA. When a training issue arose, the list of competencies was helpful in identifying the gaps and strengths. This approach helped save time and ensure an efficient use of training resources went to the real needs.

How have you utilized the Harmonized Core Competencies Framework	By professionalizing and setting the internal training strategy of TRIUM and by offering performance support services to pharma and device clients. As a result, I can speak to the challenges and interpretations of the competencies for EU researchers.
Key stakeholders impacted by the Core Competencies	• Clinical trial directors • CEOs • CRA managers • Project managers • Institutes
Impact	• Saving time identifying competencies • Used as gap analysis for training needs • Identify trends and strengths and weaknesses related to performance • Used a base to set performance strategies
Lessons learned	Different interpretation depending on organizational and country culture Overall accepted as a great starting point, but more guidance is needed to get to the operational side of things per organization
Suggested revisions of the Harmonized Core Competencies Framework	None
Year the competencies were introduced	2016

Matilde Damian (APEIC)

Author / Presenter	Matilde Damian, MD
Institution	APEIC (Association of Professionals Specialists in Clinical Research), Mexico
Title of case study	Competence-Based Certification in Clinical Research in Mexico: A Proposal
Goals and Objectives	To have a common national initiative of a Competence-Based Certification Program for Clinical Research Professionals in Mexico.
Background	- Currently, there are no formal or official requirements to work in Clinical Research in Mexico - There are many local initiatives from the academia and the pharma industry in Mexico, providing Clinical Research training, but with no agreement on its content and usually testing just knowledge - There is a need to have a common platform addressing the Certification of Clinical Research Professionals in Mexico, including all the main local associations, the academia and clinical sites, and the authorities - JTF included Mexico in the survey of Competences in Clinical Research conducted in 2015, including the main stakeholders, and completing a good sample size to be used as the basis for a Mexican Profile definition
How have you utilized the Harmonized Core Competencies Framework	To respond the JTF survey, APEIC worked with local associations to share it with the main local stakeholders. Mexico has: - A sample of 185 individual participants responded the survey - We have now the Mexican Profile definition, from the information already available - Currently the results are being showed in the second National Congress of Clinical Research attended by main stakeholders of different associations and regulatory authorities. - To confirm the results of the survey, several focus groups will be held In addition, a local training has been developed to train the basic knowledge and we begin to build a team to work with steps 2 and 3 to develop training materials and clinical cases.

Key stakeholders impacted by the Core Competencies	Main Clinical Research local associations , the academia and clinical sites, and the Minister of Health and Mexican NIH
Impact	A Competence-Based Certification program for Clinical Research Professionals in Mexico will have a direct and important positive impact on Mexico´s participation in international clinical trials, as well as in the local productivity in clinical research. Authority acceptance as a mandatory certification is expected.
Lessons learned	The survey conducted by JTF in Mexico in 2015 exploring the Harmonized Core Competencies Framework conducted has proved that a common initiative may be accepted, supported, and implemented by the main stakeholders of clinical research in Mexico. It is very important to maintain the local inertia achieved by this initiative.
Suggested revisions of the Harmonized Core Competencies Framework	Once implemented, formal evaluation of the acceptance and effectiveness of the program will be regularly performed.

Terri Hinkley (ACRP)

Author / Presenter	Terri Hinkley, RN, BScN, MBA, CCRC
Institution	Association of Clinical Research Professionals (ACRP)
Title of case study	Mission Achievement through Competence Development
Goals and Objectives	• To inform attendees of the ways by which ACRP has been actively aligning our certification and training offerings with the core competencies • To inform attendees of the continued efforts of ACRP related to workforce development and the goal of an educated, competent workforce using the core competencies as a foundation.
Background	ACRP is a collaborative member of the Joint Task Force (JTF) for Clinical Trial Competency and the acting steward of the JTF's Harmonized Core Competency Framework for Clinical Research Professionals. As an advocate for standardized competence in clinical research and the leader in workforce development, ACRP has acted on the work of the JTF by ensuring its training and certification programs align with, and support development of, the core competencies required of clinical research professionals. ACRP is leading several other initiatives to develop competence in the workforce, including identification of the core competencies required of entry-level and experienced clinical research associates through the multi-stakeholder CRA Workforce Development Task Force.
How have you utilized the Harmonized Core Competencies Framework	ACRP has acted on the work of the JTF by ensuring its training and certification programs align with, and support development of, the core competencies required of clinical research professionals. ACRP is leading several other initiatives to develop competence in the workforce, including identification of the core competencies required of entry-level and experienced clinical research associates through the multi-stakeholder CRA Workforce Development Task Force.
Key stakeholders impacted by the Core Competencies	All clinical research professionals, including those who are members of the Association of Clinical Research Professionals.
Impact	Improving clinical trial operations through workforce competence development.

Lessons learned	There is still a significant portion of the clinical research industry that is not aware of the JTF Harmonized Core Competency Framework. ACRP continues to promote the Framework as well as the competency domains and competencies. In doing so, it has become clear that some revisions are needed to ensure the domains and competencies gain wide adoption in a consolidated manner.
Suggested revisions of the Harmonized Core Competencies Framework	Some of the competencies need to be written as competency statements; at present, some are written as task statements. It is also recommended to reduce overlap between domains, particularly between GCPs and Site Operations.
Year the competencies were introduced	2014

Penelope Jester (University of Alabama at Birmingham)

Author / Presenter	Penelope M Jester, BSN, RN, MPH
Institution	University of Alabama at Birmingham
Title of case study	Developing a Clinical Trials Implementation Program: One Institution's Experience
Goals and Objectives	To describe the evolution of a clinical research training program focused on implementation and GCPs. To describe how the core competencies framework was used to develop, strengthen and focus an expanding and evolving clinical research training program.
Background	Most anyone who has worked in clinical research for the past 15 or more years, can attest that research teams rarely are required to participate in courses on how to implement clinical trials. From the Principal Investigator to the coordinator to other support staff, education on good clinical practices (GCP) and study implementation have been rare. The literature has identified this lack of education and training. (1,2) Although advanced degree programs have become common in recent years, it is challenging for full time staff to juggle returning to school with full time employment (3). 1. Sonstein SA, Seltzer J, Li R, Silva H, Jones CT, Daemen E. Moving from Compliance to Competency: A Harmonized Core Competency Framework for the Clinical Research Professional. Clinical Researcher. 2014: 18-23 2. Speicher LA, Fromell G, Avery S, Brassil D, Carson L, Stevens E, Toms M. The critical need for academic health centers to assess the training, support and career development of clinical research coordinators: Recommendations from the clinical and translational science award research coordinator taskforce. Clinical and Translational Science. 2012;5(6):470-475. 3. Carter SC, Jones CT, Jester PM. Issues in clinical research manager education and training. Research Practitioner. 2007;8:48-60.

