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Building the clinical research workforce: Challenges, capacities and competencies

Edited by
Carolynn Thomas Jones, Barbara E. Bierer, Stephen Sonstein, Hazel Ann Smith and Denise Snyder

Coordinated by
Elizabeth Johnson and Emma Akuffo

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Building the clinical research workforce: Challenges, capacities and competencies

Topic editors

Carolynn Thomas Jones — The Ohio State University, United States
Barbara E. Bierer — Brigham and Women's Hospital, Harvard Medical School, United States
Stephen Sonstein — Eastern Michigan University, United States
Hazel Ann Smith — Staffordshire University, United Kingdom
Denise Snyder — Duke University, United States

Topic coordinators

Elizabeth Johnson — Montana State University, United States
Emma Akuffo — Richmond Pharmacology Ltd., United Kingdom

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Dr. Bierer is employed by Brigham and Women's Hospital and appointed at Harvard Medical School. She is chair of the Board of Trustees of the Edward P Evans Foundation, serves on the Board of Directors of Clinithink, and is or has been a consultant on ethical issues to Eli Lilly and Merck.

Topic coordinator Emma Akuffo provides consultancy services to Richmond Pharmacology.

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Heike Wulff,
University of California, Davis, United States

*CORRESPONDENCE
Carolynn T. Jones,
jones.5342@osu.edu

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Editorial: Building the clinical research workforce: challenges, capacities and competencies

Carolynn T. Jones [1]*, Elizabeth Johnson [2], Barbara E. Bierer [3,4], Denise C. Snyder [5], Hazel Ann Smith [6], Emma Akuffo[7] and Stephen Sonstein [3]

[1]College of Nursing and Clinical Translational Science Institute, The Ohio State University, Columbus, OH, United States, [2]Mark and Robyn Jones College of Nursing, Montana State University, Bozeman, MT, United States, [3]Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard Medical School, Boston, MA, United States, [4]Division of Global Health Equity, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, MA, United States, [5]Office of Clinical Research and Clinical and Translational Science Institute, School of Medicine, Duke University, Durham, NC, United States, [6]Staffordshire University, Stoke-on-Trent, United Kingdom, [7]Scientific Learning and Development Consultancy, London, United Kingdom

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clinical research competency, clinical research professionals, JTF framework, workforce development, retention

Editorial on the Research Topic
Building the clinical research workforce: challenges, capacities and competencies

In this editorial, we summarize the identified headwinds evident in the clinical research professional workforce, ranging from capacity constraints to aligning competencies with the complexity of modern clinical research. This editorial is part of the Research Topic: "*Building the Clinical Research Workforce: Challenges, Capacities and Competencies*". To move beyond common challenges, we outline opportunities for innovation in medical and pharmacological advancements from this Research Topic.

Over the past decade and especially in the past 5 years, there has been heightened attention to the available resources and training within the clinical research workforce. With pharmaceutical research sponsors spending an average of 50% more on research and development since 2018, and with much of this spending and investment in novel therapies coming from emerging biopharma companies, the criticality of a workforce pipeline cannot be overstated during periods of intense growth and market fluctuations in new drug and device development (Mullard, 2024). The foundation for core clinical research workforce competencies was established in 2014 with the initial publication of the harmonized Joint Task Force Clinical Trial Competency Framework (JTF Framework) to establish a common lexicon of critical workforce functional skills to adapt to innovative trial designs, complex trial conduct, and novel technologies (Sonstein et al.). By 2024, the framework, with translations in 11 languages, was being applied both in the United States and internationally to educate, train, and support the clinical research workforce (Joint Task Force for Clinical Trial Competency, 2017; Sonstein et al.). In the post-COVID-19 era, the aftershocks of increasing staff turnover rates and overall workforce contraction necessitated a harmonized response across a broad spectrum of employers: academic medical center research sites, cooperative groups, contract research organizations, and pharmaceutical companies,

among others (Freel et al., 2023). The archetype of the clinical research professional (CRP) has expanded to include all individuals who support the operationalization of clinical research, including not only clinical research coordinators, clinical research nurses and midwives, but also advanced practice providers, pharmaceutical industry research physicians (e.g., medical monitors), regulatory affairs professionals, data management professionals, grant and contract administrators, ethics committee members, clinical laboratory personnel and managers, and quality assurance monitors and assistants (Mendell et al., 2024). This broad group of professionals continues to evolve but competency standards are necessary to meet the needs of a dynamic and constantly changing clinical research enterprise.

In addition to increasing staff turnover rates, additional challenges and gaps exist that affect institutions, researchers, and the CRP workforce. One gap is a generalized lack of public understanding of clinical research, which contributes to a lack of awareness that clinical research is a career path for future employees. The majority enter the profession "by accident" rather than having an intentional plan to enter the clinical research workforce at the end of secondary school (Freel et al., 2023) or higher education. As the general retirement cliff for the current CRP workforce approaches, attention is appropriately shifting to cultivating interest and inquiry among the next-generation of research-engaged graduates. This includes the opportunity to recruit and retain CRPs from diverse backgrounds and communities which in turn may facilitate a higher degree of relatability among members of the public and make them feel welcome to participate in research.

As part of an initiative to increase the integration of clinical research careers into higher education, a competency-based curriculum for training certificates, academic degrees, internships, and apprenticeships has been introduced to encourage earlier intentional entry into the field (Knapke et al.). (Kayla et al.) describe a workforce development and mentoring program specifically for research administrators, another group in the clinical research workforce experiencing staff retention challenges. The expanded adoption of decentralized or remote clinical trial models has challenged the enterprise to incorporate local talent sources, such as public health, home health, and community health workers to support the conduct of studies in non-traditional settings beyond academic medical centers and private practices (Besel et al.; Yakubov et al.). Research by (Besel et al.) provides insight into the needs of under-engaged populations, such as rural healthcare workers in cross-functional research that will enable optimal trial conduct and participant safety in variable healthcare resource settings. Additionally, the current CRP workforce lacks cultural diversity which can result in a downstream negative impact on participant recruitment for clinical trials (Tufts Center for the Study of Drug Development, 2021; Derk et al.). The inclusion of human resource departments and clinical research operational leaders in the creation of competency-based, standardized job titles, descriptions, and career progression has resulted in promising enhancements in the professionalism of these roles through better-defined upward mobility, professional development pathways and significantly reduced turnover (Snyder et al.).

The confluence of new talent pools and paradigmatic shifts in trial design has resulted in a refreshed JTF Framework that includes new emerging competencies to support its 8-domain structure, including project management competencies (Sonstein et al., 2022). Keim-Malpass et al. propose a curriculum model that focuses on dissemination and implementation (D&I) research methods and outcome assessment as important skills for researchers and CRPs. Multiple clinical research academic degree and training programs have embraced the JTF Framework as a curricular standard (Sonstein et al.) and a formal programmatic accreditation process is now available through the Commission on Accreditation of Allied Health Education Programs (2024). Process efficiencies in centralizing new hire JTF competency-based onboarding with on-demand online education (Cranfill et al.). Finally, digital badge micro-credentialing has been tested and is available for replication in other institutions and resource settings (Lee-Chavarria et al.).

Evaluating the impact of CRP onboarding, training and education programs on employee performance, satisfaction and retention can include a variety of performance metrics and interpretive feedback that permits the capture of the lived experience of CRP while navigating the new complexities of innovative trial designs and research outreach. Sundquist et al. used the JTF Framework to implement and evaluate training and performance metrics for the Canadian Cancer Center Network programs. The Competency Index for Clinical Research Professionals (CICRP) has been piloted as one of the many tools used to evaluate an academic education program in clinical research (Jones et al.) and multiple measures have been suggested for D&I evaluation (Keim-Malpass et al.). Evaluation should be considered early when implementing new CRP program initiatives. Evaluation may also include horizon-scanning to determine the influence of competency level as it pertains to managing the risks associated with the expansion of research portfolios or programs at institutions or facilities. (Besel et al.) compare the JTF competencies to categorical levels of risk associated with clinical research organizational leadership and departmental management competencies to identify flexible means of creating awareness of changes in risk (e.g., participant safety, regulations) as they relate to necessary training or expansion of institution-based educational initiatives. Risk-based models, while not new to clinical research, are becoming more prevalent in workforce readiness approaches particularly in healthcare systems that serve under- or never-engaged populations prioritized by federal law (e.g., the DEPICT Act, https://www.congress.gov/bill/117th-congress/house-bill/6584/text; the pediatric RACE Act, https://www.congress.gov/bill/115th-congress/house-bill/1231/text).

This collection reflects some of the recent trends and proposed solutions to recruit, educate and retain the current workforce while developing a strong talent pool for the future. The need for a sustainable clinical research workforce pervades global regions as adaptive, innovative trial designs and community emphasis on the co-creation of the research experience become commonplace requirements of regulatory and ethics committees. Prioritizing recruitment of populations historically under-engaged in clinical research requires a diverse research workforce and propagates the necessary inclusivity that has been elusive in past decades. In response, new competencies are emerging, and methods for evaluating outcomes and implementation at the individual and program levels are recommended at the start of projects to

promote high levels of engagement and stakeholder buy-in during periods of intense change. This Research Topic of work embodies the commitment of researchers, institutions, and advocacy groups to ensure the advancement of novel therapies through dedicated clinical research professionals for decades to come.

Author contributions

CJ: Conceptualization, Project administration, Resources, Supervision, Writing–original draft, Writing–review and editing. EJ: Project administration, Resources, Writing–original draft, Writing–review and editing. BB: Resources, Writing–original draft, Writing–review and editing. DS: Writing–original draft, Writing–review and editing. HS: Writing–original draft, Writing–review and editing. EA: Writing–original draft, Writing–review and editing. SS: Supervision, Writing–original draft, Writing–review and editing.

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Conflict of interest

Author EA was employed by Scientific Learning and Development Consultancy.

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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References

Commission on Accreditation of Allied Health Education Programs (2024). Committee on accreditation of academic programs in clinical researh. Available at: https://www.caahep.org/committees-on-accreditation/clinical-research-professional (Accessed June 6, 2024).

Freel, S. A., Snyder, D. C., Bastarache, K., Jones, C. T., Marchant, M. B., Rowley, L. A., et al. (2023). Now is the time to fix the clinical research workforce crisis. *Clin. Trials* 20 (5), 457–462. doi:10.1177/17407745231177885

Joint Task Force for Clinical Trial Competency (2017). Joint task force for clinical trial competency. Available at: https://mrctcenter.org/clinical-trial-competency/ (Accessed May 30, 2024).

Mendell, A., Fritter, J., Helm, S., Capili, B., Hildreth, L., Johnson, K., et al. (2024). Team science competencies for clinical research professionals: a multi-leveled delphi approach. *J. Clin. Transl. Sci.* 1, 25. doi:10.1017/cts.2024.509

Mullard, A. (2024). Shifts in the clinical trial landscape. *Nat. Rev. Drug Discov.* 23 (4), 239. doi:10.1038/d41573-024-00048-w

Sonstein, S. A., Kim, L. P., Ichhpurani, N., Padbidri, R., White, S. A., Aldinger, C. E., et al. (2022). Incorporating competencies related to project management into the joint taskforce core competency framework for clinical research professionals. *Ther. Innov. Regul. Sci.* 56 (2), 206–211. doi:10.1007/s43441-021-00369-7

Sonstein, S. A., Seltzer, J., Li, R., et al. (2014). Moving from compliance to competency: a harmonized core competency framework for the clinical research professional. *Clin. Res.* 28 (3), 17–23. doi:10.14524/CR-14-00002R1.1

Tufts Center for the Study of Drug Development (2021). Tufts University Impact Report, Study finds site personnel race and ethnicity highly correlates with diversity of patients enrolled. *Impact Rep.* 23 (6). Available at: https://f.hubspotusercontent10.net/hubfs/9468915/Impact%20Report%20Preview.png (Accessed August 6, 2024).

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EDITED BY
Denise Snyder,
Duke University, United States

REVIEWED BY
Mark Marchant,
University of Alabama at Birmingham, United States
Jessica Fritter,
The Ohio State University, United States

*CORRESPONDENCE
Calvo Kayla,
krc7d@virginia.edu

†These authors have contributed equally to this work and share first authorship

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Building our research administrator workforce as our clinical and translational research programs become increasingly complex

Calvo Kayla[1*†], Phillips Jennifer[1†], Burks Sandra[1] and Karen C. Johnston[1,2]

[1]Integrated Translational Health Research Institute of Virginia (iTHRIV), University of Virginia, Charlottesville, VA, United States, [2]Department of Neurology, University of Virginia School of Medicine, Charlottesville, VA, United States

Introduction: Research administrators (RA's) are critical members of the research workforce. For purposes of this article, research administrators are personnel who support the development, compliance, management, and financial oversight of sponsored research. There are currently very few institutional career development and mentoring programs available to research administrators. Recruitment and retention of quality research administrators has been especially challenging across the country in recent years.

Methods: In an effort to address this gap in training and to increase recruitment and retention, the integrated Translational Health Research Institute of Virginia (iTHRIV), a collaborative NIH-NCATS funded Clinical Translational Science Award (CTSA) hub, has developed an innovative program of workforce development and mentoring for research administrators. This article provides an overview of one institutional training and development initiative, the Research Administration Program for Training and Resources (RAPTR). RAPTR provides training, resources and mentoring to develop a Community of Practice.

Results: The program provides a forum where research administrators can share ideas, practices, and challenges.

Discussion: This manuscript describes the benefits and lessons learned from our early experience in this program. We highlight selected components that may be generalizable to other institutions and describe individualized components, which require local policies and processes.

KEYWORDS

workforce development, professional development, research administration, mentoring, research team science

Introduction

Research administrators provide specialized and unique skills that are integral to the success of a research team. Recruitment and retention of talented research administrators has been especially challenging across the country in recent years. The increase in remote work positions has allowed research administrators to choose the most desirable positions

in which to work. In our experience, research administrators are seeking the most competitive salaried positions with institutions that provide flexibility in their day-to-day work life balance, a collaborative work environment, and offers desirable career development opportunities.

It is well described that employee satisfaction improves when career development opportunities are available and such programs likely improve recruitment and retention (Wau and Purwanto, 2021). Employee retention and engagement is critical for organizations because employees are the driving force to achieve the development and accomplishment of the organization's goals and objectives (Aguenza and Som, 2012). Many studies suggest that organizations with greater personnel stability perform better than those with less stability (Pitts et al., 2011). Additionally, there is a danger of a loss of institutional memory in organizations with high levels of turnover amongst their professional staff (Shaw et al., 2005; Mustapha et al., 2011). The biggest factor in attracting, and most importantly, retaining key employees is culture (Aguenza and Som, 2012). Employees need to feel that they are part of a team, connected to the vision and direction of the organization (Ryan Carruthers, 2023). We believe a focused, connected, and collaborative team leads to greater stability in the workforce resulting in greater discovery and impact. Formal training and career development programs may help create and sustain this workforce.

Research administration is often described as a "found career." (Srainternational, 2023) These positions almost exclusively exist in research institutes and academic research institutions. Due to the exclusivity of these positions, there are very few options available for formal education. The few existing commercially available formal training programs are often expensive and overly generalized in subject matter. Professional organizations such as the National Council of University Administrators (www.ncura.edu) and the Society of Research Administrators International (www.stainternaltional.org) provide some opportunities for training, professional development, and networking, however it does not meet all needs. This leaves individual institutions with the responsibility to train their own research administrators. Even with prior experience, all research administrators entering new positions require training in specific institutional policies and processes. Those who work in a decentralized system may work in isolation, and may find it challenging to acquire this institution-specific knowledge without a structured program. Managers and supervisors may be unable to adequately train and provide support for these highly specialized roles. These factors may result in feelings of isolation, poor job satisfaction, and low retention rates without additional career development programs.

Mentoring programs can contribute to job satisfaction and career growth. Such programs have been successful in academic research for career development of other team members (Sambunjak et al., 2006) but have not been well described for research administrators. Researchers often utilize mentorship to grow and develop in their chosen field with mentors sharing their knowledge, experience, and skills. iTHRIV recognized the importance of the mentorship model as a critical component to support career growth and avoid isolation for our research administrators. Once a community of mentors and mentees is created, these programs can leverage the benefits of a Community of Practice.

A Community of Practice is a group of people who share a concern or a passion for something they do and learn how to do it better as they interact regularly (Etienne and Beverly Wenger-Trayner, 2022). Members of a Community of Practice are practitioners who develop a shared repertoire of resources: experiences, stories, tools, ways of addressing recurring problems—in short, a shared practice (Etienne and Beverly Wenger-Trayner, 2022). Communities of Practice can help with problem solving, developing confidence, sharing of resources, mapping knowledge, and identifying gaps (AMI Communities of Practice, 2023). iTHRIV sought to leverage the concepts of a Community of Practice in the development of RAPTR.

Formal training and career development programs to nurture the research administrator workforce in academic institutions are not well described in the literature. In addition, though mentoring programs are ubiquitous for the research workforce, they are conspicuously missing for research administrators at many institutions. In an effort to address the gap in professional development including formal training, mentorship, and need for a Community of Practice, iTHRIV developed this innovative program, which includes a workforce development series, peer mentoring, and office hours for group problem solving specifically for research administrators. RAPTR is intended to facilitate growth opportunities at all levels and provides a supportive environment with expert peers that is intended to improve recruitment and retention of these important research team members.

Methods

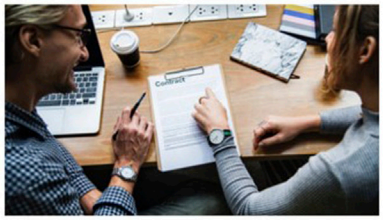
RAPTR was developed in stages to provide both virtual and in-person training, expert guidance, and written resources for participants. The program has 3 major components: 1) online training content; 2) a paired mentoring program; and 3) a Community of Practice with facilitated office hours. Nine invested members of the research administration community at the University of Virginia (UVA) initiated the RAPTR Steering Committee in late 2019. The initial charge of the committee was to assess training needs for the workforce, prioritize, and develop necessary materials/programs. Basic descriptive statistics were used for program evaluation. The committee regularly reviews feedback on all components and makes decisions about the continuation of current programing and the development of new resources.

Online resources

The Steering Committee prioritized the order of which new materials would be developed. The Orientation Series was developed first. This series (Figure 1) provides a new research administrator with a list of important contacts, information on system access and training, policies and guides, opportunities for professional development, and a glossary of terms. A second series focuses on the Proposal Submission process and includes key definitions, links to budget templates and institutional budget information (Figure 2), and tips for managing internal submission processes with a focus on NIH submissions. Both series are offered in a centralized online platform, the iTHRIV Research Concierge Portal (Portal) (Loomba et al., 2022).

RAPTR Portal Orientation Series

RAPTR Orientation Series Step 1: Grant Administration Introduction



Welcome to the School of Medicine (SOM) and the research administration community at the University of Virginia (UVa)! We understand that coming into a complex research organization can be quite challenging. A team of key representatives from across the school has assembled this onboarding document to help ease your transition into supporting research here at UVa.

The materials provided in this series of portal pages will help you familiarize yourself with all of the essential areas and resources that are available to you here at the University and the SOM. The onboarding resources covers areas including: research basics, such as finding funding opportunities, submitting proposals, monitoring your projects, and closing out sponsored awards; key contacts around the institution for information gathering and mentoring; groups and organizations for networking; a glossary of research-specific terms; and access checklists for various websites and administrative systems. It also provides a history of the school, maps of key locations, and organizational charts to help you navigate.

FIGURE 1
RAPTR portal orientation series.

RAPTR Portal Proposal Submission Series

Proposal Submission: Budgets

Budgets

Crafting a budget is an important component of grant applications. SOMOGC provides downloadable templates for budget development. Budgets and justifications along all other required documents must be submitted to SOMOGC within 5 business days of the grant proposal's due date in accordance with the SOMOGC Timely Submission Policy.

The primary components of a budget include:

- Direct costs
  - These include personnel services and other than personnel services (OTPS).
- Indirect costs (i.e., Facilities and Administrative Costs, or F&A. More information about current and historical F&A rates can be found here.)
  - F&A
    costs represent the recovery of both Facilities and Administrative costs incurred to support the sponsored program activity. For example, these costs may be used to support the University buildings and administrative staff salaries that support the grant activities.
- Budget justification
  - The budget justification details the reasoning behind each budget item. For instance, personnel should be outlined with their effort, salary, fringe benefits, and contribution to the proposed project. Remaining budget categories, such as supplies and patient care costs, should be described with a proper understanding of how much each item reasonably costs. A budget with well-justified costs can demonstrate to sponsors that the project was reasonably conceived and that actual costs are properly understood.

Some helpful tips when getting started:

- Carefully read the Request for Application (RFA) or Program Announcement (PA) for budget-related information, such as the maximum direct costs allowed and whether indirect cost rates are limited.
- Discuss a plan for the budget with the PI. For instance, ask whether it will be a multi-PI project, who the co-investigator(s) may be, as well as the other staff that may participate on the project.
- Ensure that the correct F&A and fringe benefit rates are used during budget creation. Up-to-date budgetary information about F&A rates, fringe benefit rates, the NIH salary cap, and graduate student support rates may be found here.
- A useful resource to locate salaries is the Institutional Base Salary page of the Research Administration Dashboard. Salaries can be comprised of funds from the Academic and Medical (UPG) sides of UVA. It is imperative to use one's entire Institutional Base Salary (the combination of *all* sources of salary at UVA) for budgets

FIGURE 2
RAPTR portal proposal submission series.

Mentoring program (RAMP UP)

Following the launch of RAPTR and based on feedback, it became apparent to the Steering Committee that a formal structured mentoring program would be advantageous for the RA workforce. This led to the development of the iTHRIV Research Administration Mentoring Program and University Partnership (RAMP UP). This initial pilot program within RAPTR creates a paired mentor/mentee structure to support the individualized growth and success of the participants. The

TABLE 1 RAMP UP mentor training workshop topics.

Communication Strategies
Aligning Expectations
Enhancing Understanding
Reflecting on Diversity
Fostering Wellbeing

pilot program solicited applications from research administrators primarily from the UVA School of Medicine, for both mentees and mentors though additional applications from the School of Engineering and Applied Sciences and UVA's central Office of Sponsored Programs (OSP) were also accepted. The School of Medicine was selected for the pilot as it has research administration community who expressed a need for the program. The application for mentors and mentees was created using REDCap (Harris et al., 2009; Harris et al., 2019). Mentors were required to have at least 5 years of experience in the field of research administration. The application included a section that listed subject areas in research administration and asked the applicants to note their experience/expertise. Applicants were also asked to describe their interest in and philosophy for mentoring. Supervisors were required to approve participation and final selection of mentors followed interviews by Steering Committee members.

The Steering Committee matched mentors with mentees considering mentor experience and mentee desired growth. Once selected, new mentors were required to attend a 4-h mentor training workshop hosted by a Center for Improving Mentored Experiences in Research (CIMER) trained facilitator which covered major mentoring concepts (Table 1). (Pfund et al., 2013) Though the initial cohort included thirteen mentor/mentee dyads from across UVA, RAMP UP encouraged mentees to connect with other mentors in the cohort for additional expertise and/or support. Dyads in the first-year pilot met regularly and the entire cohort met once a month for a workshop, feedback session, and/or cohort office hours. These group sessions created a small Community of Practice. Additionally, the group sessions allowed early career research administrators to appreciate their potential as mentors especially to those new to the institution. This structure provides a sustainability plan in that mentees are encouraged to advance to mentor status when appropriate thus creating a pathway for career development and a growing pool of mentors.

Early development of a community of practice

Recognizing the need to grow relationships and build community across a disconnected workforce, RAPTR began hosting virtual facilitated office hours to serve the School of Medicine RA community. Twice-monthly facilitated sessions encourage questions, discussion, and the sharing of best practices across the group. Leaders from the School of Medicine Office of Grants and Contracts and other members of the RAPTR Steering Committee moderate office hours. The RA community guides topics for discussion and often include budget development, proposal submission, institutional systems, and post award administration. Recent verbal feedback from participants requested that office hours move to a more structured format. RAPTR Office Hours were recently restructured to include the entire UVA research administration community. Each session begins with focused topic discussion led by subject matter experts and ends with open forum question and answer time.

Evaluation plans initially focused on utilization and informal feedback on programs but also includes formal evaluation of RAMP UP. The RAMP UP evaluation plan included an anonymous voluntary interim and end-of-program feedback survey. An annual follow-up survey will be distributed to review retention and career advancement rates. The Steering Committee regularly gathers all formal and informal feedback for discussion to inform continuous quality improvement efforts.

Results

The RAPTR Orientation series publicly launched in the iTHRIV Portal in the spring of 2021. The Proposal Submission series followed in late 2021. Early results show consistent utilization of all RAPTR online Portal resources. According to Google analytics from June 2023 (Table 2), the web-based resources infer that users are returning to resources multiple times. For instance, the "Orientation: Required Systems and Training" Portal page has been viewed 159 times by 63 unique users (44% of the UVA research administration workforce). We continue to capture informal feedback on the usability and value of content from these offerings.

The RAMP UP Request for Mentor applications was released in June of 2022. Nine research administrators from two schools (School of Medicine and School of Engineering and Applied Sciences) and the central Office for Sponsored Programs applied to be mentors and demonstrated broad expertise and experience (Figure 3). Additionally four Steering Committee members served as mentors to complete the cohort.

All mentors attended the required mentor training workshop either in person or virtually. Post monthly session evaluations demonstrated strong support for the training session with a 44% response rate (Figure 4). Written feedback from the mentors included appreciation for both the large and small group activities as well as the section on effective communication.

The RAMP UP Request for Mentee applications was released in July 2022. Applications ($N = 13$) demonstrated variability in years of experience and expertise in the field (Figure 5). Applicants described several reasons for wanting to participate in the program including expanding knowledge of research administration, professional development, networking, and improving knowledge of the UVA system.

Two Steering Committee members interviewed each mentee and then the full committee determined the pairings with mentors. Each mentor was assigned a single mentee. An interim participation survey was distributed to the mentees in January 2023 and 10 mentees responded (77%). Ninety percent of the mentees stated that they were meeting regularly with their mentors and that the program was meeting their expectations.

TABLE 2 Google analytics for RAPTR pageviews.

Resource title	User Type[0]	Pageviews*	Unique Pageviews^
Orientation (1): Grant Administration Introduction	New Users	125	73
	All Users	308	193
Orientation(3):Grant Administration Required Systems and Training	New Users	63	45
	All Users	159	118
Orientation(2):Grant Administrators Impo1iant Contacts	New Users	52	35
	All Users	130	91
Orientation (4):Grant Administration Inte1nal and Extemal Resom·ces	New Users	43	34
	All Users	104	79
Proposal Submission: Intemal F01ms and Routing	New Users	27	24
	All Users	72	63
School of Medicine Research Administration Po1tal for Training and Resources - RAPTR (START HERE !)	New Users	40	23
	All Users	162	109
Orientation(8):Grant Administration Professional Development	New Users	27	22
	All Users	74	56
Proposal Submission: Introduction	New Users	23	20
	All Users	68	60
Proposal Submission: Budgets	New Users	25	20
	All Users	74	61
Orientation(7):Grant Administration UVA Research Administration Policies	New Users	25	19
	All Users	69	55
Orientation (6):Grant Administration Listservs for Research Administrators	New Users	18	13
	All Users	63	40
Orientation(5):Grant Administration Institutional Research Administration Meetings	New Users	17	12
	All Users	62	43
Proposal Submission: Introduction	New Users	12	11
	All Users	46	39
Proposal Submission: Non-Federal Proposals	New Users	14	9
	All Users	36	26
Proposal Submission: Indirect Costs (F&A)	New Users	10	9
	All Users	40	29

The mentees described the value and impact of having someone answer their questions, understand the challenges they were facing were not unique, and generally expressed gratitude for inclusion in the program. Feedback also included suggestions to have a more detailed syllabus and guide for mentors and mentees to follow, as well as creating a boot camp/training program specifically for new research administrators.

The Steering Committee conducted an end of year survey in August 2023. All mentors and mentees were surveyed with a 39% response rate. The overall response to the program was positive with feedback similar to the interim survey (Figure 6). Other feedback demonstrated a need for additional tools, more structure, and support for the mentors. Clearly defined expectations were felt to be missing and will be addressed in future programs.

The facilitated office hours has an average of 10–15 attendees for each session. Early feedback showed that attendees appreciate the opportunity to informally ask questions and get answers from both peers and Leaders within the SOM Office of Grants and Contracts. Informal feedback and requests for specific content for office hours guides priority topics for upcoming sessions. As this is a new program, end of year feedback has not yet been solicited. Early markers for success for the newly structured office hours are positive.

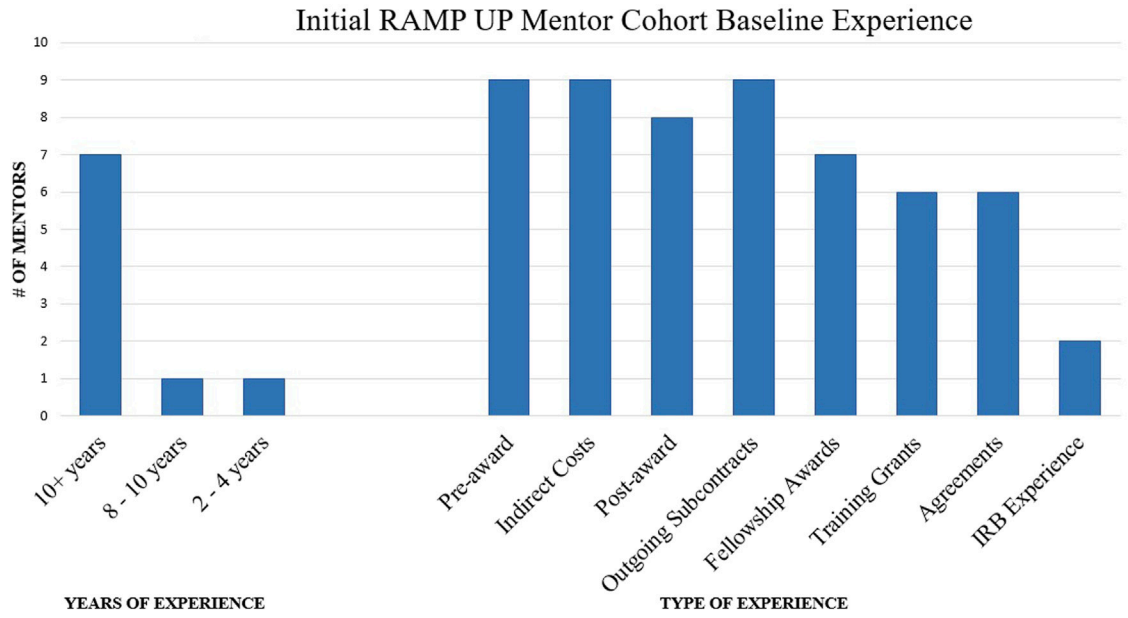


FIGURE 3
Initial RAMP UP mentor cohort baseline experience.

