Cultivating Pathways for Clinical Research Professionals through Development of an Undergraduate Certificate Program

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BACKGROUND

- Recruitment and retention of skilled clinical research professionals (CRP) remains a challenge for cancer centers in the post-pandemic era.
- Through our CRP Task Force, key stakeholders (UC Cancer Center, UC Office of Clinical Research, UC College of Medicine, UC Human Resources, and Center for Clinical and Translational Science and Training (CCTST)) are focusing on developing and implement strategies for recruitment, retention, and education of our clinical and translational sciences workforce.
- Our education working group conducted a 4-part educational needs assessment. While we saw a decrease in staff turnover rates in 2023 compared to the prior two years, the highest turnover rates across CRP roles exist in entry-level job titles.

GOALS

- Develop an undergraduate certificate program to: 1) improve the visibility of clinical research careers in the undergraduate student population at the University of Cincinnati, 2) provide training to potential CRP staff by introducing the principles of clinical and translational sciences (CTS).

METHODS

A six-step curriculum development process[1] was implemented, which included a needs assessment using both internal and external data collection.

Using the Joint Task Force JTF Core Competency Framework for the CRP version 3.1[2] to determine curriculum content, we established program learning objectives by categorizing competencies into essential, important, or not needed in an entry level CRP position. Next, we reviewed existing resources (ex. CITI training) and available UC courses for related content. No courses addressed CRP competencies according to the 3.1 Competency Framework.

We established program learning objectives and developed the curriculum: 1) seminar experience with 12 hours per week working as a patient care team member in our health system, 2) Introduction to CTS, 3) Fundamentals of Clinical Trials and 4) online seminar with 12 hours per week working in a clinical and translational research unit. The certificate is 12 credits and can be completed in 2-4 semesters **(Table 1)**

DISCLOSURES
No relevant disclosures.

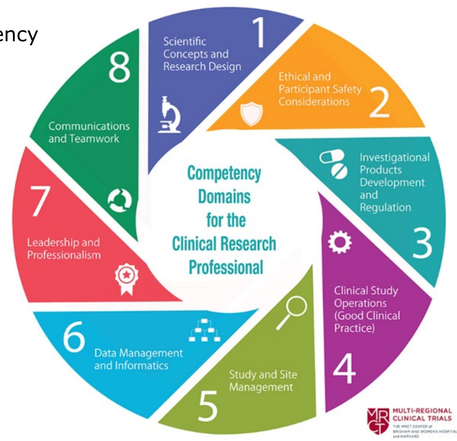
RESULTS

Table 1: Undergraduate Certificate in CTS Curriculum

Course Title	Course # (Credits)	Semester Offered (Mode)	Course Topics
Healthcare Exploration through Patient Care*	MEDS-3099 (3)	Fall/Spring (In-Person)	Seminar on healthcare career options + 12 hr/wk internship at UCMC as Patient Care Assistant
Introduction to Clinical & Translational Science	MEDS-3110 (3)	Fall (Online)	CITI-Human Subjects, GCP, Health Disparities, DEI, Project Planning & Oversight, IRB, Source Documentation, Biospecimens, Quality & Compliance, Data Management, Participant Safety
Fundamentals of Clinicals Trials	MEDS-3111 (3)	Spring (Online)	History of CTR, Drug Development and CT Phases, GCP, CFR, ICH, Informed Consent, Adverse Events, Safety Reporting, Monitoring/Audits/Inspections, Protocols, CT Team Roles, Vested Stakeholders, Study Feasibility, Study Start-up and Maintenance
Team-Based Clinical & Translational Science*	MEDS-3112 (3)	Spring (Hybrid)	Seminar on team science and project management + 12 hr/wk internship at UC/CCHMC as student CRP
Total	**12**		

*Course requirements include a *minimum* 12 hour per week, in-person paid internship.

Figure 1. JTF Competency Framework[2]



Program Goals

After completing the Certificate, students will be able to:
- Explain Good Clinical Practice (GCP) according to the NIH.
- Summarize the fundamental processes of clinical and translational science, including participant recruitment, addressing diversity, equity, inclusion, and accessibility, data collection and management, study site management, and financial management to support clinical research activities.
- Describe the stages of clinical trials and their relevant regulatory components.
- Demonstrate project management and communication skills in a team-based research setting.
- Connect the goals and outcomes of clinical and translational research to impacts in patient care and population health.

CONCLUSIONS

- To better prepare undergraduate students for careers in clinical and translational sciences, we developed a competency-based, for credit, undergraduate certificate program.
- The Certificate program is currently open for student enrollment with the first class to begin in the fall of 2024.
- A diverse group of stakeholders engaged in the development of the certificate program. With this, we have benefitted from the use of existing resources to keep program costs for development, course administration, instruction and enrollment as low as possible.

Future Directions:
- We plan to conduct program evaluations through alumni survey and an annual focus group to assess learner satisfaction and career outcomes in addition to basic course evaluations.
- As the program grows there is opportunity to explore how this certificate program internship format could be modified for existing staff working in clinical and translational sciences.
- Over time, will evaluate whether income generated from the program can be utilized to support student internship placements with research groups across the institution to remove any financial barriers for experiential learning opportunities.
- Collaborate with HR with the goal of incorporating recognition of the certificate into candidate experience level at time of hire, and tracking certificate completion with hiring for ongoing impact to our workforce.

REFERENCES

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