How have you utilized the Harmonized Core Competencies Framework	After being introduced to the "Harmonized Core Competencies Framework" in June of 2014, it became imperative to utilize the competencies to build the clinical research training program at UAB. As we have expanded our programs (i.e.: 4-hour Research Orientation Program for the entire research team within 1 month of starting in research; 24-hour intensive coordinator and research team (support staff) training; 4- to 12-hour intensive implementation and GCP training for investigators; monthly research seminars on advanced topics) utilizing the framework of domains and competencies has been used as the backbone to the didactic curriculum, hands on activities, experiential learning, etc. Using a spreadsheet of the domains/competencies, notations are made as to which of the 4 programs specifically address the competencies.
Key stakeholders impacted by the Core Competencies	Ultimately the university or institution is impacted by a strong and rigorously trained staff. An institution's 'book of business' is based on successful and sought-after investigators. For this reason, sponsors are equally critical stakeholders to seeking research staff who are competent to conduct research studies. A third stakeholder is the research staff members. Having confidence and assurance as to how to implement a research study, knowing how to be efficient and compliant with all requirements strengthens the research team's capabilities.
Impact	A well-trained staff, from investigator to study coordinator, can impact not only the quality of research, but the confidence of a research team to grow in their profession. Conducting research by professional staff who have met the competencies, we have identified that the 'hunger' for information about conducting research only grows with more information offered. Efforts are consistent to solicit from staff and investigator what topics and issues they need more information on. There is never a shortage of new items.
Lessons learned	Although many programs can start as grass roots efforts, ultimately the institution must support, promote and finally, require confirmation of competencies. Although many support staff see the value and seek out the education, investigators often find it more challenging to participate in courses and lectures on research implementation in our academic institution. For decades implementation has been relegated to the support staff, with not enough emphasis placed on investigator responsibility. With the increasing complexities in research, with decreasing research dollars available from pharma, the demand for a well-trained and educated staff is paramount.

Suggested revisions of the Harmonized Core Competencies Framework	Recommended changes to the competencies:
	   a. Minimize redundancies
	   b. Provide more explicit requirements about which competencies are required for specific roles
	   c. Expand on detailed description of specific skills staff should master and not only study coordinators and investigators

Year the competencies were introduced	2015

Carolynn Jones (The Ohio State University)

Author / Presenter	Carolynn Jones, DNP, MSPH, RN
Institution	The Ohio State University, College of Nursing Masters of Applied Clinical and Preclinical Research (MACPR)
Title of case study	Creating a 100% Online Masters in Applied Clinical and Preclinical Research Using a Competency-Based Approach and ePortfolios
Goals and Objectives	The goal of this presentation will be to highlight the application of the JTF Framework in the planning and development of the Core Course Content and Specialization Content for a new Master's Degree Program. Program goals and objectives as well as course content are mapped to the JTF Framework. We have created and used a basic checklist tool that has been shared with multiple organizations who have used this to map their own training or academic programs. Graduating students are required to create a competency-based ePortfolio where they write reflections on the core competencies and upload examples of competency based learning products.
Background	I have been producing clinical research curricula for training and for academic programs which were first created using a learning needs assessment amongst study coordinators working at UAB Medical Center and then globally among study coordinators of the HTPN Clinical Trials Network (via a Fogarty grant to provide educational modules for study coordinators working in low-resource countries. As an educator and experienced clinical researcher, I have become a member of the CoAPCR and was part of an initial working group to research publications about clinical research competencies. This led to a publication of harmonized competencies (from those publications from nursing and medicine). The subsequent JTF formation occurred and I was a member of this group, starting with an initial workshop at DIA. Unfortunately, I could not attend the initial meeting in Boston due to funding constraints.
How have you utilized the Harmonized Core Competencies Framework	I have created and used a basic checklist tool that has been shared with multiple organizations who have used this to map their own training or academic programs. Graduating students are required to create a competency-based ePortfolio where they write reflections on the core competencies and upload examples of competency based learning products

Key stakeholders impacted by the Core Competencies	• Students and employers • The OSU Medical Center has benefitted by this work as well because it has led to several talks by myself on campus and also because we enroll several students who work there. • Research Projects and participants
Impact	• Using the JTF Framework has provided a specific pattern for successful curriculum development. • Students often report that they have passed their SoCRA and ACRP Certifications easily as a result of our curriculum • Students have secured employment and promotions as a result of their academic accomplishments • We have been asked to share our curriculum detail and methods to other academic programs
Lessons learned	Even when developing a graduate master's degree program, keeping the number of total hours in the coursework to 36 total hours (a competitive number of hours compared to similar programs)- it is quite obvious that we still barely scratch the surface!
Suggested revisions of the Harmonized Core Competencies Framework	I look forward to expansion of the competencies. Using some of the work by the CTSA (Phase II ECRPTQ project) may offer some good insights into assessing competence. I think the 8 domains are still useful; however, it may be that we could merge Domains 7 and 8 and explore other important competencies that are in keeping with the needs of the research enterprise.
Year the competencies were introduced	The MACPR program started Autumn 2014. We initially used the CoAPCR competencies to initiate our program planning and processing and then converted to the JTF (slightly different competencies) as we began creating courses.

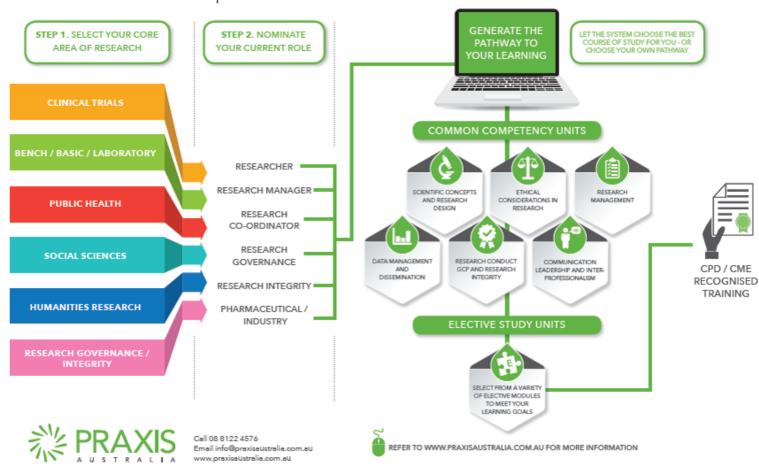# Ian Kerridge (PRAXIS Australia Ltd & University of Sydney)

Author / Presenter	Ian Kerridge, MPhil, FRACP, FRCPA
Institutions	• PRAXIS Australia Ltd • University of Sydney
Title of case study	Research Essentials – Developing Excellence in Research Design and Practice: An Australian story
Goals and Objectives	**A balanced and appropriately skilled workforce:** Through provision of comprehensive, flexible and practical education in research, this educational initiative will contribute to the development and continuation of a skilled research and health workforce who can demonstrate their ability to meet best practice requirements and to attract and graduate a varied group of students from across the research sector. **A research engaged workforce:** The diversity, depth and inter-disciplinary focus of this educational initiative will enhance research skills throughout the health and research sector in line with international best practice and in support of national objectives. It will support the design and conduct of high quality research that demonstrates application of ethical values and principles and fosters a community of researchers and the broader research workforce. **Contemporary infrastructure that meets research needs:** The educational model developed by PRAXIS Australia recognizes that the research workforce comes from many different disciplines, work in many different contexts and often also work as health providers. Through a unique, purpose- built interface, the Research Essentials course will recognize this diversity by enabling participants to select their own courses of study across the various competency domains, modules and electives or designing a course of study for the learner that is appropriate to their skills, role and needs. Our aim is to extend high-quality, innovative learning and teaching approaches to this workforce and to further develop the links between teaching, learning and research across sectors.
Background	PRAXIS Australia is an Australian NFP formed in 2015 as a result of the collaboration of two of Australia's leading tertiary Universities and Australia's largest independent Ethics Committee (IRB). PRAXIS serves to promote excellence in research through education and practice. We do this by providing specialized training and support to