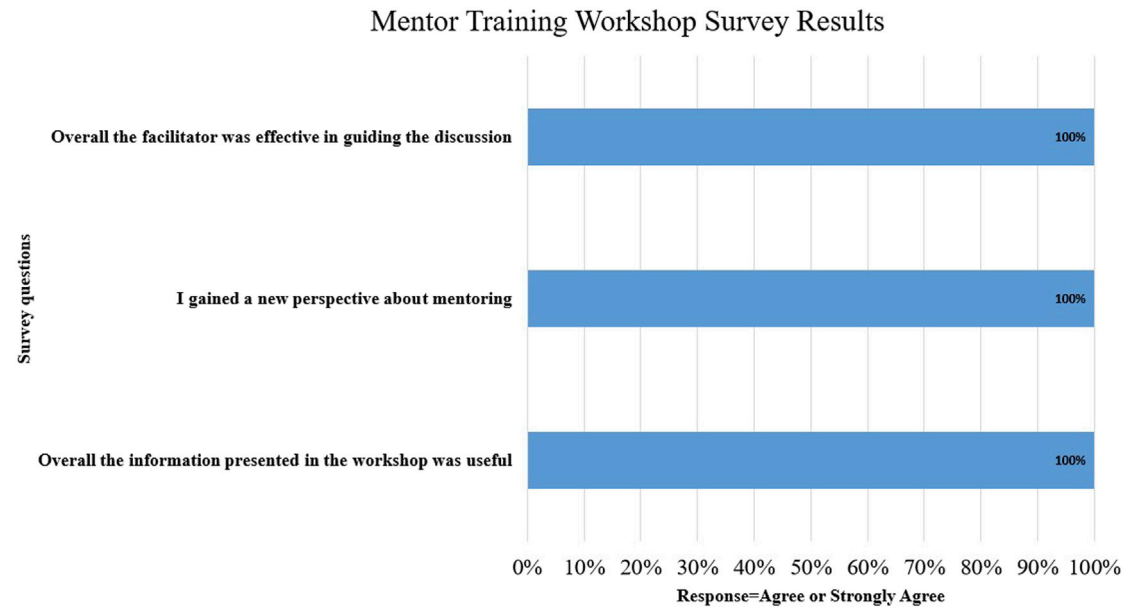


FIGURE 4
Mentor training workshop survey results.

Discussion

RAPTR, which includes online training resources, a mentoring program, and facilitated office hours, has created an early Community of Practice of research administrators at UVA. This program was created to fill a gap in supporting a critical part of the research workforce. We believe that this will be an important recruitment tool as it provides both training and career development opportunities for new recruits. Introductory resources were created to provide a guide for new research administrators as they navigate a complex web of sponsors, grant proposals, post award management, and contracts. As our institution's portfolio continues to grow and evolve and as awards become more complex, our program can be

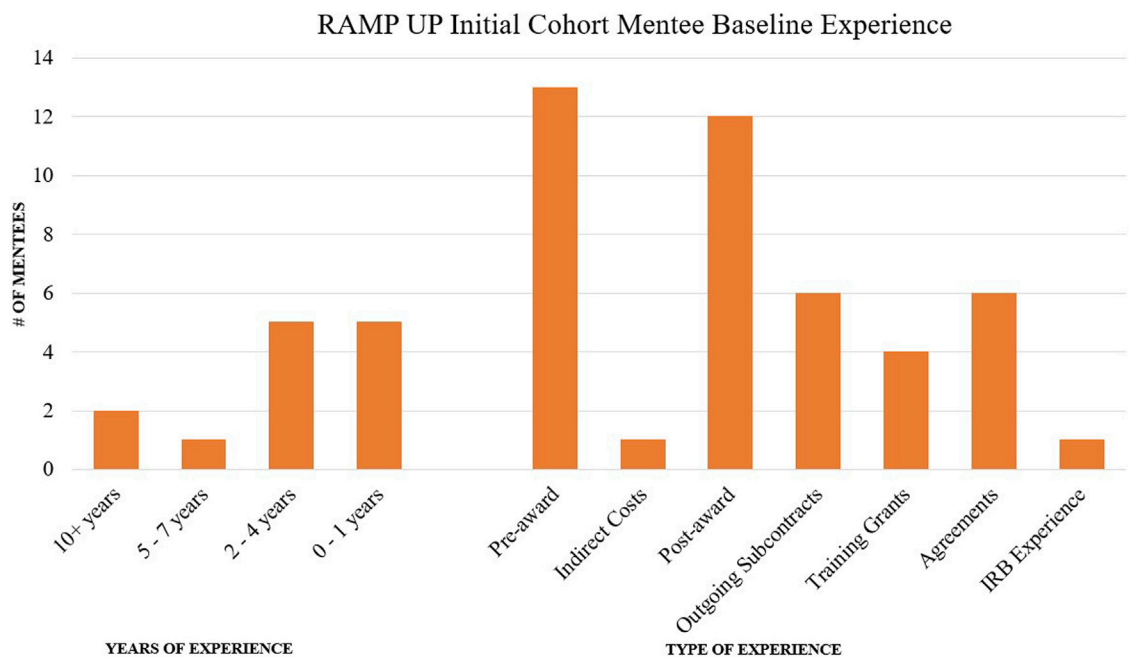


FIGURE 5
RAMP UP initial cohort mentee baseline experience.

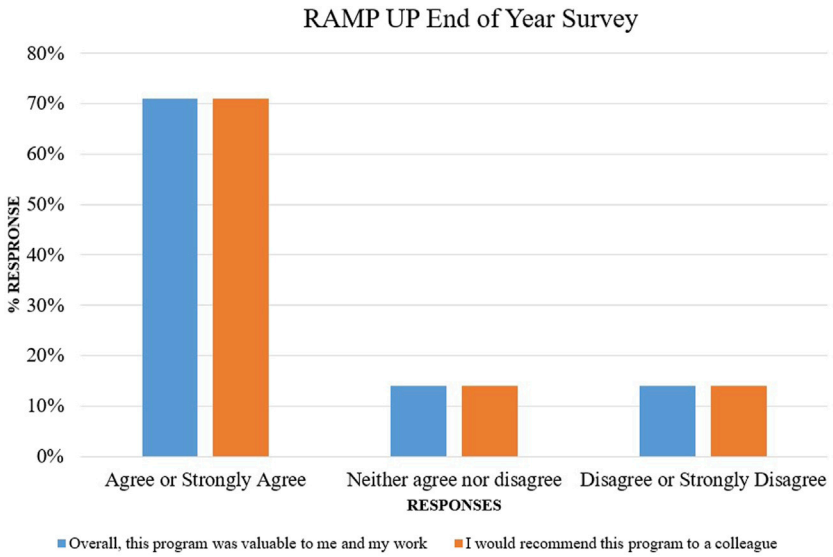


FIGURE 6
RAMP UP end of year survey.

flexible by adapting to the needs of the workforce in all three areas (online resources, mentoring, facilitated office hours). Early results suggest that such a program can help equip research administrators with the tools and support they need to manage a growing research portfolio. Though specific program and process content may vary across institutions, programs like RAPTR may have generalizable professional development concepts that can help grow the research administrator workforce across the nation.

Evaluation of RAPTR is limited by a lack of long-term impact data. As the program continues to evolve and both formal and informal feedback is collected, we will more clearly be able to define the most impactful components. Future directions of our program include the formation of sub-committees under the

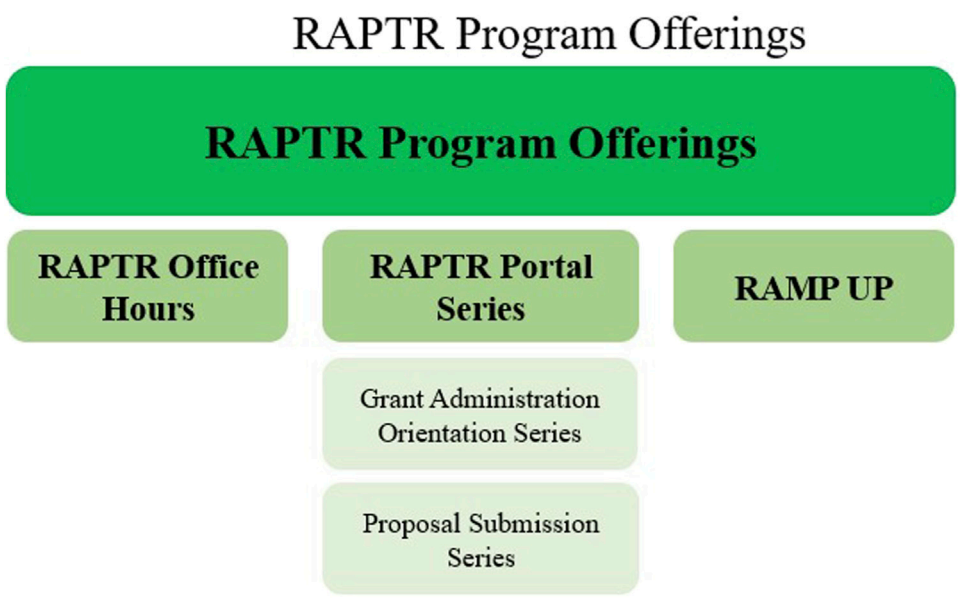


FIGURE 7
RAPTR program offerings.

guidance of the RAPTR Steering Committee to address individual components of the program. An education subcommittee will be charged with a re-design and dissemination of the currently available online resources to address recent institution wide financial and grant management systems changes affecting our entire research administration community. The continued need for these online materials is evident as the field and the systems advance rapidly. Additional resources will also be created to include topics relevant to the entire RA workforce at UVA. Facilitated office hours will be more topic guided (reporting, budgeting, payroll allocations, etc.) and will be made available to all RAs across the institution. Additional programs may include a boot camp for new research administrators and a foundational Research Administration Certificate program.

The RAMP UP sub-committee is evaluating the interim and year-end feedback and will offer a more structured mentoring program focused on professional development. In response to feedback, the program will provide a written guide for both mentors and mentees and develop a template for a compact between dyad members to align expectations. New workshop session topics for dyads will include Leadership, Building a Network, and Developing an Engaging Presentation. The inclusion of a capstone project that benefits the research administration community at UVA will be piloted as part of the 1-year mentoring program.

Conclusion

Through the development of RAPTR, we are building a community of educators and learners with a passion and dedication for research administration. These programs (Figure 7) increase the knowledge, skills, and abilities and hopefully job satisfaction of an important part of the research workforce. This grass roots effort started in the UVA School of Medicine and is now engaging other schools, departments, and leadership within the institution.

RAPTR is just one approach to supporting the career development of our research administrators as part of our workforce development programs. Additional consideration of innovative and impactful approaches to grow this critically important component of our research teams is warranted.

Data availability statement

Publicly available datasets were analyzed in this study. This data can be found here: https://www.ithriv.org/raptr.

Author contributions

CK: Writing–original draft, Writing–review and editing. PJ: Writing–original draft, Writing–review and editing. BS: Writing–original draft, Writing–review and editing. KJ: Writing–original draft, Writing–review and editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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References

Aguenza, B. B., and Som, A. P. M. (2012). Motivational factors of employee retention and engagement in organizations. *Int. J. Adv. Manag. Econ.* 1 (6), 88–95.

Ami Communities of Practice, (2023). Communities of practice | COP AMI. Available at: https://cop.montessori-ami.org/community-of-practice (Accessed August 4, 2023).

Etienne and Beverly Wenger-Trayner, (2022). Introduction to communities of practice - wenger-trayner. Available at: https://www.wenger-trayner.com/introduction-to-communities-of-practice/ (Accessed August 4, 2023).

Harris, P. A., Taylor, R., Minor, B. L., Elliott, V., Fernandez, M., O'Neal, L., et al., and REDCap Consortium (2019). The REDCap consortium: building an international community of software platform partners. *J. Biomed. Inf.* 95, 103208. Epub 2019 May 9. PMID: 31078660; PMCID: PMC7254481. doi:10.1016/j.jbi.2019.103208

Harris, P. A., Taylor, R., Thielke, R., Payne, J., Gonzalez, N., and Conde, J. G. (2009). Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *J. Biomed. Inf.* 42 (2), 377–381. Epub 2008 Sep 30. PMID: 18929686; PMCID: PMC2700030. doi:10.1016/j.jbi.2008.08.010

Loomba, J. J., Wasson, G. S., Chamakuri, R. K. R., Dash, P. K., Patterson, S. G., Potter, M. M. A., et al. (2022). The iTHRIV Commons: a cross-institution information and health research data sharing architecture and web application. *J. Am. Med. Inf. Assoc.* 29 (4), 631–642. doi:10.1093/jamia/ocab262

Mustapha, N., Ahmad, A., Uli, J., and Idris, K. (2011). Work-family facilitation and family satisfaction as mediators in the relationship between job demands and intention to stay. *Asian Soc. Sci.* 7 (6), 142. doi:10.5539/ass.v7n6p142

Pfund, C., House, S., Spencer, K., Asquith, P., Carney, P., Masters, K. S., et al. (2013). A research mentor training curriculum for clinical and translational researchers. *Clin. Transl. Sci.* 6 (1), 26–33. Epub 2012 Dec 6. PMID: 23399086; PMCID: PMC3572855. doi:10.1111/cts.12009

Pitts, D., Marvel, J., and Fernandez, S. (2011). So hard to say goodbye? Turnover intention among U.S. Federal employees. *Public Adm. Rev.* 71 (5), 751–760. doi:10.1111/j.1540-6210.2011.02414.x

Ryan Carruthers, (2023). 6 ways to retain remote workers – and make them feel part of the team. TLNT. Available from: https://www.tlnt.com/articles/6-ways-to-retain-remote-workers-and-make-them-feel-part-of-the-team (Accessed August 4, 2023).

Sambunjak, D., Straus, S. E., and Marušić, A. (2006). Mentoring in academic medicine: a systematic review. *Jama* 296 (9), 1103–1115. doi:10.1001/jama.296.9.1103

Shaw, J. D., Gupta, N., and Delery, J. E. (2005). Alternative conceptualizations of the relationship between voluntary turnover and organizational performance. *Acad. Manag. J.* 48 (1), 50–68. doi:10.5465/amj.2005.15993112

Srainternational, (2023). Research administration careers hiring. Available at: https://www.srainternational.org/blogs/srai-news/2022/02/09/research-administration-careers-hiring (Accessed August 4, 2023).

Wau, J., and Purwanto, P. (2021). THE EFFECT OF CAREER DEVELOPMENT, WORK MOTIVATION, AND JOB SATISFACTION ON EMPLOYEE PERFORMANCE. *jabm*. Published online May 31. doi:10.17358/jabm.7.2.262

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EDITED BY
Carolynn Thomas Jones,
The Ohio State University, United States

REVIEWED BY
Elizabeth Johnson,
Montana State University, United States

*CORRESPONDENCE
Jessica Keim-Malpass,
jlk2t@virginia.edu

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Disseminating for impact: creating curriculum activities for translational dissemination for the clinical and translational research workforce

Jessica Keim-Malpass[1,2]*, Jennifer Phillips[2] and Karen C. Johnston[2,3]

[1]Division of Pediatric Hematology-Oncology, University of Virginia School of Medicine, Charlottesville, VA, United States, [2]Integrated Translational Health Research Institute of Virginia (iTHRIV), University of Virginia, Charlottesville, VA, United States, [3]Department of Neurology, University of Virginia School of Medicine, Charlottesville, VA, United States

There has been an increased focus on the practices associated with dissemination for the translation of research to clinical practice and ultimately, policy. Simultaneously, there has been attention placed on the role of the clinical research workforce in supporting optimal dissemination efforts for impact and societal benefit. Curriculums focused on education opportunities for dissemination for translational scientists have been under-reported. The Translational Science Benefits Model (TSBM) is a framework that has been developed to support assessment of clinical and translational research outcomes that measure impact (both in the clinical and community setting) beyond traditional citations in academic journals/bibliometric activities. The TSBM framework outlines more than 30 different facets of impact and can provide a basis for operationalizing broad impacts of research for translational and clinical scientists. Engagement science offers methods and modalities to work with individual stakeholders, and collaborators in a team science model, and engagement with external scholars and society. This article will describe the use of the TSBM framework and engagement science strategies to develop a translational dissemination framework with novel components for evaluation of dissemination and implementation activities. We propose using the translational dissemination framework to guide the development of an educational curriculum for the clinical research workforce. We outline the educational domains and proposed evaluation criteria essential in implementing this innovative translational dissemination educational content for the clinical and translational research workforce.

KEYWORDS

translational science, clinical research workforce, translational dissemination, dissemination and implementation, dissemination

Introduction

For nearly 20 years the fields of dissemination and implementation (D&I) have developed within the translational sciences domain to extend basic, clinical, and public health research findings to practice to achieve improved health outcomes for both individuals and populations (Viglione et al., 2023). D&I work seeks to foster eventual clinical implementation of tailored and efficacious interventions in real-world environments, make advancements in public health infrastructure, and translate research findings to inform policy (Shelton et al., 2022). D&I approaches have epistemological underpinnings of pragmatism, supporting the understanding of the essential nature of the underlying complexity of people, communities, and systems in disseminating, adopting, and sustaining interventions within real-world settings and contexts (Mehta et al., 2021; Aves et al., 2017). Previous research has noted that translation can often be slow and inconsistent and that dissemination rarely leads to changes in clinical guidelines or clinical practice alone (Gonzales et al., 2012).

Unlike more specialized scientific or clinical disciplines, D&I activities and research span numerous scientific fields, methodological approaches, and health research settings across the translational spectrum from bench research to society (Norton et al., 2017). When Norton and colleagues (2017) mapped the networks of researchers engaged with D&I activities, they found very active engagement of existing researchers in well-defined and small scientific networks (i.e., very similar author networks within similar disciplinary backgrounds and limited diversity of the researchers). Norton and colleagues' network analysis pushes us to consider how to re-envision and include emerging translational scientists across disciplinary domains within D&I activities.

D&I sciences have been embraced as critical concepts within the lifecycle of translational researcher (Meissner et al., 2020; Shelton et al., 2022). While few have argued the growing importance of the D&I sciences, there has been less attention placed on how to educate the clinical research workforce (defined broadly as early/middle/senior career scientists, research staff associated with laboratory and clinical research settings, members of the scientific, geographic, or illness communities) to inspire translational research efforts. The Clinical and Translational Science Awards (CTSAs) are funded through the National Institutes of Health/National Center for Advancing Translational Science (NCATS) and include a focus on workforce development of clinical and translational researchers. NCATS defines translation broadly as the process of turning observations into interventions that are adopted and sustained to improve health (Mehta et al., 2021). CTSAs fund translational research infrastructures in over sixty academic medical research centers and enable multidisciplinary investigators to 1) facilitate translational research and training across the translational continuum (e.g., basic, clinical, population sciences); 2) provide training to facilitate workforce development, and 3) develop, demonstrate, and disseminate effective research tools and solutions to overcome translational roadblocks (Shelton et al., 2022).

The end goal of D&I integration is to ultimately improve the quality and impact of translational research to improve the health of individuals and communities (Mahoney et al., 2022). To this end, CTSA hubs offer a prime environment to integrate translational dissemination strategies and education curriculum to reach the basic, clinical, and population health research workforce, early-stage investigators (i.e., the K Scholars) and the general communities the CTSAs work within and serve. Emerging scholars and scholar communities often note a gap in their own scientific backgrounds and training in that they want their impact to stretch beyond traditional academic or scientific communities, yet they are not explicitely taught how to disseminate for impact or approach dissemination from an equity-oriented perspective. The epistemological approaches and methodological decisions that support co-created research designs and dissemination plans with communities of interest are often counter to the traditional clinical and translational scientific methods. Therefore, perspectives that integrate novel approaches to D&I efforts are needed to inspire collective action.

Previous scholars have developed core D&I domains for education and integration, particularly for use within the CTSA context and environment (Leppin et al., 2021; Mehta et al., 2021; Mahoney et al., 2022; Shelton et al., 2022) We propose building on previous work to further develop these educational opportunities through a novel translational dissemination framework to guide the development of an educational curriculum for the clinical research workforce. The translational dissemination framework requires more broadly defining scientific activities that lead to impact in the health of individuals and communities. It also requires purposeful integration of a health equity orientation through the development and evaluation of key activities. We will outline the processes, educational domains, and evaluation criteria essential in implementing the translational dissemination education curriculum for the clinical and translational research workforce.

The translational science benefits model

The Translational Science Benefit Model (TSBM) was developed in 2018 by interdisciplinary translational scientists at Washington University in St. Louis (Luke et al., 2018) The purpose of TSBM was to broadly define scientific activities that lead to downstream impact in areas of clinical/medical, public health, economic/innovation, and policy/legislative impacts and advances (Luke et al., 2018). The TSBM benefits were identified using Delphi process with the ultimate goal of two phases of translation - the first being more traditional dissemination of research results through manuscripts and conferences for a scientific audience, and the second phase including dissemination to a broader audience which includes clinicians, policymakers, health advocates, communities, and funders (Luke et al., 2018; Takagi-Stewart et al., 2023).

Engagement science has been introduced as a central process representing specific methodologies related to translational sciences and D&I (Meissner et al., 2020). Engagement science is very closely linked to methodologies supported by community-based participatory research (CBPR) and action research in that it include bidirectional communication, collaboration, reciprocity, transparency, and trust (Meissner et al., 2020; Skinner et al.,

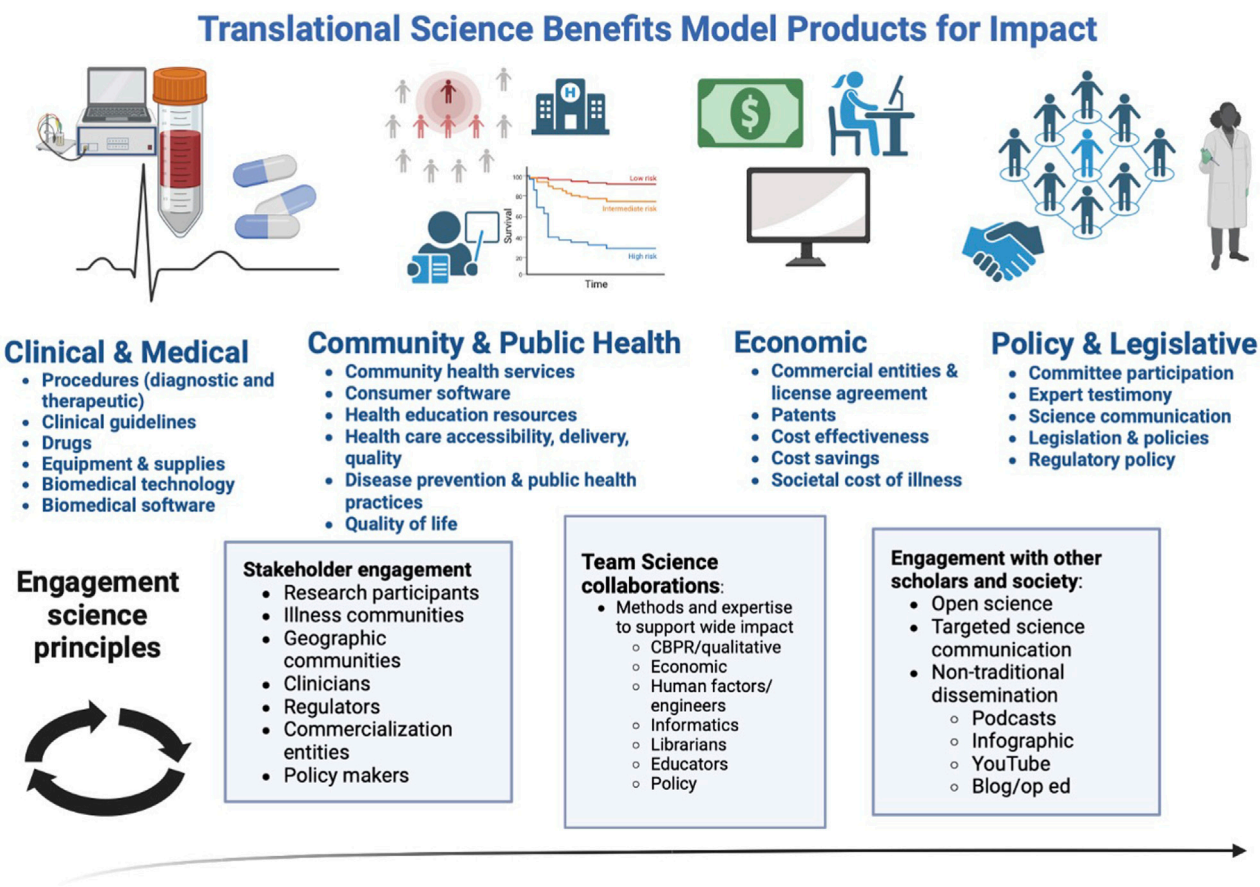

FIGURE 1
Translational Dissemination Framework: Intersection of Translational Science Benefit Model and engagement science principles across the research lifecycle.

2015; Weitzman et al., 2018) When these approaches are used in conjunction with the TSBM, the process allows for early and ongoing communication and centering of priorities that allow for dissemination activities to be conceptualized and acted upon much further upstream in the research process.

Novel frameworks are needed to support translational dissemination in a manner that is equity-oriented, or working to reduce the power imbalances represented by research participants, illness-oriented communities, historically marginalized groups, and/or geographic communities (Baumann et al., 2023). The clinical and translational science workforce represents individuals from a wide range of prior educational experiences and multidisciplinary background. Core content focused on translational dissemination concepts and techniques is an area of needed attention. Herein, we propose the translational dissemination framework which represents an intersection of the TSBM model, engagement science and equity-oriented principles across the research lifecycle (Figure 1). In this figure, the TSBM broadly defines products for impact across the clinical and medical, community and public health, economic, and policy and legislative sphere. Simultaneously engagement science principles allow for methodological perspectives that allow researchers to actualize products of impact through a patient/community-centered and equity-oriented approach.

Current curriculum content and plans for the future

We are in the process of expanding our D&I core at the hub integrated Translational Health Research Institute of Virginia (iTHRIV), an NIH-NCATS funded CTSA Hub. Our current educational activities seek to introduce key translational dissemination concepts while also developing an environment to interact with other scientists and research staff interested in D&I engagement (i.e., clinical pharmacists, clinical research coordinators, engineers, data scientists, statisticians, and health disparities researchers all meeting in the same forum to discover their joint interest in equity-oriented approaches to technology-enabled medication adherence). Future work involves extending the curriculum offerings and continually assessing uptake and reach. Table 1 highlights the proposed content delivery examplars and learning environment mapped to the translational dissemination domain. Learning objectives for these curriculum activities include: 1) Identify priority translational dissemination goals and supporting activities for your own program of research or research role; 2) Increase familiarity with engagement science methods and approaches to increase stakeholder engagement throughout the research lifecycle; 3) Identify community partners with diverse experiences and expertise that can be partners in research; 4)

TABLE 1 iTHRIV Planned translational dissemination content exemplars and learning environment.

Domain	Content delivery exemplars	Learning environment
Methods for stakeholder engagement	Community engagement studios	Online focus groups where members of various stakeholder groups are consulted and compensated for their time (CTSA-wide)
Team science collaboration	Team translational science projects	Small group projects where K Scholars use team science approaches to develop and conduct a translational science project (K Scholars)
Engagement with outside scholars and society	Dissemination and implementation consultative service	Drop-in online sessions where any aspect of D&I can be introduced for a topic of discussion; principles of open science are reinforced; overview of non-traditional dissemination; methods and frameworks to support D&I; importance of stakeholder engagement across the translational science research lifecycle (CTSA-wide). Provides context for current gaps in training
Introduction to the Translational Science Benefits models to conceptualize dissemination for impact	Intersection of Dissemination & Implementation CTSA Core and K Scholars program	Recorded online learning videos; framework to guide guest speakers of the K Scholars program (CTSA wide & K Scholars)

Increase networking activities to Identify scientists with complementary skill sets that could collaborate on team science to support translational dissemination.

These learning activities are intended to be delivered in an online environment with opportunities for real-time engagement with multiple sessions to allow for full concept engagement. The various curriculum activities are meant to take place over the course of a calendar year (August through late July).

Evaluation

Metrics for uptake, reach, and adoption are central to the ongoing evaluation process. Gonzales and colleagues previously developed competencies for translational researchers engaged in D&I sciences including the following (Gonzales et al., 2012).

- Use theories and methods of multiple disciplines in developing integrated research frameworks *[can be quantified through bibliometric analyses]*
- Integrate concepts and methods from multiple disciplines in designing interdisciplinary research protocols *[can be assessed through collaborative contributions of team members on a research study protocol]*
- Investigate hypotheses through interdisciplinary research [*can be quantified by assessing the educational background and department affiliation of members of the research team]*
- Draft funding proposals/grants for interdisciplinary research programs *[can be quantified by assessing agency and disciplinary breadth of grant funding applications submitted]*
- Disseminate interdisciplinary research results both within and outside the discipline - including both journals and conference presentations *[can be assessed through bibliometric analysis and network analysis of authorship]*
- Author publications with scholars from other disciplines *[can be assessed through bibliometric analysis and network analysis of authorship]*

The D&I evaluation competencies that (Gonzales et al., 2012) proposed can be extended by allowing for a larger scope of translational products that define impact across the research lifecycle such as the impact products included in the TSBM model (Luke et al., 2018). Shea and colleagues also extend D&I domains and competencies by adding elements incorporated through the engagement sciences such as the centering of community engagement and contextual learning within the evaluation components (Shea et al., 2017) These evaluation domains include items such as (exemplars chosen only) (Shea et al., 2017).

- Level of introspection and openness *[can be assessed through self-reflection]*
- Knowledge of stakeholder/community characteristics *[can be assessed through understanding of demographics, historical events, examination of power dynamics through co-created needs assessments]*
- Ability to organize the partnership in a way that facilitates collective decision-making and the ability to adapt to the needs of the community through the research process *[can be assessed through collaborative selection of implementation framework, intervention(s), outcomes, dissemination plans, observation of formal and informal processes of decision making]*
- Assessment of communication effectiveness *[can be assessed through the use of plain language, active listening]*
- Assessment of equitable distribution of resources and credit *[can be assessed through inclusion as authors on manuscripts, grants, provision of equity in resource allocation in budgets]*
- Sustainability of partnership *[can be assessed through history of partnerships, stakeholders/partners become self-sustaining, ongoing time and commitment of effort]*

Baumann et al. (2023) present guiding principles to healthcare equity in D&I science which must also be incorporated in future evaluation components (Baumann et al., 2023).

