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Advancing workforce diversity by leveraging the Clinical and Translational Science Awards (CTSA) program

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Abstract

Clinical trials continue to disproportionately underrepresent people of color. Increasing representation of diverse backgrounds among clinical research personnel has the potential to yield greater representation in clinical trials and more efficacious medical interventions by addressing medical mistrust. In 2019, North Carolina Central University (NCCU), a Historically Black College and University with a more than 80% underrepresented student population, established the Clinical Research Sciences Program with support from the Clinical and Translational Science Awards (CTSA) program at neighboring Duke University. This program was designed to increase exposure of students from diverse educational, racial, and ethnic backgrounds to the field of clinical research, with a special focus on health equity education. In the first year, the program graduated 11 students from the two-semester certificate program, eight of whom now hold positions as clinical research professionals. This article describes how leveraging the CTSA program helped NCCU build a framework for producing a highly trained, competent, and diverse workforce in clinical research responsive to the call for increased diversity in clinical trial participation.

Background

Biomedical research and innovation are critical to improving medical treatments and human health. Non-Hispanic White Americans make up 60.1% of the US population [1], yet according to the Food and Drug Administration (FDA) 2020 Drug Trial Snapshot, they make up 75% of participants in clinical trials while participation among Black/African Americans (8%), Native Americans (unreported), Asians (6%), and Hispanics/Latinos (11%) remains low [2]. The lack of representative clinical trials has direct implications for the health outcomes of non-White groups, reflecting the well-established differences in drug responses [3] and disease pathology [4,5] between racial/ethnic populations.

More broadly, a recent systematic review of Phase 1 oncology trial publications involving biopharmaceutical agents demonstrates that imbalances in subject enrollment persist globally and fail to represent the target populations [6]. Researchers reported that the distribution of participants was predominately White/Caucasian (62.2%), with the US distribution even more heavily skewed toward White/Caucasian participation (84.2%). These results are supported by FDA reporting that only 2.74% of global participants in oncology trials were Black or African-American [7]. This is particularly troubling when we consider that Black/African Americans have significantly higher incidences of and worse outcomes for cancer [8].

Sufficient participation of diverse groups in clinical studies is critical to determine the true safety and efficacy of new therapies. Without a genuinely representative sample population, researchers risk losing critical health information pertaining to the differential effects of potential new treatments on the target population, thus perpetuating the widening gap of health disparities in the US healthcare system [9,10].

In 2020, the FDA issued guidance to industry for enhancing diverse participation in clinical trials that addressed expanding enrollment and eligibility criteria to better reflect the population most likely to use the potential drug [11]. Strategies for promoting diversity in clinical trials should also include addressing medical mistrust through culturally competent communication and transparency in clinical research [12]. One promising means to this end is to cultivate more