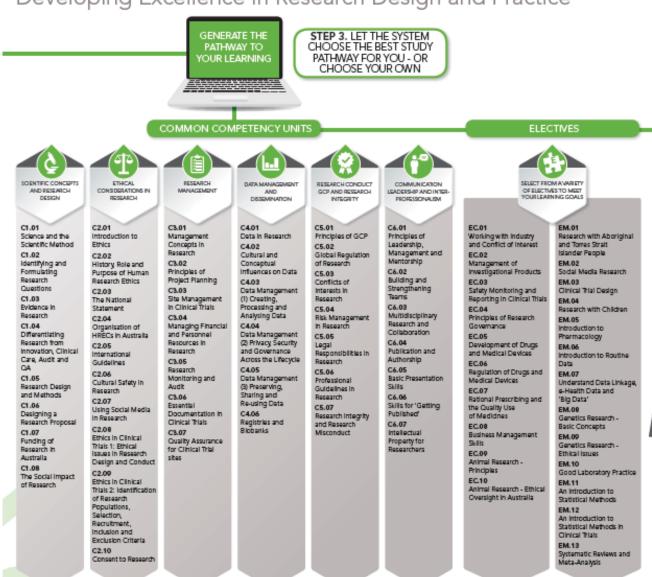|	
	the research ethics and research communities across Australia and internationally. For research to be effective and efficient in a highly competitive environment, and for it to yield sustained benefits to the Australian and global community, all of those involved in research require sufficient training both to ensure competence and to maintain and extend their skills. At present there is no national approach to educational development for the research sector and no group or institution is currently providing an affordable, accessible, comprehensive, flexible and accredited (by means of CPD or other nationally recognized accreditation) training product to the broader Australian research workforce.
How have you utilized the Harmonized Core Competencies Framework	Over the last decade researchers, educators and research funders worldwide have identified the competencies required to ensure the optimal efficiency and rigor of health and medical research. Most notably, the HARVARD MRCT has compiled an internationally agreed set of competency domains for Research Professionals. PRAXIS Australia, as the only Australian partner of the Harvard MRCT group, have been authorized to apply these domains to the Australian research setting and feed the outcomes of the Australian experience back to the international consortium. Working with a broad group of experts drawn from all sections of the research workforce and comprising many of the national experts in research and education, PRAXIS Australia has recognized that simply translating the Harvard Competencies model into an Australian context would be a lost opportunity to improve the Australian research and education environment. Instead, working from work done by Harvard and the NHMRC, PRAXIS is seeking to design new educational initiatives that meet the diverse needs of the Australian research workforce, are not controlled by any single academic institution and are aimed at ensuring that the workforce is research competent and engaged and are able to maintain, expand and develop their skills into the future – thereby consolidating and ensuring the place of research in the Australian educational, health and medical sector. For these reasons, the nature of the competency domains applied have been substantially expanded, with a planned release in 2016 of around 70 individual modules under the described domains, and including the addition of elective units - as illustrated by the diagram below.
Key stakeholders impacted by the Core Competencies	PRAXIS has had important interactions with a number of key research stakeholders and continues to grow and build our relationships more broadly. Current involvements include: **NHMRC:** Our Board and Advisory Group have worked closely with

	the NHMRC to ensure that PRAXIS's educational initiatives are consistent with research competencies identified in Australia and internationally. **Industry:** Our Advisory Committees are comprised of members of industry groups and PRAXIS provides invited training and education services to industry across a number of medical, research and health related areas, including NGOs. **The health system and health and medical researchers:** Through tailored and planned education services, PRAXIS provides training opportunities to institutions in the public and private health arenas across a growing number of jurisdictions that are designed to meet the unique needs of the institution's workforce**.** **Consumers:** PRAXIS has involvement with the consumer health forum and is involved with the early planning of collaborative projects that facilitate discussion around consumer involvement in research.
Impact	**Research Essentials** is due for launch in early September 2016. We will have additional information about the impact of this service to present at the meeting.
Lessons learned	**Research Essentials** is due for launch in early September 2016. We will have additional information about lessons learned to present at the meeting.
Suggested revisions of the Harmonized Core Competencies Framework	The work done by the MRCT group to formulate this Competency Framework is excellent. We have a few very minor suggestions, noting that we are not yet in a position to make an informed judgement about deficiencies currently. Some thoughts for now: 1. It does not accommodate competencies required of non-clinical trial researchers, e.g. social sciences, public health etc. 2. It is uncritical, e.g. of evidence-generation, of translation and of industry influence on generation of clinical trial data 3. It is relatively inflexible (of different roles/disciplinary needs and research fields). Research Essentials has tried to accommodate the Harmonized Competencies plus expand them in order to provide this flexibility.
Year the competencies were introduced	September 2016

Supplemental Documents: Research Essentials

Developing Excellence in Research Design and Practice

GENERATE THE PATHWAY TO YOUR LEARNING

STEP 3. LET THE SYSTEM CHOOSE THE BEST STUDY PATHWAY FOR YOU - OR CHOOSE YOUR OWN

COMMON COMPETENCY UNITS

ELECTIVES

SCIENTIFIC CONCEPTS AND RESEARCH DESIGN | ETHICAL CONSIDERATIONS IN RESEARCH | RESEARCH MANAGEMENT | DATA MANAGEMENT AND DISSEMINATION | RESEARCH CONDUCT GCP AND RESEARCH INTEGRITY | COMMUNICATION LEADERSHIP AND INTER-PROFESSIONALISM | SELECT FROM A VARIETY OF ELECTIVES TO MEET YOUR LEARNING GOALS

Scientific Concepts and Research Design
- C1.01 Science and the Scientific Method
- C1.02 Identifying and Formulating Research Questions
- C1.03 Evidence in Research
- C1.04 Differentiating Research from Innovation, Clinical Care, Audit and QA
- C1.05 Research Design and Methods
- C1.06 Designing a Research Proposal
- C1.07 Funding of Research in Australia
- C1.08 The Social Impact of Research

Ethical Considerations in Research
- C2.01 Introduction to Ethics
- C2.02 History, Role and Purpose of Human Research Ethics
- C2.03 The National Statement
- C2.04 Organisation of HRECs in Australia
- C2.05 International Guidelines
- C2.06 Cultural Safety in Research
- C2.07 Using Social Media in Research
- C2.08 Ethics in Clinical Trials 1: Ethical Issues in Research Design and Conduct
- C2.09 Ethics in Clinical Trials 2: Identification of Research Populations, Selection, Recruitment, Inclusion and Exclusion Criteria
- C2.10 Consent to Research

Research Management
- C3.01 Management Concepts in Research
- C3.02 Principles of Project Planning
- C3.03 Site Management in Clinical Trials
- C3.04 Managing Financial and Personnel Resources in Research
- C3.05 Research Monitoring and Audit
- C3.06 Essential Documentation in Clinical Trials
- C3.07 Quality Assurance for Clinical Trial sites

Data Management and Dissemination
- C4.01 Data in Research
- C4.02 Cultural and Conceptual Influences on Data
- C4.03 Data Management (1) Creating, Processing and Analysing Data
- C4.04 Data Management (2) Privacy, Security and Governance Across the Lifecycle
- C4.05 Data Management (3) Preserving, Sharing and Re-using Data
- C4.06 Registries and Biobanks

Research Conduct GCP and Research Integrity
- C5.01 Principles of GCP
- C5.02 Global Regulation of Research
- C5.03 Conflicts of Interests in Research
- C5.04 Risk Management in Research
- C5.05 Legal Responsibilities in Research
- C5.06 Professional Guidelines in Research
- C5.07 Research Integrity and Research Misconduct

Communication Leadership and Inter-professionalism
- C6.01 Principles of Leadership, Management and Mentorship
- C6.02 Building and Strengthening Teams
- C6.03 Multidisciplinary Research and Collaboration
- C6.04 Publication and Authorship
- C6.05 Basic Presentation Skills
- C6.06 Skills for 'Getting Published'
- C6.07 Intellectual Property for Researchers