- Racism must be recognized as a fundamental driver of healthcare inequities *[can be assessed through analysis of written curriculum documentation and video transcripts]*
- Multisector partnerships *[can be assessed through engagement science domains]*
- Active engagement of community members *[can be assessed through engagement science domains]*

- Contextual understanding of healthcare delivery and impact on communities *[can be assessed through engagement science domains]*

We posit extending these evaluation components by including measures associated with:

- Community-engaged results return of research findings (either on an individual or community level) *[can be assessed through frequency and modality of results return]*
- Economic assessments that include distributional cost effectiveness and assessments of equity impacts *[can be assessed through analysis of curriculum documentation and eventual practices]*
- Centering of impact of interventions on patients, families, clinicians, and other end-users *[can be assessed through representation of outcome measures and team science nature of the proposal using methods that focus on end-user experience]*
- Use of open science practices *[can be assessed through bibliometric analysis of available documentation of key research stages, results, manuscript, and study data availability]*
- Use of public-engaged non-traditional dissemination strategies *[can be assessed through quantity of infographics, podcasts, YouTube videos, virtual abstracts]*
- Sustained team science collaboration *[can be assessed through network analysis of multidisciplinary approaches used over time and expansion of team across projects]*

Further engagement with our own stakeholders is needed to co-design and finalize collaborative evaluation frameworks for equity-oriented translational dissemination that include the CTSA D&I, community engagement, and research workforce core groups, as well as the training programs (K and T Scholars). An optimal framework for translational D&I evaluation includes wide ranging products of dissemination incorporated within the TSBM framework, an orientation that centers health equity, along with methodological approaches and contextual learning supported through the engagement sciences. Expanding the core competencies through integration with TSBM products of impact and components of the translational dissemination framework will be the product of future work of our CTSA.

Conclusion

Translational scholars have thoughtfully outlined the central importance and requirements of D&I components within national CTSA development (Leppin et al., 2021; Mehta et al., 2021; Mahoney et al., 2022; Shelton et al., 2022). At our local NIH-NCATS funded CTSA hub, iTHRIV, we are implementing the dissemination components through the actualization and evaluation of a novel translational dissemination framework that 1) expands products of impact through the TSBM model to include a very broad view of dissemination activities that impact the health and wellbeing of individuals and communities, 2) integrates methodological approaches central to engagement sciences. Over time, we will evaluate the translational dissemination framework for equity-oriented health impact. We anticipate that this framework is one approach that allows translational researchers to actualize the products of impact through patient-and community-centered approaches. We recognize that future engagement with diverse stakeholders in the D&I community is needed to finalize key concepts and approaches. Further, educational model testability needs to be explicated through variable operationalization and measurement of long-term impact.

Author contributions

JK-M: Conceptualization, Methodology, Writing–original draft, Writing–review and editing. JP: Project administration, Resources, Writing–review and editing. KJ: Funding acquisition, Resources, Writing–review and editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

References

Aves, T., Allan, K. S., Lawson, D., Nieuwlaat, R., Beyene, J., and Mbuagbaw, L. (2017). The role of pragmatism in explaining heterogeneity in meta-analyses of randomised trials: a protocol for a cross-sectional methodological review. *BMJ Open* 7, e017887. doi:10.1136/bmjopen-2017-017887

Baumann, A. A., Shelton, R. C., Kumanyika, S., and Haire-Joshu, D. (2023). Advancing healthcare equity through dissemination and implementation science. *Health Serv. Res.* doi:10.1111/1475-6773.14175

Gonzales, R., Handley, M. A., Ackerman, S., and O'sullivan, P. S. (2012). A framework for training health professionals in implementation and dissemination science. *Acad. Med.* 87, 271–278. doi:10.1097/ACM.0b013e3182449d33

Leppin, A. L., Baumann, A. A., Fernandez, M. E., Rudd, B. N., Stevens, K. R., Warner, D. O., et al. (2021). Teaching for implementation: a framework for building implementation research and practice capacity within the translational science workforce. *J. Clin. Transl. Sci.* 5, e147. doi:10.1017/cts.2021.809

Luke, D. A., Sarli, C. C., Suiter, A. M., Carothers, B. J., Combs, T. B., Allen, J. L., et al. (2018). The translational science benefits model: a new framework for assessing the health and societal benefits of clinical and translational sciences. *Clin. Transl. Sci.* 11, 77–84. doi:10.1111/cts.12495

Mahoney, J. E., Stevens, K. R., and Mehta, T. (2022). Cross walk between consensus recommendations and new NCATS PAR-21-293 requirements for D&I in CTSA hubs. *J. Clin. Transl. Sci.* 6, e17. doi:10.1017/cts.2022.4

Mehta, T. G., Mahoney, J., Leppin, A. L., Stevens, K. R., Yousefi-Nooraie, R., Pollock, B. H., et al. (2021). Integrating dissemination and implementation sciences within Clinical and Translational Science Award programs to advance translational research: recommendations to national and local leaders. *J. Clin. Transl. Sci.* 5, e151. doi:10.1017/cts.2021.815

Meissner, P., Cottler, L. B., Eder, M. M., and Michener, J. L. (2020). Engagement science: the core of dissemination, implementation, and translational research science. *J. Clin. Transl. Sci.* 4, 216–218. doi:10.1017/cts.2020.8

Norton, W. E., Lungeanu, A., Chambers, D. A., and Contractor, N. (2017). Mapping the growing discipline of dissemination and implementation science in health. *Scientometrics* 112, 1367–1390. doi:10.1007/s11192-017-2455-2

Shea, C. M., Young, T. L., Powell, B. J., Rohweder, C., Enga, Z. K., Scott, J. E., et al. (2017). Researcher readiness for participating in community-engaged dissemination and implementation research: a conceptual framework of core competencies. *Transl. Behav. Med.* 7, 393–404. doi:10.1007/s13142-017-0486-0

Shelton, R. C., Dolor, R. J., Tobin, J., Baumann, A., Rohweder, C., Patel, S., et al. (2022). Dissemination and implementation science resources, training, and scientific activities provided through CTSA programs nationally: opportunities to advance D&I research and training capacity. *J. Clin. Transl. Sci.* 6, e41. doi:10.1017/cts.2022.377

Skinner, H. G., Calancie, L., Vu, M. B., Garcia, B., DeMarco, M., Patterson, C., et al. (2015). Using community-based participatory research principles to develop more understandable recruitment and informed consent documents in genomic research. *PLoS ONE* 10, e0125466. doi:10.1371/journal.pone.0125466

Takagi-Stewart, J., Avery, A., Deshpande, S. J., Andersen, S., Combs, T., Vavilala, M. S., et al. (2023). Using a community-informed translational model to prioritize translational benefits in youth concussion return-to-learn programs. *Health promot. Pract.* 2023, 152483992211509. doi:10.1177/15248399221150911

Viglione, C., Stadnick, N. A., Birenbaum, B., Fang, O., Cakici, J. A., Aarons, G. A., et al. (2023). A systematic review of dissemination and implementation science capacity building programs around the globe. *Implement. Sci. Commun.* 4, 34. doi:10.1186/s43058-023-00405-7

Weitzman, E. R., Magane, K. M., and Wisk, L. E. (2018). How returning aggregate research results impacts interest in research engagement and planned actions relevant to health care decision making: cohort study. *J. Med. Internet Res.* 20, e10647. doi:10.2196/10647

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EDITED BY
Barbara E. Bierer,
Harvard Medical School, United States

REVIEWED BY
Kimberly McCall,
University of Alabama at Birmingham, United States

*CORRESPONDENCE
Julia Derk,
julia.derk@duke.edu
Tracie Locklear,
tlockl12@nccu.edu

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A novel cross-institutional college internship program to train future diverse leaders in clinical research with data-driven approaches to assess impact

Julia Derk[1,2,3]*, Kafui Dzirasa[1,2,3,4] and Tracie Locklear[2,5]*

[1]The Collective for Psychiatric Engineering at Duke University School of Medicine, Durham, NC, United States, [2]Duke-North Carolina Central University Clinical and Translational Science Institute Workforce Development Core, Durham, NC, United States, [3]Howard Hughes Medical Institute, Durham, NC, United States, [4]Department of Psychiatry, School of Medicine, Duke University, Durham, NC, United States, [5]Biomanufacturing Research Institute and Technology Enterprise, North Carolina Central University, Durham, NC, United States

The field of Clinical Research, like many other scientific disciplines, has struggled to recruit and retain talented researchers from diverse communities. While there is a strong history of documenting the problem, having a diverse and inclusive workforce is hindered by the lack of data-driven approaches, cross-institutional partnerships, access to mentors, and positive immersive experiences for people from underrepresented groups. Here, we describe a novel initiative for North Carolina Central University Clinical Research Sciences Program (NCCU-CRSP) student interns to partner with Duke University to have immersive clinical and pre-clinical research training in a 15-week internship as the culminating experience towards their degree for a Bachelor of Science in Clinical Research. The goals of the internship are: 1) to give hands-on training to enhance the impact of classroom-based learning, 2) broaden their understanding of the wide swath of positions available to them, 3) promote their sense of self-efficacy, confidence, science identity, research identity, and connections to the pre-clinical and clinical community, and 4) prepare them to be workforce ready upon graduating. The students dedicate 75% of their time to clinical research with Duke University at Pickett Road and 25% to pre-clinical research in the Collective for Psychiatric Neuroengineering in the Duke Psychiatry Department of the School of Medicine. They will also receive eight 1-h professional development training sessions from the Duke-NCCU Clinical and Translational Science Initiative's Workforce Development Team and five 1-h sessions based on the Entering Research Curriculum developed by the Center for the Improvement of Mentored Experiences in Research (CIMER). Finally, they will be brought in as a cohort and coached on peer mentoring and mutual support frameworks to enhance their sense of community. These student-interns will perform pre- and post-internship self-assessment surveys to quantify their self-efficacy, feelings of belonging, access to research opportunities and mentors, and to give details of their future education and career goals. We will evaluate the impact of the internship using validated tools and apply these findings for future optimization of program design and tactical advice for other programs with shared missions. Furthermore, we will email them on an annual basis with follow-up surveys to assess the longitudinal impact of this internship program, their educational experiences at NCCU, what job titles they hold, how prepared they feel for

their roles, and what they hope their future career trajectory will be. Collectively, these approaches will apply theoretical frameworks developed by social and cognitive psychology, vocational theory, and educational research to clinical research training with the goals of recruiting and training talented and diverse leaders within clinical research. We hope that by evaluating our successes, failures, strengths, and liabilities through empirically derived evidence we will also inspire future studies that use data-driven approaches to elevate our approaches as we work together to train and recruit talented researchers from diverse communities into our scientific enterprise and to launch them with more in-depth experiential learning that will empower them to succeed.

KEYWORDS

clinical research, internships, cross-institution collaboration, diversity equity and inclusion, key competence in science and technology

Introduction

The field of clinical research has identified an immense need to develop a more diverse and inclusive workforce (Locklear et al.; NSF, 2022). While Black, African American, Latino/a, Hispanic, Indigenous, and Native individuals comprise more than 30% of the US population, they comprise less than 19% of bachelor's degrees and 15% of PhDs in biological sciences, thereby designating them as Historically Underrepresented (HU) groups (Statistics, 1994; NSF, 2022). Furthermore, the significant lack of diverse representation amongst clinical trial participants can drive a slew of problems, including compromising the generalizability of clinical research findings, undermining trust in the medical establishment and research community, and compounding health disparities (Improving Representation, 2022). There are ample emerging data illuminating how important physician-patient race concordance is, particularly in the context of boosting health service utilization and reducing infant mortality rates (LaVeist et al., 2003; Alsan et al., 2018; Greenwood et al., 2020). Similarly, studies have shown that more diverse personnel at clinical trial workplaces correlates to increased diversity in patients recruited to studies and African American women report to be more motivated to join studies if there is race concordance with the practitioners of the study (Frierson et al., 2019; Tufts Center for the Study of Drug Development, 2021). While many have identified the issues of a lack of diversity in the clinical research workforce and have measured its scope, novel and innovative tactics are required if we want to make real change (Byars-Winston et al., 2011; Valantine and Collins, 2015; Byars-Winston et al., 2016; Hitchcock et al., 2017; Winn Ariel et al., 2019). The number of clinical trials and the scope of clinical research are rapidly expanding, which requires an influx of workforce-ready individuals into our field if we aim to keep up with demand (US National Library of Medicine). We need education, training, and workforce development approaches paired with high-quality assessments to quantify the impact of interventions on 1) diversifying our field and 2) increasing the number of workforce-ready applicants to meet the ever-expanding needs of the field. Our methods must overcome the long-standing legacies of systemic inequality and structural racism to improve access to the education, training, and mentoring required for a robust career in clinical research. The time has come for large-scale investments to build sustainable, multifaceted, and empowered training programs that will equip the next-generation of diverse leaders in clinical science to achieve their goals and contribute to transformative breakthroughs.

We are fortunate to live in a time where there is tremendous innovation around how to evaluate the impact of educational interventions to improve diversity, equity, and inclusion outcomes. Specifically, six key domains have been empirically shown to improve retaining diverse individuals in the research enterprise: 1) development of scientific identity, 2) development of research identity, 3) increased self-efficacy, 4) improved sense of belonging, 5) expanding expected outcomes, and 6) good mentorship (Bakken et al., 2006; Graham et al., 2013; Byars-Winston et al., 2016; Winn Ariel et al., 2019). In this perspective article, we detail a pioneering internship program at the interface of Duke University clinical and pre-clinical research and North Carolina Central University (NCCU), a predominantly Black university located five miles away from Duke. 95% of NCCU students come from underrepresented racial and ethnic backgrounds and 61% of students were awarded Pell Grants last year, thus this group of students is a significantly more diverse population of individuals than the current population of clinical research professionals. Furthermore, we describe the implementation of validated tools to assess the impact of the internship on the six key domains described above that have been previously shown to promote recruitment and retention into any field. Through this pilot project, we hope to build long-term sustainability for our student interns and to contribute to a moonshot goal of diversifying the clinical research workforce to reflect the US population demographics by 2030 through data-driven approaches that promote equity and inclusion of talented, diverse leaders within the field of clinical research (Envisioning a TransformedBoard on Health Sciences PolicyHealth and Medicine DivisionNational Academies of Sciences et al., 2021).

Program design and methodology

This perspective article presents a novel approach for a capstone internship experience for seniors graduating with a Bachelor of Science in Clinical Research from NCCU. We apply adapted tools to assess the impact this experience has on the six key domains that have been shown to improve recruitment and retention in

communities and vocational tracks for other fields. The intern participants will gain multifaceted, cross-institutional experiences in which they dedicate 75% of their time to clinical research with Duke University at Pickett Road paired with a Clinical Research Coordinator doing an NIH funded study. The other 25% of their time will be devoted to conducting pre-clinical research in the Collective for Psychiatric Neuroengineering focused on genetic engineering and gene therapy principles. In both settings, they will conduct rigorous analyses of the literature, develop technical skills, and work collaboratively to achieve progress in their respective studies. They will also receive eight 1-h sessions of professional development training from the Duke-NCCU Clinical and Translational Science Initiative's Workforce Development Team and five 1-h sessions based on the Entering Research Curriculum developed by the Center for the Improvement of Mentored Experiences (Balster et al., 2010). The student interns will be brought in as a cohort and coached on peer mentoring and mutual support frameworks to enhance their sense of community. There will also be a network of formal and informal mentors who are specifically dedicated to improving their technical and interpersonal skills for success in the clinical research workforce.

Traditionally, there are no required educational backgrounds or specific competencies to become a clinical research professional. However, there are still stark diversity and equity issues in the field. There is mounting pressure to grow the clinical research workforce as the number of registered trials increases. However, strictly adding more people won't solve all the field's issues. If we aim to promote equity to reduce health disparities, we must maintain a steadfast focus on the goals: 1) growing this workforce, 2) recruiting talent from diverse communities, and 3) enhancing feelings of belonging and inclusion to retain individuals from diverse backgrounds throughout the process. The NCCU Clinical Research Science Program aims to create a robust curriculum that trains students from diverse backgrounds to develop core competencies that will empower them to be leaders in clinical research. In addition to their classroom training in pursuit of a Bachelor of Science, this internship program aims to facilitate them gaining professional skills, confidence, self-efficacy, sense of belonging, and to promote their identity as top-tier researchers and scientists. We hope to empower a well-qualified cohort of students to obtain roles as clinical research professionals with strong skills in core competency domains that the Joint Task Force for Clinical Trial Competency and Clinical Research Professional Workforce Development has recently developed (Sonstein and Jones, 2018).

While we have trained to the competencies outlined in the article above, the learning objectives for the internship are to test the "workability" of our cohort, specifically as follows.

1) Be able to follow Good Clinical Practices in the conduct of clinical research
2) Understand and describe the roles of various clinical research professionals within the clinical research team
3) Apply professionalism and interpersonal skills to ensure success in clinical and scientific workplaces
4) Build skillsets in quantitative research
5) Apply literature review skills to develop and share new knowledge in clinical and scientific research workplace
6) Execute well-researched presentations with confidence
7) Incorporate professional and research experiences into resumes and increase marketability of the scholars

Importantly, we will administer in-depth pre- and post-evaluations that rely on validated tools to determine the impact of our intervention on promoting recruitment and inclusion in a field (Gloria and Kurpius, 2001; Hurtado et al., 2007; Byars-Winston et al., 2011; Trujillo and Tanner, 2014; Byars-Winston et al., 2016). From these self-assessment surveys, we will quantify their changes in self-efficacy, feelings of belonging, access to research opportunities, access to research mentors, detail their future career goals, and use qualitative and quantitative measures to assess their confidence, comfort, and expectations of success within the clinical research field (Table 1). By doing so before and after the internship experiences of multiple cohorts, we will develop a robust understanding of the impact of this internship experience on our student interns with depth and nuance based on empirical evidence. Additionally, we will query the internship preceptors for each student to evaluate the interns' skills, growth, and readiness to enter the workforce. Finally, we will do an annual survey following up with each intern to determine their career trajectory longitudinally and to ask how ready they felt to take on their new positions, to climb the career ladder in Clinical Research, and to determine if they were retained long-term in the field.

Many of these key focus areas overlap with the goals of the Joint Task Force for Clinical Competencies Domains (Figure 1) (Sonstein and Jones, 2018). We will develop their skills for Competency 1: Scientific Concepts and Research Design in both the Clinical Research at Pickett Road and the Pre-Clinical Molecular Neuroscience Research with the Collective for Psychiatric Neuroengineering by giving hands-on research experiences, helping interns to design experiences, analyze the literature, develop technical and interpersonal expertise to accomplish the goals of their research, and to take pieces of the studies from conception to execution and analysis. They will have thorough Ethical Training which aligns with Domain 2, including engaging in the Entering Research Curriculum (focusing on case studies of responsible conduct in research, setting expectations, and ethics discussions), attending an IRB meeting, and online learning with Clinical Research Coordinators and Experimental Scientists daily. We are giving them hands-on training to apply what they've learned in the classroom regarding Competency 4: Good Clinical Practice and Operations in the Clinical Research Setting. By promoting self-efficacy, a sense of belonging, and scientific identity in our students, we empower them to develop Competency 7: Leadership and Professionalism and Competency 8: Communication and Teamwork. We are further supporting Competency 8 through immersive experiences where they must work as a team to solve problems, give presentations, and develop their collaboration skills to accomplish the assigned tasks as an internship cohort. Taken together, we aim to integrate the advice and direction from Clinical Research and Research Mentorship experts to provide a holistic internship experience that will empower our students to be workforce-ready by up-skilling them in the key domains identified by this highly respected council.

TABLE 1 Variables to be evaluated through pre- and post-assessments of student interns in the NCCU Clinical Research Science Program.

Self-efficacy
Confidence in conducting high quality clinical research
Confidence in understanding how a biology laboratory operates
Confidence in molecular biology techniques in the laboratory
Confidence in understanding and describing the roles of various clinical research professionals within a clinical research team
Confidence with applying good clinical practices to clinical research
Confidence in your capacity to succeed in clinical or pre-clinical research
Confidence in yourself professionally, in general
Confidence in talking about clinical research with other professionals
Confidence in talking about pre-clinical research with other professionals
Confidence in applying statistics to a research question
Confidence conducting quantitative research
Confidence conducting a literature review
Confidence applying a literature review to share knowledge with others in the workplace
Confidence in executing a well-researched presentation
Confidence in applying to your first job after you graduate
Confidence in having a strong career in clinical research that supports your goals in life
Sense of belonging
Comfort level in a scientific lab
Comfort level in a clinical research setting
Comfort level in any professional work setting
Satisfaction with access to clinical research opportunities
Satisfaction with access to clinical research mentors
Access to opportunities and mentors in clinical research.
Expected outcomes
A clinical research career would allow me to work that makes a difference in people's lives or society.
A clinical research career would allow me to work that I find satisfying
A clinical research career would allow me to go into a field with high employment demand
A clinical research career would allow me to get respect from other people
A clinical research career would allow me to earn an attractive salary.
How important do you think it is to have clinical research mentors?
How important do you think internships are to your Confidence in yourself?
How important do you think it is to have access to role models?
How important do you think it is to have peer colleagues in your STEMM career?
Clinical research Identity
Current Major
Future plans for higher education

(Continued in next column)

TABLE 1 (*Continued*) Variables to be evaluated through pre- and post-assessments of student interns in the NCCU Clinical Research Science Program.

Clinical research Identity
Future plans for job titles to hold
I can picture myself being successful as a clinical science researcher
I am already successful as a clinical science researcher
Access to mentors and experiences
Clinical research scientist mentor numbers and frequency of contact
Hands-on research experience in clinical research opportunities
Pre-clinical research scientists mentor numbers and frequency of contact
Clinical research or pre-clinical research workplace access
Pre-clinical research science mentor numbers and frequency of contact
Clinical or pre-clinical research internship access

Discussion and future remarks

Our mission is to develop a clinical research training program that diversifies the field through a robust understanding of the strengths and liabilities of our approach over multiple cohorts. This depth of understanding will be mission-critical to maximize our capacity to empower our student interns to become leaders in clinical research. We aim to apply the powerful tools and foundational theoretical frameworks that leaders in vocational psychology have developed in response to the critical need to increase the number of workforce-ready clinical researchers while concurrently diversifying the workforce. Analyzing our impact along the way will allow for iterative design to optimize our program in the future. We will use the gained knowledge to generate tactical advice for other programs with shared missions for the mutual edification of our programs.

Additionally, we will follow our interns longitudinally throughout their career trajectories to allow us to develop systems to assess the long-term impact interventions have on retention. In the near future, we also aim to query future employers as to how "job-ready" the graduates from our program were compared to other competitive applicants and what their primary foci are in the hiring process into their field. Finally, we will continue to document this journey and raise funds for this training program to bring about awareness and promote sustainability that will allow for a larger and more meaningful impact on future cohorts and larger participant pools.

While these strategies may only provide a partial solution to the long-standing systems of inequality that we must overcome, they provide three key improvements: 1) a framework that can be utilized and repurposed as we collectively work to recruit, train, and retain diverse researchers in clinical research (or other fields), 2) the application of vocational psychology theoretical frameworks to clinical research training opportunities as a novel synergistic integration of the fields, and 3) an opportunity to continue to revise our training models based on data-driven insights. If successful, we will contribute to the intentional deconstruction of systemic barriers that have historically driven health, economic, and educational inequalities that have held us back as a society and as a clinical research field.

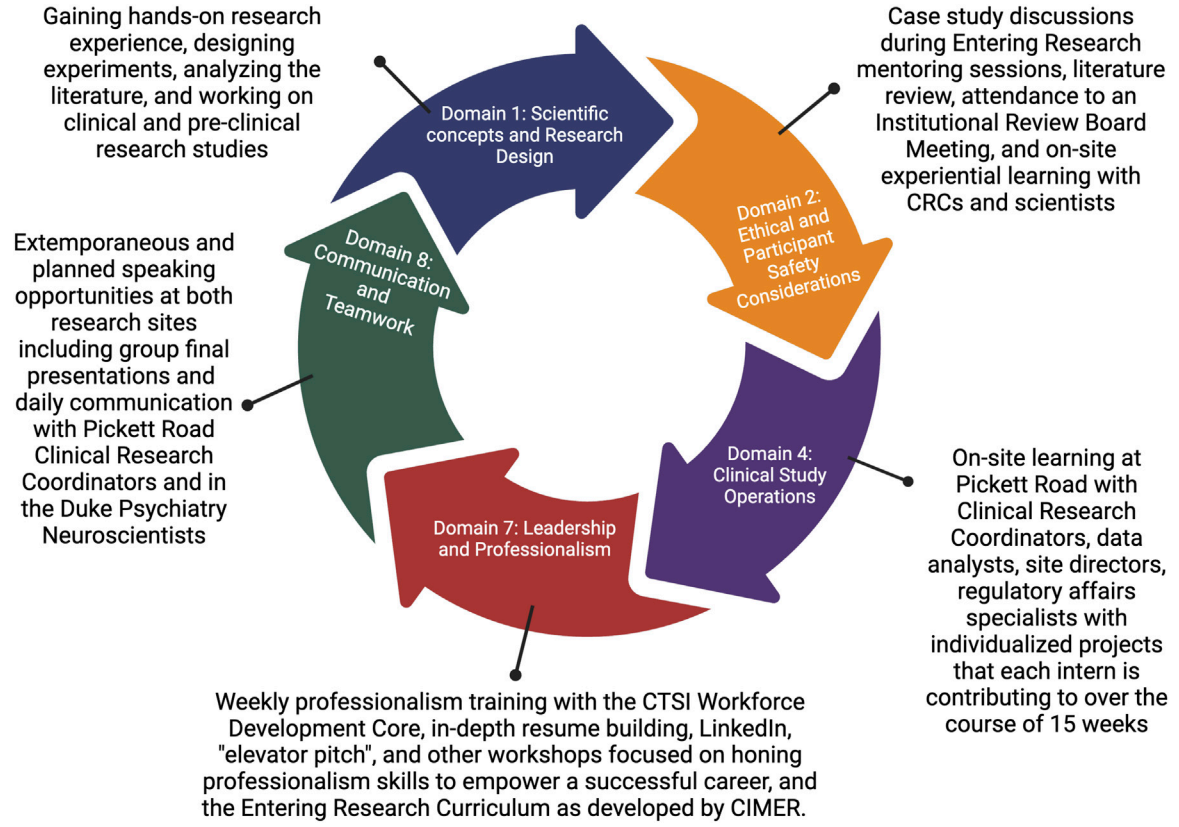

FIGURE 1
Joint Task Force key competency domains for clinical research and their alignment with internship activities.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary material, further inquiries can be directed to the corresponding authors.

Author contributions

JD: Conceptualization, Data curation, Formal Analysis, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing–original draft, Writing–review and editing. KD: Conceptualization, Funding acquisition, Methodology, Project administration, Resources, Supervision, Writing–review and editing. TL: Conceptualization, Funding acquisition, Investigation, Methodology, Project administration, Resources, Supervision, Writing–review and editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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References

Alsan, M., Garrick, O., and Graziani, G. C. (2018). Does diversity matter for health? Experimental evidence from Oakland (Working Paper 24787). *Natl. Bureau Econ. Res.* doi:10.3386/w24787

Bakken, L. L., Byars-Winston, A., and Wang, M.-F. (2006). Viewing clinical research career development through the lens of social cognitive career theory. *Adv. Health Sci. Educ. Theory Pract.* 11, 91–110. doi:10.1007/s10459-005-3138-y

Balster, N., Pfund, C., Rediske, R., and Branchaw, J. (2010). Entering research: a course that creates community and structure for beginning undergraduate researchers in the STEM disciplines. *CBE Life Sci. Educ.* 9, 108–118. doi:10.1187/cbe.09-10-0073

Byars-Winston, A., Gutierrez, B., Topp, S., and Carnes, M. (2011). Integrating theory and Practice to increase scientific workforce diversity: a framework for career development in graduate research training. *CBE—Life Sci. Educ.* 10, 357–367. doi:10.1187/cbe.10-12-0145

Byars-Winston, A., Rogers, J., Branchaw, J., Pribbenow, C., Hanke, R., and Pfund, C. (2016). New measures assessing predictors of academic persistence for historically underrepresented racial/ethnic undergraduates in science. *CBE Life Sci. Educ.* 15, ar32. doi:10.1187/cbe.16-01-0030

Envisioning a TransformedBoard on Health Sciences PolicyHealth and Medicine DivisionNational Academies of Sciences, Engineering, and Medicine (2021). Envisioning a transformed clinical trials enterprise for 2030. *Proc. a Workshop*. doi:10.17226/26349

Frierson, G. M., Pinto, B. M., Denman, D. C., Leon, P. A., and Jaffe, A. D. (2019). Bridging the Gap: racial concordance as a strategy to increase African American participation in breast cancer research. *J. Health Psychol.* 24, 1548–1561. doi:10.1177/1359105317740736

Gloria, A. M., and Kurpius, S. E. (2001). Influences of self-beliefs, social support, and comfort in the university environment on the academic nonpersistence decisions of American Indian undergraduates. *Cultur. Divers. Ethn. Minor. Psychol.* 7, 88–102. doi:10.1037/1099-9809.7.1.88

Graham, M. J., Frederick, J., Byars-Winston, A., Hunter, A.-B., and Handelsman, J. (2013). Science education. Increasing persistence of college students in STEM. *Science* 341, 1455–1456. doi:10.1126/science.1240487

Greenwood, B. N., Hardeman, R. R., Huang, L., and Sojourner, A. (2020). Physician-patient racial concordance and disparities in birthing mortality for newborns. *Proc. Natl. Acad. Sci. U. S. A.* 117, 21194–21200. doi:10.1073/pnas.1913405117

Hitchcock, P., Mathur, A., Bennett, J., Cameron, P., Chow, C., Clifford, P., et al. (2017). The future of graduate and postdoctoral training in the biosciences. *eLife* 6, e32715. doi:10.7554/eLife.32715

Hurtado, S., Han, J. C., Sáenz, V. B., Espinosa, L. L., Cabrera, N. L., and Cerna, O. S. (2007). Predicting transition and adjustment to college: biomedical and behavioral science aspirants' and minority students' first year of college. *Res. High. Educ.* 48, 841–887. doi:10.1007/s11162-007-9051-x

Improving Representation, Improving representation in clinical trials and research: building research equity for women and underrepresented groups. (2022). doi:10.17226/26479

LaVeist, T. A., Nuru-Jeter, A., and Jones, K. E. (2003). The association of doctor-patient race concordance with health services utilization. *J. Public Health Policy* 24, 312–323. doi:10.2307/3343378

Locklear, T., Dickerson, K. C., and Dzirasa, K. A more diverse biomedical and healthcare workforce is within our reach. *Mod. Healthc.* 2, 20223.

NSF (2022). Women, minorities, and persons with disabilities in science and engineering. Available at: https://ncses.nsf.gov/pubs/nsf21321.

Sonstein, S. A., and Jones, C. T. (2018). Joint task Force for clinical trial competency and clinical research professional workforce development. *Front. Pharmacol.* 9, 1148. doi:10.3389/fphar.2018.01148

Statistics, N. Women, minorities, and persons with disabilities in science and engineering. *Var. pagings (National Cent. Sci. Eng. Statistics, Natl. Sci. Found.*, 1994). Available at: https://www.nsf.gov/statistics/women/.

Trujillo, G., and Tanner, K. D. (2014). Considering the role of affect in learning: monitoring students' self-efficacy, sense of belonging, and science identity. *CBE Life Sci. Educ.* 13, 6–15. doi:10.1187/cbe.13-12-0241

Tufts Center for the Study of Drug Development (2021). Tufts University Impact Report, New Study finds site personnel race and ethnicity highly correlated with diversity of patients enrolled. Available at; https://f.hubspotusercontent10.net/hubfs/9468915/Impact%20Report%20Preview.png.

