

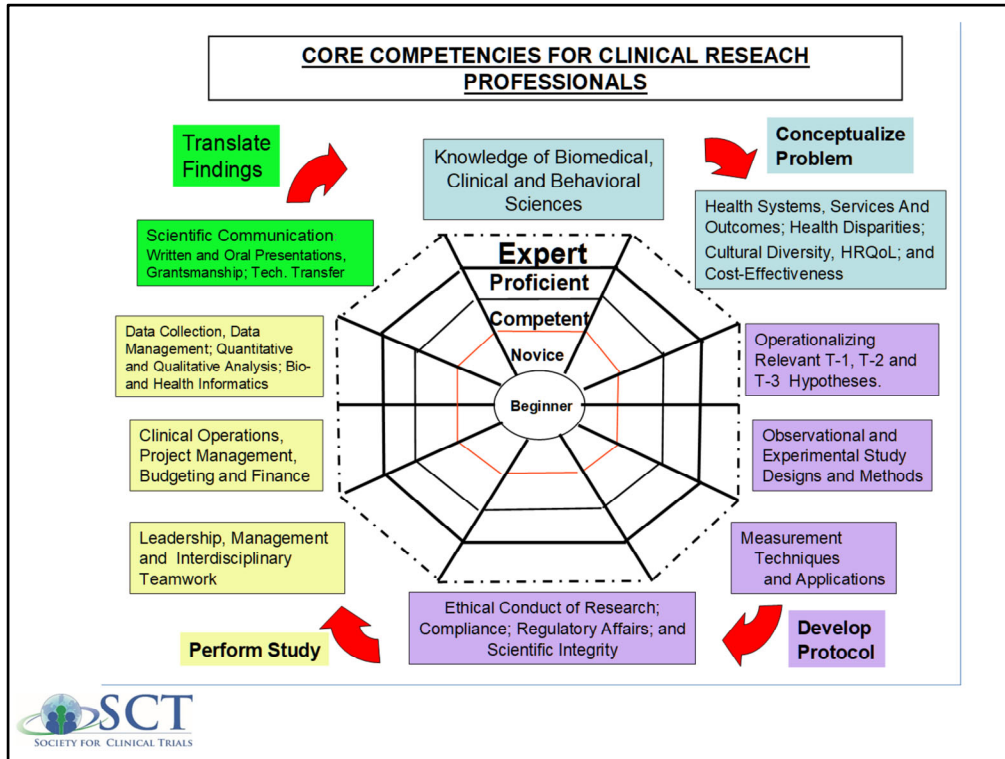


**Assessing the Competency of the Clinical
Research Workforce:
Formal Education; Role in the Research
Enterprise; and Years of Experience**

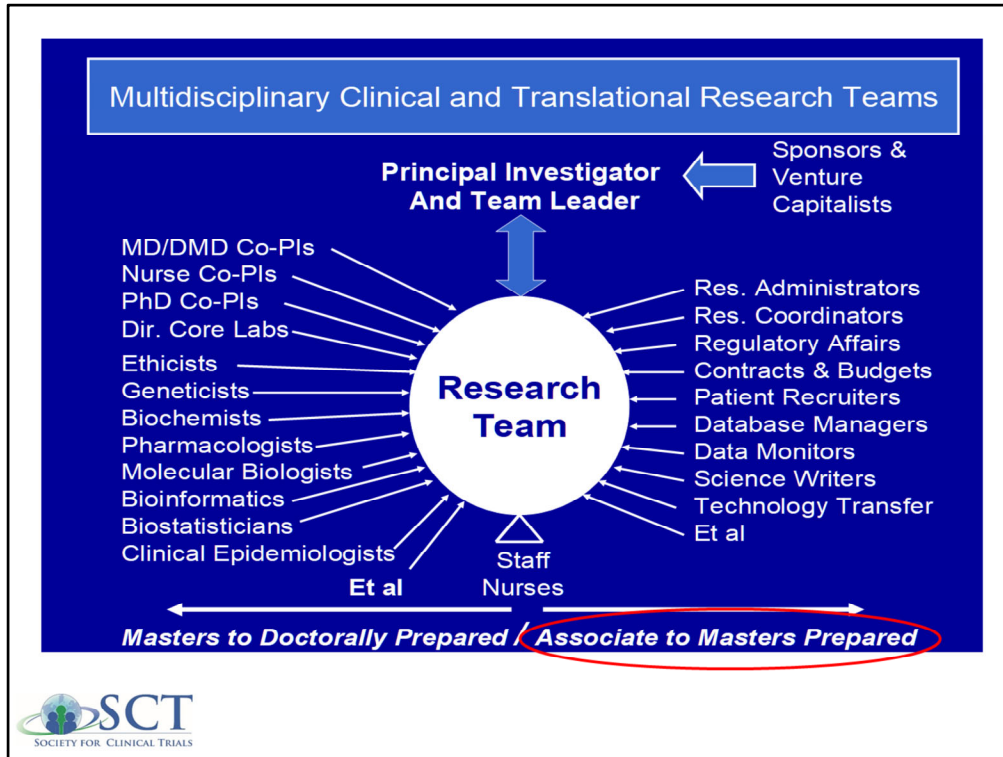
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Society for Clinical Trials Annual Meeting, Pre-Recorded July 26, 2020.