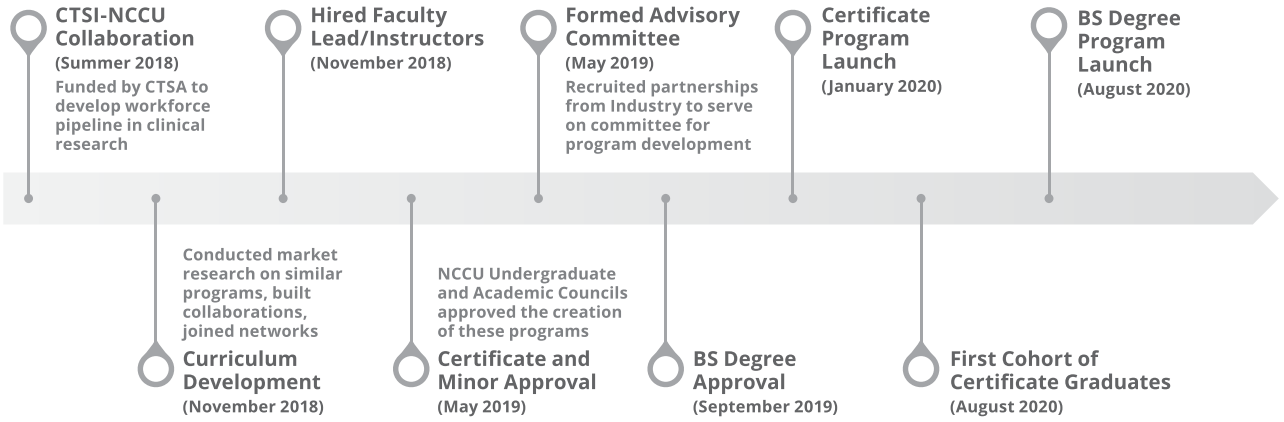

Fig. 1. Program timeline. BS = Bachelor of Science; CTSA = Clinical and Translational Science Awards; CTSI = Clinical and Translational Science Institute; NCCU = North Carolina Central University.

diversity in the biomedical and clinical research workforce [13,14]. This article describes how leveraging Duke University's Clinical and Translational Science Awards (CTSA) program helped North Carolina Central University (NCCU) build a framework for producing a highly trained, competent, and diverse workforce in clinical research responsive to the call for increased diversity in clinical trial participation.

Answering the Call for Workforce Diversity: The Duke/NCCU Partnership

The National Institutes of Health CTSA program aims to close the gap between research and clinical care by creating "best practice laboratories" geared toward innovation in the clinical and translational research ecosystem while disseminating and implementing lessons learned. CTSA leadership has acknowledged the need to train a new generation of adaptable, diverse individuals in the clinical and translational sciences workforce [15].

NCCU ranks 13th nationally as a Historically Black College and University and boasts a top 10 ranking in Social Mobility with a student body of 80% minority students [16]. The university has a well-established workforce development pathway to the pharmaceutical industry through its research institutes, the Biomanufacturing Research Institute and Technology Enterprise (BRITE), and the Julius L. Chambers Biomedical and Biotechnology Research Institute (JLC-BBRI). In 2017, the Duke Clinical and Translational Science Institute, supported in part by the CTSA program, and NCCU formalized a partnership to develop programs geared toward research training, student mentoring, internships, and community engagement to address inequity in clinical and translational research. Initially, the Duke/NCCU Workforce Development Core, consisting of a team of faculty and staff from Duke and NCCU, convened meetings over several months to assess curricular needs and brainstorm possible course content. The first product emanating from this collaboration was the Duke Translational Research Concepts and Careers (TRECC) online curriculum (available at https://sites.duke.edu/trecc/), a free, asynchronous curriculum with modules covering eight topics: (1) Introduction to Clinical Research; (2) Articulating Questions, Generating Hypotheses, and Choosing Study Designs; (3) Data Collection and Management; (4) Research Ethics in the Context of Clinical Research; (5) Regulating Medical Products: FDA Oversight of Drugs and Devices; (6) Community and Stakeholder Engagement: Definitions, Principles, and Approaches; (7) Equity in Research; and (8) Introduction to the Science of Team Science [17]. Once finalized, these modules were and remain freely available to the public via a public-facing website and to Duke and NCCU students interested in the clinical and translational workforce through the Duke learning management system. To date, 220 users have interacted with the modules via the Duke LMS, and 142 users have completed modules; metrics for public utilization of the materials are unavailable. The TRECC online curriculum was followed in 2019 by the creation of the NCCU Clinical Research Sciences (CRS) program, an academic, degree-based program specifically designed to provide in-depth training in clinical research for NCCU students (Fig. 1) [18].

Why Establish a Clinical Research Training Program at NCCU?

Clinical research is a lucrative and rapidly growing industry in North Carolina, with biopharmaceutical companies, contract research organizations, and academic research organizations serving as a steady source of jobs for professionals in the clinical research field. Biopharmaceutical research companies alone support more than 251,000 jobs in North Carolina, generating $74.5 billion in economic activity for the state [19]. Additionally, there are more than 250 organizations specializing in clinical trial management, providing 13,000 jobs to North Carolinians [20]. Many of these companies are located in Research Triangle Park, a mere 10 miles from NCCU.