US National Library of Medicine *ClinicalTrials.gov trends, charts, and maps*.

Valantine, H. A., and Collins, F. S. (2015). National Institutes of Health addresses the science of diversity. *Proc. Natl. Acad. Sci. U. S. A.* 112, 12240–12242. doi:10.1073/pnas.1515612112

Winn Ariel, S., DelSignore, L., Marcus, C., Chiel, L., Freiman, E., Stafford, D., et al. (2019). Applying cognitive learning strategies to enhance learning and retention in clinical teaching settings. *MedEdPORTAL* 15, 10850. doi:10.15766/mep_2374-8265.10850

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EDITED BY
Stephen Sonstein,
Eastern Michigan University,
United States

REVIEWED BY
Kimberly McCall,
University of Alabama at Birmingham,
United States
Audra N. Iness,
Baylor College of Medicine, United States
Jared Kerr,
University of North Carolina Wilmington,
United States

*CORRESPONDENCE
Jacqueline Knapke,
knapkeje@uc.edu

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Development of an undergraduate certificate in clinical and translational science: improving competence of the clinical research workforce

Jacqueline Knapke[1,2]*, Michelle Marcum[3], Angela Mendell[2] and Patrick Ryan[2,4]

[1]Department of Family and Community Medicine, University of Cincinnati, Cincinnati, OH, United States, [2]Center for Clinical and Translational Science and Training, University of Cincinnati, Cincinnati, OH, United States, [3]Cancer Center, University of Cincinnati, Cincinnati, OH, United States, [4]Department of Pediatrics, Division of Biostatistics and Epidemiology, Cincinnati Children's Hospital Medical Center/ University of Cincinnati, Cincinnati, OH, United States

Introduction: Academic research centers often struggle to recruit and retain a well-trained and diverse clinical and translational science (CTS) workforce. In particular, the clinical research professional (CRP) career pathway is not well known to undergraduate students and other individuals outside of academic medicine despite being a potential career route. To address these workforce challenges, the CRP Task Force at the University of Cincinnati (UC) aims to train a competent and diverse CRP workforce through targeted educational programming in the UC undergraduate population.

Methods: Using a six-step curriculum development process that included: 1) performing a needs assessment, 2) determining content, 3) writing goals and objectives, 4) selecting the educational strategies, 5) implementing the curriculum, and 6) evaluating the curriculum, we designed an undergraduate certificate program in CTS.

Results: The needs assessment included both internal and external data gathering to inform curriculum development and program decisions. Content was determined using the Core Competency Framework for the Clinical Research Professional Version 3.1., and program learning outcomes were written with both the competency framework and local workforce needs in mind. Educational strategies were selected based on optimization of available resources and local expertise with an emphasis on interactive didactics complemented by experiential learning. Implementation is underway and evaluation will follow once students begin enrolling.

Discussion: By educating an undergraduate student population about CTS methods and career opportunities, we anticipate increased numbers of well-qualified, diverse applicants who pursue CRP careers locally and regionally.

KEYWORDS

workforce development, clinical and translational science, clinical and translational research, curriculum development, undergraduate research training, clinical research professional

1 Introduction

Academic research centers frequently face challenges in the recruitment and retention of well-trained, diverse clinical research professionals (CRPs) for multiple reasons, including a lack of professional identity characterized by insufficient training programs, ill-defined pathways for career advancement, and feelings of low value and burnout (Knapke and Jenkerson, 2022; Knapke and Snyder, 2022; Freel et al., 2023). Freel, et al. (2023) provides a compelling summary of the alarming scale of the problem nationally, and the risk the problem poses to the integrity, quality, and innovation of clinical and translational science (CTS) in the United States. Although CRP retention has not been well-studied in academic medical centers, the turnover rate in healthcare averaged 22.7% in 2022 ('2023 NSI National Health Care Retention & RN Staffing Report', 2023). In clinical research organizations (CROs), the average turnover rate from 2017 to 21 was 26.2% ('2022/23 Clinical Research Organization Insights Report: Managing Talent and Pay in a Competitive Market and Volatile Economy', 2023). However, it is difficult to compare staffing trends in healthcare and industry to academic research environments. Duke University reported a reduction in CRP turnover from 23% to 16% following implementing a competency-based workforce initiative (Stroo et al., 2020). The COVID-19 pandemic exacerbated CRP workforce problems; one study found that 37% of academic research centers reported decreased staffing and increased turnover as a result of the pandemic (Samuels et al., 2023). Managers and principal investigators (PIs) at the Cincinnati Academic Health Center (AHC) face similar problems to those seen at the national level. The Cincinnati AHC is comprised of three hospitals and one academic institution: the University of Cincinnati Medical Center (UCMC), Cincinnati Children's Hospital Medical Center (CCHMC), the Cincinnati VA, and the University of Cincinnati (UC), which includes the Colleges of Medicine, Nursing, Allied Health, and Pharmacy on its health sciences campus. Combined, UC and CCHMC employ approximately 1,200 CRPs, but both organizations struggle to recruit and retain a CTS workforce locally, mirroring similar challenges at the national level. During the 2022 fiscal year, turnover rates at both institutions ranged from 18.7% to 37.5%, with the highest turnover rates occurring in the early-to mid-level titles. Turnover rates at these levels introduce a critical roadblock to sustaining high-quality clinical and translational research (CTR) implementation and management.

To overcome these workforce challenges, leaders at the Cincinnati AHC organized a CRP Task Force comprised of key stakeholders from the Center for Clinical and Translational Science and Training (CCTST), the UC Cancer Center, the UC Office of Clinical Research, the Department of Environmental and Public Health Sciences, the UC College of Education, Criminal Justice and Human Services, UC Human Resources, and the Department of Pediatrics/CCHMC. The goal of the Task Force is to develop and implement strategies to recruit, train, and retain CRPs to support the clinical research enterprise at the Cincinnati AHC. Three workgroups within the task force were formed to focus on recruitment, education, and retention. The work described in this paper was completed by the education workgroup, whose goals are to support and promote for-credit training opportunities and non-credit professional development for new and existing CRPs.

Despite the critical role CRPs play in the generation of evidence to support better health outcomes for both individuals and populations, this career pathway is not well known to undergraduate students and other individuals outside of academic medicine despite being a potential career route. Summer research programs for undergraduates and medical students are the most common method for introducing students to research (Black et al., 2013; Kolber et al., 2016; Howell et al., 2019; Avila et al., 2022). Summer programs can also be an effective way to introduce underrepresented minority students to research and prepare them for CTS career pathways (Ghee et al., 2016; Smalley and Warren, 2020; Prince et al., 2023). In Arkansas, an undergraduate curriculum rooted in a real-world CTS study was developed, offered, and evaluated, demonstrating high satisfaction among learners (James et al., 2023). Temple University School of Medicine requires medical students to complete 2 week training in CTS and one CTS scholarly activity during their 4 years of medical school (Feldman, 2015). Evidence suggests that virtual programming is an effective training method when in-person is not feasible (Corson et al., 2021; Lemacks et al., 2022; James et al., 2023). Evidence also suggests that research experience during undergraduate study increases students' awareness of career options, improves their preparation for graduate training, and ultimately impacts their decisions to pursue advanced degrees and careers related to research (Seymour et al., 2004; Hunter et al., 2007; Adedokun et al., 2012; Yaffe et al., 2014).

Locally, we coordinate several efforts to introduce students to research principles and careers. Every semester, the workforce development core of our Center for Clinical and Translational Science and Training visits undergraduate courses across several programs to introduce students to CTS careers and training opportunities. Research 101 is an asynchronous research primer available to medical students and summer research students (Blackard et al., 2022; 2023). Every summer, the Summer Undergraduate Research Fellowship (SURF) program awards research fellowships to 150 undergraduate students from UC and other institutions. The Office of Undergraduate Research on UC's main campus also provides programs and resources to help students access research experiences across an array of disciplines. However, currently, there is no formal training pathway specific to CTS that results in a major, minor, or certificate for undergraduates at UC. In order to introduce and better prepare undergraduate students for careers in CTS, the education workgroup of the CRP Task Force at the Cincinnati AHC sought to develop a competency-based, for-credit undergraduate certificate program by undertaking a six-step curriculum development process.

2 Pedagogical frameworks

Two pedagogical frameworks informed our task: existing CRP competencies and an established six-step curriculum development method. We began with CRP competencies that were developed by a national consortium of medical association leaders and industry collaborators called the Joint Task Force (JTF) for Clinical Trial Competency, organized by the Multi-Regional Clinical Trials (MRCT) Center of Brigham and Women's Hospital and Harvard. This framework has undergone multiple iterations between 2014-20;

we utilized the most recent "Core Competency Framework for the Clinical Research Professional Version 3.1." (Sonstein et al., 2014; 2020; JTF Task Force, 2017). The Core Competency Framework for the CRP Version 3.1 defines 49 competency statements that address CRP knowledge, skills, and attitudes under 8 scientific domains: 1) Scientific Concepts and Research Design, 2) Ethical and Participant Safety Considerations, 3) Investigational Products Development and Regulation, 4) Clinical Study Operations (Good Clinical Practice), 5) Study and Site Management, 6) Data Management and Informatics, 7) Leadership and Professionalism, and 8) Communications and Teamwork. Additionally, we utilized a six-step curriculum development process described by Schneiderhan, Guetterman and Dobson (2019) that included: 1) performing a needs assessment, 2) determining content, 3) writing goals and objectives, 4) selecting the educational strategies, 5) implementing the curriculum, and 6) evaluating the curriculum.

3 Learning environment

UC is designated a "very high research activity" university by the Carnegie Commission, holding ~$206.6 million in grants in 2019 with $89.4 million coming from the NIH. The College of Medicine received $105.3 million in sponsored awards in 2019 and was ranked in the top 38% of medical schools for research in the 2020 *U.S. News and World Report* rankings. The College of Medicine is composed of 23 departments, 5 basic science and 18 clinical, which retain in excess of 2,000 faculty. CCHMC is a 700-bed non-profit organization serving as the AHC's major teaching facility for pediatrics and as the only children's hospital in the Cincinnati metropolitan area (population 2.3 million). Of 184 pediatric institutions surveyed nationally, CCHMC is consistently ranked top 3 in the Honor Roll of America's Best Children's Hospitals compiled by *U.S. News & World Report*. CCHMC has a major emphasis on research and held over $240 million in grants with over $161 million coming from the NIH in 2019. The two institutions are located on the same campus and have a long record of close collaboration. There are constant interactions between researchers and clinicians, and CCHMC faculty hold dual appointments in the UC College of Medicine. The institutions are administratively linked in many endeavors ranging from clinical to research and education. This emphasis on research impacts the learning environment in a multitude of ways (e.g., collaborations across faculty research, training grants, core facilities, and CRP training). UC's undergraduate population includes approximately 40,000 students, with a quarter identifying as a racial or ethnic minority. Reaching a small fraction of those students and introducing them to CTS principles and career opportunities could have a major impact on local workforce development.

4 Methods

The education subgroup of the CRP Task Force followed the six-step curriculum development process outlined by Schneiderhan, Guetterman and Dobson (2019) to design an undergraduate certificate program in CTS.

4.1 Needs assessment

An educational needs assessment is a data-gathering exercise to understand what the needs for a particular discipline or group of learners are and why a curriculum should be developed and implemented. It can include a wide range of data sources: consultations with those familiar with the field and/or potential learners, data-driven descriptions of an educational gap in a particular discipline, or accreditation or regulatory specifications (e.g., Accreditation Council for Graduate Medical Education requirements) that must be achieved.

Our needs assessment included four components. We gathered information from local CTS leaders about the undergraduate majors where most of their employees come from, and then we conducted an internal review with program directors from these programs, seeking to better understand the major curricula and their students' educational needs and career interests. We also provided the directors with an overview of CTS careers and noted their perceptions of how well an undergraduate certificate would fit the needs and interests of their student populations. We worked with local CTS leaders and Human Resources to conduct an internal review of employment needs within the local CTS research workforce. We reviewed and summarized relevant competitor programs (both internal and external). When reviewing external programs, we focused on direct competitors: undergraduate certificate programs offered by 4-year universities. Finally, we completed an external market analysis to better understand career opportunities for potential graduates. These components occurred simultaneously over approximately 6 months and are described in Table 1.

4.2 Determine content

The next step was to consider areas of content that should be included in the curriculum, making decisions about what to focus on and prioritize. Subject matter experts are important to include in this step of the process, as they are familiar with large thematic areas as well as content specifics that could inform the organization of the training program or coursework. Our process for determining content included two components: a review and prioritization of existing competencies and a review of relevant undergraduate courses that already existed at our institution.

Using the Core Competency Framework for the CRP Version 3.1 as a foundation, we carefully reviewed the competencies with subject matter experts (including a CRP, a CRP manager, and a CTS director) to determine areas of prioritization that would best support the types of studies commonly conducted at our AHC. We categorized each competency as essential, important, or not needed in an entry-level CRP position. We also adjusted competency language when necessary to make competency achievement feasible in undergraduate learners, e.g., lowering the level of competency to "understanding" or "summarizing" rather than "analyzing" or "evaluating" (Bloom, 1956). We also noted competencies that should be introduced in the certificate curriculum, but that would be further explicated as part of employee onboarding and/or required training.

TABLE 1 Needs assessment components.

Data source	Data type	Component	Brief description
Internal	Qualitative	Review of Undergraduate Major Program Directors	Meetings with program directors from undergraduate majors with anticipated high levels of student interest
Internal	Qualitative & Quantitative	Review of Local CTS Workforce Needs	Meetings with CTS research managers and directors Review of human resource data related to CRP recruitment and retention
Internal & External	Qualitative & Quantitative	Review of Relevant Competitor Programs	Web-based research to identify and summarize existing programs both internally and at external institutions
External	Quantitative	Market Analysis of CTS Career Opportunities	Market analysis using Lightcast, an external labor analytics company

The second component of our content determination process was reviewing existing courses at our institution that were relevant to the content areas within the JTF competencies. This entailed searching for several keywords within the course catalog, collating a list of potential course numbers, and then examining the internal course management system and reviewing details such as course descriptions and student learning outcomes for alignment with program competencies. The "determine content" step of the curriculum development process resulted in an early draft of required courses for the certificate program.

4.3 Write goals and objectives

Once content areas were identified and prioritized using the Core Competency Framework for the CRP Version 3.1, we established goals and objectives for the certificate program. Schneiderhan, Guetterman and Dobson (2019) draw an important distinction between goals and objectives: goals are broad and general statements of knowledge or skill that learners should attain, while objectives are specific and measurable outcomes learners should achieve after program completion. Goals were drawn from the content areas outlined in step two, and objectives were more specific summaries of the competencies to be achieved. We chose the verbs for our objectives carefully, focusing on achievement that could be measured (e.g., describe or compare) as opposed to more vague characterizations of achievement (e.g., know or appreciate).

4.4 Select educational methods

Given the plethora of methods available to contemporary educators (e.g., lectures, flipped classrooms, case studies, experiential learning, hands-on skill delivery, web-based synchronous or asynchronous learning, role plays, etc.), selecting strategies to effectively facilitate the curriculum was a critical step in the development process. Strategy selection required us to give holistic consideration to several elements of the program that had been identified and described in the first three steps: the needs of the disciplinary field and the learners (step 1), effective content delivery based on these needs (step 2), and the optimal methods to support and measure achievement of program learning objectives (step 3). As we considered strategies to teach undergraduate students introductory principles of CTS, we consulted with stakeholders who had knowledge regarding two key facets that would impact our training strategies: 1) the real-life challenges and opportunities when engaging with an undergraduate student population, and 2) the on-the-job needs of a new CRP hire. We also consulted with potential instructors of the content areas to talk through benefits and barriers of different methods of content delivery.

4.5 Curriculum implementation

Implementation of the curriculum encompassed several discrete but related tasks such as identifying the necessary resources (e.g., personnel, time, facilities, and budget), obtaining any necessary internal and external stakeholder support, designing an educational management plan that includes logistical details regarding curriculum components, educational methods, barrier mitigation, and other implementation processes such as learner recruitment, retention, and program completion. The final step is actual delivery of the curriculum to learners, sometimes via pilot rollouts or a phased approach over time. In our case, several of these tasks had been discussed in earlier steps of the development process but this step brought them all together in a formal program proposal required by our institution for the new program approval process. During this step, we brainstormed and contacted potential course instructors, discussed admission requirements, considered budgetary or logistical limitations, and identified existing resources at our institution that could be leveraged to implement or improve educational methods.

4.6 Curriculum evaluation and improvement

Evaluation is an essential element to any educational program, not only for continuous program improvement but also for reporting program outcomes to key stakeholders. Evaluation is iterative in nature, often including formative (process) and summative (outcome) evaluation methods. Schneiderhan, Guetterman and Dobson (2019) describe a five-step curriculum evaluation process: 1) determine how evaluation results will be used, 2) identify the best metrics for evaluating objective achievement,

3) collect data, 4) analyze data, and 5) improve the program using results. Our evaluation planning included an exploration of data that would be obtained through the common administrative processes at our institution, identified gaps within those data that we determined were important in order to measure program success, and developed measures and accompanying processes to collect data in order to effectively evaluate the program. We gave careful consideration to whom these data would be important to (e.g., key stakeholders, institutional administrators, and potentially granting agencies who may support our training efforts), and we discussed ways to embed evaluation measures into learner assessments at the course level. We also developed a utilization plan for evaluation results, designed to promote regular review of evaluation data and integration of curriculum changes annually, as needed and informed by evaluation results.

5 Results

5.1 Needs assessment

5.1.1 Review of undergraduate major program directors

Our information-gathering from local CTS leaders identified Biological Sciences, Medical Sciences, Psychology, and Public Health as the most common undergraduate majors held by their employees, allowing us to select these as programs that could potentially yield high numbers of interested students. Meetings with the program directors of these four majors led us to conclude that an undergraduate certificate was the appropriate educational path to pursue due to limited room for additional credits in student major curricula, as well as student preference for a certificate rather than a minor. Program directors were unanimously in favor of development of the program. The majority were unaware of CTS career pathways that might be appropriate for their graduates, but felt there would be high levels of interest from their students and that the skills taught in such a certificate program would be new yet complementary to content offered through existing courses. These programs also offer significant numbers of majors: approximately 900 in Biological Sciences, 375 in Medical Sciences, 1,000 in Psychology, and 125 in Public Health.

5.1.2 Review of local CTS workforce needs

In addition, our meetings with CTS research managers and directors at the Cincinnati AHC led to a better understanding of the workforce challenges they have faced, revealing that although recruitment and retention have long plagued the CTS field, the COVID-19 pandemic exacerbated the problem, and the workforce has not recovered. The CRP workforce at the Cincinnati AHC includes approximately 1,200 positions, encompassing titles from clinical research assistant (high school diploma required) to clinical research director (master's required, some staff have doctorates). UC employs approximately 400 CRPs and CCHMC employs approximately 800 CRPs. Additionally, several corporate Clinical Research Organizations (CROs) operate large offices in the Cincinnati area, primarily specializing in clinical trials. In 2022, turnover rates at the Cincinnati AHC varied from 20% to 37.5% at CCHMC and 19%–32% at UC, with the highest rates occurring in the entry- and median-level position titles. A search of job postings in July 2023 using "clinical research" as a keyword results in 389 results at UC and 247 at CCHMC.

5.1.3 Review of relevant competitor programs

We reviewed potential competitor programs both at UC and at external institutions. We found no similar programs locally, but web-based research allowed us to summarize primary components of external competitor programs as shown in Table 2. An important discovery within this review was that all of the existing programs in our geographic region were only open to students enrolled at those universities (i.e., UC students could not enroll in them).

5.1.4 Market analysis of CTS career opportunities

In addition to the local market needs described above, we worked with UC Online to conduct a market analysis using Lightcast. (Lightcast—Labor Market Analytics, 2023). The Lightcast report, run in June 2023, found over 13,000 unique job postings for CRP positions with a median advertised salary of $78,600. The median income for CRPs from June 2022 to May 2023 showed a steep increase of 16% because the number of open jobs currently exceeds the supply of qualified applicants. The minimum education levels for employment were: 11% required a high school diploma or GED, 11% required an associate's degree, and 78% required a bachelor's degree. Given that large majority of entry level jobs require a bachelor's degree, we determined that students graduating with a baccalaureate degree would benefit from targeted training in CTS in the form of a certificate that would complement their major curricula. Colleges and universities were the top employers of CRPs.

5.2 Determining content

The competency review process generated a final list of prioritized competencies that are essential and/or important to an undergraduate learner who might begin an entry-level position after graduation. The final list acknowledged that while all of the competencies are essential or important to a CRP over the lifetime of their career, many of them will be acquired with onboarding, professional development training, and career experience; thus, some competencies need only to be introduced to undergraduate trainees so that they are aware of common processes, terms, or aspects of CTS. Table 3 provides details on how competencies were prioritized for undergraduate education. Changes to competency language in order to bring them to an undergraduate/introductory level are provided in red. Competencies that may be supported by completion of the Collaborative Institutional Training Initiative Program (CITI) training as part of employment onboarding are noted with an asterisk. Alignment with competencies was the major driving force of the content determination process, but careful review of the external programs summarized in Table 2 was also informative as we considered different ways to organize the topics into required courses.

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TABLE 2 External undergraduate certificate programs with institution, program name, mode of offering, number of credits, and required courses.

Institution, *Program Name,* mode of offering	Number of credits or courses	Required courses
The Ohio State University	13 credits	- Medical Terminology for the Health
Certificate in Clinical Trials Sciences		Professions
Online—both synchronous and asynchronous		- Drug Discovery, Development and Delivery
		- Clinical Trials from Concept to Launch
		- Clinical Trials Data Management and Monitoring
Temple University	18 credits	- Health and Disease in American Society
Certificate in Health Research		- Statistical Methods in Sociology
Hybrid		- Research Design and Methods
		- Two additional course electives from a list
University of California—Berkeley	12 credits	- Introduction to Clinical Research: Clinical Trial
Certificate in Clinical Research Conduct and Management		Phases and Design
Hybrid		- Clinical Trial Planning: Protocol Development
		Data Management and Clinical Site Activities
		- Clinical Trial Implementation: Site Initiation
		Subject Recruitment, Monitoring and Safety
		Reporting
		- Clinical Trial: Data Analysis, Regulatory Audits
		Vendor Selection and Project Management
University of Hawaii at Manoa	6 courses	- Introduction to Cancer
Clinical Research Professional Certificate Program		- Introduction to Clinical Research
Online		- Human Subjects Protection
		- Community-Based Participatory Research
		- Clinical Research Advanced Topics
		- Clinical Trials Ethics
University of Kentucky	12–15 credits	- Research in Human Health Sciences
Certificate in Research in Human Health Sciences		- Research Experience in Health Sciences
Hybrid		- Out-of-Discipline Course at 300 level or higher
		- Dissemination Requirement/Presentation-Manuscript Preparation
Washington University in St. Louis	21 credits	- Fundamentals of Clinical Research
Certificate in Clinical Research Management		Management I
Hybrid		- Fundamentals of Clinical Research
		Management II
		- Pharmacology for Clinical Research
		- Research Ethics and Regulatory Affairs
		- The Business of Clinical Research
		- Introduction to Data and Information
		Management in Health Sciences
		- Practicum/Capstone

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TABLE 3 Core competency framework for the CRP version 3.1, prioritized for undergraduate education.

Scientific domain/Core competency	Essential	Important	Not needed
1. Scientific concepts and research design: Encompasses knowledge of scientific concepts related to the design and analysis of clinical trials			
1.1 Apply principles of biomedical science to investigational product discovery and development and health-related behavioral interventions	x		
1.2 Identify scientific questions that are potentially testable clinical research hypotheses		x	
1.3 Identify the elements and explain the principles and processes of designing a clinical study	x		
1.4 Maintain awareness of new technologies, methodologies and techniques which enhance the conduct, safety and validity of the clinical study			x
1.5 Critically analyze clinical study results			x
2. Ethical and Participant Safety Considerations: Encompasses care of patients, aspects of human subject protection, and safety in the conduct of a clinical trial			
2.1 Differentiate between Describe standard of care and clinical study activities	x		
2.2 Define the concepts of "clinical equipoise" and "therapeutic misconception" as they relate to the conduct of a clinical study		x	
2.3 Apply relevant national and international principles of human subject protections and privacy throughout all stages of a clinical study*		x	
2.4 Explain the evolution of the requirement for informed consent from research participants and the principles and content of the key documents that ensure the protection of human participants in clinical research*		x	
2.5 Describe the ethical issues involved when dealing with vulnerable populations and what additional safeguards should be in place for those populations*	x		
2.6 Evaluate and apply an understanding of the relevant ethical issues and cultural variation as it applies to the commercial aspects of the clinical research and investigational product development process			x
2.7 Explain why inclusion, exclusion, and other criteria are included in a clinical protocol to assure human subject protection	x		
2.8 Summarize the principles and methods of distributing and balancing risk and benefit; through selection and management of clinical study subjects*	x		
3. Investigational Products Development and Regulation: Encompasses knowledge of how investigational products are developed and regulated			
3.1 Discuss the historical events that precipitated the development of governmental regulatory processes for investigational products*	x		
3.2 Describe Summarize the roles and responsibilities of the various institutions participating in the investigational products development process		x	
3.3 Explain Summarize the investigational products development process and the activities which integrate commercial realities into the life cycle management of medical products		x	
3.4 Summarize the legislative and regulatory framework that supports the development and registration of investigational products and ensures their safety, efficacy and quality	x		
3.5 Describe Summarize the specific processes and phases that must be followed for the regulatory authority to approve the marketing authorization for a medical product	x		
3.6 Describe the pre- and post- approval safety reporting requirements of regulatory agencies		x	
3.7 Appraise the issues generated and the effects of global expansion on the approval and regulation of medical products			x
4. Clinical Study Operations (Good Clinical Practice): Encompasses study management and GCP compliance; safety management (adverse event identification and reporting, post-market surveillance, and pharmacovigilance), and handling of investigational product			
4.1 Explain Summarize how the design, purpose, and conduct of individual clinical studies fit into the goal of developing a new intervention		x	
4.2 Describe the roles and responsibilities of the clinical investigation team as defined by Good Clinical Practice Guideline	x		
4.3 Evaluate Understand the design, conduct and documentation of clinical studies as required for compliance with Good Clinical Practice Guideline		x	
4.4 Compare and contrast Summarize the regulations and guidelines of global regulatory bodies relating to the conduct of clinical studies		x	
4.5 Describe Summarize appropriate control, storage and dispensing of investigational product		x	

(Continued on following page)

TABLE 3 (*Continued*) Core competency framework for the CRP version 3.1, prioritized for undergraduate education.

Scientific domain/Core competency	Essential	Important	Not needed
4.6 Differentiate Summarize the types of adverse events (AEs) that may occur during clinical studies and explain the identification process and reporting requirement to IRBs/IECs, sponsors and regulatory authorities	x		
4.7 Describe how global regulations and guidelines assure human subject protection and privacy during the conduct of clinical studies*		x	
4.8 Describe the role and process of monitoring a clinical study	x		
4.9 Describe the role and purpose of clinical study audits	x		
4.10 Describe the various methods by which safety issues are identified and managed in clinical studies	x		
5. Study and Site Management: Encompasses content required at the site level to run a study (financial and personnel aspects). Includes site and study operations (not encompassing regulatory/GCPs)			
5.1 Describe the methods used to determine whether to sponsor, supervise or participate in a clinical study			x
5.2 Develop and manage Understand the functional and operational efficiencies and personnel resources necessary to conduct a clinical study		x	
5.3 Describe the management and training approaches to mitigate risk to improve clinical study conduct	x		
5.4 Develop strategies to manage participant recruitment, retention, compliance and track study activities	x		
5.5 Identify the legal responsibilities, liabilities and accountabilities that are involved in the conduct of clinical studies		x	
5.6 Identify and explain the specific procedural, documentation and oversight requirements of principal investigators, sponsors, CROs and regulatory authorities that relate to the conduct of a clinical study as they relate to the CRP	x		
5.7 Identify, organize, analyze and report Describe why project performance evaluation is necessary for comprehensive management of a clinical study	x		
6. Data Management and Informatics: Encompasses how data are acquired and managed during a clinical trial, including source data, data entry, queries, quality control, and correction and the concept of a locked database			
6.1 Describe the role and importance of statistics and informatics in clinical studies		x	
6.2 Describe the origin, flow, and management of data through a clinical study		x	
6.3 Describe best practices and resources required for standardizing data collection, capture, management, analysis, and reporting	x		
6.4 Describe, develop, and implement processes for data quality assurance	x		
7. Leadership and Professionalism: Encompasses the principles and practice of leadership and professionalism in clinical research			
7.1 Describe and apply the principles and practices of leadership, management and mentorship in clinical research			x
7.2 Identify ethical and professional conflicts associated with the conduct of clinical studies and implement procedures for their prevention or management*	x		
7.3 Identify and apply the professional guidelines and codes of ethics that apply to the conduct of clinical research*	x		
7.4 Describe the impact of regional diversity and demonstrate cultural competency in clinical study design and conduct	x		
8. Communications and Teamwork: Encompasses all elements of communication within the site and between the site and sponsor, CRO, and regulators. Understanding of teamwork skills necessary for conducting a clinical trial			
8.1 Describe the importance of team science and methods necessary to work effectively with cross-functional, multidisciplinary and inter-professional research teams, which may include external partners	x		
8.2 Discuss the relationship and appropriate communication between Sponsor, CRO and clinical research site	x		
8.3 Effectively communicate the content and relevance of clinical research findings to colleagues, advocacy groups and the non-scientist community		x	
8.4 Describe the components of a traditional scientific publication		x	

The bold values are the domain names while the sub-numbers (1.1, 1.2 etc) are the competencies under those domains. Domain 1 is a different font than the other domains.

The second piece of the determination and prioritization of content entailed a thorough review of existing courses at UC that might be incorporated into a certificate curriculum. No courses were identified that were specific enough in scope to be a good fit for the certificate. Completion of this step of the curriculum development process led to development of a 12-credit curriculum detailed in

TABLE 4 Proposed curriculum for undergraduate certificate in CTS, with JTF competency domains.

Course name (credits) mode of offering	Topics	Competency domains
Healthcare Exploration Through Patient Care (3) In-person	• Core competencies for healthcare professionals, outlined by the American Association of Medical Colleges (*The Core Competencies for Entering Medical Students*, 2023)	1, 2, 7, 8
	• Internship experience in hospital setting	
Introduction to Clinical and Translational Science (3) Online	• CTR spectrum	1, 2, 6
	• Career tracks	
	• Ethics & Human Research Participant Regulations	
	• Grants vs. Industry-Sponsored	
	• Study methods	
	• Data collection/management	
	• Introductory biostatistics/informatics	
	• Diversity, Equity, and Inclusion (DEI) & health disparities	
Fundamentals of Clinical Trials (3) Online	• GCP	2, 3, 4, 5
	• Safety and Adverse Events	
	• Regulatory	
	• Phases of clinical trials	
	• Vested stakeholders	
Healthcare Exploration through Clinical and Translational Research (3) Hybrid	• Leadership	5, 7, 8
	• Professionalism	
	• Communication	
	• Team Science	
	• Project management (participant recruitment and retention, timelines, budgets, workflows, team roles)	
	• Internship experience with a CTS research office	

The bold values are the names of the courses.