The title of the presentation is “Assessing the Competency of the Clinical Research Workforce: Formal Education, Role in the Research Enterprise and Years of Experience. I’m Carolynn Thomas Jones presenting on behalf of the co-investigators, Dr. Carl Hornung and Jered Ker.



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.

Purpose

- Assess and compare the competence of clinical research professionals working in different research settings with the competence of recent graduates of academic clinical research programs.
- Evaluate the Competency Index for Clinical Research Professionals (CICRP) as a tool for:
 - staffing clinical research teams;
 - identifying the need for continuing education and/or training; and,
 - evaluating the quality of clinical research education and training programs.



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.

Data Sources

Two previous surveys: (JTF, DIAMOND) and Current CoAPCR Survey

1. Joint Taskforce on the Harmonization of Competencies for the Clinical Research Professional (JTF)
 - Hornung CA, Jones CT et al. Competency indices to assess the knowledge, skills and abilities of clinical research professionals. *Int J Clinical Trials* 2018 Feb;5(1):46-53
2. **Development, Implementation and Assessment Of Novel Training in Domain-Based Competencies (DIAMOND); NCATS U01TR002013**
 - Hornung CA et al. Indices of clinical research coordinator's competence. *Journal of Clinical and Translational Science* 3: 75-81.
3. Consortium of Academic Programs in Clinical Research (CoAPCR)
 - Kerr, J., Hornung, C., Jones, C., Neidecker, M. Competency index for clinical research professionals (CICRP): Measuring competence of CoAPCR students. Presented at: Annual Meeting of the Consortium of Academic Programs in Clinical Research; April 14, 2019; Nashville, TN.



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.

Defining Core Competencies for Clinical Research Professionals

Joint Taskforce on the Harmonization of Competencies for the Clinical Research Profession (JTF)

- JTF, with input from several organizations including ACRP, SoCRA, Pharma and academic programs (CoAPCR) identified 51 activities and functions to be the core competencies of clinical research professionals.
- Activities grouped into eight (theoretical) competency domains.



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.

JTF Core Competency Domains



- **SCIENTIFIC CONCEPTS AND RESEARCH DESIGN:** Knowledge of scientific concepts related to the design and analysis of clinical trials.
- **ETHICAL AND PARTICIPANT SAFETY CONSIDERATIONS:** Care of patients, aspects of human subject protection and safety in the conduct of a clinical trial.
- **INVESTIGATIONAL PRODUCT DEVELOPMENT AND REGULATION:** Knowledge of how drugs, devices, and biologicals are developed and regulated.
- **CLINICAL TRIAL OPERATIONS (GCP):** GCP compliance, safety management, and handling of investigational product.
- **STUDY AND SITE MANAGEMENT:** Site and management of study operations .
- **DATA MANAGEMENT AND INFORMATICS:** How data are acquired and managed during a clinical trial.
- **LEADERSHIP AND PROFESSIONALISM:** The principles and practices of leadership and professionalism in clinical research.
- **COMMUNICATION AND TEAMWORK:** All elements of communication within the site and between the site and sponsor including teamwork skills necessary for conducting a clinical trial.



Sonstein et al, 2014

<https://mrctcenter.org/clinical-trial-competency/>

The eight domains illustrated here are now internationally accepted competencies for clinical research professionals, with additional information located on the MRCT website at Harvard.

Developing Competency Indices for Clinical Research Professionals

- JTF surveyed clinical research coordinators, monitors, data managers, regulatory affairs and patient safety experts working in various clinical research settings in the US, Canada, Latin America, Europe and the far East. (n=1460)
 - Respondents indicated how confident they felt performing each of the “core competencies” –Dichotomized as “Not Competent” and “Competent”.
- Factor Analysis of responses from CRCs, CRAs, Data Managers, Regulatory Affairs and Research Administrators (**N = 238**) working in the US or Canada yielded 5 factors defined by 20 Core Competency activities or functions.