The CRS program at NCCU was established to expose students from diverse educational and ethnic backgrounds to career opportunities in clinical research, with a special focus on health equity education. The CRS program provides students with three paths to a successful career: a two-semester 12-credit hour certificate in clinical research, an 18-credit hour minor, and a 120-credit hour Bachelor of Science degree in Clinical Research. Separately, these programs target students from varied STEM and health sciences backgrounds who are interested in pursuing careers in clinical research, including roles as biomedical laboratory scientists, community educators, clinical research coordinators, epidemiologists, nurses, pharmacists, and physicians. Graduates from the CRS program are especially well-suited for the clinical research workforce because they have formal education in a health or STEM field,

strong knowledge of clinical research, and hands-on experience in clinical trial data management.

How Was the CRS Program Built?

To build a competitive program, NCCU leaders reached out to academic institutions in North Carolina with programs in clinical research, specifically Durham Technical Community College (DTCC), the University of North Carolina at Wilmington, and Campbell University. These institutions are members of the Consortium of Academic Programs in Clinical Research (CoAPCR) and have adopted an academic curriculum based on the framework outlined by the Joint Task Force for Clinical Trial Competency, explicitly designed for clinical research professionals. This framework outlines eight domains of competency for clinical research professionals: (1) Scientific Concepts and Research Design; (2) Ethical and Participant Safety Considerations; (3) Investigational Products Development and Regulation; (4) Clinical Study Operations; (5) Study and Site Management; (6) Data Management and Informatics; (7) Leadership and Professionalism; and (8) Communications and Teamwork [21,22]. NCCU joined the CoAPCR and adopted the Joint Task Force for Clinical Trial Competency framework for its own curricular design purposes.

Getting buy-in from industry partners early on was also critical because NCCU wanted to build a program relevant to current industry needs and hiring expectations. To gain additional input from these partners, Duke and NCCU convened a 1-day advisory committee meeting to solicit input on the program curriculum. Industry representatives from IQVIA, Q2 Lab Solutions, Parexel, the Duke Office of Clinical Research, and the Department of Health Policy and Management at the University of North Carolina at Chapel Hill met for a round table discussion about what the curriculum should include, as well as desired long-term outcomes. The participants highlighted the need for hands-on training in tools such as regulatory documentation, maintenance of trial master files, computer skills (e.g., R, SAS), and preparation for professional certification by the Association of Clinical Research Professionals and the Society of Clinical Research Associates. Industry partners also committed to providing summer and semester-long internship opportunities, mentorship, and guest lectures for students in the program.

What Are Noteworthy Features of the CRS Program?

Based on feedback from industry partners and hiring trends in the clinical research industry, the program decided to target applicants who were: (1) college graduates with a Bachelor of Science degree or (2) current NCCU students pursuing a Bachelor of Science degree [23]. The curriculum teaches to all eight competency domains outlined by the Joint Task Force for Clinical Trial Competency, while applying a focus on health disparities that emphasizes health equity and the need to enhance workforce diversity. In addition to the TRECC modules that are utilized as part of the curriculum, the CRS program leverages the Duke/NCCU partnership to recruit expert guest lecturers on special topics including regulatory affairs, biobanking, diversity and inclusion in clinical trials, clinical operations, and institutional review boards.

Additionally, "Just Ask: An Introduction to Equity and Diversity in Clinical Research" has been incorporated into the course materials for all students in the CRS program [24]. This online module, created by Dr Nadine J. Barrett in collaboration with the Duke Clinical and Translational Science Institute, Duke Office of Clinical Research, and Duke Cancer Institute, provides an overview of health disparities, health equity, and the current state of diversity in clinical research for Duke employees conducting human subjects research. The module is designed to support study teams by filling a knowledge gap and providing additional resources and ideas for incorporating health equity and inclusion into research study plans. In the CRS program curriculum, it provides a foundational understanding of how health disparities adversely affect communities. We have paired the module with guest lectures given by community-based researchers and experts within the Duke Office for Institutional Equity. Together, these components serve as a call to action for future clinical research professionals, highlighting the importance of their roles in the clinical research workforce and the need to increase diversity to improve the health outcomes for all Americans.