Table 4, including general topics for each course as well as competency domains.

5.3 Writing goals and objectives

Steps two to three were completed concurrently: as the curriculum was being discussed, so were the goals and objectives (or student learning outcomes, in the language of our specific institution) being developed. The overarching goal for the certificate program is broad and general, following the guidelines of Schneiderhan, Guetterman and Dobson (2019): to introduce undergraduate students to the principles of CTS in order to prepare them for CTS research careers upon graduation. The objectives for the certificate program are much more specific, measurable, and grounded in the Core Competency Framework for the CRP Version 3.1:

- Explain Good Clinical Practice 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 the goals and outcomes of patient care and population health.

5.4 Selecting educational methods

Training undergraduate students was a new concept to the majority of CRP Task Force members, so we relied heavily on the expertise of our undergraduate program directors to understand student needs when considering how best to deliver the curriculum. Two key points guided decision-making of

certificate educational methods: undergraduate students are often limited in time and the number of credits they can devote to non-major curriculum requirements, and although the AHC is less than 1 mile from UC's main campus, most undergraduates are not physically present on the AHC campus. Requiring students to attend numerous in-person courses on the AHC campus would likely prohibit their participation in the program.

Balancing student needs with the desired level of competency upon program completion, we determined a hybrid program was optimal. Two experiential learning courses were incorporated into the curriculum: a paid work experience course where students attend a weekly, 2.5 h evening seminar and work as a patient care team member at the UCMC approximately 12 h per week over one semester, and a second research experience where students work in a clinical and translational research unit at UC or CCHMC over the course of a semester while also participating in an online weekly seminar. To balance these in-person requirements with more flexibly scheduled courses, the remaining two required courses will be offered online.

Two national professional societies offer CRP credentialing: the Society of Clinical Research Associates (SOCRA) and the Association of Clinical Research Professionals (ACRP). Although the certificate will not be credentialed through SOCRA or ACRP, we plan to explore that possibility post-implementation. Both SOCRA and ACRP accept some form of CRP-related coursework as part of their credentialing process (ACRP, 2023; SOCRA, 2023). Students will be provided with certification information as part of the program as well, and they may choose to pursue CRP certification after graduation. The undergraduate certificate curriculum should help students move toward certification if desired and allow them to choose the credentialing society that best meets their needs.

5.5 Curriculum implementation and curriculum evaluation/improvement

We are currently in steps five to six of the curriculum development process, with most of the work framed around the formal approval and implementation process required by our institution. New certificate program proposals undergo a multi-step internal review process using a proposal template that includes many of the components addressed above, in addition to a financial plan to support the program. We determined minimum admission criteria: must be an undergraduate enrolled at UC, minimum 2.5 grade point average, must include a personal statement describing educational interests and career goals, and must include one letter of support from a faculty member or professional manager. We identified a program director and a program coordinator to manage administrative tasks and advise students, as well as core faculty for the new courses, supporting their development of syllabi. We collaborated with the Office of Undergraduate Education within the College of Medicine to determine what baseline administrative support they offer, such as course ordering and course evaluation. We also developed an evaluation plan to supplement basic course evaluations; it includes an annual student focus group and alumni survey to evaluate learner satisfaction and career outcomes, identifying areas of strength and improvement.

6 Discussion, acknowledgement of limitations, and lessons learned

The six-step curriculum development process achieved several critical goals as we sought to establish an undergraduate training program in CTS. The results of our needs assessment not only supported anecdotal evidence we had from informal exchanges with principal investigators and clinical research directors, but also uncovered important new information we had not previously considered, particularly related to the national landscape (e.g., typical minimum educational requirements for an entry-level job and income trends). Steps one to five allowed us to engage with key stakeholders in meaningful ways, guiding information-gathering and decision-making in order to design the best possible program using national competencies while also leveraging institutional strengths and addressing the unique needs of our local student population.

This project had several limitations. We have not completed the final two steps of the process: implementation and evaluation. The major work of developing the curriculum is accomplished, however, and we anticipate our program proposal will be approved in 2024, with a soft launch of the new program shortly after. A second limitation is the informal way in which we collected qualitative data from stakeholders in needs assessment. We kept meeting notes in this early phase, not recording or transcribing what was said in order to allow for more careful review. We mitigated this limitation by continuing to engage stakeholders throughout, sharing results and obtaining their feedback as the curriculum came together. Future work following the process outlined above would benefit from formalized data collection and analysis procedures so that they may be reported more fully and replicated when desired.

Our CRP Task Force learned several lessons during the development process, which we wish to present here for others working in CTS education. The first is the importance of identifying key stakeholders and working to build bridges and relationships early in the process. Continuous engagement with a diverse group of stakeholders—spanning content experts working in the CTS field, educators knowledgeable about institutional policies and undergraduate student needs, and curriculum development and evaluation experts familiar with CTS workforce development—benefited us throughout the process, helping to identify the right individuals with whom to confer so that we avoided potential missteps. A second lesson learned is to leverage existing resources wherever possible, particularly at large academic institutions where infrastructure to support new training and programming is already in place. Our capacity may have been limited by the grant funding we rely upon to do our work but combining our grant-funded efforts with the vast resources available at our institution expanded our capability far beyond the grant-specific portion. A final suggestion to others pursuing this type of project is not to become too attached to particular plans or ideas early in the process. In our experience, plans shifted regularly

throughout each step and an unwillingness to change course or adapt to new information would have hindered progress.

The curriculum development process described by Schneiderhan, Guetterman and Dobson (2019) and followed in the study presented proved an effective framework to develop a new undergraduate certificate program in CTS. It provided a systematic approach to a potentially daunting task, breaking it down into manageable components. Following the process allowed for regular stakeholder engagement and provided a clear path to completion, generating enthusiasm for the positive impact this undergraduate certificate may have on our local CTS workforce.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary material, further inquiries can be directed to the corresponding author.

Author contributions

JK: Writing–original draft, Writing–review and editing. MM: Writing–review and editing. AM: Writing–review and editing. PR: Writing–review and editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

References

2022/23 Clinical Research Organization Insights Report, 2023 2022/23 Clinical Research Organization Insights Report (2023). *Managing talent and Pay in a competitive market and volatile Economy*. Virginia, United States BDO USA. Available at: https://www.bdo.com/getmedia/a6fb62d9-36f2-46d9-a053-deeffc84ca30/TAX_GES_2022-2023-BDO-CRO-Insights-Report.pdf?ext=.pdf (Accessed: October 20, 2023).

2023 NSI National Health Care Retention & RN Staffing Report, 2023 2023 NSI National Health Care Retention & RN Staffing Report (2023). Nursing solutions, inc. Available at: https://www.nsinursingsolutions.com/Documents/Library/NSI_National_Health_Care_Retention_Report.pdf (Accessed October 20, 2023).

Acrp, (2023). CCRC certification. Available at: https://acrpnet.org/certification/crc-certification/ (Accessed: October 20, 2023).

Adedokun, O., Zhang, D., Parker, L., Bessenbacher, A., Childress, A., and Burgess, W. (2012). Understanding how undergraduate research experiences influence student aspirations for research careers and graduate education. *J. Coll. Sci. Teach.* 42 (1), 82–90.

Avila, A. H., Weixelbaum, J. H., and Compton, W. M. (2022). The national institute on drug abuse summer research internship program: building a diverse national scientific workforce. *Neuropsychopharmacology* 47 (13), 2184–2188. doi:10.1038/s41386-022-01377-3

Black, M. L., Curran, M. C., Golshan, S., Daly, R., Depp, C., Kelly, C., et al. (2013). Summer research training for medical students: impact on research self-efficacy. *Clin. Transl. Sci.* 6 (6), 487–489. doi:10.1111/cts.12062

Blackard, J. T., Knapke, J. M., Ryan, P. H., Schuckman, S., Veevers, J., Hardie, W. D., et al. (2022). *Research 101:* an online course introducing medical students to research. *J. Clin. Transl. Sci.* 6 (1), e102. doi:10.1017/cts.2022.435

Blackard, J. T., Knapke, J. M., Schuckman, S., Veevers, J., Hardie, W. D., and Ryan, P. H. (2023). Introducing trainees to research using an online, asynchronous course. *J. Clin. Transl. Sci.* 7 (1), e155. doi:10.1017/cts.2023.579

Bloom, B. (1956). *Taxonomy of educational objectives, handbook I: the cognitive domain*. 2nd edn. New York: David McKay Co Inc.

Corson, T. W., Hawkins, S. M., Sanders, E., Byram, J., Cruz, L. A., Olson, J., et al. (2021). Building a virtual summer research experience in cancer for high school and early undergraduate students: lessons from the COVID-19 pandemic. *BMC Med. Educ.* 21 (1), 422. doi:10.1186/s12909-021-02861-y

Feldman, A. M. (2015). Incorporating clinical and translational science into the undergraduate medical education curriculum. *Clin. Transl. Sci.* 8 (4), 267. doi:10.1111/cts.12333

Freel, S. A., Snyder, D. C., Bastarache, K., Jones, C. T., Marchant, M. B., Rowley, L. A., et al. (2023). Now is the time to fix the clinical research workforce crisis. *Clin. Trials* 20, 457–462. doi:10.1177/17407745231177885

Ghee, M., Keels, M., Collins, D., Neal-Spence, C., and Baker, E. (2016). Fine-tuning summer research programs to promote underrepresented students' persistence in the STEM pathway. *CBE—Life Sci. Educ. Marsteller* 15 (3), ar28. doi:10.1187/cbe.16-01-0046

Howell, L. P., Wahl, S., Ryan, J., Gandour-Edwards, R., and Green, R. (2019). Educational and career development outcomes among undergraduate summer research interns: a pipeline for pathology, laboratory medicine, and biomedical science. *Acad. Pathol.* 6, 2374289519893105. doi:10.1177/2374289519893105

Hunter, A.-B., Laursen, S., and Seymour, E. (2007). Becoming a scientist: the role of undergraduate research in students' cognitive, personal, and professional development. *Sci. Educ.* 91 (1), 36–74. doi:10.1002/sce.20173

James, L., Venable, T., Caro, A., Moran, J. H., Nesmith, C., Gannon, M. A., et al. (2023). Development of a clinical and translational research curriculum for undergraduate students. *J. Clin. Transl. Sci.* 7 (1), e118. doi:10.1017/cts.2023.532

JTF Task Force (2017). The Joint task force for clinical trial competency and the harmonized core competency framework for the clinical research professional. Available at: https://mrctcenter.org/clinical-trial-competency/framework/domains/ (Accessed August 15, 2023).

Knapke, J. M., Jenkerson, M., Tsao, P., Freel, S., Fritter, J., Helm, S. L., et al. (2022). Academic medical center clinical research professional workforce: Part 2 – issues in staff onboarding and professional development. *J. Clin. Transl. Sci.* 6 (1), e81. doi:10.1017/cts.2022.412

Knapke, J. M., Snyder, D. C., Carter, K., Fitz-Gerald, M. B., Fritter, J., Kolb, H. R., et al. (2022). Issues for recruitment and retention of clinical research professionals at academic medical centers: Part 1 – collaborative conversations Un-Meeting findings. *J. Clin. Transl. Sci.* 6 (1), e80. doi:10.1017/cts.2022.411

Kolber, B. J., Janjic, J. M., Pollock, J. A., and Tidgewell, K. J. (2016). Summer undergraduate research: a new pipeline for pain clinical practice and research. *BMC Med. Educ.* 16 (1), 135. doi:10.1186/s12909-016-0648-7

Lemacks, J. L., Greer, T., Aras, S., Iverson, C., Willis, D., Duplantis, T., et al. (2022). Mississippi INBRE Outreach Scholars program: adapting a summer scholars program to the virtual world amidst the COVID-19 pandemic. *Adv. Physiology Educ.* 46 (3), 472–480. doi:10.1152/advan.00026.2021

Lightcast - Labor Market Analytics (2023). *Lightcast*. Available at: https://www.lightcast.io (Accessed: August 22, 2023).

Prince, L. Y., Williams, T. B., Allen, A. R., McGehee, R. E., and Thomas, B. R. (2023). Outcomes of the UAMS summer undergraduate research program to increase diversity in research and health professions. *Adv Physiology Educ.* 47 (1), 20–25. doi:10.1152/advan.00201.2022

Samuels, M. H., Hommeyer, E., Booty, B., Frost, K., and Morris, C. (2023). Impact of the COVID-19 pandemic on CTSA clinical research centers over 2 years. *J. Clin. Transl. Sci.* 7 (1), e116. doi:10.1017/cts.2023.543

Schneiderhan, J., Guetterman, T. C., and Dobson, M. L. (2019). Curriculum development: a how to primer. *Fam. Med. Community Health* 7, e000046. doi:10.1136/fmch-2018-000046

Seymour, E., Hunter, A. B., Laursen, S. L., and DeAntoni, T. (2004). Establishing the benefits of research experiences for undergraduates in the sciences: first findings from a three-year study. *Sci. Educ.* 88 (4), 493–534. doi:10.1002/sce.10131

Smalley, K. B., and Warren, J. C. (2020). Disparities elimination summer research experience (DESRE): an intensive summer research training program to promote diversity in the biomedical research workforce. *Ethn. Dis.* 30 (1), 47–54. doi:10.18865/ed.30.1.47

SOCRA (2023). *Certification: candidate eligibility*. Available at: https://www.socra.org/certification/ccrp-certification-exam/candidate-eligibility/ (Accessed: October 20, 2023).

Sonstein, S. A, Seltzer, J., Li, R., Silva, H., Jones, C. T., and Daemen, E. (2014). Moving from compliance to competency: a harmonized core competency framework for the clinical research professional. *Clin. Res.* 28 (3), 17–23. doi:10.14524/CR-14-00002R1.1

Sonstein, S. A., Namenek Brouwer, R. J., Gluck, W., Robert Kolb, H., Aldinger, C., Bierer, B. E., et al. (2020). Leveling the Joint task force core competencies for clinical research professionals. *Ther. Innovation Regul. Sci.* 54 (1), 1–20. doi:10.1007/s43441-019-00024-2

Stroo, M., Asfaw, K., Deeter, C., Freel, S. A., Brouwer, R. J. N., Hames, B., et al. (2020). Impact of implementing a competency-based job framework for clinical research professionals on employee turnover. *J. Clin. Transl. Sci.* 4 (4), 331–335. doi:10.1017/cts.2020.22

The Core Competencies for Entering Medical Students (2023). *Association of American medical Colleges*. Washington, D.C. Available at: https://students-residents.aamc.org/applying-medical-school/article/core-competencies.

Yaffe, K., Bender, C., and Sechrest, L. (2014). How does undergraduate research experience impact career trajectories and level of career satisfaction: a comparative survey. *J. Coll. Sci. Teach.* 044, 25–33. doi:10.2505/4/jcst14_044_01_25

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EDITED BY
Hazel Ann Smith,
Staffordshire University, United Kingdom

REVIEWED BY
Marissa Stroo,
Duke University, United States
Kimberly McCall,
University of Alabama at Birmingham, United States
Carolynn Thomas Jones,
The Ohio State University, United States

*CORRESPONDENCE
Amin Yakubov,
amin.yakubov@nyulangone.org
James Holahan,
james.holahan@nyulangone.org

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The development of a clinical research educational training for community health workers using the joint task force for clinical trial competency framework

Amin Yakubov[1,2]*, Dina Pimenova[1], Alzahraa Ahmed[1], Romelia Corvacho[1], Joanna Madigan[1], Jay Naik[1], Chen Lyu[1], Anita McFarlane[1], Victoria Foster[1], Megan Haseltine[1], Alexandr Trifonov[1], Ivette Cabrera[1], Clarissa Rios[1], Rachel Gross[1], Melanie Jay[1], Aaron Lord[1], Gabrielle Gold-von Simson[1,2], Brita Roy[1], Amy Freeman[1], Nadia Islam[1,2] and James Holahan[1,2]*

[1]Langone Medical Center, New York University, New York, NY, United States, [2]NYU Clinical and Translational Science Institute, New York, NY, United States

Introduction: The NYU Clinical & Translational Science Institute, in collaboration with a number of community-engaged initiatives, developed a training for community health workers (CHWs) to enhance health literacy about clinical research. This innovative research training provides CHWs with a basic level of competency in clinical research to convey the importance of research to communities and better advocate for their health needs. CHWs are an underutilized resource to engage diverse populations in clinical research. The training also addresses the need to expand and diversify the clinical research workforce—integrating CHWs into research teams and connecting underserved populations with research opportunities to enhance quality of care.

Methods: Structured individual interviews and focus group sessions were held with CHWs as well as clinical research faculty and staff to identify knowledge gaps in clinical research and identify best practices for educating community members on research. Using the Joint Task Force (JTF) for Clinical Trial Competency framework, an online course was developed consisting of 28 modules offered asynchronously for internal and external audiences. Topics include the fundamentals of clinical research, scientific concepts and research design, research ethics, study management, clinical study operations, communications, and teamwork, as well as the importance of diversity and equity in research and the barriers to participation.

Results: Learning was evaluated using multiple choice questions after each module to ensure the fundamental level of knowledge was obtained. A separate survey, completed at the conclusion of the course, evaluated the quality of training.

Discussion: The course aims to enhance the knowledge and skills of CHWs to help promote greater understanding of clinical research within the communities they serve, including the risks and benefits of clinical research and opportunities for participation. As members of the research team, community stakeholders can help

design interventions tailored to the unique needs, culture, and context of their communities. In addition, this research training equips trainees with skills to engage the community actively, involving them in the research process and ensuring community priorities are represented in research through more community engaged processes.

KEYWORDS

community health worker (CHW), community centered research, clinical research education, workforce development, diversity in research, clinical research

Introduction

Community Health Worker (CHW) is an umbrella term for an array of health practitioners who operate under various titles globally and whose overarching mission is to serve and engage the needs of culturally distinct communities toward improving health outcomes. Titles include: CHW, patient navigator, promotora, outreach specialist, community advocate, and community health educator, among others (CACHW.org, 2023). CHWs are essential frontline public health professionals who leverage their intimate understanding of local communities and often serve as trusted intermediaries between the members of those communities and both medical and social service systems. Equipped with an understanding of their community's cultural characteristics, behaviors, and attitudes, CHWs are uniquely positioned to explain and navigate individuals through complex health systems and to communicate individual, family, and community-level needs to service providers to improve access to, and quality of, care. Through this integral "bridging" work, CHWs enhance the self-sufficiency and knowledge of community members and the community itself, strengthen relationships with service delivery agencies, and influence attitudes and practices through education, informal counseling, social support, and advocacy (Jackson and Gracia, 2014; Olaniran et al., 2017; American Public Health Association, 2019).

The key roles CHWs fulfill within the health service delivery landscape is demonstrated by their increased recognition within federal health-related legislation and strategic planning. In 2009, the US Bureau of Labor Statistics identified CHW as a Standard Occupational Classification, and the Department of Health and Human Services included CHWs within its five overall goals for reducing health disparities (Koh et al., 2011; Malcarney et al., 2017). The Patient Protection and Affordable Care Act (Public Law 111–148) and Health Care and Education Reconciliation Act of 2010 (Public Law 111–152) further encourages CHW integration into healthcare settings (Public Law 111-148 111th Congress Act, 2010; Public Law 111-152 111th Congress Act, 2010; Islam et al., 2015; Rodriguez, 2022). The Centers for Disease Control and Prevention funds CHW projects in multiple therapeutic areas, including heart disease, diabetes, and COVID-19 and in 2022 S.3479—Building a Sustainable Workforce for Healthy Communities Act was introduced in the Senate, a bill reauthorizing and revising a CDC grant program to develop and/or expand CHW programs (Congress, 2021; Rodriguez, 2022). Despite an increase in national recognition, CHWs still lack standardized certification and training requirements that are consistent across states. The trainings often focus on CHW core competencies such as communication, individual and community assessment, and outreach skills, but do not include information on clinical research (Rosenthal et al., 2014-2022). For example, at NYU Langone Health (NYULH), the CHW training programs focus on various health areas, including Alzheimer's Disease, behavioral health, diabetes, epilepsy, substance use, cancer, HIV, heart disease, hypertension, and social determinants of health (SDOH) (e.g., housing, food security, and federal benefits). Job preparedness for these programs is provided via CHW core competency training developed and promoted by community colleges and community-based organizations (CBOs), which is supplemented by project-specific training unique to the role of the CHW.

CHWs focus primarily on service delivery and health promotion but their contribution to research spans recruitment, outreach, survey implementation and administration, focus group facilitation, SDOH support, and disseminating data and results to communities in ways tailored to them. Despite "Evaluation and Research Skills" being a recognized CHW Core Competency by Rosenthal et al. (Rosenthal et al., 2014-2022), many CHWs lack training in the fundamentals of research, including scientific concepts, study design and methodology, biomedical ethics, and barriers to recruitment and retention of research participants. It is particularly important for CHWs who work with racial and ethnic minorities and immigrant populations to be knowledgeable of these barriers, which include logistical concerns, lack of insurance coverage, and historical mistrust of research and the healthcare system due to past exploitation. Involving CHWs in the research process can be one way of overcoming these barriers (Killough et al., 2023). CHWs can provide social support, build trust, and act as intermediaries between underrepresented communities and researchers to ensure that study materials, such as recruitment methods, are actionable for community members. For example, CHWs can navigate complex healthcare systems, provide language support, engage in health education, and reduce barriers to care by addressing financial toxicities—such as commuting expenses, child and family care, unemployment, and food insecurity—through referrals, continuous follow-up, and coordination with the appropriate entities. As the CHW profession evolves, these health professionals will play a pivotal role in collecting and reporting information related to the health status of community members, which is imperative for research design, implementation, and recruitment (Olaniran et al., 2017). This development will also address calls to open new career paths for CHWs in various research fields and expand the CHW workforce (10; 14).

A well-trained community-based workforce in research is better prepared to engage the community actively while enhancing their knowledge of research and participation in trials. In addition, as we

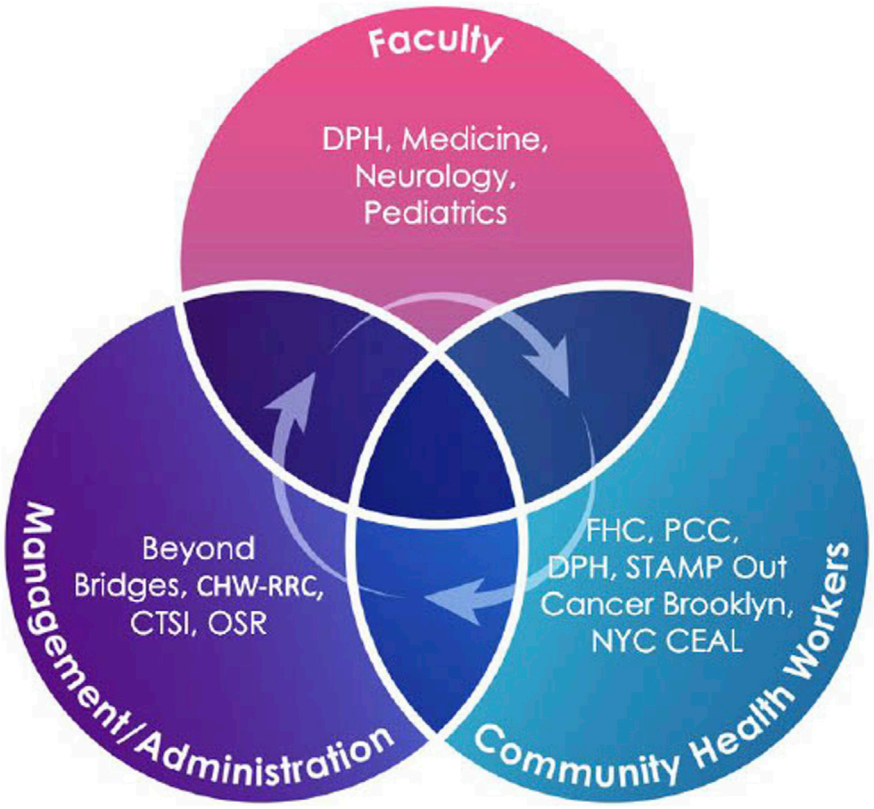

FIGURE 1
CHW Research Training Stakeholders. Stakeholders involved in the development of the training: the NYU Clinical & Translational Science Institute (CTSI), the NYU Community Health Worker Research & Resource Center (CHW-RRC), the Beyond Bridges Initiative, the Beatrice W. Welters Breast Health Outreach & Navigation Program, STAMP Out Cancer Brooklyn, the NY Community Engagement Alliance (NYCEAL) network, and departments of Neurology, Pediatrics, Medicine, and Population Health (DPH).

recruit more diverse participants into clinical research, it will be imperative to have a community-centered, multi-lingual, and diverse, research-trained workforce that reflects the population (Murphy et al., 2023). For example, CHWs who understand their clients' health conditions are able to navigate them to eligible therapeutic clinical trials. By understanding the availability of research options, CHWs can lower barriers to recruitment including by dispelling myths and misconceptions about research and reducing social and economic barriers. A research-knowledgeable workforce of CHWs can engage simultaneously with the community and researchers to help promote, study, and address the needs of the community, ultimately helping improve the health of their clients and communities (Killough et al., 2023). This contributes to translational science by ensuring that innovations progress not only unidirectionally from the bench to the bedside and community, but also cyclically back from the community again (Plasencia et al., 2023). For example, CHWs can help inform researchers on the ongoing state of their communities, such as trends of cancer diagnoses, environmental exposures, or social needs impacting health, thus creating an ongoing feedback loop of the health and social needs of the community (Plasencia et al., 2023). Lastly, as the COVID-19 pandemic has demonstrated, research demand can outpace the supply of clinical research professionals at times of public health emergencies (Freel et al., 2023). Expanding the capacity of the research workforce is essential for preparing for future outbreaks/emergencies and spikes in diseases among the population. CHWs can be a research-ready, highly-skilled, and trained workforce that can inform and respond to emerging disasters within their communities.

Methods

The Community Health Worker Research Training is an intra-institutional and multi-departmental initiative to train CHWs within the NYULH health system and nationwide. This initiative involved input and support from the NYU Clinical & Translational Science Institute (CTSI), the NYU Community Health Worker Research & Resource Center (CHW-RRC), the Beyond Bridges Initiative, the Beatrice W. Welters Breast Health Outreach & Navigation Program, STAMP Out Cancer Brooklyn, the New York Community Engagement Alliance (NYCEAL), NYU-CUNY Prevention Research Center (NYU-CUNY PRC), and the Office of Science and Research (OSR). Members of the CTSI Community Engagement and Population Health Research (CEPHR) group, along with NYU Grossman School of Medicine faculty and research staff, initially identified the need for a research training in response to a gap in culturally competent trainings for CHWs in

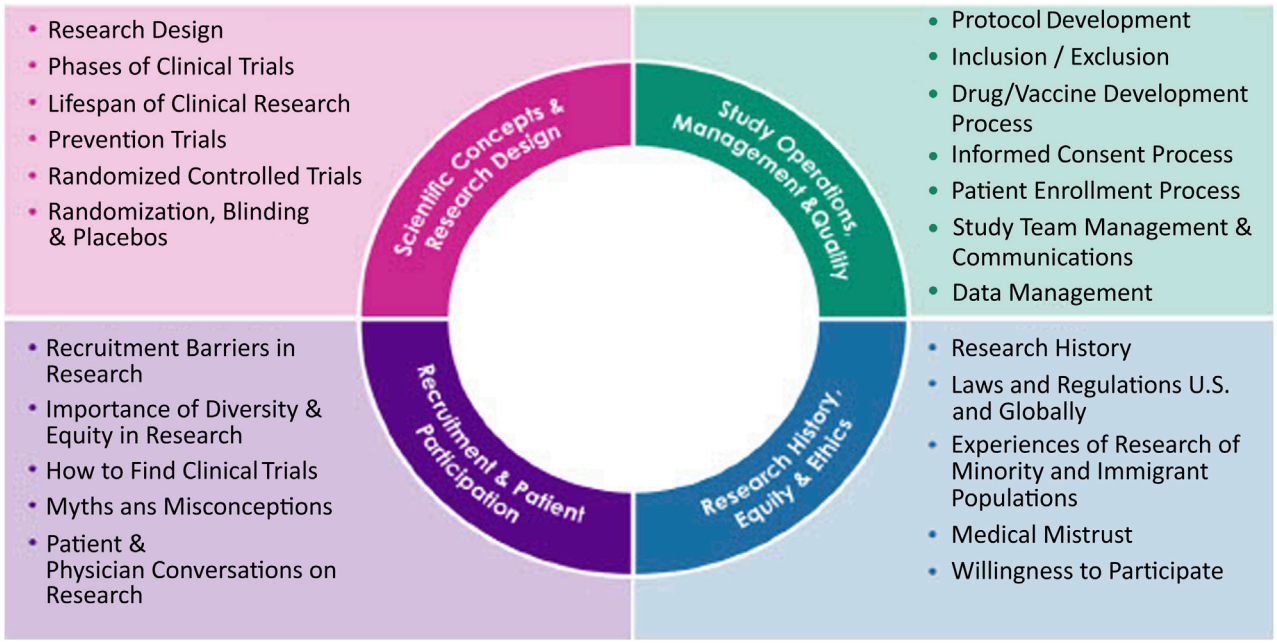

FIGURE 2
CHW Research Training Competencies. Research training competencies across 28 different modules on scientific concepts and research design, study operations, study management and quality, recruitment and patient participations, and research history, equity, and ethics. Seminar 1 includes the scientific concepts and research design, study operations, management and quality. Seminar 2 includes recruitment and patient participation and research history, equity and ethics.

the fundamentals of clinical research. Plasencia et al. recommend that CHW trainings are codeveloped with the participation of CHWs to leverage their in-depth knowledge of marginalized communities (Plasencia et al., 2023). This curriculum was codeveloped through a collaborative partnership with CHWs to ensure the training was informed by both research and community input. Feedback was obtained via individual interviews and group sessions with representatives from the Departments of Population Health, Medicine, Pediatrics, and Neurology, as well as the Perlmutter Cancer Center and the Family Health Centers (Figure 1). These feedback sessions with expert stakeholders identified several gaps in clinical research knowledge, including understanding research foundations and research processes, the drug and vaccine development process, identifying research opportunities, and experiences of research in minority and immigrant populations. Best practices were also identified by those with experience developing CHW training and education, who recommended that trainings be offered virtually, on-demand, and at no cost, and that they be easily accessible to all CHWs nationally.

The Joint Task Force (JTF) for Clinical Trial Competency was used as a framework for developing the curriculum, as it outlines a comprehensive set of competencies for clinical research professionals used by organizations worldwide (Sonstein and Jones, 2018). The JTF competencies include 47 leveled competency statements across eight domains that are expressed at a Basic, Skilled, and Advanced level. For the purpose of this training, we sought to convey a basic level of competency to promote a fundamental understanding of clinical research. Modules were selected based on knowledge gaps identified in interviewing faculty, staff, and CHWs. Examples of the competency-based training modules include scientific concepts and research design, ethical participation and safety considerations, development and regulation of investigational products, clinical study operations and good clinical practice, study and site management, data management and informatics, leadership and professionalism, and communications and teamwork. Given the unique role of CHWs, we included additional competencies to ensure that the experiences of research on Latine, Middle East and North Africa (MENA), Former Soviet Union (FSU), and East Asian populations were well represented. These include the history and ethics of biomedical and clinical research broadly and in particular regions such as Central and Latin America, MENA, FSU, and East Asia.