Hornung, C.A., Jones, C.T., Calvin-Naylor, N.A., Kerr, J., Sonstein, S.A., Hinkley, T., Ellingrod, V.L. (2018). Competency indices to assess the knowledge, skills and abilities of clinical research professionals. *Int J Clin Trials* 5(1):46-53. DOI: <http://dx.doi.org/10.18203/2349-3259.ijct20180130>



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.

Competency Index for Clinical Research Professionals CICRP-I: General Index + Four Sub-scales

Factor 1: GENERAL COMPETENCY (the operation and management of clinical research) - 10 core competency items

SUBSCALES:

- **Factor 2: ETHICS AND PATIENT SAFETY** - 5 core competency items.
- **Factor 3: MEDICINE DEVELOPMENT** - 5 core competency items.
- **Factor 4: DATA MANAGEMENT** - 5 core competency items.
- **Factor 5: SCIENTIFIC CONCEPTS** - 5 core competency items.



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.

The DIAMOND Project

- Development, Implementation, and Assessment Of Novel Training in Domain-based Competencies
- Funded by the National Center for the Advancement of Translational Science: U01TR002013 (*April 2017 – March 2020*) diamondportal.org
 - University of Michigan
 - Ohio State University
 - Nationwide Children’s Hospital
 - Tuft University
 - Affiliated Hospitals
 - University of Rochester



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)

DIAMOND Survey

- Online survey of clinical research professionals working at DIAMOND 4 CTSA hubs and partnering hospitals.
 - The 4 CTSA hubs are Carnegie I Research Institutions and represent a ‘sample’ of 60 CTSA Institutions.
- Demographics included: education, research experience,
- 20 CICRP Core Competency Items
 - *95 respondents working as a CRC with at least 1 year of clinical research experience are the subjects in this analysis.*
 - Assumption: CRCs at a CTSA will work with complex protocols, so may represent the most competent with varied experience.



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.

CICRP-II: The “Gold Standard” for CRCs

- Analysis of CICRP-I in the JTF data revealed that individuals in different clinical research roles exhibited significant differences in scores on the General Index and each of the 4 sub-scales.
- 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.



Emerging from the DIAMOND analyses was the CICRP-II index, as a Gold Standard 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.

CICRP-II

– Factor analysis of responses to the 20 CICRP items by 95 experienced CRCs at the CTSA hubs and affiliated hospitals yielded 2 factors, 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 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

CoAPCR Student Survey Respondents

- Respondent Demographics (n=189)
 - Graduates (n=45*) from the 2017 and 2018 classes.
 - 17 without or <1 yr of clinical research experience*
 - Baccalaureate degree or higher (n=172)
 - 13 with a doctoral degree; 25 with a nursing degree.
 - Prior research Experience:
 - None (n=48)
 - > 5 years experience (n=86)
 - Prior research experience (n=110) by type:
 - CRC (n=60)
 - CR Nurse Manager (n=13)
 - Research Associate (n=37)
 - Pharma Employer Settings (n=92)
 - CRO, SMO, Biotech or Pharmaceutical company
 - Membership in ACRP or SoCRA (n=90).



