NJ ACTS: Experiences in Developing a Clinical Research Coordinator Badge

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Introduction

A shortage of a well-trained Clinical trial workforce threatens delivery of new drugs, devices, & innovations

Academic Medical Center Clinical Research Coordinator Barriers
- Low recruitment and retention numbers
- Low salaries
- Poor career laddering
- decentralized employment structure
- Lack of awareness of or access to clinical research job opportunities

NIH CTSA NCATS brought awareness to the problem
- Recruitment and retention of CRCs topics at the ACTS Translational Science 2022
- Collaborative conversations at Un-Meeting Sessions between Sept 2020 and Feb 2021
- NIH highlights the importance of Diversity in Clinical Research Workforce

NJ ACTS solution
- Incorporate pathways to diversity and equity within CRC workforce.
- Micro-credentialing as a training, education, and job recruitment tool
- Digital badges as symbols validating a learned skill or competency that represent a subset of a micro-credential

Overview of Data Collection

Course Development
- Domain selection: 6/8 JTF Domains
- KOL & Senior CRO designated 5-9 competencies/domain
- Course Description: 5 modules to be completed in 4 weeks
- 172 survey questions/module

Beta-Tester Demographics
- Gender Identity
- Ethnicity
- Age
- Highest Level of Education
- Relevance of Degree to Human Subjects Research (HSR)
- Years of Experience Level in HSR

Beta-Tester Outcomes
- Assessment item difficulty
- Quiz Attempt Rate
- Completion Rate
- Time Completion Rate
- Competency Inclusion identification
- Course Feedback

CRC Module Breakdown

Scientific Concepts and Research Design
- Describes the foundational principles governing drug development including pharmacokinetics and pharmacodynamics, and reviews how a suspected adverse drug reaction (ADR) may be identified. Participants will also learn some basic research designs and statistics used to evaluate drug effectiveness and apply this knowledge to critically analyze study results.

Ethical and Participant Safety Considerations
- Encompasses the ethical care of patients enrolled in a clinical trial. Participants will learn about the historical events that have led to the current human subject's protection regulations and evolution of informed consent. The mission, functions, and procedures of the Institutional Review Boards and treatment of vulnerable subjects are reviewed.

Investigational Products Development & Regulation
- Includes the regulations that must be followed when bringing product to market. Investigational New Drug Applications (INDAs) and New Drug Applications (NDAs) are described, and the stages of drug development are reviewed in detail.

Clinical Study Operations and Site Management
- Takes the participant on the drug development journey by covering events taking place at a study site and at the sponsor. It operationalizes the conduct of a clinical trial and reviews specific tasks that must be performed.

Data Management & Informatics
- Reviews how study data is handled as well as data privacy regulations. Rules regulating reporting of adverse drug reactions are also covered.

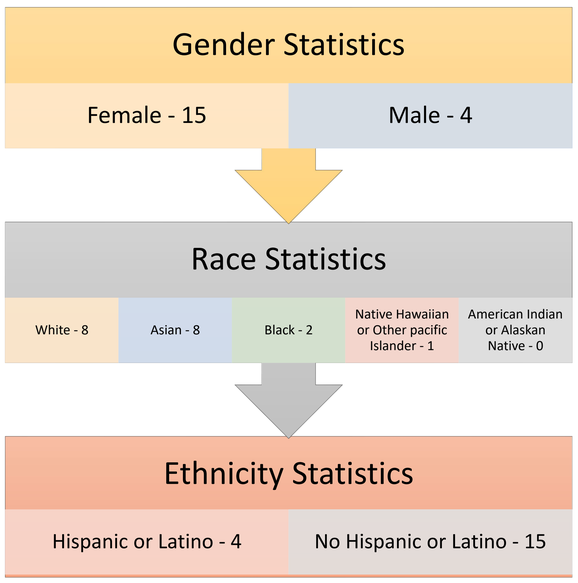
Path to Workforce Equity

Asynchronous virtual format opens doors for outreach to underrepresented workforce populations

Low cost and short duration open doors to CRC Careers for diverse socio-economic groups