By leveraging the JTF core competency framework, we created a research training that is tailored to CHWs and takes into consideration the populations we serve in New York City. The course includes 28 online, asynchronous modules grouped into 2 seminars. Seminar 1 (Foundations of Research) includes 20 modules while Seminar 2 (Research Ethics and the Importance of Diversity and Equity in Research) includes 8 modules (Figure 2). Each module is approximately 5 min long with voiceover narration provided by CHWs to represent a variety of voices and accents that reflect the intended target audience. The course is offered asynchronously for internal audiences via the NYULH FOCUS platform and external audiences via the RISE web-based platform. Trainees are required to complete multiple-choice quizzes after each module and answer all questions correctly in order to proceed to the next module, with the ability to retake quizzes as needed. Each module consisted of 1–4 questions assessing knowledge of the material presented. A separate exit survey was

TABLE 1 Post-exit survey participant responses.

Question	# (%)
Primary role	
CHW	197 (79.76)
Patient Navigator	32 (12.96)
Other	18 (7.29)
Last time you took a research training	
This was my first time	79 (31.98)
In the past 12 months	72 (29.15)
Between 1–5 years ago	93 (37.65)
More than 5 years ago	3 (1.21)
Scale question 1: How well do you understand the basic concepts of clinical research? Please rate on a scale of 0–5, with 0 being "not at all" and 5 being "very well"?	
0	6 (2.34)
1	7 (2.83)
2	19 (7.69)
3	67 (27.13)
4	78 (31.58)
5	70 (28.34)
Scale question 2: How well do you understand the history of clinical research? Please rate on a scale of 0–5, with 0 being "not at all" and 5 being "very well"?	
0	21 (8.5)
1	7 (2.83)
2	18 (7.29)
3	52 (21.05)
4	72 (29.15)
5	77 (31.17)
Scale question 3: How confident are you in applying the knowledge gained to your work? Please rate on a scale of 0–5, with 0 being "not at all confident" and 5 being "very confident?	
0	8 (3.24)
1	4 (1.62)
2	11 (4.45)
3	61 (24.70)
4	83 (33.60)
5	80 (32.39)
Recommend training to others	
Yes	247 (100)
No	0 (0)
Training provide practical skills	
Yes	245 (99.19)
No	2 (0.81)
Overall quality	
Poor	1 (0.4)
Average	116 (46.96)
Neutral	108 (43.72)
Good	22 (8.91)
Excellent	0 (0)
Top 5 most valuable modules (Seminar 1)	
Module 2 (Differences between clinical research and clinical trials)	151 (61.13)
Module 8 (What do we learn from clinical trials?)	126 (51.01)
Module 5 (Phases/lifespan of clinical trials)	124 (50.2)
Module 3 (Types of study designs)	120 (48.58)
Module 6 (The drug and vaccine development process step-by-step guide)	118 (47.77)
Top 5 most valuable modules (Seminar 2)	
Module 2 (Experiences of Research on Minority and Immigrant Populations, Medical Mistrust & Willingness to Participate (WTP) in Research)	159 (64.37)
Module 5 (Importance of diversity in clinical research)	146 (59.11)
Module 4 (Recruitment in clinical trials)	128 (51.82)
Module 3 (Why do clinical trials take so long? Trial enrollment process and barriers)	107 (43.32)
Module 1 (Barriers to research and historical events)	106 (42.91)

The participant responses summarized using descriptive statistics in counts (%) for categorical variables.

developed by research team members with experience in evaluation and survey design to gather feedback and evaluate perceptions of knowledge uptake, quality of training, and module preferences. This

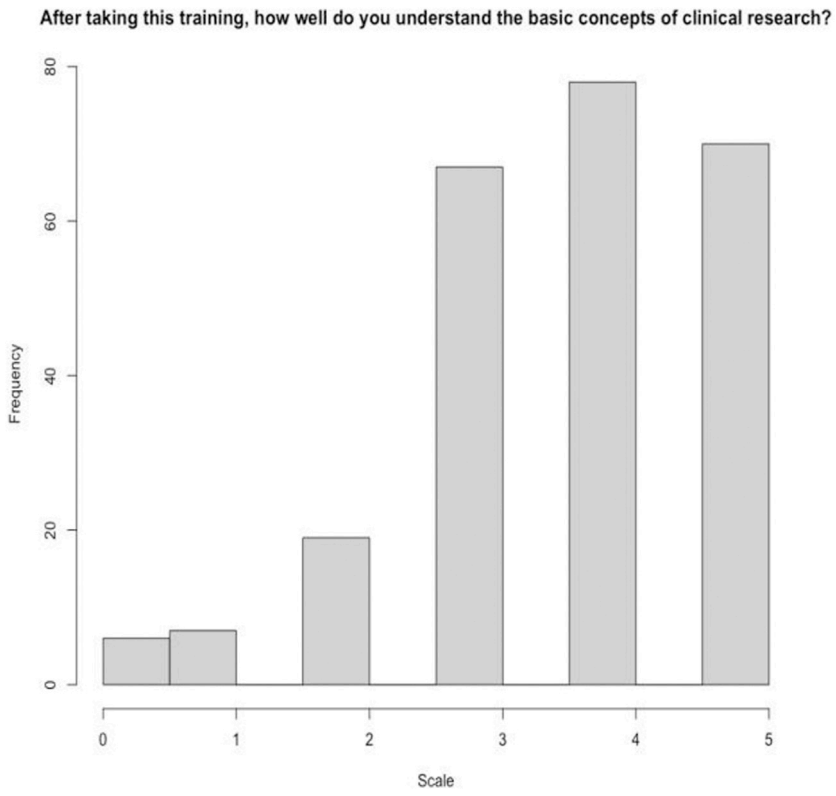

FIGURE 3
Understanding basic concepts of clinical research (seminar 1) (score 0–5).

survey included multiple-choice, Likert scales, and free text responses. Open-ended text was coded into positive and negative responses and then further grouped into categories (e.g., applicability of training, relevance of content, quality of quiz questions). Participants who completed the exit survey were offered a $30 Amazon gift card for completion. The training was advertised to NYULH-affiliated CHWs through various mechanisms, including targeted e-mails and messages, tabling at events, and outreach to the CHW listservs. It was also advertised externally through partner organizations that engage CHWs, such as the CONNECT forum and Center for Community Health Alignment, and presented at the National Association of Community Health Workers (NACHW) Unity Conference in Austin, Texas (2023).

Results

The participant responses were summarized using descriptive statistics in counts (%) for categorical variables. Chi-square test or Fisher's exact test was used whenever appropriate to test the association between participants' understanding of the basic concepts in Seminar 1 and Seminar 2 and individual module preferences. 428 participants accessed the training and of those, 318 completed training modules requiring a 100% score to proceed to the next module. 247 participants completed an optional post-training exit survey. Of those who completed the survey, 197 (80%) identified as CHWs, 32 (13%) identified as patient navigators, and 18 (7%) identified as other (community outreach coordinators, patient liaisons, navigators, social workers, research assistants, and managers). Trainees represented over 197 unique institutions nationwide, including academic medical centers, non-profit organizations, CHW networks, and private companies. When asked if they have completed prior research trainings, 79 (32%) respondents indicated that this was their first research training. Of those that have participated in research trainings in the past, 72 (29%) completed it in the past 12 months, 93 (38%) between 1–5 years ago, and 3 (1.0%) more than 5 years ago (Table 1).

As part of the exit survey, participants were asked to rate how well they understood the concepts presented in each of the seminars on a Likert scale from 0–5, with 0 meaning they did not understand the concepts at all and 5 meaning they understood the concepts very well. 148 (60%) of respondents indicated a 4 or higher on understanding the concepts in Seminar 1, which covered the foundations of clinical research, and 149 (60%) of respondents indicated a 4 or higher on understanding the concepts in Seminar 2, which covered the history of clinical research and the importance of diversity (Figures 3, 4). Participants were also asked to rate how confident they felt applying the training and knowledge to their everyday roles on a Likert scale from 0–5, 0 being not at all confident and 5 being

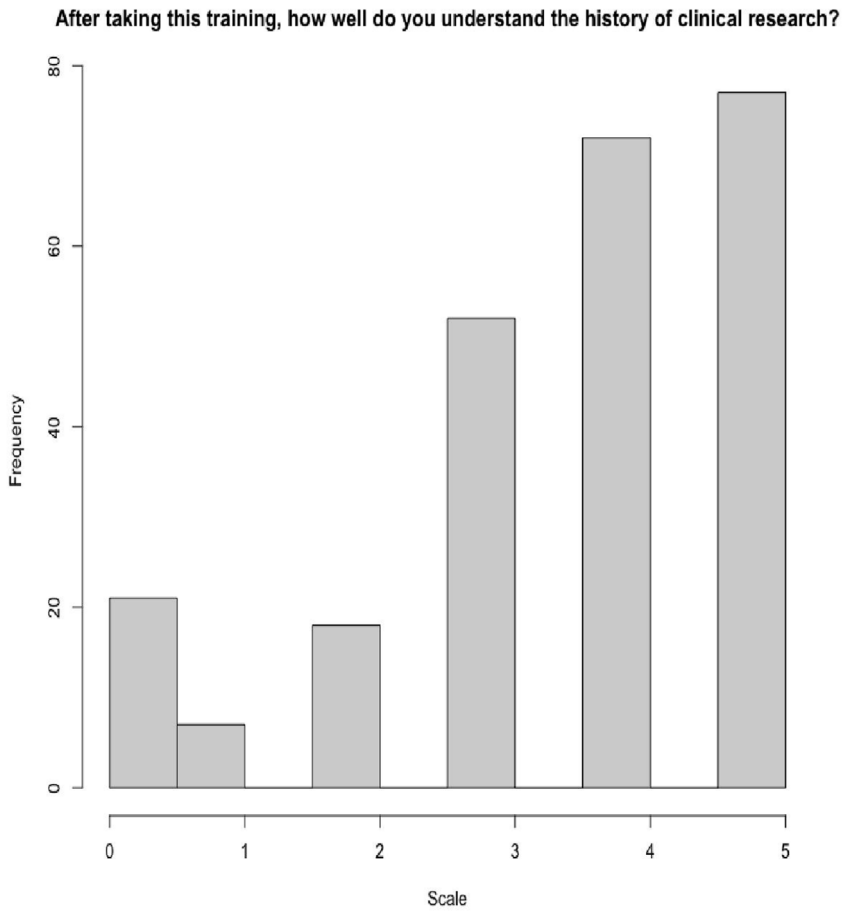

FIGURE 4
Understanding clinical research history and the importance of diversity and equity in research (seminar 2) (score 0–5).

very confident. 224 (91%) indicated a 3 or higher, indicating that they felt moderately confident to very confident. When asked if this training provided practical skills, 245 (99%) indicated favorably. 224 (91%) participants indicated that they found the quality of the training good or excellent and all 247 participants indicated that they would recommend this training to others (Table 1).

Participants were also asked to rate which modules they found most valuable to their overall learning and training experience. Seminar 1 (Foundations of Research) includes 20 modules while Seminar 2 (Research Ethics and the Importance of Diversity and Equity in Research) includes 8 modules (Table 2). The top 5 most valuable trainings in Seminar 1 included topics on the foundations of clinical research, the differences between study designs, protocol development, the drug and vaccine development process, and the importance of having power statistics in research. The top 5 most valuable trainings in Seminar 2 included topics on research history, understanding the influence of research on minority health, the lifespan of clinical trials, the importance of recruitment, and communicating with providers about clinical research. The most desirable trainings in both seminars included topics on the foundations of clinical research and clinical trials, and the understanding of the importance of diversity and equity in clinical research (Table 3).

Lastly, 62 participants provided free text survey responses. Of those, 55 (84%) provided information on the importance of this course and how it fills gaps in knowledge, while 7 (11%) indicated that the quiz questions were too difficult. Free text responses included, “modules were so knowledgeable and helpful,” “as a [CHW] this course helped me a lot to understand the investigator process,” and “quizzes were difficult and tricky.” We also received personal messages from the majority of participants with feedback including, “I had a great time during this training session, even my colleague that was with me couldn’t help but join me,” “the training has revived my professional zeal,” and “the training was awesome and encouraging, this is the first time I feel that I am in the right profession.” When evaluating for understanding by seminar and module, we noted an association between top scored modules and a moderate understanding of the concepts. We noted that there was a significant relationship between the responses for scale question 1 and responses for each of the top most rated modules in seminar 1 (Table 4). Interestingly, of the top 5 rated modules in Seminar 1, modules 3, 5, and 8 were statistically significant in providing a score of 3 or higher in understanding basic concepts of clinical research. Similarly, we noted a statistically significant relationship for scale question 2 and responses for modules 1, 4, and 5 in Seminar 2. Of the top

TABLE 2 Seminars 1 and 2 module topics.

Seminar 1: Research foundations	
Module 0	Introduction to modules
Module 1	Why clinical trials?
Module 2	Differences between clinical research and clinical trials
Module 3	Types of study designs
Module 4	Phases of clinical trials
Module 5	Phases/lifespan of clinical trials
Module 6	The drug and vaccine development process step-by-step guide
Module 7	What is a preventative trial?
Module 8	What do we learn from clinical trials?
Module 9	What is a protocol?
Module 10	How are protocols designed?
Module 11	What are protocol inclusion/exclusion criteria?
Module 12	Importance of having number of participants and power statistics
Module 13	Clinical trial terminology: What is randomization?
Module 14	Randomized controlled trials
Module 15	Clinical trial terminology: What is a placebo and blinding?
Module 16	Clinical trial terminology: What is an informed consent?
Module 17	Why participate in clinical trials?
Module 18	Patient Enrollment Timeline
Module 19	End of study
Seminar 2: Research History and Importance of Diversity and Equity in Research	
Module 1	Barriers to research and historical events
Module 2	Experiences of Research on Minority and Immigrant Populations, Medical Mistrust & Willingness to Participate (WTP) in Research
Module 3	Why do clinical trials take so long? Trial enrollment process and barriers
Module 4	Recruitment in clinical trials
Module 5	Importance of diversity in clinical research
Module 6	How to find and participate in clinical research
Module 7	Myths & Misconceptions
Module 8	Always ask your doctor about clinical research

5 rated modules in Seminar 2, modules 5, 6, and 8 were statistically significant in providing a score of 3 or higher in understanding the history of clinical research (Table 4). Furthermore, 224 (91%) participants indicated that they would apply the knowledge learned to their daily work and recommend the training to others (Table 1).

Discussion

We found that the Community Health Worker Research Training, developed as an equitable partnership between academic researchers and CHWs, enhanced the research knowledge, awareness, and skills of CHWs as evidenced by their improvements in knowledge. CHWs often lack adequate and standardized training in the fundamentals of clinical research and understanding of the importance of increasing diversity and equity in research (George et al., 2021; Plasencia et al., 2023). This educational curriculum aims to address this gap and build CHWs' capacity to serve as champions of clinical research within their communities, which can help promote and address the needs of community members. This training also addresses the gap in the research workforce by potentially expanding its capacity to incorporate CHWs onto research teams. It is crucial that the development of a curriculum build upon current CHW training competencies and take into account the past experiences of CHWs to improve organizational readiness and their seamless integration into healthcare systems (George et al., 2021). We accomplished this goal by leveraging the knowledge of CHWs and other key stakeholders to build upon the competencies and experiences of CHWs while incorporating research specific training. In recent years, there has been a leveling of the competency framework that includes fundamental, skilled, and advanced levels demonstrating increased competencies that occur through experience and career growth (Sonstein et al., 2020). Our CHW training provides a fundamental level of competency in clinical research with the following objectives: 1) Improve understanding of the foundations of clinical research, 2) Improve understanding of the importance of research diversity and equity in clinical research, and 3) Enhance research health literacy for CHWs through culturally appropriate trainings.

Over the course of developing and launching this training, we found that there is a pervasive need for CHWs in New York City and the U.S. broadly to expand their knowledge of clinical research. Murphy et al. identified a similar gap and developed an online course for CHWs on research best practices (Murphy et al., 2023). The training was received positively as both useful and relevant by both English-speaking and Spanish-speaking CHWs, further demonstrating a need for this training. Within the first 5 weeks of launching this training, we were able to engage 428 participants from 197 institutions across the country. Of the 247 survey respondents, one-third reported that it was their first time taking a research training and nearly all (99%) reported that this training provides practical tips and guidelines for CHWs that will be used in their day-to-day roles. These results demonstrate that the curriculum fulfilled an unmet need in CHW training. All respondents stated that they would recommend this training to others and, in fact, many stated that they learned about this training as a referral from a colleague or recommendation from a CHW organization. These findings provide evidence of feasibility, acceptability, and satisfaction which can inform larger-scale roll-out of the training. Although all respondents recommended this training to their colleagues, Seminar 1 was rated more highly than Seminar 2, suggesting that there is a greater need for foundational-level training in clinical research rather than understanding a more holistic and comprehensive research history. In reviewing survey

TABLE 3 Top 5 module preferences by role (seminar 1) and (seminar 2).

Module preferences (seminar 1)		CHW	Navigator	Other
Module 2	Checked	127	11	13
(Differences between clinical research and clinical trials)	Unchecked	70	7	19
Module 8	Checked	101	11	14
(What do we learn from clinical trials?)	Unchecked	96	7	18
Module 5	Checked	92	14	18
(Phases/lifespan of clinical trials)	Unchecked	105	4	14
Module 3	Checked	88	12	20
(Types of study designs)	Unchecked	109	6	12
Module 6	Checked	96	12	10
(The drug and vaccine development process step-by-step guide)	Unchecked	101	6	22
Module Preferences (Seminar 2)		CHW	Navigator	Other
Module 2	Checked	127	14	18
(Experiences of Research on Minority and Immigrant Populations, Medical Mistrust & Willingness to Participate (WTP) in Research)	Unchecked	70	4	14
Module 5	Checked	117	15	14
(Importance of diversity in clinical research)	Unchecked	80	3	18
Module 4	Checked	92	14	22
(Recruitment in clinical trials)	Unchecked	105	4	10
Module 3	Checked	85	10	12
(Why do clinical trials take so long? Trial enrollment process and barriers)	Unchecked	112	8	20
Module 1	Checked	79	13	14
(Barriers to research and historical events)	Unchecked	118	5	18

Top 5 most rated modules by role in seminar 1, including topics on the foundations of clinical research, the differences between study designs, protocol development, the drug and vaccine development process, and the importance of having power statistics in research. Top 5 most rated modules by role in seminar 2, including topics on research history, understanding the influence of research on minority health, the lifespan of clinical trials, the importance of recruitment, and communicating with providers about clinical research.

write-in responses, many also provided suggestions for future training modules, including understanding research barriers in rural health and exploring the myths and misconceptions of research within underserved communities.

In May 2023, the FDA released guidance on decentralized clinical trials, highlighting the importance of engaging the community and recruiting and retaining diverse populations (Silver Spring and MD: Center for Drug Evaluation and Research, 2023). As research protocols become more decentralized, teams will need to become more community-focused to reach historically underserved groups. This requires a rethinking of the research workforce and the framework for how research teams are developed. As Figure 5 demonstrates, future teams will need to be agile and dynamic in their composition. They will require the involvement of a variety of experts, including researchers, nurses, coordinators, pharmacists, and CHWs. Creating such teams with CHWs and the community in mind will enable a bi-directional channel from the community to the research team and back, thus ensuring that the community and its needs are studied and that all patients are provided with equitable access to research opportunities. Given their training to work within community settings and understand the needs of the communities they serve, CHWs will play an increasingly pivotal role in the research workforce in conducting clinical research and delivering interventions. Research-trained CHWs can lead in a variety of tasks, including navigating community members to studies open to enrollment, participating on community advisory boards for research, educating community members on the importance of research, and serving on academic research teams to assist with recruitment and delivery of community-based interventions. As members of the research team, CHWs can take on leadership roles and, with the input of stakeholders, help design interventions tailored to the unique needs, culture, and context of the populations they serve. Focus groups conducted by Killough et al. demonstrated that CHWs have a need for transparency and effective communication from researchers (Killough et al., 2023). To promote research engagement with diverse populations, the study suggests involving CHWs from the beginning of the research process, focusing on collaboration rather than persuading them of the value of research, addressing confidentiality concerns, and prioritizing dissemination of research findings in accessible ways (Killough et al., 2023). This training helps establish a research-ready

TABLE 4 Scale question 1 and 2. "After taking this training, how well do you understand the basic concepts of clinical research? Please rate on a scale of 0–5, with 0 being "not at all" and 5 being "very well") by top 5 preferred modules (seminar 1). "After taking this training, how well do you understand the history of clinical research? Please rate on a scale of 0–5, with 0 being "not at all" and 5 being "very well") by top 5 preferred modules (seminar 2).

Seminar 1 modules		Scale Q1 (foundations of clinical research by module preference)						
		0	1	2	3	4	5	*p*-value[a]
Module 2	Checked	6	7	9	48	36	45	<.001
(Differences between clinical research and clinical trials)	Unchecked	0	0	10	19	42	25	
Module 8	Checked	6	7	12	25	35	41	<.001
(What do we learn from clinical trials?)	Unchecked	0	0	7	42	43	29	
Module 5	Checked	0	0	7	28	39	50	<.001
(Phases/lifespan of clinical trials)	Unchecked	6	7	12	39	39	20	
Module 3	Checked	0	0	7	21	44	48	<.001
(Types of study designs)	Unchecked	6	7	12	46	34	22	
Module 6	Checked	6	7	4	34	26	41	<.001
(The drug and vaccine development process step-by-step guide)	Unchecked	0	0	15	33	52	29	
Seminar 2 Module		Scale Q2 (Research History by Module Preference)						
		0	1	2	3	4	5	*p*-value[a]
Module 2	Checked	10	5	13	37	48	46	0.42
(Experiences of Research on Minority and Immigrant Populations, Medical Mistrust & Willingness to Participate (WTP) in Research)	Unchecked	11	2	5	15	24	31	
Module 5	Checked	21	6	8	31	39	41	0.001
(Importance of diversity in clinical research)	Unchecked	0	1	10	21	33	36	
Module 4	Checked	0	1	3	30	39	55	<0.001
(Recruitment in clinical trials)	Unchecked	21	6	15	22	33	22	
Module 3	Checked	11	3	5	26	24	38	0.18
(Why do clinical trials take so long? Trial enrollment process and barriers)	Unchecked	10	4	13	26	48	39	
Module 1	Checked	0	0	3	27	28	48	<0.001
(Barriers to research and historical events)	Unchecked	21	7	15	25	44	29	

Of the top 5 rated modules in Seminar 1, modules 2, 3, 5, 6, and 8 were statistically significant in providing a score of 3 or higher in understanding those modules. Of the top 5 rated modules in Seminar 2, modules 1, 4, and 5 were statistically significant in providing a score of 3 or higher in understanding those modules.

[a]Chi-square test was used or fisher exact test were used whenever appropriate. Fisher's exact test was used when the cell count was under 5. Significant p values were marked red and defined as $p < 0.05$.

CHW workforce that can be formally incorporated into research teams going forward.

There were several limitations of our training and its evaluation. One limitation is that the training provides only a fundamental level of knowledge related to the JTF core competencies. While it introduces CHWs to research concepts, this level of training may not be sufficient for CHWs to actively participate as members of the research team. Future trainings can build on this curriculum by incorporating competencies at the skilled and advanced levels, as defined by the Joint Task Force for Clinical Trial Competency (Sonstein and Jones, 2018). Further, this training was developed by academic researchers and CHWs at NYU Langone Health, located in New York City, and as such did not include specific modules geared toward rural populations as well as racial or ethnic minorities that do not reside in NYC, which may be important for CHWs in other parts of the country. Although we collected organizational affiliations in our post-exit survey, we did not collect demographic information of all trainees, making it difficult to assess generalizability of findings. It also did not include disease-specific research training required for recruitment of patients into specific disease-focused research protocols. This virtual, asynchronous training provides many advantages, including access, convenience, and a pace-based format, as well as the potential to add future modules depending on need. However, it lacks the ability to solicit real-time feedback and discussion through skill-based exercises and concept exploration that an in-person or synchronous training may offer. As we continue to disseminate the training to institutions nationwide, we will assess what other competencies may be needed and partner with other hubs in the Clinical & Translational Science Award (CTSA) network to build

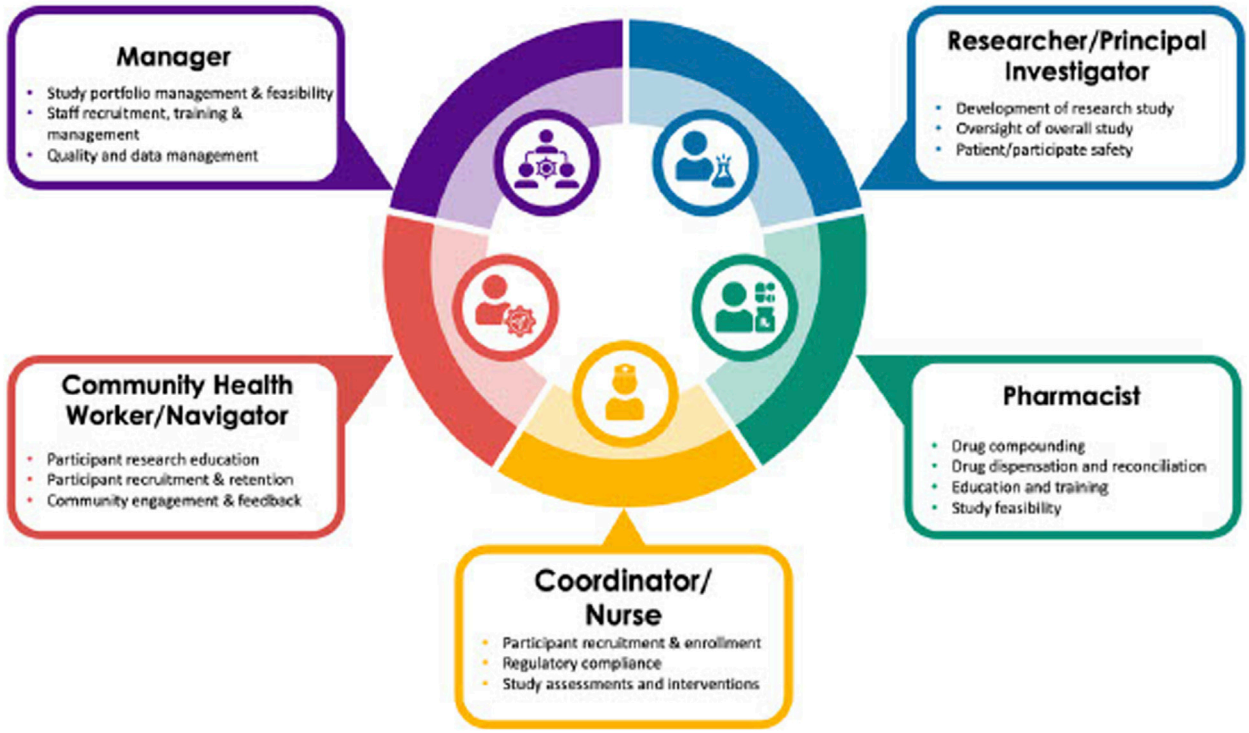

FIGURE 5
Community-Centered Integrated Research Team. Community-centered research teams integrated with principal investigators, pharmacists, managers, coordinators, nurses, and community health workers and research navigators. Creating such teams with CHWs and the community in mind will enable a bi-directional channel from the community to the research team and back, thus ensuring that the community and its needs are studied and that all patients are provided with equitable access to research opportunities.

out additional training modules. Our evaluation also had limitations in that it only assessed knowledge and self-reported skill attainment. Although respondents were required to answer all quiz questions correctly to complete the modules, the FOCUS and RISE training platforms do not provide information on the number of times respondents re-took the quiz to achieve the passing score. Future studies will assess the impact of the training on changes to attitudes and behaviors. The training did not include a pre-survey to establish a baseline level of understanding of clinical research knowledge. We only used a retrospective survey to assess participant change in knowledge and perceptions of the training itself. We will incorporate pre-post test design into the training going forward in order to further evaluate knowledge uptake.

Our immediate plans for the future include dissemination of the training across the CTSA network to ensure that CHWs are trained within those hubs across the country. We will also engage specific academic institutions and community-based organizations (CBOs) which employ CHWs but may not be affiliated with the CTSA network. In addition, based on exit survey responses, we are also developing training materials that can be utilized by CHWs in the field as a reference for frequently asked questions they may encounter from community members when discussing the importance of clinical research. These documents will include links to studies that are open to enrollment, making it easy for CHWs to navigate patients to eligible research opportunities. We will also develop community-facing materials that include basic information about clinical research and opportunities for participation that can be distributed to clients who are engaged in conversations about research. These materials will be vetted by health literacy experts to ensure that all information is presented at an appropriate reading level and context for diverse populations. We also plan to translate these materials into different languages, which will be particularly valuable in cities with large multi-lingual immigrant populations.

As we develop the future research workforce, it is imperative to expose CHWs to different research approaches and promote community-based research (Killough et al., 2023). Schleiff et al. recommend that as research becomes more decentralized and community-focused, CHW training should include skill-based courses, clinical and public health courses, as well as certifications and degrees (Silver Spring and MD: Center for Drug Evaluation and Research, 2023). Further, Olaniran et al., suggest that future training frameworks should focus on competencies or educational qualifications (Olaniran et al., 2017). Clinical research should be formally identified as one of these competencies and incorporated into education and training curriculums for CHWs. Our long-term goals include expanding modules into different topics to meet the needs of diverse populations, incorporating competencies at the skilled and advanced levels, and including disease-specific trainings. In addition, we plan to work with Kingsborough Community College to incorporate the curriculum into their Community Health Worker Training Program, which is a free, credited didactic program carried out in collaboration with the NYU

Family Health Centers, one of the largest federally qualified health center networks in the country. As part of our evaluation strategy, we will longitudinally track participant outcomes to understand whether CHWs who complete the training ultimately pursue roles in clinical research. As part of a larger recruitment effort, we are also exploring the possibility of educating CHWs on protocols that recruit large populations, rare-diseases, or hard-to-reach communities. Forming collaborative cross-disciplinary research teams can be challenging, as individuals with varied training and expertise in different fields must work together to integrate under a single research endeavor. We will take a team science approach when incorporating CHWs onto research teams to ensure that all members' perspectives are considered and the linguistic, cultural, and technical expertise of CHWs are recognized and fully optimized. As we expand our training, we plan to integrate CHWs into the clinical research team through a step-wise approach. CHWs will first be trained to assist with translations/interpretations, patient navigation, reducing financial toxicities, and conducting community education on research protocols. By upskilling with additional trainings, CHWs will ultimately be able to serve in more advanced roles, such as performing clinical assessments, assisting with regulatory submissions, and collecting and entering data. This will provide career advancement and a more well-defined path into a career in research.