*** Graduates lacking experience were key comparators.**



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.**

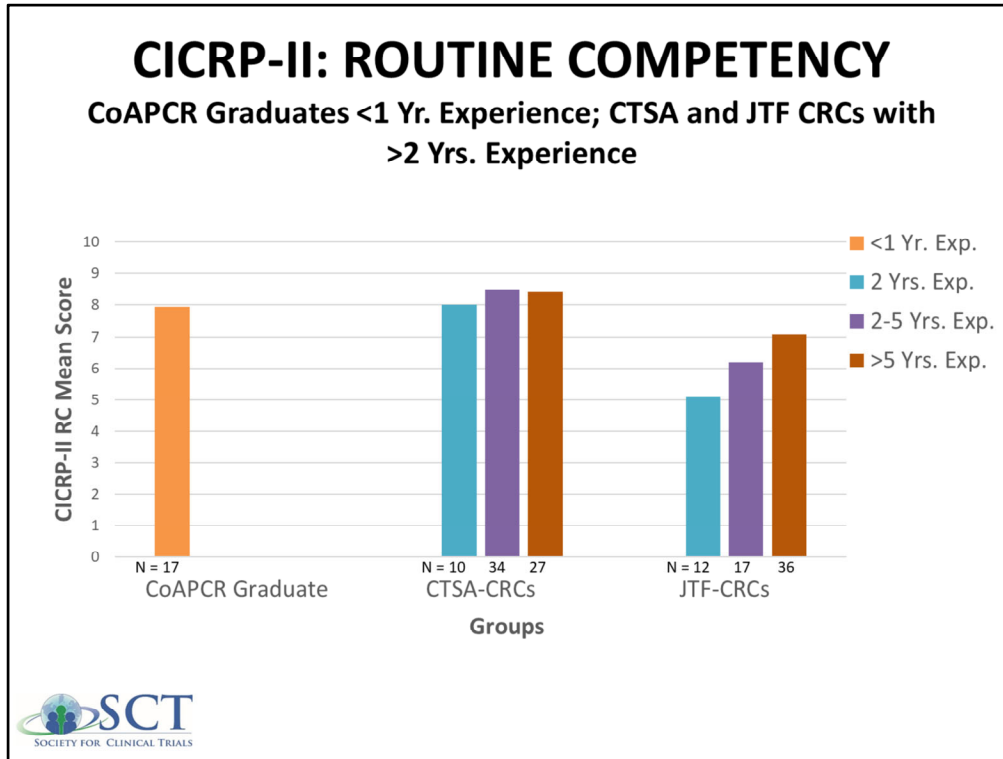
Analysis

- **Survey Comparison Groups:**
 - **JTF:** Clinical Research Coordinators at various sites in the US and Canada surveyed by the JTF (N= 65).
 - **DIAMOND:** Experienced Clinical Research Coordinators working at research intensive sites surveyed by the DIAMOND project (N=61).
 - **CoAPCR:** CICRP-II Routine and Advanced Indices for CoACPR Graduates (N = 17).
- **Explored differences between groups by comparing scores on CICRP-I and CICRP-II (General Index and Sub-scales)**



We compared CRCs from all three studies: JTF, DIAMOND and CoAPCR Students, comparing scores on CICRP-1 and CICRP II

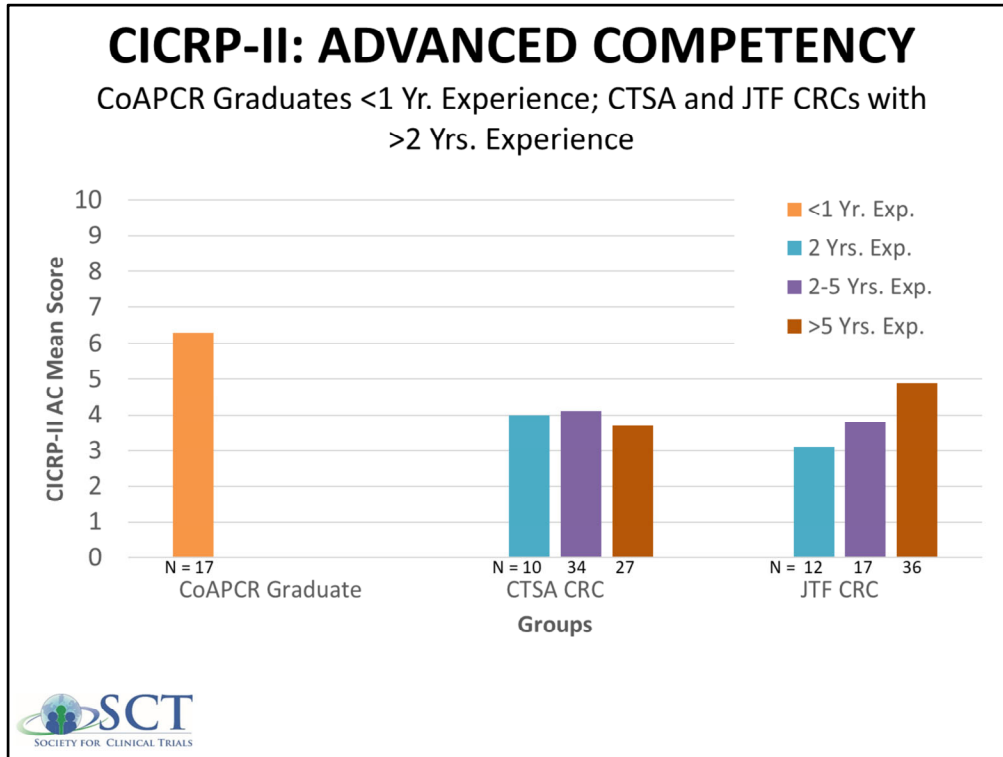
We want to point out that because of the number of comparisons made and the small sample sizes involved in these multiple comparisons, we do not provide the customary tests of statistical significance (sic) and p-values.



This graph shows the comparator groups based on years of experience and the CICRP-II Routine Competency Mean Scores

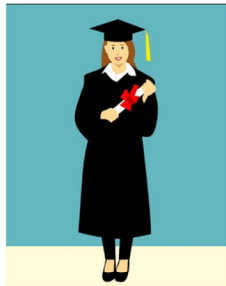
The group in orange are the academic Graduates with less than 1 year of clinical research experience.