Electives (EC)
- EC.01 Working with Industry and Conflict of Interest
- EC.02 Management of Investigational Products
- EC.03 Safety Monitoring and Reporting in Clinical Trials
- EC.04 Principles of Research Governance
- EC.05 Development of Drugs and Medical Devices
- EC.06 Regulation of Drugs and Medical Devices
- EC.07 Rational Prescribing and the Quality Use of Medicines
- EC.08 Business Management Skills
- EC.09 Animal Research - Principles
- EC.10 Animal Research - Ethical Oversight in Australia

Electives (EM)
- EM.01 Research with Aboriginal and Torres Strait Islander People
- EM.02 Social Media Research
- EM.03 Clinical Trial Design
- EM.04 Research with Children
- EM.05 Introduction to Pharmacology
- EM.06 Introduction to Routine Data
- EM.07 Understand Data Linkage, e-Health Data and 'Big Data'
- EM.08 Genetics Research - Basic Concepts
- EM.09 Genetics Research - Ethical Issues
- EM.10 Good Laboratory Practice
- EM.11 An Introduction to Statistical Methods
- EM.12 An Introduction to Statistical Methods in Clinical Trials
- EM.13 Systematic Reviews and Meta-Analysis

Robert Kolb (University of Florida Clinical Translational Science Institute)

Author / Presenter	H. Robert Kolb, RN, BS, CCRC
Institution	University of Florida Clinical Translational Science Institute (UF CTSI)
Title of case study	Utilization of JTF Framework for CTSI Grant Renewal
Goals and Objectives	To present how a CTSI's successful grant renewal addresses the CTSA's Strategic Goal 1, to "Chart new pathways for developing the translational workforce by reshaping the pathways and support mechanisms for translational research careers," and incorporates the core competencies concept in its overarching vision for work force development.
Background	The JTF recognition of the newly established and accepted eight core competency domain framework (Sonstein, 2014) aims to clarify the roles and competencies for clinical research coordinators. These core competencies have been vetted by CTSA investigators on the Enhancing Clinical Research Professionals' Training and Qualifications (ECRPTQ) NCATS supplement study. The University of Florida was an early adopter of the JTF conceptual framework.
How have you utilized the Harmonized Core Competencies Framework	The UF CTSA RFA submission required that all CTSI education and training initiatives be aligned around a common competency framework to support program organization, integration, and adoption of common assessment and quality improvement measures. We employed the competencies developed by the Joint Task Force as a template to frame this vison. The UF CTSI Translational Workforce Development (TWD) Program is directed by the vision to enhance effective learning required to successfully pursue careers in clinical and translational research as it aligns and expands access to a competency-based portfolio of learning opportunities for faculty, staff, students and community members. TWD uses the Association of Clinical Research Professionals (ACRP) eLearning programs with multiple options for completing recognized training that is linked directly to the competencies. Additionally, we are conducting comparative studies with the ACRP eLearning programs and other established vendors of online training modules to establish optimal platforms for communicating core competencies while identifying the best available content to present a competency-based individual education plan. Our goal is to couple the vetted curriculums and platforms to preceptorships with experienced research personnel to

	create an evolving culture of competency within the CTSI over the course of our current grant cycle.
Key stakeholders impacted by the Core Competencies	Clinical Research Coordinators and Allied Research Professionals CTSI's Mentored Career Development (KL2) Program. UF TL1 Program training doctoral and dual-degree-seeking investigators
Impact	Core Competencies concepts were referenced a total of 69 times in the UF KL2, U54 and TL1 award application citing Sonstein (2014) where applicable. Core Competencies language is diffused throughout the CTSI Research Training Program Plan and Work Force Development Directorate; Training and Research Academy for Clinical and Translational Science (TRACTS); Professional Development, Mentor Development, & Educational Development & Evaluation. Most significantly impacted is Research Coordinator programming, addressing identified critical needs. Directed pilot funding awards focus on educational evaluation research with studies such as " Evaluation and Assessment of Online Training Programs for Clinical Research Professionals – Reaching towards a Common CTSA Rubric"; "Evaluating a Novel Model for Training Clinical Research Staff"; "Evaluating an Innovative, Standardized Training Model for Clinical Research Staff- Multi-institution Collaboration with Johns Hopkins University ICTR, University of Miami CTSI and University of Florida CTSI".
Lessons learned	Introducing concepts of competency to build common clinical research education upon in an ever changing health care environment requires an acknowledgement of the need for such a set of common competencies. Active and conscious collaboration among the appropriate academic groups, professional intersections, and affiliated health care institutions is essential to creating a climate in which a full understanding of the need to find common ground is found. Local adaptions of the common core are expected as local cultural orientations interpret the nature and values associated with a common core curriculum. Introducing a vision of professionalization that is grounded in core competencies remains highly self-directed, particularly among the coordinators and professionals supporting the enterprise, requiring champions to bring context to the endeavor. The UF CTSI TWD Directorate's commitment to professional development of clinical research coordinators as well as investigators is essential. Steps forward include coordinating directed and strategized communication to catalyze institutional attitudes towards a common core of competencies. Professional organizations such as ACRP play an instrumental role through active support of their local

	chapters in disseminating resources and guidance. In addition, the generation and application of new knowledge about how and why research teams learn, select best practices, and change their behaviors is needed and should be supported by local funding through CTSI Pilot awards and other mechanisms. Challenges that lie ahead include the development of behaviorally anchored descriptions that support the utility of domain specific competencies.
Suggested revisions	Core competencies, needed to contribute to translational research, could be reframed around the "wheel" to allow the concepts of Leadership and Professionalism to become self-evident, while the domain of Communications and Team works becomes a hub around which the remaining 6 domains interconnect.
Year introduced	September 2014

Greg Koski (ACRES)

Author / Presenter	Greg Koski, PhD, MD
Institution	Alliance for Clinical Research Excellence and Safety (ACRES)
Title of case study	Beyond Competency: Building a Professional Clinical Research Workforce for the Future
Goals and Objectives	Considerable multi-stakeholder effort has been invested in to identify and categorize the core competencies expected of practitioners in clinical research. The goal of this presentation is to elaborate and illustrate the ways and means by which these competencies can be leveraged to develop a truly professional workforce for clinical research globally and discuss the challenges and rewards of doing so, using real-life scenarios and experiences from work in progress.
Background	ACRES is a non-profit, global, multi-stakeholder initiative to build a comprehensive integrated system for clinical innovation worldwide. Born at the MRCT Summit 4 years ago, ACRES continues a broad matrix of activities focused on building essential systems components. Among the most important of these is a global network of high-performing, sustainable sites of excellence. This goal is dependent upon creating and supporting a full complement of well-trained professionals with demonstrated competence in all essential areas of the research endeavor. ACRES has been a significant contributor to the initiatives to establish the Core Competency Framework and is now using that framework as part of its systems-focused development.
How have you utilized the Harmonized Core Competencies Framework	The Core Competencies are being incorporated into ongoing development of standards and processes for an innovative dynamic accreditation process and development of the professionals needed for the future of clinical innovation. Rigorous accreditation and professional certification processes that will recognize and reward effective application of the competency- based framework are essential for the new professional paradigm that will characterize the future of clinical research and precision medicine.
Key stakeholders impacted by the Core Competencies	The key stakeholders impacted by these initiatives include sites and their personnel, CROs, sponsors, regulatory agencies, physicians and patients— the entire clinical research ecosystem.
Impact	Adoption of a competency-based professional paradigm for clinical research and integrated care will enhance productivity, participation, quality, safety and efficiency, reducing costs, accelerating not only

	development of new medical products, but also their integration and evaluation with respect to treatment outcomes.
Lessons learned	There is a yin/yang dynamic at work during this accelerating move toward professionalism, a movement that is now beginning to mature. Many rapidly and willingly endorse adoption of the new framework, while others fear that it will so elevate the bar of expectations as to become a barrier to participation for some. Others are concerned about potential bureaucratic barriers, while others can clearly envision the positive rewards. Care must be taken to ensure that all voices are heard, that goals are clear, that expectations are appropriate, and rewards realized.
Suggested revisions	Ultimately, the competencies must be evaluable through metrics that have yet to be developed and implemented. There needs to be a concerted collaborative effort with all stakeholders to develop and test such metrics and methods for their utilization.
Year introduced	ACRES participated in the development of the competencies and is currently working to incorporate them into several initiatives with and through our strategic allies worldwide.