The future of the clinical research workforce relies on the strengthening of a community-based workforce of clinical research professionals (CRPs), as it is integral to increasing diversity, decentralizing research, and ensuring that underserved populations have access to research opportunities in advancing clinical research as a care option (CRAACO). Clinical research professionals (CRPs) are the bedrock of clinical research and are comprised of a variety of members of the clinical research workforce beyond the principal investigator (e.g., coordinators, data analysts, nurses, regulatory professionals, project managers) (Freel et al., 2023). CHWs are critical, versatile, and effective members of the healthcare workforce that advocate for communities, connect clients to resources, and improve the quality of care of patients (Landers and Levinson, 2016). Yet they are some of the lowest-paid healthcare professionals with lack of career advancement opportunities, resulting in turnover and attrition (Smithwick et al., 2023). A focus group study conducted by the Center for Community Health Alignment indicated that creating specialized training should be the main factor for CHW career advancement (Smithwick et al., 2023). Future endeavors should create direct pathways for further education, specialized professional development, and integration into clinical spaces and research, giving rise to a nationally trained CHW workforce that can help improve participation rates and be prepared for future pandemics (Lau et al., 2021; Ahmed et al., 2022; Klein et al., 2022; Rodriguez, 2022; Smithwick et al., 2023). CHWs are primed to take on these roles as they are healthcare professionals with the necessary skills in recruitment, patient intervention, data collection, education, and health promotion.

The clinical research profession is in crisis with high staff turnover, lack of quality training, and high barriers to entry that require 2 years of research experience (Stabile et al., 2023). For every person seeking a position in clinical research, there are seven jobs posted with job growth expected at a rate of 9.9% by 2026 (Freel et al., 2023). Furthermore, there is a dearth of diverse, patient-facing healthcare research professionals, which exacerbates efforts to recruit diverse patient populations to research studies. Freel et al., outline key areas for workforce development and regeneration, including clear identity and visibility of CRPs, baseline standards for training and jobs roles, raising awareness, universal competency-based assessments, and increasing diversity in the CRP workforce (Freel et al., 2023). We are attempting to address these imperatives for clinical research workforce regeneration through the CHW research training and workforce development by 1) promoting the profession to other lateral members of the healthcare system, 2) establishing a standard for career development for CHWs entering research roles, 3) raising awareness about CHWs in the research workforce, 4) elevating the standards of research CHWs through module-based training, 5) expanding and defining the research roles for CHWs, and 6) diversifying the workforce by attracting individuals who work within the communities they serve. As we continue to expand our trainings and tools, we hope to reduce the barriers to entry for CHWs to be formally incorporated into the research team. The future of the clinical research workforce relies on research-trained CHWs, as they are integral to our mission of increasing the diversity of research professionals, decentralizing research, and ensuring that underserved populations have access.

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Data availability statement

The raw data supporting the conclusion of this article will be made available by the authors, without undue reservation.

Author contributions

AY: Conceptualization, Data curation, Formal Analysis, Methodology, Project administration, Writing–original draft, Writing–review and editing, Resources, Software, Supervision. DP: Conceptualization, Data curation, Methodology, Project administration, Resources, Software, Writing–original draft, Writing–review and editing. AA: Conceptualization, Data curation, Methodology, Project administration, Resources, Software, Writing–original draft, Writing–review and editing. RC: Conceptualization, Data curation, Methodology, Project administration, Resources, Software, Writing–original draft, Writing–review and editing. JM: Project administration, Resources, Software, Supervision, Writing–review and editing. JN:

Data curation, Project administration, Resources, Software, Writing–review and editing. Chen Lyu: Data curation, Methodology, Validation, Visualization, Writing–review and editing. AM: Conceptualization, Software, Writing–review and editing. VF: Conceptualization, Software, Writing–review and editing. MH: Conceptualization, Software, Writing–review and editing. AT: Conceptualization, Software, Writing–review and editing. IC: Conceptualization, Software, Writing–review and editing. CR: Conceptualization, Software, Writing–review and editing. RG: Supervision, Writing–review and editing. MJ: Supervision, Writing–review and editing. AL: Supervision, Writing–review and editing. GG-v: Supervision, Writing–review and editing. BR: Resources, Supervision, Writing–review and editing. AF: Methodology, Validation, Writing–review and editing. NI: Conceptualization, Formal Analysis, Methodology, Project administration, Resources, Supervision, Writing–review and editing. JH: Conceptualization, Formal Analysis, Funding acquisition, Methodology, Project administration, Resources, Supervision, Validation, Writing–original draft, Writing–review and editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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References

Ahmed, S., Chase, L. E., Wagnild, J., Akhter, N., Sturridge, S., Clarke, A., et al. (2022). Equity in health insurance schemes enrollment in low and middle-income countries: a systematic review and meta-analysis. *Int. J. Equity Health* 21 (1), 21. doi:10.1186/s12939-021-01608-x

American Public Health Association (2019). Community health workers. Available from: https://www.apha.org/apha-communities/member-sections/community-health-workers.

Cachw.org, (2023). CACHW.org. Available from: https://cachw.org/job-titles.

Congress, (2021). Building a sustainable workforce for Healthy communities act. https://www.congress.gov/bill/117th-congress/senate-bill/3479/text.

Freel, S. A., Snyder, D. C., Bastarache, K., Carolynn Thomas, J., Marchant, M. B., Rowley, L. A., et al. (2023). Now is the time to fix the clinical research workforce crisis. *Clin. Trials* 20, 457–462. doi:10.1177/17407745231177885

George, S., Silva, L., Llamas, M., Ramos, I., Joe, J., Mendez, J., et al. (2021). The development of a novel, standards-based core curriculum for community facing, clinic-based community health workers. *Front. Public Health* 9, 663492. doi:10.3389/fpubh.2021.663492

Hohl, S. D., Thompson, B., Krok-Schoen, J. L., Weier, R. C., Martin, M., Bone, L., et al. (2016). Characterizing community health workers on research teams: results from the centers for population health and health disparities. *Am. J. Public Health* 106 (4), 664–670. doi:10.2105/AJPH.2015.302980

Islam, N., Nadkarni, S. K., Zahn, D., Skillman, M., Kwon, S. C., and Trinh-Shevrin, C. (2015). Integrating community health workers within patient protection and affordable care act implementation. *J. Public Health Manag. Pract.* 21 (1), 42–50. doi:10.1097/PHH.0000000000000084

Jackson, C. S., and Gracia, J. N. (2014). Addressing health and health-care disparities: the role of a diverse workforce and the social determinants of health. *Public Health Rep.* 129 (1_Suppl. 2), 57–61. doi:10.1177/00333549141291S211

Killough, C. M., Madaras, A., Phillips, C., Hettema, J., Ceballos, V., Fuentes, J. E., et al. (2023). Community health worker insights on promoting research engagement with diverse populations. *Front. Public Health* 10, 10. doi:10.3389/fpubh.2022.959504

Klein, K. G., Tucker, C. M., Ateyah, W. A., Fullwood, D., Wang, Y., Bosworth, E. T., et al. (2022). Research interests, experience, and training of community health workers: a mixed method approach. *J. Community Health* 47 (6), 949–958. doi:10.1007/s10900-022-01122-3

Koh, H. K., Graham, G., and Glied, S. A. (2011). Reducing racial and ethnic disparities: the action plan from the department of health and human services. *Health Aff.* 30 (10), 1822–1829. doi:10.1377/hlthaff.2011.0673

Landers, S., and Levinson, M. (2016). Mounting evidence of the effectiveness and versatility of community health workers. *Am. J. Public Health* 106 (4), 591–592. doi:10.2105/AJPH.2016.303099

Lau, D., Soucie, J., Willits, J., Scholle, S., Kangovi, S., Garfield, C., et al. (2021). CRITICAL INPUTS FOR SUCCESSFUL COMMUNITY HEALTH WORKER PROGRAMS. Available from: https://www.ncqa.org/wp-content/uploads/2021/11/Critical-Inputs-for-Successful-CHW-Programs_White-Paper_November2021-2.pdf.

Malcarney, M. B., Pittman, P., Quigley, L., Horton, K., and Seiler, N. (2017). The changing roles of community health workers. *Health Serv. Res.* 52, 360–382. doi:10.1111/1475-6773.12657

Murphy, S. L., Jay, G., Samuels, E., Eakin, B., Harper, A. E., Piatt, G., et al. (2023). Evaluation of an online research best practices training for community health workers and promotoras. *J. Clin. Transl. Sci.* 7 (1), e195. doi:10.1017/cts.2023.624

Olaniran, A., Smith, H., Unkels, R., Bar-Zeev, S., and van den Broek, N. (2017). Who is a community health worker? – a systematic review of definitions. *Glob. Health Action* 10 (1), 1272223. doi:10.1080/16549716.2017.1272223

Plasencia, G., Kaalund, K., and Thoumi, A. (2023). Training latinx community health workers as clinical research and health care system navigators. *Am. J. Public Health* 113 (11), 1157–1159. doi:10.2105/AJPH.2023.307418

Public Law 111-148 111th Congress Act (2010). The patient protection and affordable care act. Available from: https://www.congress.gov/111/plaws/publ148/PLAW-111publ148.pdf.

Public Law 111-152 111th Congress Act (2010). Health care and education reconciliation act of 2010. Available from: https://www.govinfo.gov/content/pkg/PLAW-111publ152/pdf/PLAW-111publ152.pdf.

Rodriguez, N. M. (2022). Community health workers in the United States: time to expand a critical workforce. *Am. J. Public Health* 112 (5), 697–699. doi:10.2105/AJPH.2022.306775

Rosenthal, E. L., Menking, P., John J, St., Fox, D., Holderby-Fox, L. R., Redondo, F., et al. (2014-2022). *The community health worker core consensus (C3) project reports and website*. El Paso, TX, USA: Texas Tech University Health Sciences Center El Paso.

Schleiff, M. J., Aitken, I., Alam, M. A., Damtew, Z. A., and Perry, H. B. (2021). Community health workers at the dawn of a new era: 6. Recruitment, training, and continuing education. *Health Res. Policy Syst.* 19 (S3), 113. doi:10.1186/s12961-021-00757-3

Silver Spring, MD : Center for Drug Evaluation and Research (2023). Enhancing the diversity of clinical trial populations: eligibility criteria, enrollment practices, and trial designs - digital Collections - national Library of Medicine. Available from: https://collections.nlm.nih.gov/catalog/nlm:nlmuid-9918249008406676-pdf?_gl=1.

Smithwick, J., Nance, J., Covington-Kolb, S., Rodriguez, A., and Young, M. (2023). Community health workers bring value and deserve to be valued too: key considerations in improving CHW career advancement opportunities. *Front. Public Health* 11, 1036481. doi:10.3389/fpubh.2023.1036481

Sonstein, S. A., and Jones, C. T. (2018). Joint task Force for clinical trial competency and clinical research professional workforce development. *Front. Pharmacol.* 9, 9. doi:10.3389/fphar.2018.01148

Sonstein, S. A., Namenek Brouwer, R. J., Gluck, W., Robert Kolb, H., Aldinger, C., Bierer, B. E., et al. (2020). Leveling the Joint task Force core competencies for clinical research professionals. *Ther. Innovation Regul. Sci.* 54 (1), 1–20. doi:10.1007/s43441-019-00024-2

Stabile, S., Cenna, R., Sinna, V., Veronica, F., Mannozzi, F., Federici, I., et al. (2023). Clinical trial units and clinical research coordinators: a system facing crisis? *AboutOpen* 10, 1–3. doi:10.33393/ao.2023.2508

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EDITED BY
Stephen Sonstein,
Eastern Michigan University,
United States

REVIEWED BY
Honorio Silva,
IFAPP Academy, Inc., United States
Carolynn Thomas Jones,
The Ohio State University, United States
Stephanie Freel,
Duke University, United States

*CORRESPONDENCE
Stephen Sundquist,
ssundquist@oicr.on.ca

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Minding the gaps: assessing and addressing clinical research core competencies across a network of Canadian cancer centres

Stephen Sundquist[1]*, Diana Kato[1], Raisa Chowdhury[1], Christine Samara[2,3,4] and Janet E. Dancey[1,5]

[1]Canadian Cancer Clinical Trials Network, Toronto, ON, Canada, [2]Clinical Research Program, Odette Cancer Centre, Sunnybrook Research Institute, Toronto, ON, Canada, [3]Faculty Associate, Clinical Research Management & Regulatory Science Programs, Edson College of Nursing and Health Innovation, Arizona State University, Tempe, AZ, United States, [4]Member, JTF for Clinical Trial Competency Committee, MRCT of Brigham and Women's Hospital and Harvard, Boston, MA, United States, [5]Canadian Cancer Trials Group, Queen's University, Kingston, ON, Canada

The Canadian Cancer Clinical Trials Network (3CTN, the Network), established in 2014 to address the decline in academic cancer clinical trials' (ACCT) activity, has successfully achieved incremental year-over-year accrual targets as well as implemented recognized performance measures and supports for improving efficiency and quality of trial activities at member sites across Canada. As part of efforts to address ongoing challenges of staff recruitment, retention, and turnover in academic institutions that have been more recently exacerbated by the pandemic, the Network's Performance Strategy Sub-Committee (PSC) oversaw surveys of site clinical research professionals intended to capture workforce development status and identify knowledge gaps using the Joint Task Force Core Competency Framework (JTF CCF) as the standard basis for assessment. Accountable to the 3CTN Management Committee, the PSC consists of clinical research operations experts across Canada responsible for overseeing implementation and monitoring progress of this initiative. Staff at 3CTN's adult sites evaluated and reported trial personnel core competencies and gaps according to each domain/leveled competency statement of the framework. The most frequently noted competency gaps were in the domains of: Investigational Product Development and Regulation (28%); Scientific Concepts and Research Design (16%); and Study and Site Management (14%). Reported data was compiled and represented in the 3CTN Core Competency Report, developed as a web-based, interactive tool enabling members and stakeholders to filter data to enumerate and quantify workforce competency gaps at their site, within their node of affiliated sites, or across the national Network. Concurrently, an environmental scan and review of education resources was conducted and reviewed by the PSC. Embedded links to curated learning and development resources were incorporated into the report and associated with each domain/leveled competency statement to provide ready access to high-quality learning and development resources where needed. In the remaining years of its current strategic plan, 3CTN will continue to monitor, develop collaborative initiatives to

target prioritized clinical research competency gaps and create opportunities for ongoing assessment and reporting by sites to capture changes in workforce core competencies over time.

KEYWORDS

core competency, workforce development, clinical research, professional development, research training

1 Introduction

The Canadian Cancer Clinical Trials Network (3CTN, the Network) was established in 2014 to address a national decline in academic cancer clinical trials activity (Canadian Cancer Research Alliance, 2011). Network objectives include providing support for clinical trial infrastructure at cancer centres and hospitals across Canada to ensure the accrual and efficient execution of ACCTs. Current 3CTN members are clinician investigators and clinical research professionals in trial units of 39 adult cancer centres and hospitals. In some provinces, larger Network Cancer Centers (NCC) also support trial unit operations at Network Affiliated Cancer Centres (NACC) within their region (Figure 1), with a total of 11 NCC and 28 NACCs. 3CTN membership at NCCs typically consists of ~5–10 clinical research professionals within the trial unit, whereas NACC teams comprise of ~two to five staff. The Network's communications, operations processes and infrastructure enable member centres to work collaboratively, exchange knowledge and best practices, and develop research competencies for improved trial conduct. Collectively, Network member sites have successfully achieved incremental improvements in year-over-year accrual targets as well as implemented standard performance measures and supports for improving trial activation times and quality within member sites across Canada (Xu et al., 2021).

Since the commencement of its current 5-year strategic period in 2022, 3CTN-member Cancer Centres have consistently cited unprecedented staffing challenges affecting trial unit performance, capacity, and development progress. Healthcare staff reallocation to frontline care in the first months of the COVID-19 pandemic and prolonged periods of uncertainty and flux impacting local operating practices and the clinical trial environment contributed to widespread burnout and turnover (Knapke et al., 2022a; Knapke et al., 2022b; Sundquist et al., 2022; Freel et al., 2023). Departures due to elective retirement decisions or internal transfers to other roles offering more flexible work arrangements were among the reasons cited. Already a common occurrence within academic institutions, moves to roles within pharma, cancer agencies or other external organizations were more frequently reported at this time. More competitive compensation packages, flexible work arrangements and/or professional development opportunities offered are frequent draws.

While issues of retention and resulting challenges for sustaining research core competencies present significant challenges for all sites, most Canadian cancer centre trial units tend to be small, with trials conduct often undertaken by only a handful of coordinators and research nurses. This makes them especially vulnerable to turnover where onboarding, orientation and core training of new hires can take months to complete and draws heavily on managers' and co-workers' already dealing with

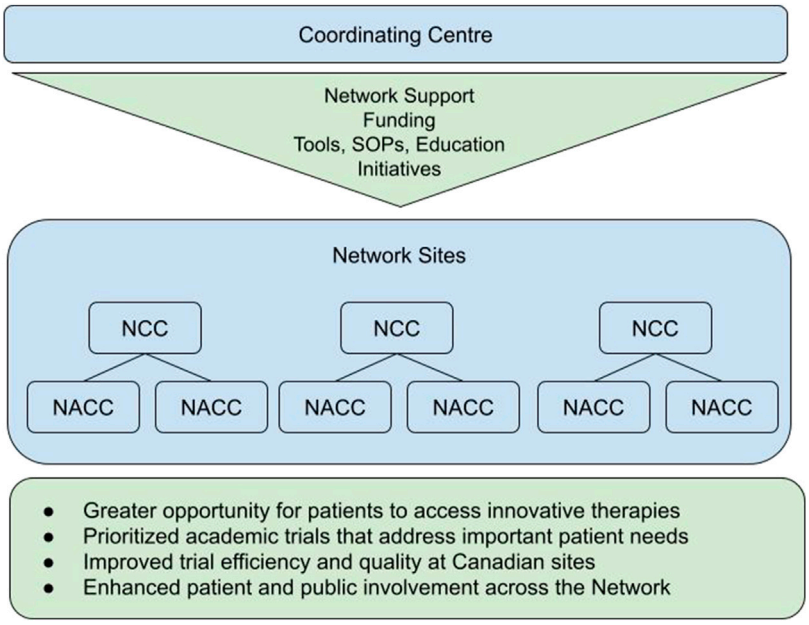

FIGURE 1
3CTN organizational framework.

FIGURE 2
Joint task force core competency framework. Source: https://mrctcenter.org/clinical-trial-competency/.

increased workloads. Typically, turnover has longer-term impacts on sites' operating capacity, trial performance and quality improvement goals as lost team-level efficiencies and core competencies are re-established.

As part of a strategic priority to support member sites' workforce recruitment, retention, and development, and guided by its Performance Strategy Sub-Committee (PSC), the 3CTN Coordinating Centre team undertook a systematic approach to:

1. Identify Network-wide clinical research professional core competency gaps through a survey of 3CTN member sites using JTF CCF as a standard basis of assessment. The framework defines the competency domains and associated skills necessary to conduct high quality, ethical and safe clinical trials was used as a standard basis of assessment (Figure 2) (Sonstein and Jones, 2018).
2. Identify resources aligned with core competency domains to support clinical trials research education and training for staff.
3. Develop an interactive web-based report for sites to review competency results and directly access links to available education and training resources for identified gap areas.

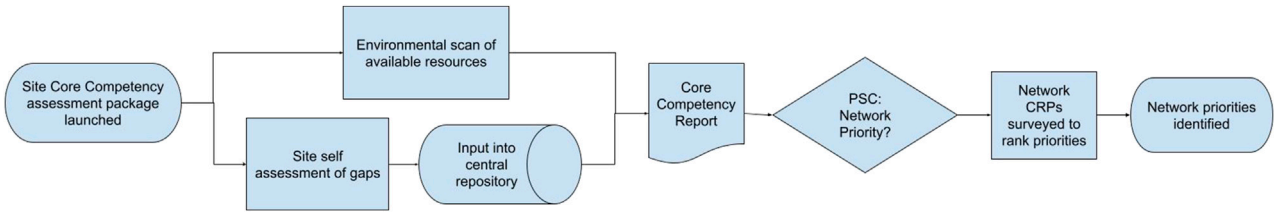

FIGURE 3
Overview of the process to identify Network-wide core competency priorities.

2 Methods

Beginning in 2021 and as part of the membership application for the Network's 2022–2027 business period, 3CTN centres evaluated and reported staff core competencies and gaps in detail according to each domain/leveled competency statement of the JTF core competency framework (see survey in, Supplementary Table S2). On behalf of their teams, site leads (e.g., trial unit manager, team leads drawn from various clinical research professional roles) reported on overall capacity to perform competencies associated with each leveled competency statement. An inability to perform described activities was identified as a gap. Relevant guidance documents and other reference materials were also included to illustrate competency standards and help guide assessments for each domain. Individual sites were expected to draw from their results to identify competency domains requiring improvement over the period as part of deliverables tied to their Network agreements.

Results from all sites' assessments were inputted into 3CTN's central database, forming the basis of the PSC's evaluation and selection of national priorities for professional development and serving as a reference for tracking progress over time. Members of the PSC were asked to select an initial set of leveled competency statement gaps identified from the site assessments to be considered for Network-level support. The basis of selection considered the prevalence of gaps cited by respondents, the expected level of effort required to develop competencies within multiple trial site teams, and anticipated impact (high to low) that could be realized in each area. Also considered were the existence of accessible training or learning resources, and potential benefit to 3CTN priorities for improving trial capacity, performance, and accrual. All clinical research unit team members at Network sites were then requested in a follow-up survey to score priorities for each of the leveled competency statements identified by the PSC based on expected benefit from competency development to their role/team performance (see survey in, Supplementary Table S3). A comment box was included to capture additional suggestions for training topics.

The PSC also oversaw an environmental scan and review of available educational materials to curate a trusted list of resources for developing competencies associated with each leveled competency statement for all domains. An initial search of clinical research training and education programs was conducted using repositories from known sources of clinical research training and education programs from CITI Program, Society of Clinical Research Associates (SoCRA), Association of Clinical Research Professionals (ACRP), Network of Networks (N2), Canadian Clinical Trials Group (CCTG). A general search using clinical research core competency keywords was also completed to capture any additional resources. Each were categorized by core competency domain, resource type (i.e., course, webinar, document) and reviewed by the PSC. A total of 89 resources were identified and incorporated via links within the 3CTN Core Competency Report, created to provide a visual representation of the pan-Canadian Network survey results, overall and by site type (NCC, NACC), within the interactive, web-based resource. Engagement of Network clinical research professionals during development helped validate the web-based tool's utility and usability for end users. An overview of the process is provided in Figure 3.

3 Results

During the initial 3CTN renewal application process, trial unit leads from 41 Network sites reported gaps associated with leveled competency statements under each domain. Refer to Table 1 for a summary of the proportion of identified competency areas by domain as reported from the site assessment and Supplementary Table S1 for a further breakdown by leveled competency statement.

The 3CTN PSC then evaluated which of the leveled competency statements from the summary report should be considered as priorities for Network-wide collaborative development strategies. Selection of an initial set of six leveled competency statements was based on prevalence of identified gaps, capacity for addressing each as well as potential impact for 3CTN's strategic objectives for improving academic cancer trial conduct. Forty individual respondents from sites completed the follow-up survey and submitted scores based on relative need and importance. Respondents were typically research managers or research coordinators involved in the submission and management of the 3CTN grants along with their site's leading investigator. Table 2 shows average scores, overall and by researcher role, associated with each leveled competency statement area. Ranking based on overall scores determined the final ranking of topics to be addressed first through Network-supported access to relevant learning opportunities, resource materials, educational workshops, or other initiatives.

4 Discussion

For 3CTN, maintaining and developing core competency levels across Canada's academic cancer trial environment is required for

TABLE 1 Core Competency domain gap areas as reported from site assessment.

#	Competency domain	% of all reported gaps
1	Scientific Concepts and Research Design	16.3
2	Ethical and Participant Safety Considerations	4.9
3	Investigational Products Development and Regulation	28.1
4	Clinical Study Operations	10.1
5	Study and Site Management	13.9
6	Data Management and Informatics	9.0
7	Leadership and Professionalism	8.0
8	Communication and Teamwork	9.7

TABLE 2 Network sites' priority ranking of the six leveled competency statement gap areas selected by the PSC for initial Network-wide focus (n = 40 respondents).

Research role	# of respondents by role	Average score (1 = highest priority; 6 = not a priority)					
		Top priority leveled competency statements[a]					
		D4.1	D4.7	D4.8	D5.5	D6.1	D6.3
Clinical Research/Project Coordinator	7	2.00	2.43	2.29	1.86	2.43	1.86
Clinical Research Manager	18	2.89	2.72	2.83	2.17	3.67	2.17
Clinical Research Nurse	3	4.00	4.00	2.00	1.67	2.00	2.00
Investigator	5	4.40	3.60	3.20	3.40	3.60	2.40
Other[2]	7	3.71	3.00	2.71	2.43	3.57	2.14
Average Score		**3.15**	**2.93**	**2.70**	**2.28**	**3.30**	**2.13**
Ranking		**5**	**4**	**3**	**2**	**6**	**1**

[a]Refer to detailed leveled competency statements in Supplementary Table S1, Supplementary Table S2 Research Associate, Research Program Manager, Quality Assurance Specialist, Research Database Coordinator, Canadian Cancer Trials Group (Collaborative trial group sponsor) representative, Network funder representatives (n = 2).
The bold values represents the Average Score (1 = highest priority; 6 = not a priority). Ranking: sequential ranking of priorities from 1 to 6, with 1 = highest priority and 6 = lowest priority.

realizing our strategic aims and progress on national-level initiatives. Therefore, along with working to address other factors that present challenges to sites' sustained improvement in trial performance and capacity, supporting clinical research professional development was recognized as an essential activity. For sites in particular, an effective approach needs to be agile and foster ready access to resources relevant to diverse trial staff roles and responsibilities. Doing so better enables leadership to monitor and manage development within their trial teams. An approach based on the JTF CCF provided the level-setting standard for individual knowledge and skills assessment as well as a mechanism for gauging progress or other changes over time.

Clinical research sites typically rely on institutional training requirements mandated for clinical research professionals, accessing courses covering topics and guidelines such as Good Clinical Practice, Tri-Council Policy Statement 2 (TCPS 2), Introduction to Clinical Research, and Health Canada Food and Drug Regulations, Part C, Division 5 to supplement role orientation and on-the-job learning. Most Canadian sites have access to core training materials made available by their institutions or through memberships in established research networks in accordance with individual clinical research professional development plans. However, training course completion alone should not be taken to imply that the appropriate core competencies are in place to perform responsibilities fully compliant with applicable regulations and guidelines as well as highest ethical standards governing clinical research. Ascertaining core competency levels throughout an individual's professional development is a crucial activity enabled by use of the JTF CCF as a standardized approach.

The 3CTN Core Competency Report facilitates this process by uniquely amalgamating available high-quality learning resources identified for each leveled competency statement into a single, functional tool. Accessible via our website, trial site managers can view report data at any time to enumerate and quantify workforce competency gaps. Professional development plans for clinical research professionals to address individual- or site-level gap areas can then be supported by directly accessing matched training resources of interest via links embedded within the report tool (Freel et al., 2023). The Report's illustration of strengths and gaps for each domain filterable by site or province is designed to help inform resource development plans at the institutional, provincial, or national levels for 3CTN, its stakeholders and partners. For example, NCCs can use the 3CTN Core Competency Report to review and modify their onboarding plans and as part of their role to support trial unit operations at

NACCs within their node, or as a basis for discussing joint training objectives.

Aggregate data obtained from all member sites at the beginning of our current 5-year strategy represented a snapshot of time and served as an initial step focused on identifying the general scale of competency gaps for each domain's leveled competency statements. Initial site assessments did not therefore include a more in-depth reporting of competency level (i.e., Basic, Skilled or Advanced) related to each statement. In addition, the follow-up survey conducted to score priorities identified by the PSC did not include responses from members at all sites and the sample size was small for some clinical research roles. Recognizing these limitations, site clinical trial unit leaders subsequently participated in Network meetings to review and discuss findings as well as inform on tools needed to assist with training. A comprehensive evaluation is planned during the third year of our current strategy that will address cited limitations in order to provide a more complete picture for the Network that fully reflects all elements of the JTF framework. Results will also capture the number and proportion of sites that have incorporated use of the JTF framework and the 3CTN Core Competency Report in their staff development plans as well as provide insights on the effectiveness of Network initiatives implemented to support learning priorities identified by the PSC. The follow up site assessment may otherwise spotlight emerging areas that could benefit from new initiatives, training materials or other resources targeting unmet needs.

Connections with aligned organizations is essential for our success in this area, particularly where development of training content may be required. For example, Network contributions and member access to materials and mentoring opportunities arising from recent investments in Clinical Trials Training Platforms by the Canadian Institutes of Health Research as part of its Clinical Trials Fund (Canadian Institutes of Health Research, 2022).

For the remainder of its current strategic plan period, 3CTN aims to organize dedicated workshops with topics related to identified priority gap areas, either during annual stakeholder meetings or scheduled virtual webinars providing peer-to-peer learning platforms for member clinical research professionals from across Canada. As well, we will continue to collaborate on new initiatives and encourage ongoing assessment and reporting by sites to capture changes in workforce core competencies over time.

Data availability statement

The datasets presented in this study can be found in online repositories. The names of the repository/repositories and accession number(s) can be found in the article/Supplementary Material.

Author contributions

SS: Conceptualization, Formal Analysis, Funding acquisition, Methodology, Project administration, Visualization, Writing–original draft, Writing–review and editing. DK: Conceptualization, Data curation, Formal Analysis, Methodology, Project administration, Visualization, Writing–original draft, Writing–review and editing. RC: Data curation, Formal Analysis, Project administration, Visualization, Writing–review and editing. CS: Conceptualization, Methodology, Writing–original draft, Writing–review and editing. JD: Conceptualization, Formal Analysis, Funding acquisition, Methodology, Writing–review and editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fphar.2023.1294335/full#supplementary-material

References

Canadian Cancer Research Alliance (2011). *Report on the state of cancer clinical trials in Canada*. Toronto: Canadian Cancer Research Alliance.

Canadian Institutes of Health Research (2022). Training grant: clinical trials training platforms. Available from: https://www.researchnet-recherchenet.ca/rnr16/vwOpprtntyDtls.do?all=1&masterList=true&next=1&org=CIHR&prog=3697&resultCount=25&sort=program&type=EXACT&view=currentOpps&language=E.