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.

Results and Observations



**CICRP – II- Routine
Competency Score**

**CICRP-II Advanced
Competency Score**

*CTSA CRC or Community Setting CRC
Experience Equivalency*

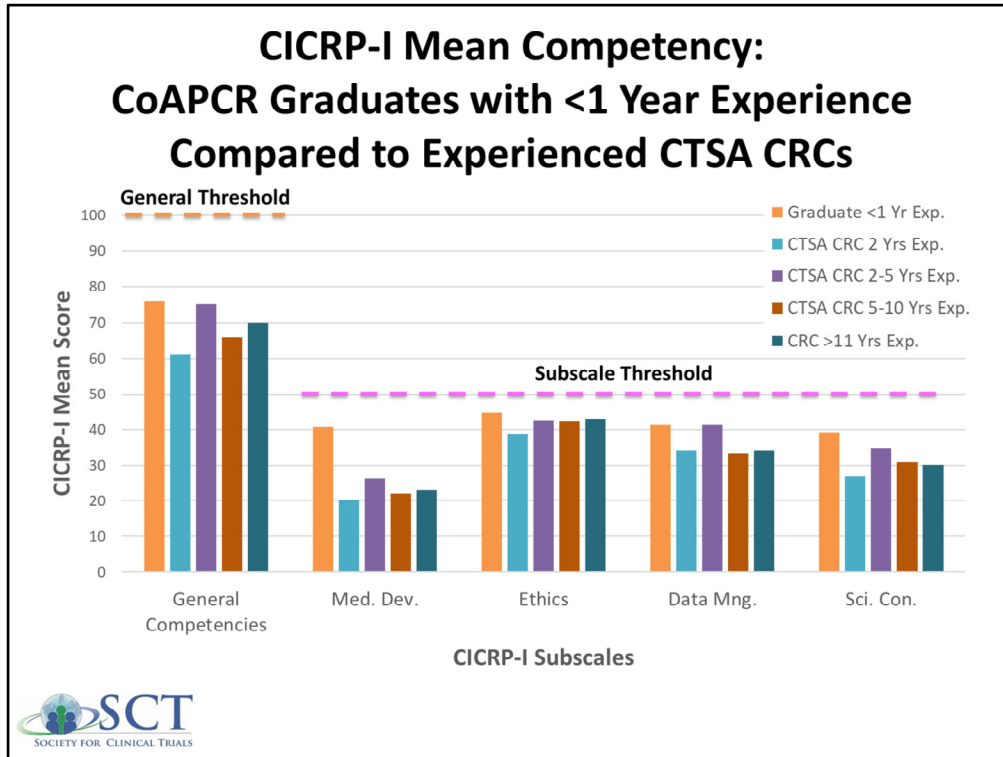
**Graduate of CoAPCR
(Novice)**

>5 yrs as CRC

>5 yrs as CRC



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 CTSA with varying levels of experience. Again the CoAPCR graduates are in orange.

Looking at the Mean Competency Scores from CICRP-1 Factors;

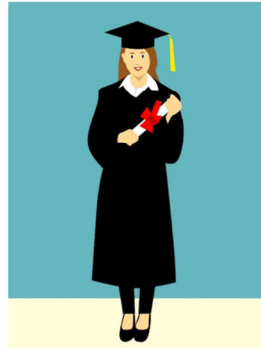
- the general competencies are measured at a general threshold of 0-100 (orange dashed line).
- The subscale factors threshold are measured at a threshold of 0 to 50 (pink dashed line)

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.

Some Further Observations Based on Responses to CICRP-I

A Business Case for Academic Education in Clinical Research

CoAPCR Graduates



CTSA CRCs

≥

- Ethics/Pt Safety
- Data Mgt
- Scientific Concepts

>

- Regulatory affairs
- Medicines/Device Dev't reporting requirements



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.

Conclusions and Implications

- **Education in a formal academic program can prepare individuals to function at a high level in the clinical research enterprise.**
 - The competencies mastered in a degree granting program are equivalent to several years of on-the-job experience.
- **CICRP-I and CICRP-II is a useful tool for Human Resource**
 - Assessing the readiness of individuals to function on a clinical research team
 - Insuring research teams qualified individuals
- **Both CICRP Indices valuable tools for:**
 - Assessing preparedness for professional certification examinations
 - Assessing the need for continuing education and training
 - Evaluating the quality of education and training programs



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



Thank you for viewing this presentation and for your interest in clinical research workforce development.

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