Tammi Masters (INC Research)

Author / Presenter	Tammi Masters, RN, CCRC, TMIACR
Institution	INC Research
Title of case study	Competency-Based Training for Entry-Level CRAs
Goals and Objectives	To develop an integrated training and management model based on globally accepted monitoring competencies for entry level CRAs to increase productivity and sponsor confidence in ability.
Background	Recognizing that the talent pool for experienced CRAs was limited, INC Research began an entry level CRA training program. Utilizing a blended training approach, qualified individuals completed self-paced modules, attended lecture sessions and an instructor led face to face training. Upon completion of the training program, individuals were observed conducting a monitoring visit to verify competency. However, gaining sponsor confidence in order to fully utilize the entry level CRAs on a project remained a challenge. In 2014, INC Research partnered with IAOCR, the accrediting organization for the international clinical research industry based in the UK, to map training to the IAOCR global learning outcomes framework for Part I of the Monitoring Credential (MIACR). This included developing competencies which were then mapped to the JTF Core Competencies. IAOCR provides independent verification of competency allowing the entry level CRA to earn Part 1 of the 3 part credential upon successful completion of the training. In 2016, the training program was incorporated into a management model which permitted focused training to occur over a period of 12 weeks prior to project assignment.
How have you utilized the Harmonized Core Competencies Framework	INC Research has developed competencies and mapped the CRA training to each competency with built-in tollgates to ensure progress as the entry level CRA moves through the training process and move from knowledge, to application of knowledge, to independent functioning and growing mastery of knowledge. The training program was then integrated into a management model that allowed the CRA to focus on development of knowledge, skills and abilities for each competency while providing on site experience prior to project assignment.

Key stakeholders impacted by the Core Competencies	- Entry level CRAs - Managers - Project managers - Business unit leaders
Impact	Benefits: - Concentrated time for training coupled with onsite 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 - Over 90% have project assignments awaiting and sponsor approved at the time they are deployed to their permanent BU reflecting sponsor confidence (Jan 2016-Aug 2016)
Lessons learned	- Mapping competencies to learning outcomes creates a robust targeted training program and enables employees to feel confident and competent. - Verification of competency is essential in confirming that the employee is able to apply knowledge, skills and abilities learned from the training. - Adding periodic tollgates ensures that the employee is progressing as expected and allows for recalibration of the employee's training if deficiencies are observed. - Protecting training time permits the employee to focus on the learning process. If the employee must balance training with workload, they will struggle with mastering and internalizing concepts. - Line management support, dedicated CRA I training and oversight, has provided clear guidance, oversight, and close mentoring through their learning process.
Suggested revisions	
Year introduced	2016

Fiona O'Neill (NIHR Clinical Research Network)

Author / Presenter	Fiona O'Neill, PhD
Institution	National Institute for Health Research Clinical Research Network (NIHR CRN)
Title of case study	Using the Harmonized Core Competencies to Inform the Development of an Integrated Workforce Framework in the UK
Goals and Objectives	1. To describe the development of the NIHR as a whole system approach to the development of research capacity and capability in the English National Health service (NHS) 2. To outline the changing composition of the research workforce and the national response 3. To describe how the Harmonized Core Competencies are informing the development of an Integrated Framework for research delivery staff in the NHS
Background	The National Institute for Health Research (NIHR) is the research arm of the National Health Service (NHS) in England. Over the last 10 years the NIHR has contributed to the health and wealth of the nation and is now seen as the most comprehensive research system in the world. In 2014/15 more than 260,000 people took part in NIHR research studies. The NIHR Clinical Research Network (NIHR CRN) provides the infrastructure within health care provider organizations that supports high quality clinical research to take place. This includes funding a workforce of around 10,000 staff who are employed within health care organizations. This workforce provides the expertise and capacity to support the safe and effective delivery of clinical research and is critical to the continued success of the NIHR. This workforce includes registered clinical professionals (e.g. Clinical Research Nurses), Principal Investigators (who are mainly but not always medically qualified) and Clinical Support Services including Allied Health Professionals. There is also a growing number of clinical professionals without registration (i.e. practitioners and Support staff). This unregistered workforce is steadily growing, particularly in large urban hospitals where there are acute shortages of nurses; the contribution of this mainly graduate workforce is of critical importance to our future.

	Although there are a number of competency frameworks in use across the NIHR, they no longer reflect the changing composition of the research delivery workforce. There is ongoing work to develop an Integrated Workforce Framework. The Framework will provide overarching role descriptors for the workforce and provide a more coherent approach to knowledge and skills development. The Framework is also a prerequisite in order to establish the professional identity of these new roles within our workforce and to start to answer questions about how best to provide the right level of assurance. A national project team has been established and a scoping project is currently in progress that will report in early 2017.
How have you utilized the Harmonized Core Competencies Framework	The national group has had contact with members of the Joint Task Force over the last two years. As part of the scoping exercise the NIHR project group is exploring the potential of utilizing the competency domains as part of the Integrated Framework. An initial workshop with key stakeholders representing our research delivery workforce agreed that the competency domains are helpful. There are ongoing discussions about how the domains can be integrated and how they might need to change to reflect the UK context.
Key stakeholders impacted by the Core Competencies	The NHS, in common with healthcare systems around the world is facing a number of workforce challenges and the research workforce will continue to diversify. A key driver for the Integrated Workforce Framework is to provide more visibility for research career pathways for our graduate workforce. We also need to continue to provide assurance for commercial investors that the UK has a highly skilled workforce with the capacity and capability to deliver. The project group includes stakeholders from across the research delivery system in the UK and also involves NHS workforce planners.
Impact	As the project is still in scoping stage we are not able to report on impact at the present time.
Lessons learned	The project is still in scoping stage.
Suggested revisions of the Harmonized Core Competencies Framework	The competency domains are providing a very useful starting point to the development the Framework in the UK. We are also looking at how to articulate the clinical competencies required to deliver safe and ethical clinical research. This is particularly important considering the growth in the number of unregistered practitioners in our workforce. The Framework will also address how our research workforce can progress from novice to expert.

Year the competencies were introduced	Connecting and engaging with the Harmonized Core Competency Framework remains an important aspect of our scoping study. The source will be clear and recognizable as the framework develops and the links with the Joint Task force are valued. Ensuring the quality and safety of clinical research and taking a responsive, evidenced-based approach that adopts the learning from our international colleagues remain important principles for our work.