CRC Badge Program is translatable to AMC adoption across CTSA hubs to target hub specific underrepresented communities

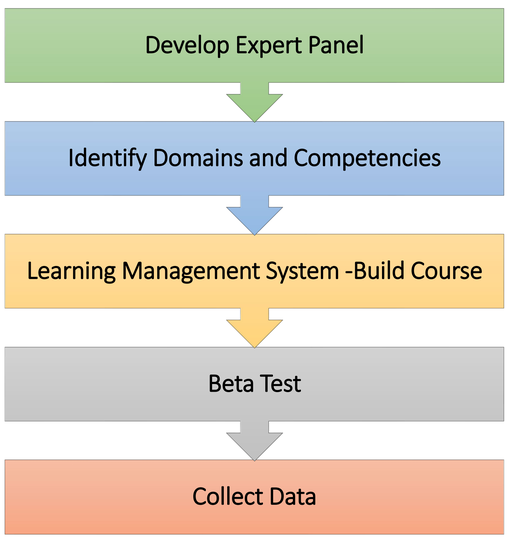
Path to Workforce Equity Statistics



Objective

Describe the development of a micro-credentialling program and CRC Badge that provides condensed competency-based clinical research knowledge and enables clinical research naive professionals interested in breaking into the field a pathway to entry level CRC positions.

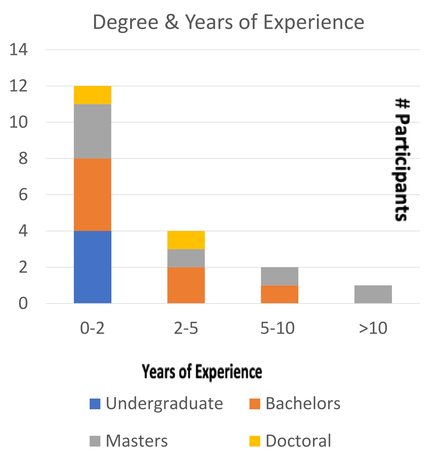
Methods



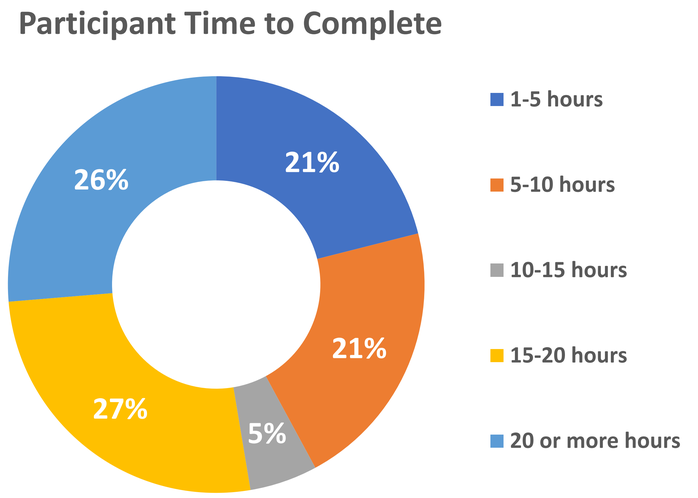
Course Design

I. Module Overview
II. Recordings
III. Handouts
IV. Discussion
V. Quiz-25 MC questions, 1 hour to complete, 3 attempts to score 90%

