The title of the presentation is “Assessing the Competency of the Clinical Research Workforce: Forma
This slide conceptualizes the clinical research process and competencies needed for researchers from novice to expert.
Clinical research is a multidisciplinary endeavor. This illustrates the clinical research team and further suggests the complexity of conducting clinical research. For the purpose of this lecture, we are focusing on the clinical research professionals on the left side of the illustration.
The purpose of our work is to compare the competence of clinical research professionals working in different research settings with the competence of recent graduates of academic clinical research programs by evaluating an instrument, *The Competency Index for Clinical Research Professionals (CICRP)*, for a variety of workforce development functions.
We are reporting data from two surveys of clinical research professionals working in different research-intensive settings and from a third survey of students and recent graduates of academic research degree programs. References are shown here on this slide.
The Joint Task force for clinical trial competency identified 51 core competencies of clinical research professionals and those activities are grouped into eight (theoretical) competency domains.
The eight domains illustrated here are now internationally accepted competencies for clinical research professionals, with additional information located on the MRCT website at Harvard.
The JTF conducted a global survey of clinical research professionals working in multiple countries. We conducted a post-survey factor analysis of clinical research professionals working in the US and Canada yielding 5 factors defined by 20 core competency activities.
The 5 Factors were:
1. General Competency Index comprised of 10 competency items
2. And the 4 factor subscales: Ethics; Medicines Development; Data Management, and Scientific Concepts- each having 5 core competency items.
We then use the CICRP index in a survey of clinical research professionals working at the four diamond CTSA hubs (Michigan, Ohio State, Tufts and Rochester)
The CTSA hubs are Carnegie 1 Research Institutions and represent a “sample” of the 60 CTSA institutions.

We used the 20 competency items from the CICRP index.

- Data from 95 respondents working as a CRC with at least 1 year of clinical research experience are the subjects of our subsequent analysis.
- Our assumption is that: CRCs at a CTSA will work with complex protocols, so may represent the most competent with varied experience.
Emerging from the DIAMOND analyses was the CICRP-II index, as a Gold Standards for Clinical Research Coordinators a subset of the clinical research professional group.

The differences in scores suggested the need to create an assessment tool specifically for the role of CRC just as CRAI is a tool specifically for PIs.
In CICRP II, 2 factors emerged, each defined by 10 competency items:

- **Routine Activities**- carried out by CRCs in their everyday work (e.g., GCPs)
- **Advanced Activities**- specialized regulatory functions performed by CRCs
In a third study, we administered the CICRP survey to students and recent graduates of CoAPCR programs. These students were seeking or graduated with specific degrees in clinical research.

The demographics illustrated here show the breadth of types and caliber of students enrolled in formal academic programs in clinical research, from PhD to nurses to other undergraduate degrees. For the purpose of our comparative analyses, we focused on respondents to the survey who were graduates lacking experience in clinical research.
We compared CRCs from all three studies: JTF, DIAMOND and CoAPCR Students, comparing scores on CICRP-I and CICRP-II. We want to point out that because of the number of comparisons made and the small sample sizes involved in these multiple comparisons, we do not provide the customary tests of statistical significance (sic) and p-values.
This graph shows the comparator groups based on years of experience and the CICRP-II Routine Competency Mean Scores.
The group in orange are the academic Graduates with less than 1 year of clinical research experience.

As a comparison, we have three groups from the CTSA-CSRCs and the JTF CRCs with varying levels of experience.
This graph shows the CICRP-II Advanced Competency mean scores for the 3 groups. The academic graduates with less than 1 year of experience are in orange. As a comparison, the graph illustrates mean scores from CTSA and JTF CRCs with varying years of experience.
Looking at the CICRP-II index scores, with respect to competence to perform the routine functions and advanced functions required of a CRC, it appears that the competency of a novice graduate of an academic program in clinical research is equivalent to 5 or more years of experience as a CRC.
This graph illustrates a comparison of graduates with less than 1 year of experience to those working at CTSAs with varying levels of experience. Again the CoAPCR graduates are in orange.

Looking at the Mean Competency Scores from CICRP-1 Factors;
• the general competencies are measured at a general threshold of 0-100 (orange dashed line).
• The subscale factors threshold are measured at a threshold of 0 to 50 (pink dashed line).

CoAPCR graduates with less than 1 year of experience demonstrated perceived competence at a similar score level as CTSA CRCs with 2 – 5 years of experience for General Competencies and Data Management Competencies; and exceeded those for Medicines Development, Bioethics and Scientific Concepts.
CICRP-I scores show years of experience as a CRC at a research intensive site is associated with only small differences in competency when assessed by the General Index as well as by the subscales.

**Graduates of a CoAPCR program with less than one year of experience:**
- score equal to or a little higher than the CTSA CRCs on Ethics/Pt Safety; Data Management and Scientific Concepts assessment measures.
- score much higher than CTSA CRCs in competencies related to regulatory affairs and the complicated reporting requirements of medicine and device development.

Experience does not appear to translate into increases in competence when compared to Academic clinical research education and supports the business case and importance of setting educational goals for the workforce.
We conclude that formal education in clinical research can be worth several years of on-the-job experience, and that both CICRP Indices can be valuable tools for:

- Assessing preparedness for professional certification examinations, and evaluating the quality of education and training programs.
Thank You!

- Thank you for your interest in clinical research workforce development.
- For access to the CICRP tool and scoring instructions, go to diamondportal.org.
- Additional questions can be addressed to Dr. Carlton Hornung at cahornung@Louisville.edu

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