Thomas Perorazio (University of Michigan)

Authors / Presenters	Vicki Ellingrod, PharmD Brenda Eakin, MS Thomas Perorazio, PhD
Institution	Michigan Institute for Clinical & Health Research (MICHR), University of Michigan
Title of case study	Development of a Competency-Based Training Program for Clinical Research Study Teams
Goals and Objectives	The goal of this project is to create a training program that will increase knowledge of the clinical trials process and to purposefully and deliberately foster critical thinking and acquisition of problem-solving skills that can be applied on the job. Learning Objectives: 1. Using the principles of GCP, identify responsibilities of investigators and study team members in conducting clinical trials 2. Contrast standard of care vs. research activities 3. Through case study analysis, identify 'root causes' of non-compliance 4. Demonstrate preventive actions to avoid non-compliance 5. Identify frequently occurring data problems when implementing a clinical research study 6. Demonstrate best practices for data management 7. Practice communication skills during informed consent encounters to evaluate comprehension levels of participants and their families
Background	Study team members who conduct clinical trials – both faculty and staff – are highly trained in their fields, but often their education in the mechanics of carrying out a research study is less robust. Research study team members often learn through experience and may rely on colleagues for advice in managing the myriad details of clinical trials. This very common approach is problematic because 1) lack of a systematic training approach may result in knowledge gaps, 2) incomplete, inadequate, or inaccurate information may be transmitted, and 3) there is no documentation of information presented or how/when it is learned. This training program aims to rectify these issues by providing a standardized, competency-based education plan that will result in enhanced clinical trial outcomes. Through this project, we created a comprehensive education and training program for all members of

	research teams who participate in clinical trial research studies at the University of Michigan Health Systems.
How have you utilized the Harmonized Core Competencies Framework	This training program was developed as a series of modules, each of which is focused on a separate competency domain. Learning objectives and module content were based on selected skills statements from each competency domain. The resulting training program includes modules for Clinical Research Coordinators (CRCs) and faculty covering the competency domains of Clinical Trials Operations, Study & Site Management, Data Management & Informatics, and Ethics & Participant Safety Considerations. The modules were created as stand-alone units, so they can be combined in multiple ways to meet the needs of a variety of study team members. This program employs a blended learning model. Foundational knowledge is provided via online or digital materials, which learners must complete before attending classroom-based face-to-face training sessions. Time spent in the classroom is primarily focused on hands-on activities that reinforce knowledge through application using case-based and group learning simulations. This program also includes competency-based assessments, requiring learners to perform a particular skill and be scored using a standardized rubric in which a trained observer evaluates the performance of a learner on a specific task. Completion of tasks satisfactorily at specified work levels are documented through an ePortfolio system.
Key stakeholders impacted by the Core Competencies	Key stakeholders include clinical research coordinators (CRCs), faculty Principal Investigators (PIs), and other members of clinical research study teams.
Impact	The impact of this program will be to provide a structured, sustainable, and scalable training program based on accepted competency standards for the performance of clinical trials. The addition of competency-based assessments provides an objective measure of the program's impact.
Lessons learned	While all members of clinical research study teams may require training in similar competency domains, the level at which the skills are taught needs to be tailored to each specific group. Utilizing Blooms Taxonomy and Miller's Pyramid of Clinical Competence to design learning material and activities at the appropriate level is crucial to presenting effective competency-based education programs.

Suggested revisions of the Harmonized Core Competencies Framework	No revisions suggested.
Year the competencies were introduced	CRC training – 2010 PI training - 2016

Supplemental Document 1: Competency Map — Clinical Trials Training Curriculum for Faculty

Competency Map - Clinical trials training curriculum for faculty

Module	Competency Domain	Skills Statements	Training Type	Learning Objectives
Clinical Trials Operations (GCP)	Study & Site Management	• Recognize management and training approaches to mitigate risk to improve clinical trial conduct. • Develop strategies to manage participant recruitment, study activities, and track progress • Differentiate the types of adverse events (AEs) that occur during clinical trials, understand the identification process for AEs, and describe the reporting requirements to IRBs/IECs, sponsors, and regulatory authorities.	Online – to be completed before coming to workshop REQUIRED CITI GCP training https://www.citiprogram.org/ OPTIONAL: The Study Protocol Parts I and II https://globalhealthtrainingcentre.tghn.org/study-protocol/	1. Define Good Clinical Practices (GCP) for investigations 2. Explain why GCP is important in conducting clinical trials 3. Using the principles of GCP, define the responsibilities of investigators in conducting clinical trials 4. List practical applications of GCP in clinical trials 1. List the basic sections and design of a research protocol 2. Identify methods to monitor study safety and

				reporting using a research protocol 3. Identify strategies to overcome common errors when creating a protocol
	Clinical Trials Operations (GCPs) Study & Site Management	• Describe the roles and responsibilities of the clinical investigation team as defined by GCP guidelines. • Describe the various methods by which safety issues are identified and managed during the phases of clinical trials. • Identify the legal and regulatory responsibilities, liabilities, and accountabilities that are involved in the conduct of clinical trials.	Classroom 1. Lecture – Good Clinical Practice for research faculty: Making the change from clinician to researcher (45 min) 2. Small group hands-on Activity– Using a mock study protocol, practice writing schedule of events to differentiate between standard of care and research activities and create a study budget (30 min) 3. Online resources – (provide links to UM resources)	Lecture: 1. Define GCP and explain its impact on the clinical research process 2. Using the principles of GCP, define the responsibilities of investigators in conducting clinical trials 3. Define the purpose of a clinical research protocol 4. Define and contrast standard of care vs. research activities 5. Explain 'root causes' of non-compliance 6. Identify actions to prevent non-compliance Activity: 1. Differentiate between standard of care and research activities 2. Identify research activities and delegation of

				duties according to principles of GCP 3. List items included in a study budget
			Total Time – 75 min	

Good Clinical Practice			No online training	
	Clinical Trials Operations (GCPs)	• Describe the purpose and process for monitoring clinical trials. • Describe the purpose and process of clinical trial audits. • Evaluate the conduct and documentation of clinical trials as required for compliance with GCP guidelines.	Classroom 1. Lecture – Monitoring and Audits; intro to ClinicalTrials.gov (60 min) 2. Small group hands-on Activity - case study review – responding to monitoring reports (30 min) 3. Online resources – (provide links to UM resources)	Lecture: 1. Using FDA-defined principles of GCP, distinguish between DSMB, Monitoring, and Audits and explain their impact on the research process 2. Define non-compliance and identify reasons that may contribute to non-compliance Activity: 1. Evaluate items included in monitoring reports 2. Demonstrate preventive actions to avoid non-compliance
			Total Time – 90 min	

| Informed Consent, ethical and safety issues | Clinical Trials Operations (GCPs)

Ethical & Participant Safety | • Summarize the principles of distributive justice through selection | Online – to be completed before coming to workshop

OPTIONAL: Ethical Issues in Clinical Research | 1. Explain how research abuses have led to international recommendations guiding human subjects research
2. Define investigator responsibilities in |

	Considerations	and engagement with clinical trial participants.	http://clinicalcenter.nih.gov/training/training/crt.html AMA Health Literacy Video https://www.youtube.com/watch?v=BgTuD7l7LG8 (4 minutes)	conducting ethical clinical trials 3. Explain how health research developments are reported by the media 4. List strategies for working with reporters
	Ethical & Participant Safety Considerations	• Apply relevant principles of human subject protections and privacy throughout all stages of a clinical trial. • Define vulnerable populations and additional safeguards needed for protection of those populations.	Classroom 1. Lecture – Obtaining valid informed consent (45 min) 2. Hands-on Activity – case-based informed consent critique (30 min) 3. Online resources (provide links to UM resources)	Lecture: 1. Explain the purpose of informed consent 2. Identify standard requirements of informed consent documents 3. Identify strategies for assessing participant understanding during the informed consent process Activity: 1. Identify communication skills for interacting with potential study participants and their families 2. Critique informed consent encounters for the use of strategies for evaluating comprehension level of study participants
			TOTAL TIME – 75 min	

1. Online training modules will provide background and supplemental knowledge for each module. Specific skills will be taught and demonstrated in the face-to-face training.
2. Online programs will include multiple choice tests and will need to be completed prior to attending face-to-face training.