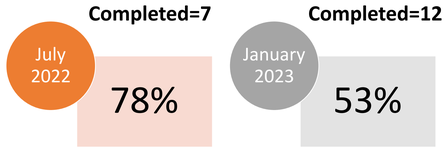
Demographics for Badge Completers

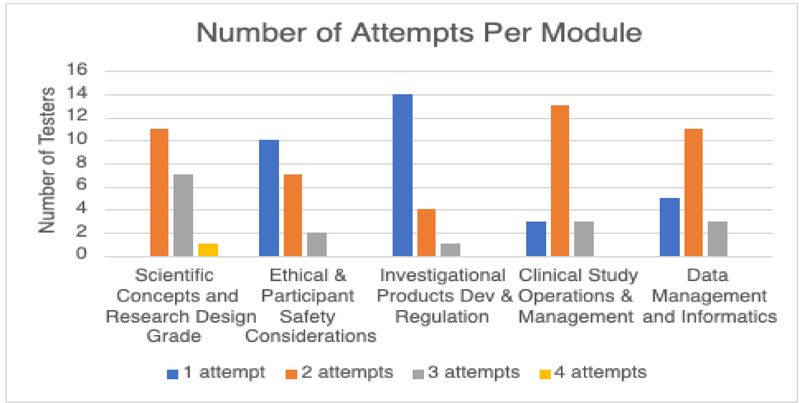


Completion Statistics

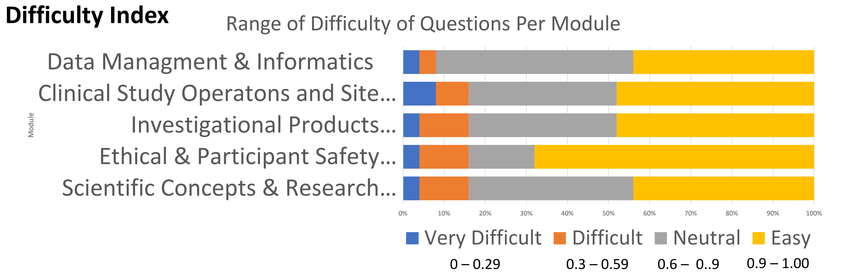


Completion Rate 59.3% (Completed N=19)

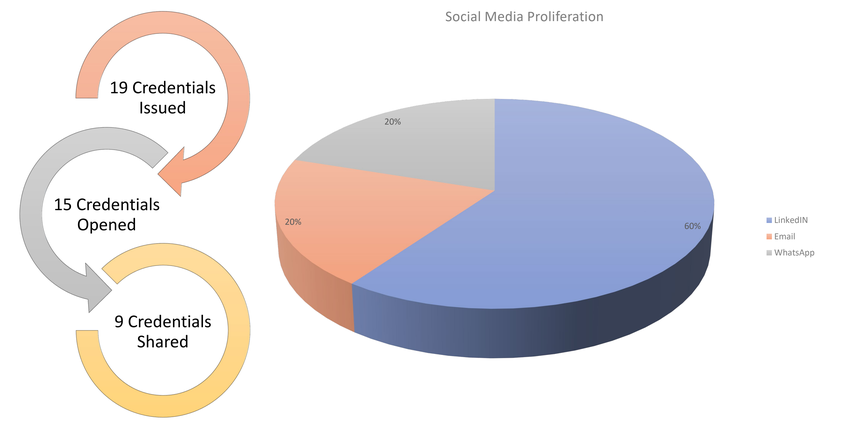




Quiz Item Analysis (25 questions/module)



Post Badge Use of Credentials



Discussion

This poster summarizes the development of a clinical research coordination training badge to be used as a tool to educate and recruit individuals into study coordinator positions at a major AMC. Nineteen individuals with varying clinical research experience completed the course and received an electronic badge. Survey questions asking about the quality and performance of the course were extremely favorable. The Difficulty Index for the quizzes indicated that questions were predominantly "easy" or "neutral" which is commensurate with entry or foundational level skills which confirmed our goal of creating a course for the novice individual.
When asked about what the participants liked best about the course, comments included: "Easy to Follow" "I really enjoyed the presenter" "the organization and content and the way it was presented was excellent" and "very comprehensive"

Given this excellent feedback and limited need for corrections and editing, the decision was made to proceed in March 2023 to the next phase of this project which included making the course available to enrolled students, faculty and staff at Rutgers, Princeton, and NJIT (NJ ACTS Community).

Future Research

Evaluate the effectiveness of the badging program with regard to increasing employment, promotion and clinical trial efficiencies. We will also be administering a valid and reliable knowledge test both pre and post course enrollment to determine student learning.

https://njacts.rbhs.rutgers.edu/

Acknowledgments

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