Students in the CRS program also gain hands-on experience in clinical data management, as well as career networking, interview preparation, and mentoring to better prepare them for the workforce. Importantly, students learn about how health disparities and lack of access to care can affect minority participation in clinical research and discuss strategies to promote diverse enrollment in clinical trials. Tables 1–3 show the curriculum for the 12-credit hour certificate program, minor degree, and Bachelor of Science degree in Clinical Research. In May of 2021 with funding from

Table 1. *Certificate in Clinical Research curriculum*

Course title	Credits
First semester	
Principles of Clinical Research	3
Medical Terminology (online)	2
Good Clinical Practice	1
Semester total	6
Second semester	
Clinical Trial Management I	3
Clinical Rotation	3
Semester total	6
Total	12

Table 2. *Minor degree in Clinical Research*

Course title	Credits
Principles of Clinical Research	3
Medical Terminology (online)	2
Good Clinical Practice	1
Clinical Trial Management I	3
Pharmacology	3
Regulatory Sciences	3
Presentation Skills	1
Protocol Design	1
Biobanking and Interpreting Lab Data	1
Total	18

Table 3. *Bachelor of Science degree in Clinical Research*

Course title	Credits
Principles of Clinical Research	3
Pharmaceutical Data Science/Biostatistics	3
Clinical Biostatistics	3
Clinical Trial Management I	3
Clinical Trial Management II	3
Clinical Biochemistry	3
Pharmacology	3
Regulatory Sciences	3
Pathophysiology	3
Pharm Tech Writing	3
Medical Bioethics	3
Pharmacovigilance	3
Advanced Data Management	3
Medical Terminology (online)	2
Presentation Skills	1
Literature Review	1
Interpersonal Skills	1
Clinical Trial Protocol Design	1
Biobanking and Interpreting Lab Data	1
Good Clinical Practice	1
Clinical Research Internship	14
Total (to be added to General Education courses for a total of 120)	61

NCIDEA, the CTSA grant, and other sources, the CRS program launched a summer internship program for students to gain work experience in the clinical research field. To date, 20 students have been placed in 10-week summer internships at clinical research organizations.

As of April 2022, the program has graduated 11 students from the Certificate in Clinical Research Program, with an additional nine students graduating in May 2022. Of the current graduates, eight are currently employed in the clinical research field, two graduates are employed in (non-clinical) pharmaceutical research, and one graduate is finishing the last semester of a Bachelor of Science degree in Public Health at NCCU. The first cohort of Bachelor of Science degree in Clinical Research students is expected to graduate in Spring 2024.

Conclusion

Promoting diversity in the biomedical and clinical research workforce is a rational strategy for addressing medical mistrust as factors inhibiting the recruitment of representative populations for clinical trials. The CRS program at NCCU is positioned to be a model of a comprehensive workforce development program committed to providing students from diverse backgrounds with the educational and networking tools needed to compete for career opportunities in clinical research. While other academic programs in clinical research exist, NCCU is unique in its capacity to address these challenges in effectively reaching and communicating with underrepresented populations and building trust with populations that have a historical mistrust of medical professionals. The CRS program continues to expand and gain traction toward recruiting and training underrepresented students, to increase workforce diversity in the state. To further widen our workforce pathway to industry jobs, the program has developed a relationship with the Clinical Trials Research Associate Program at DTCC and will begin offering transfer credits toward a Bachelor of Science degree in Clinical Research after completion of an Associate's Degree in Clinical Sciences at DTCC. The demand for clinical research professionals continues to grow by leaps and bounds [25]. The CRS program at NCCU is prepared to answer the call.

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