Supplemental Document 2: Competency Map — Clinical Trials Training Curriculum for Clinical Research Coordinators

Competency Map - Clinical trials training curriculum for Clinical Research Coordinators

Module	Competency Domain	Skills Statements	Training Type	Learning Objectives
Data Management	Data Management & Informatics	1) Describe the typical flow of data throughout a clinical research study 2) Summarize the process of electronic data capture and the importance of information technology in data collection, capture, and management 3) Describe the ICH GCP requirements for data correction and queries	Online: Fundamentals of Data Management UM resource	

			Classroom
			
			1. Lecture – Overview, Fundamentals of Data Management
			2. Small Group Activity (study coordinator facilitators)
			  a. Case study; Review study protocol
			  b. Practice writing schedule of events from a research protocol
			  c. Create and critique CRFs
				1. Define the roles of study developers, data managers, study coordinators, statisticians, and study monitors in data management
				2. Describe tools and processes designed to improve the quality and efficiency of conducting clinical research studies
				3. Recognize frequently occurring data problems when implementing a research study
				4. List best practices for data management

			TOTAL TIME – 2.5 hours	

Module	Competency Domain	Skills Statements	Training Type	Learning Objectives

GCP & Essential Documents	Clinical Trials Operations (GCPs)
	
	Study & Site Management
		1) Summarize the conduct and management of clinical trials.
		2) Describe the roles and responsibilities of the clinical investigation team as defined by GCP guidelines
		3) Evaluate the documentation of clinical trials as required for compliance with GCP guidelines
		4) Describe the purpose of clinical trial audits
		5) Describe the various methods by which safety issues are identified and managed during the development and post-marketing phases of clinical research
		
		1) Identify and explain the specific procedural, documentation, and oversight
			Online
			
			ICH Guidelines for Good Clinical Practice
			https://globalhealthtrainingcentre.tghn.org/ich-good-clinical-practice/
			
			Classroom
			
			1. Lecture – Overview of GCP and Essential Documents
			2. Hands-on Activity
			  a. Case study; Practice interpreting a protocol and writing a schedule of events
			  b. Review regulatory binder and essential documents
			  c. Identify common errors in record keeping
			  d. Identify purpose for audits and documentation needed
				1. Define GCP and explain its impact on the research process
				2. Define non-compliance and identify reasons that may contribute to non-compliance
				3. List preventive actions to avoid non-compliance
				4. Summarize methods for keeping the regulatory binder up to date
				5. Identify at least 2 types of source documents and at least 4 items usually found in a regulatory binder
				6. Recognize errors in source documentation
				7. List techniques for maintaining accurate source documents

		requirements of PIs, sponsors, contract research organizations (CROs), and regulatory authorities related to the conduct of a clinical trial		
		TOTAL TIME – 2.5 hours		

Module	Competency Domain	Skills Statements	Training Type	Learning Objectives
Conducting & Obtaining Valid Informed Consent	Ethics & Participant Safety Considerations	1) Compare and contrast clinical care and clinical management of research participants. 2) Compare the requirements for human subject protections and privacy and ensure their implementation throughout all stages of a clinical trial 3) Explain the foundational documents that inform laws and guidelines for informed consent and the protection of human study participants 4) Define vulnerable populations and	Online NIH Clinical Center: Ethical Issues in Clinical Research http://clinicalcenter.nih.gov /training/training1.html	

			Classroom
			
			1. Lecture – Conducting & Obtaining Ethical, Valid Informed Consent
			2. Small Group Activity
			  a. Review and practice effective communication strategies to evaluate participant understanding of research participation
			  b. Role-play activity; obtaining informed consent
				1. Identify regulations pertaining to informed consent and necessary components of the document.
				2. Demonstrate necessary communication skills when interacting with potential study participants

		additional safeguards needed for protection of those populations 5) Summarize the principles and methods of distributing and balancing risk and benefit through selection and management of clinical trial subjects		and their families.
			TOTAL TIME – 2.5 hours	

Honorio Silva (Rutgers University School of Health Related Professions & IFAPP)

Author / Presenter	Honorio Silva, MD
Institutions	• Rutgers University School of Health Related Professions, Newark, New Jersey • IFAPP (International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine), The Netherlands
Title of case study	The JTF Core Competencies in Latin America: Inter-Regional and Intra-Regional Differences
Goals and Objectives	To identify possible differences in the perception of competence, relevance for the job and additional needs for training among clinical research professionals from Latin America (LA), as compared to Western Europe and USA/Canada, with focus on Principal Investigators
Background	The implementation of the JTF International Survey on Core Competencies in Clinical Research was successful in their initial validation. However, global differences in the perception of competence and relevance for the job among members of the clinical research team (Principal Investigators-PIs, Clinical Research Coordinators-CRCs, Clinical Research Associates/Monitors-CRAs and Clinical Research Managers-CRMs, etc,) were identified Interestingly the majority of competences were considered relevant by the PIs, though this perception was lower among the other functions. Mexico contributed with about 50 % of the LA subpopulation and its sample included mostly PIs. A sub-analysis of the sampled population was conducted including only those participants responding to the full questionnaire (n=839). Inter-regional comparisons (Latin America vs. Western Europe Vs USA) and intraregional comparison (Mexico Vs rest of Latin America Vs Rest of the World) were made using t-tests for independent groups and p values < 0.05 for statistical significance.

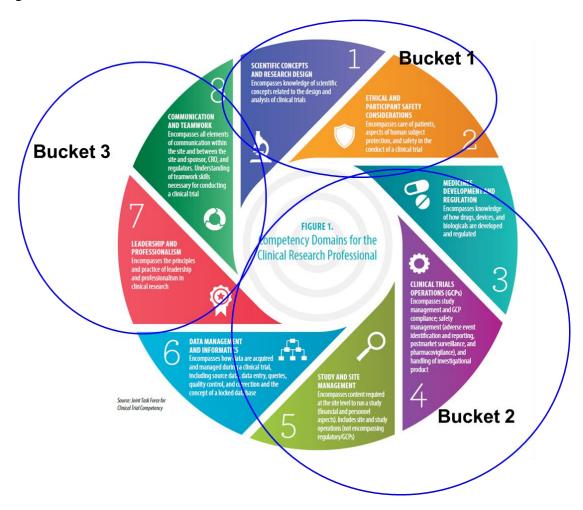| How have you utilized the Harmonized Core Competencies Framework	The preliminary results confirm significant differences in the perception of domains for competence and relevance among PIs from LA as compared to those from USA and Western Europe. Interestingly, this perception is even higher among PIs from Mexico, as contrasted to the rest of LA subpopulation. Training needs were also higher for the Mexican PIs. Likewise, the perception of competence (two domains) and relevance for the function (in all domains) was higher for the Latin American CRAs as compared to the USA. The training needs were also higher. Similar differences were found among CRMs though to a lower extent (one domain and two domains, respectively). Interestingly, few differences were found were contrasting the perception of competence and relevance among CRAs and CRMs from Western Europe and the USA.
Key stakeholders impacted by the Core Competencies	These preliminary results suggest the need for further validation among clinical research professionals from Latin America particularly among PIs, as compared to the USA or Western Europe, particularly because of the distribution of PIs among the total sample. Additional training programs for the LA PIs should be taken into consideration involving all stakeholders (regulatory agencies, sponsors, academic institutions, education providers etc.).
Impact	Systematic competency based training for all members of the clinical research team should be considered based upon the confirmed regional differences.
Lessons learned	Validation of competencies and assessment of training/education needs should always be conducted on regional/country bases. Educational programs could be implemented accordingly.
Suggested revisions of the Harmonized Core Competencies Framework	Further validation initiatives would lead to the revision of the Harmonized Core Competencies Framework, particularly to the confirmation of the "true" core competencies applicable to "all" members of the clinical research team.

Subasree Srinivassan (Alexion)

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Title of case study	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
Goals and Objectives	Present a use case of the core competency framework in development of a holistic training program for medical monitors at a mid-sized biopharma company.
Background	The drug development industry is a highly regulated environment into which physicians (clinicians, medical monitors) are often placed, with little or no prior clinical trial training. Often training is dictated by demonstration of completion of training via reading of Standard Operating Procedures and use of electronic systems necessary for conduct of clinical trials. Application of these procedures to the job is largely left to the user, leading to 'trained and compliant' but not always competent to carry out the job requirements in an effective and consistent manner. The Core Competency Framework of the Joint Task Force for Clinical Trial Competency provides a good foundation on which to build training, assess performance and nurture career growth for clinicians involved in the design, execution and interpretation of clinical trials.
How have you utilized the Harmonized Core Competencies Framework	A cross-disciplinary group of individuals were tasked with the formation of teams and sub-teams to map the existing training curriculum for clinicians to the competency framework, identify gaps in the curriculum and develop a tool box with hands on job aids for clinicians to use as part of the onboarding and training process. Two large teams with representation from various groups (clinical development, statistics, clinical pharmacology, pharmacovigilance, data management, clinical operations and site monitoring, human resources, learning and training and quality and regulatory compliance) were formed and met regularly for 3-4 months. The first team (curriculum training map team-CTM) was tasked with mapping all of the existing training which includes SOPs, drug development basics and systems training modules, to the competency framework.

	The second team (Bootcamp team-BC) was tasked with development of hands on job aids for key skills that were necessary and used often by clinicians during the execution of a clinical trial. Figure one shows the mapping of competencies into 3 buckets that were then further broken down by the kinds of training already in existence in an effort to identify gaps as well as possibly eliminate redundant or irrelevant training modules.
Key stakeholders impacted by the Core Competencies	Clinical development, clinical operations, quality and compliance, learning and development (Human resources)
Impact	The CTM team identified core competencies 1 and 2 being met by the existing modules of training in drug development basics that had been developed with the DCRI. These modules were offered as an optional training and provided for continuing education credits. Competencies numbers 3-6 with the regulations and execution of clinical trials, were grouped together. Training in this area was largely dealt with via learning of the standard operating procedure. The team identified this area as the one in most need of job aides that would entail consistency and competency in the execution of clinical trials; this activity was taken on by the BC team. Competencies 7 and 8 were identified as critical competencies for success of a clinician; however formal training in these competencies was largely lacking and often left to the initiative of individuals or their managers. The BC team developed 26 job aids that were placed on an accessible SharePoint site on the intranet, as a resource for clinicians. These aids would be revisited often by respective authors to ensure currency and who would also serve as subject matter experts. Newly hired clinicians would spend time perusing these job aids with hands on assistance by subject matter experts. Figure 2 portrays a list of these job aids. As a result of this new mapping, there was an overall reduction in the number of training modules for clinicians by about 20% and identification of key gaps that could be filled with relevant modules or face to face training.
Lessons learned	Application of the core competency framework to improve training of clinicians in industry involved in the design, execution and interpretation of clinical trials will make them a more competent workforce. This framework could be applied in a way as to genericize training across the industry, making it amenable to achievement of levels of competency. Compliance with regulations may be better judged by attainment of these competencies than mere demonstration

	of completion of discrete modules of training on standard operating procedures.
Suggested revisions of the Harmonized Core Competencies Framework	None identified
Year the competencies were introduced	Year of analysis- 2015 (Implementation planned)

Figures 1 and 2:
Figure 1:

FIGURE 1. Competency Domains for the Clinical Research Professional

Figure 2:

List of job aids created.
- Protocol authoring tool
- Meet and greet the study team
- Safety monitoring-Listings review tool
- Safety reporting tool
- Medical Safety teams procedures and roles
- Statistical analysis plan decoding tool
- Data presentation plan dos and don'ts
- Protocol deviation tool
- Quick tips for JReview
- Spotfire training modules and video clips
- Database closure aid and checklist
- Tables listing and figures
- Topline results presentation
- IB guidance document
- Aggregate safety reporting guidance document
- Complete study report comprehensive guidance
- Case report form checklist
- Helpful hints- complete study report
- General safety concepts for medical monitors

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Institutions	• Michigan Institute for Clinical & Health Research (MICHR), University of Michigan • Tufts Clinical and Translational Science Institute (CTSI) • The Ohio State University
Title of case study	Education and Training of Clinical & Translational Study Personnel: A Competency-Based Approach
Goals and Objectives	Competency-based curriculum is essential to ensure excellence in quality and safe performance of clinical research. Increasingly complex clinical trials demand a highly trained workforce. Current training has been ad hoc rather than competency-based. The Enhancing Clinical Research Professionals' Training & Qualifications (ECRPTQ) project goal was to explore standardized competency-based education for workforce development.
Background	ECRPTQ was led by faculty from six Clinical and Translational Science Award (CTSA) sites; all other sites contributed expertise and time. The competencies from the Joint Task Force (JTF) for Harmonized Core Competencies in Clinical Research was selected for use. Domain workgroups refined competency statements and identified training gaps and included social/behavioral input. A single set of consensus competency statements was produced. The 51 competency statements were reviewed; 34 were modified to enhance meaning and focus, 5 were rewritten as assessments, 3 new statements were added. 115 training gaps and 429 potential assessments were identified across domains. ECRPTQ concluded that clinical research training exists across domains but is inadequate, especially for study coordinators. Standardized competency assessments were lacking across all domains. This project was the first to involve all CTSA institutions—representing a unique collaboration. ECRPTQ established a

	harmonized framework for a competency-based curriculum which will positively impact clinical trials. The project validated the current variable nature of study team roles and institutional training policies. The work clearly underscored the need for standardized training that is easily accessible with minimal cost. Educators and program leaders must continue to develop competency-based education that supports enhanced clinical trials.
How have you utilized the Harmonized Core Competencies Framework	Joint Task Force (JTF) for Harmonized Core Competencies in Clinical Research was selected as the framework for the Enhancing Clinical Research Professionals' Training & Qualifications (ECRPTQ) project. Domain workgroups refined competency statements and identified training gaps and included social/behavioral input. A single set of consensus competency statements was produced.
Key stakeholders impacted by the Core Competencies	Key stakeholders include clinical research coordinators (CRCs) and Principal Investigators (PIs). Other members of clinical research study teams may gain educational value from the core competencies.
Impact	The Enhancing Clinical Research Professionals' Training & Qualifications (ECRPTQ) project will impact the competence and training of the clinical research team across the CTSA consortium. With the adoption of the competencies, we hope to show an impact on the safety and quality of clinical trial execution.
Lessons learned	In order to implement the core competencies across the CTSA consortium, educational programs need to be identified, or developed, that provide training to the core competencies at varying levels, from novice to expert. Assessment rubrics also need to be developed so competence can be evaluated and assessed.
Suggested revisions of the Harmonized Core Competencies Framework	No revisions suggested.
Year the competencies were introduced	ECRPTQ PI and CRC core competencies proposed – 2015 Awaiting final approval for National Center for Advancing Translational Sciences (NCATS) to adopt core competencies.

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

Please find the article on the following pages.