Freel, S. A., Snyder, D. C., Bastarache, K., Jones, C. T., Marchant, M. B., Rowley, L. A., et al. (2023). Now is the time to fix the clinical research workforce crisis. *Clin. Trials* 20 (5), 457–462. doi:10.1177/17407745231177885

Knapke, J. M., Jenkerson, M., Tsao, P., Freel, S., Fritter, J., Helm, S. L., et al. (2022b). Academic medical center clinical research professional workforce: Part 2 – issues in staff onboarding and professional development. *J. Clin. Transl. Sci.* 6 (1), e81. doi:10.1017/cts.2022.412

Knapke, J. M., Snyder, D. C., Carter, K., Fitz-Gerald, M. B., Fritter, J., Kolb, H. R., et al. (2022a). Issues for recruitment and retention of clinical research professionals at academic medical centers: Part 1 – collaborative conversations Un-Meeting findings. *J. Clin. Transl. Sci.* 6 (1), e80. doi:10.1017/cts.2022.411

Sonstein, S. A., and Jones, C. T. (2018). Joint Task Force for clinical trial competency and clinical research professional workforce development. *Front. Pharmacol.* 9, 1148. doi:10.3389/fphar.2018.01148

Sundquist, S., Kato, D., Xu, R. Y., Schoales, J., Kulendran, S., and Dancey, J. E. (2022). The impact of COVID-19 on academic cancer clinical trials in Canada and the initial response from cancer centers. *Curr. Oncol.* 29 (4), 2435–2441. doi:10.3390/curroncol29040197

Xu, R. Y., Kato, D., Pond, G. R., Sundquist, S., Schoales, J., Lalani, S., et al. (2021). Advancing academic cancer clinical trials recruitment in Canada. *Curr. Oncol.* 28 (4), 2830–2839. doi:10.3390/curroncol28040248

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EDITED BY
Denise Snyder,
Duke University, United States

REVIEWED BY
Stephanie Freel,
Duke University, United States
Rebecca Brouwer,
Duke University, United States

*CORRESPONDENCE
Jamie M. Besel,
jbesel@billingsclinic.org

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Reimagining the joint task force core competency framework for rural and frontier clinical research professionals conducting hybrid and decentralized trials

Jamie M. Besel[1,2]*, Elizabeth A. Johnson[2,3], Jiahui Ma[3,4] and Becky Kiesow[5]

[1]Billings Clinic, Collaborative Science and Innovation, Billings, MT, United States, [2]Mark and Robyn Jones College of Nursing, Montana State University, Bozeman, MT, United States, [3]Biomedical Innovation for Research and Development Hub, Montana State University, Bozeman, MT, United States, [4]Norm Asbjornson College of Engineering, Montana State University, Bozeman, MT, United States, [5]Billings Clinic, Diabetes Research, Billings, MT, United States

Introduction: Clinical research professionals (i.e., clinical research assistants, clinical research nurses, clinical research coordinators, etc.), as outlined by the Joint Task Force (JTF) Core Competency Framework, are highly trained to support the breadth of clinical trial operations and manage participant care. Clinical research professionals are uniquely equipped with a scope of practice that permits product administration, participant assessments, and data management. As clinical trials grow in complexity and their management expands beyond traditional, site-based operations models to decentralized and/or hybrid models, the need becomes great to ensure adequate staffing. However, rural hospitals frequently lack the research staff or patient recruiters that would allow them to support decentralized clinical trials across a sizeable rural geographic demographic.

Methods: This paper examines the contributory factors of the clinical research professional workforce contraction and response efforts at professional and organizational levels within a large, Magnet-designated healthcare system in the rural northwestern United States. Perspectives are shared on adapting the Core Competency Framework to reflect the unique strengths and opportunities towards decentralized trials in rural regions of the United States and areas of priority for workforce cultivation and retention. A descriptive survey was used to gather initial data identifying the current research perspectives of healthcare workers working across a rural community. Participants were asked to complete questions about the JTF Competency domains and behavior-based questions.

Analysis: Both competency and behavior-based questions were asked and related to roles. These were then cross-referenced using a Rasmussen Ladder system. Descriptive statistics were conducted for sample characteristics, self-reported competency domain questions, and behavior questions.

Results and discussion: Survey findings suggest that although healthcare workers and clinical research teams interact, they are unlikely to ask their patients to participate in research. Based on the limited response rate, results suggest that

better education throughout the rural community could benefit from decentralized research efforts. Increased use of technology was also highlighted as an area of interest.

KEYWORDS

clinical trial enrollment, rural, frontier, decentralized trials, clinical research professional, joint task force competency framework, clinical research workforce

Introduction

The complexity and number of clinical trials have increased significantly over the past several years. Between 2010 and 2020, there was a 300% increase in the number of clinical trials registered on ClinicalTrials.gov (U. S National Library of Medicine, 2023). Clinical research professionals (CRPs) are healthcare professionals highly trained to support most of the day-to-day clinical trial activities, as outlined by the Joint Task Force (JTF) Core Competency Framework (Sonstein and Jones, 2018; Sonstein et al., 2022). They are the "boots on the ground" clinical trial workforce critical to successful clinical trial procedures in real-life situations (Ibrahim et al., 2022).

As the number and complexity of clinical trials have increased over time, so have the responsibilities of CRPs. Clinical research professionals require foundational knowledge and technical expertise in scientific communications and data management; however, they also need other strengths, such as problem-solving and critical thinking (Baer et al., 2011; Chacon and Janssen, 2021). As their management expands beyond traditional, site-based operations models to decentralized and hybrid models, the need to recruit and retain experienced CRPs is even greater (Ibrahim et al., 2022; Freel et al., 2023). However, the CRP workforce continues to decline rapidly, a problem only compounded in rural and frontier areas of the United States. Rural hospitals frequently lack research staff or patient recruiters that would allow them to support decentralized clinical trials across a sizeable rural geographic demographic (Baquet et al., 2006; Seidler et al., 2014; Iglehart, 2018; Winter et al., 2018; Schmidt et al., 2020; Bharucha et al., 2021).

Decentralized clinical trial (DCT) activities occur at locations other than traditional trial sites; these activities may occur at trial participants' homes or in local healthcare facilities convenient for trial participants (LaHucik, 2021; DiMasi et al., 2023). In hybrid DCTs, some trial activities involve in-person visits by trial participants to other non-traditional clinical trial sites, such as participants' homes or virtual meetings (U.S. Food and Drug Administration, 2023). Although general competencies for CRPs have been described in the literature, the competencies unique to decentralized trials in rural areas have not been detailed in the literature nor outlined by governing bodies, leaving a significant gap in supporting the development of this essential research workforce. The CRP profession faces a workforce and diversity shortage (Freel et al., 2023). There is a heterogeneity in CRPs with various levels of education that exist. Clinical research professionals are responsible for a wide variety of trials and may not be specific to one indication, which adds to the complexities of the job. While early-phase research is being conducted in rural areas, the most prevalent trial types consist of Observational, Phase 3, Phase 4, and investigator-initiated pilot studies (Goodson et al., 2022).

Nationally, the clinical research workforce has seen workload and study complexity alterations over the past 15 years, corresponding with a 300% increase in registered clinical trials (U. S National Library of Medicine, 2023). Organizations seeking to become more adaptive and innovative often see that culture change is the most challenging part of the transformation process (Walker and Soule, 2017). Rural healthcare and research sites continue to struggle to maintain and retain adequately trained staff with researchers finding less than 12% of US physicians practice in rural areas (MacQueen et al., 2018).

There is a lack of literature surrounding implementing and adapting the JTF Core Competency Framework among United States rural research-driven healthcare systems. However, studies conducted by Schmidt et al. (2020) and Quilliam et al. (2022) have demonstrated a turn in focus toward those centers that have the outreach capabilities to otherwise under-represented populations. Schmidt et al. (2020) conducted qualitative descriptive interviews with 18 rural research professionals with perspectives including low research visibility in clinical care service environments; misconceptions related to lack of research capacity as a rural organization; and overall lack of knowledge and training due to organizational system structures which impede effective change management. Similarly, Quilliam et al. (2022) conducted a qualitative descriptive study, which included 20 participants who echoed the lack of tailoring training to the rural context of conducting clinical research, particularly ensuring that the training is deemed relevant and easily applied into practice.

This paper examines the contributory factors of the CRP workforce reduction and response efforts at professional and organizational levels within a large, Magnet-designated healthcare organization in the rural northwest United States. Perspectives are shared as to adapting the Core Competency Framework to reflect the unique strengths and opportunities towards decentralized trials in rural states and areas of priority for workforce cultivation and retention.

About the healthcare organization

Geographically located between the great hospital complexes of Minneapolis and Seattle, our large Magnet-designated healthcare organization is uniquely positioned to perform clinical research throughout this rural region. The healthcare system includes three regional branch clinics and 20 Critical Access Hospitals providing healthcare across a sparsely-populated rural and frontier area of over 162,000 square miles—roughly the geographic size of Ohio, Indiana, Illinois, and West Virginia *combined*. Providers, learners, and all staff across the organization have internal access to support for research activities, including clinical and device trials, investigator-initiated translational research, and quality improvement initiatives. The organization is involved in Phase I, II, III, and IV clinical trials and

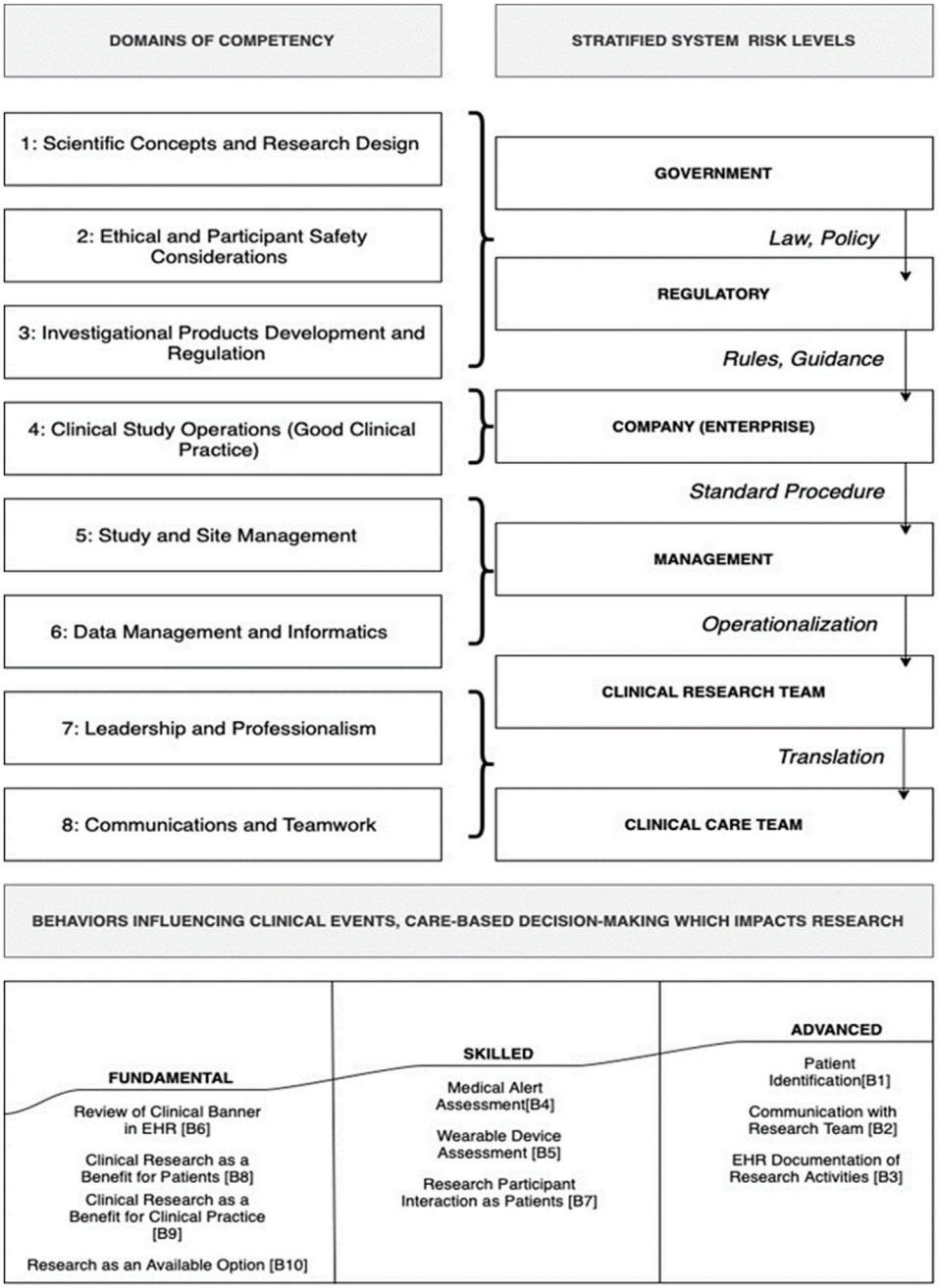

FIGURE 1
Rassmussen ladder of framework competencies and healthcare system clinical operations.

has over 30 years of experience in health system research. Since the research program's inception in 1988, our staff have worked with over 75 pharmaceutical companies, offering over 250 clinical research studies to patients.

With 15 full-time employees dedicated to research across three key departments driving the clinical research portfolio, challenges exist in ensuring that change management efforts are rolled out seamlessly. Knowing that 50%–70% of change management efforts fail (Mansaray, 2019), we look towards the JTF Core Competency Framework to support research personnel and expansion efforts. Employing a well thought out system, like the JTF Core Competency Framework, should set our organization up for success as we implement new research functionality in our EHR system.

Guiding frameworks

Joint task force core competency framework

Competency frameworks are essential to achieving high institution performance (Sonstein and Jones, 2018; Sonstein

et al., 2022). Developed in 2014, The Joint Task Force (JTF) Core Competency Framework intends to align clinical researchers worldwide by using a comprehensive set of competencies expected to aid in building a person's skillset from basic to advanced levels. Using 8 competency domains and 48 specific competency statements, skills are broken down into three levels—fundamental, skilled, and advanced (Sonstein and Jones, 2018; Sonstein et al., 2020). This framework encompasses the knowledge, skills, and attitudes necessary for conducting clinical research within organizations and creates a roadmap to help develop CRPs. Instead of focusing solely on regulatory compliance, the framework identifies professional competency encompassing a clinical trial's various aspects. Limitations exist using the framework as it does not consider non-interventional, quasi-experimental, mixed methods, and qualitative studies (Ibrahim et al., 2022). Implementation into the rural healthcare setting will require adaptation to represent the complexity of the work environment and different education levels.

Rasmussen ladder (risk management framework)

Given the constant flux in the healthcare industry, there is a continuous appraisal of risk to clinical research operations with the ebb and flow of change at the largest system levels (policy, regulations) and the local systems of research conduct (team collaboration and participant-based encounters). To aid in categorizing and appraising risk across systems levels, organizations employ Rasmussen's risk management framework (Rasmussen, 1986; Rasmussen, 1997; Brady and Naikar, 2022). The risk management framework (Figure 1) aids in the appraisal of staff behaviors and skill sets as they relate to external factors that may affect the completion of tasks (Rasmussen, 1986; Lintern, 2010). External factors are categorized from mesosystem to microsystem: government (law), regulatory (regulations), company (enterprise), management (plans and policy); and staff (action) (Donovan et al., 2015). These factors as system levels influence one another and thus the ability of an organization and its staff to complete work safely and compliant with oversight entities. As the clinical research industry is highly regulated but varied in its company-specific organization of policies and procedures, the Rasmussen risk management framework was employed in this study to evaluate the organizational enterprise for non-overt influences on quality clinical trial conduct across a wide geographic and cultural range of locations. In conjunction with the JTF Core Competency Framework, the lens of classical risk management modeling gleans insight into how competency level may influence the organizational approach to risk associated with clinical research programs or departments.

Purpose

The purpose of this study was twofold: 1) explore the self-perceived competence level among the 8 domains of the JTF Core Competency Framework among organizational research and clinical care professionals and 2) examine self-reported frequency in behaviors associated with clinical research risk management. Together, these two aims provide the foundation for understanding contributory factors associated with rural clinical research workforce recruitment and retention. Furthermore, as the rural organization expands the clinical research technological infrastructure across its vast geographical expanse of locations, this study serves as an initial insight into priority areas during the period of change among the risk management attributes. The long-term goal of this research is to iterate an adaptive version of the JTF Core Competency Framework congruent to rural organizations to inform best training and workforce recruitment/retention practices with a focus on decentralized trial conduct.

Methods

Design and approach

A descriptive survey design was selected to gather initial, formative data that reflects research and clinical care personnel's perspectives, behaviors, and beliefs surrounding the core competencies (Kelley et al., 2003). Given the geographical distances between the 23 affiliated facilities, an online survey was selected to promote better reach of the study.

The order of survey questions, significant domains, and the behaviors to align with risk management attributes were selected through listening sessions with key informants from the rural healthcare organization, including a clinical research coordinator and nurse manager. Upon final consensus, the survey was reviewed by the organization's Privacy and Exemption Committee along with organizational executive leadership for discussion. The risk management attributes were defined and selected based on priority stratifications surrounding the healthcare system: *Government* and *Regulatory* (Macrosystem); *Management* and *Company (Enterprise)* (Mesosystem); *Clinical Care Team- Clinical Events* and *Clinical Research Staff* (Microsystem).

Sample and recruitment

Upon approval by the Montana State University Institutional Review Board (Protocol #2023-604) and the organization's Privacy and Exemption Committee, a Qualtrics survey link was internally distributed through the Intranet and via the organization email listserv. Purposeful and snowball sampling was employed, targeting facility locations affiliated with the rural healthcare organization and groups of clinical research professionals, medical leadership, nursing leadership, and administration. Participants were included if 18 years of age or older, proficient in written English, and if they were an employee in either a clinical care or research role with the ability to complete the survey online. The following groups were included in the email recruitment: research personnel, physicians, physician assistants, nurse practitioners, nursing (hospital and clinic), library, laboratory, leadership, pharmacy, and care management.

Data collection

Data were collected from August through September 2023 via an anonymized Qualtrics survey link hosted by Montana State University, a research partnering institution for this project.

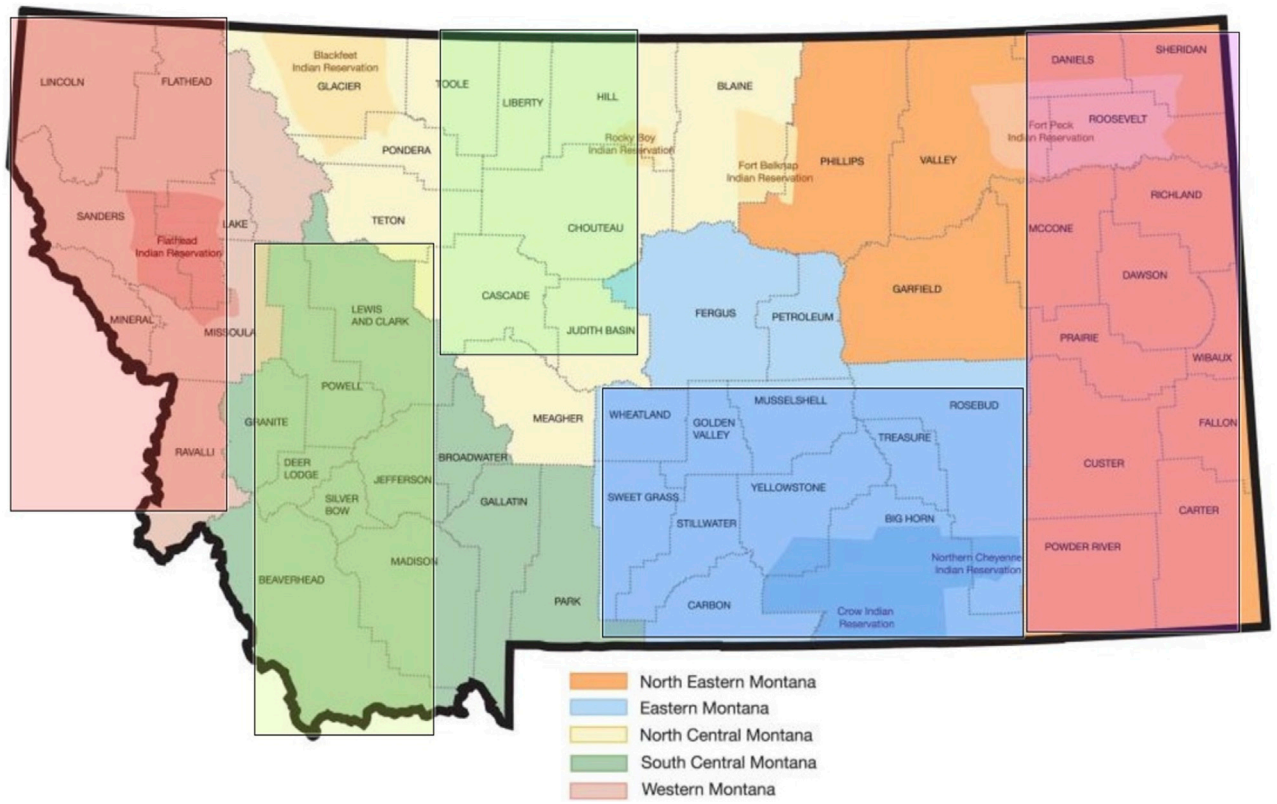

FIGURE 2
Categorized regional map of Montana for response selection.

Upon clicking the survey link, a study overview, and a checkbox to indicate consent to proceed to the response fields were provided. Participant demographic and organizational role-based characteristics were first obtained, followed by an interactive regionalized map of the state, which permitted the participant to select the area of state in which their facility was located: Northeastern, Eastern, North Central, South Central, and Western (Figure 2).

An organizational role was requested, which included the categorization of licensed versus non-licensed professionals and those who primarily worked in a research or clinical setting. Participants then proceeded to the JTF Core Competency Framework domain questions, which asked for self-reports of competency level as *fundamental* (can perform the task at an essential level with possible coaching/supervision); *skilled* (can perform the task independently with moderate expertise and high-quality work output); and *advanced* (ability to teach or supervise others with the application of critical thinking and problem-solving). See Table 1 for the listing of domains provided for self-evaluation. Participants used an electronic slider to move their cursor to their self-reported degree of competency with 0 being not competent at all and 100 being fully competent. *Fundamental* skillset was considered 0-50, *skilled* 60-80, and *advanced* 80-100.

After self-evaluation of competency across the eight framework domains, participants then responded to behavior-based questions noted in Table 2 which align with the framework domains and the six attributes of risk management adapted to the context of clinical research, as determined by the organization's research professionals. Some domains and attributes were measured more than others due to the significance placed by the organization on these elements of research personnel competency, including Domain 8 (*Communications and Teamwork*) and Domain 2 (*Ethical and Participant Safety Considerations*). Doubly measured attributes included: *Clinical Care Team- Clinical Event*, *Management*, and *Company (Enterprise)*. Participants provided their responses in Likert format, which spanned *Never (1), Sometimes (2), Half the Time (3), Most of the Time (4),* and *Always (5).*

Upon completion of the behavior questions, the participant had the option to include their e-mail address to be entered into a raffle for one $150 Amazon electronic gift card. An additional opportunity for iterative, focus group feedback and organizational report-out pertaining to these competencies was offered at the end of the survey; participants inputted their e-mail address in the corresponding field if they were interested in continuing to share their perspectives related to clinical research core competencies at a later date.

Data management and analysis

Data were stored in a secure, encrypted repository hosted by Montana State University. Raw data downloaded from Qualtrics was then placed in restricted-use folders to protect the privacy and confidentiality of participants. Folder access was controlled and

TABLE 1 JTF competency domains itemized on survey with description.

Domain number and title	Domain description
1: Scientific Concepts and Research Design	Encompasses knowledge of scientific concepts related to the design and analysis of clinical trials
2: Ethical and Participant Safety Considerations	Encompasses care of patients, aspects of human subject protection, and safety in the conduct of a clinical trial
3: Investigational Products Development and Regulation	Encompasses knowledge of how investigational products are developed and regulated
4: Clinical Study Operations (Good Clinical Practice)	Encompasses study management (adverse event identification and reporting, post-market surveillance, and pharmacovigilance), and investigational product handling.
5: Study and Site Management	Encompasses content required at the site level to run a study (financial and personnel aspects). Includes site and study operations (not encompassing regulatory/GCPs)
6: Data Management and Informatics	Encompasses how data are acquired and managed during a clinical trial, including source data, data entry, queries, quality control, and correction and the concept of a locked database
7: Leadership and Professionalism	Encompasses the principles and practice of leadership and professionalism in clinical research
8: Communications and Teamwork	Encompasses all elements of communication within the site and between the site and sponsor, CRO, and regulators. Understanding of teamwork skills necessary for conducting a clinical trial.

TABLE 2 Survey questions examining behaviors related to core competency framework and risk management.

Behavior-based question	Alignment with domain (itemized)	Risk management attributes
1: I ask the patient if they are part of research or clinical trial	4: Clinical Study Operations (Good Clinical Practice)	Company (Enterprise)
2: I communicate with research teams to develop or implement the patient's plan of care	8: Communications and Teamwork	Clinical Research Staff
3: I document in the Electronic Health Record that the patient is part of research or clinical trial	6: Data Management and Informatics	Regulatory
4: I assess for medical alert bracelets on each patient	2: Ethical and Participant Safety Considerations	Clinical Care Team- Clinical Events
5: I assess for wearable devices on each patient	3: Investigational Products Development and Regulation	Clinical Care Team- Clinical Events
6: I review the patient's banner in the Electronic Health Record for each patient as part of handoff	8: Communications and Teamwork	Clinical Care Team- Clinical Events
7: I interact with clinical trial/research participants as patients	5: Study and Site Management	Management
8: I believe that clinical research benefits my patients	2: Ethical and Participant Safety Considerations	Government
9: I believe that clinical research benefits my clinical or leadership practice	7: Leadership and Professionalism	Management
10. I believe clinical research is important to make available to my patients	1: Scientific Concepts and Research Design	Company (Enterprise)

limited to only those researchers identified on this project to the Montana State University Institutional Review Board. Data to be used for analysis was kept separately from raw data within the repository.

Survey responses were initially organized using Excel and then coded for analysis using R programming language (Version R-4.30) (R Core Team, 2013). Descriptive statistics were then conducted for sample characteristics (licensure status and role) as well as the self-reported competency domain questions and behavior questions (Table 3). Fisher's exact tests were conducted given the small, pilot sample size. Odds ratios were then calculated for licensure status which was significantly associated with behavior ratings and competency levels (fundamental, skilled, advanced, Table 4).

Ethical considerations

This study was deemed minimal risk by the Montana State University Institutional Review Board. To maintain the privacy and confidentiality of those participating, data that may easily identify organization personnel were not collected, such as demographics and facility location of employment. Given the rural and micropolitan settings where these facilities are located, there is a high degree of risk of identifying participants due to the low overall sample population across the organization's enterprise. As such, professional roles were delineated by the presence or absence of licensure and daily role function as majority research-based or clinical care. Emails provided for the Amazon electronic gift card raffle were destroyed after the raffle was completed to protect further the identity of those who completed the survey.

TABLE 3 Sample characteristics, competency and behavior ratings.

Demographic information						
	Licensed			Non-Licensed		
Licensure status	13 (61.9)			8 (38.10)		
	Clinical			Research		
Role	17 (80.95)			4 (19.05)		
Competency Rating						
	Fundamental	Skilled	Advanced	Missing		
Domain 1	5 (23.81)	4 (19.05)	10 (47.62)	2 (9.25)		
Domain 2	2 (9.25)	3 (14.29)	11 (52.38)	5 (23.81)		
Domain 3	6 (28.57)	4 (19.05)	6 (28.57)	5 (23.81)		
Domain 4	3 (14.29)	4 (19.05)	9 (42.86)	5 (23.81)		
Domain 5	6 (28.57)	4 (19.05)	7 (33.33)	4 (19.05)		
Domain 6	3 (14.29)	2 (9.25)	8 (38.10)	8 (38.10)		
Domain 7	3 (14.29)	5 (23.81)	8 (38.10)	5 (23.81)		
Domain 8	3 (14.29)	2 (9.25)	8 (38.10)	8 (38.10)		
Behavior Question Rating						
	Never	Sometimes	Half Time	Most Time	Always	Missing
Behavior 1	6 (28.57)	2 (9.25)	-	2 (9.25)	1 (4.76)	10 (47.62)
Behavior 2	5 (23.81)	2 (9.25)	1 (4.76)	1 (4.76)	3 (14.29)	9 (42.86)
Behavior 3	5 (23.81)	3 (14.29)	-	1 (4.76)	3 (14.29)	9 (42.86)
Behavior 4	3 (14.29)	4 (19.05)	-	2 (9.25)	1 (4.76)	11 (52.38)
Behavior 5	2 (9.25)	3 (14.29)	-	4 (19.05)	2 (9.25)	10 (47.62)
Behavior 6	1 (4.76)	2 (9.25)	-	-	7 (33.33)	11 (52.38)
Behavior 7	3 (14.29)	6 (28.57)	-	1 (4.76)	3 (14.29)	8 (38.10)
Behavior 8	-	-	-	5 (23.81)	9 (42.86)	7 (33.33)
Behavior 9	-	-	1 (4.76)	4 (19.05)	9 (42.86)	7 (33.33)
Behavior 10	-	-	1 (4.76)	3 (14.29)	10 (47.62)	7 (33.33)

*The value in each cell: Frequency (Relative Frequency %).

Results

A descriptive survey was used to gather initial data identifying the current research perspectives of healthcare workers working across a rural community in the northwest. Participants were asked to complete questions about the JTF Competency domains and behavior-based questions. Of the 21 respondents, more participants were licensed (61.9%) and enrolled in a clinical work setting (80.95%). Although healthcare workers interact with clinical research participants (Behavior 7) and believe clinical research is important to make available to patients (Behavior 10), they are unlikely to ask the patient to participate in a research study and work with the research team (Behaviors 1 and 2). Nearly half (47.62%) of participants identified an advanced competency skill in Domain 1(Scientific Concepts and Research Design) and 52.38% in Domain 2 (Ethical and Participant Safety Considerations). Conversely, participants did not feel as competent with study and site management (Domain 5) and clinical study operations (Domain 3).

Fisher's exact test revealed that licensure status was significantly associated withDomain 7 (Leadership and Professionalism) rating (Table 4). Participants with skilled (OR = 9.88e+16) and advanced (OR = 5.24e+08) ratings for Domain 7 had a higher chance to be licensed compared to participants with fundamental leadership and professionalism skills (Figure 3).

Discussion

Through an iterative refinement process with participants and other key stakeholders, this study explored initial, formative data that reflects the perspectives, behaviors, and beliefs of research and clinical care personnel surrounding the JTF core competencies. This

TABLE 4 Domains and competency behaviors examined by licensure status and role.

	Licensure status	Role
Domain 1	0.22	0.12
Domain 2	0.10	0.73
Domain 3	0.33	1.00
Domain 4	0.29	0.76
Domain 5	0.35	0.37
Domain 6	1.00	1.00
Domain 7	**0.01***	0.33
Domain 8	1.00	1.00
Behavior 1	1.00	0.45
Behavior 2	1.00	0.23
Behavior 3	1.00	0.18
Behavior 4	0.60	0.30
Behavior 5	0. 36	1.00
Behavior 6	0.10	0.30
Behavior 7	0.54	0.15
Behavior 8	1.00	1.00
Behavior 9	1.00	0.23
Behavior 10	1.00	0.63

*Denotes significance $p < 0.05$; Missing values were excluded in the Fisher's exact test.

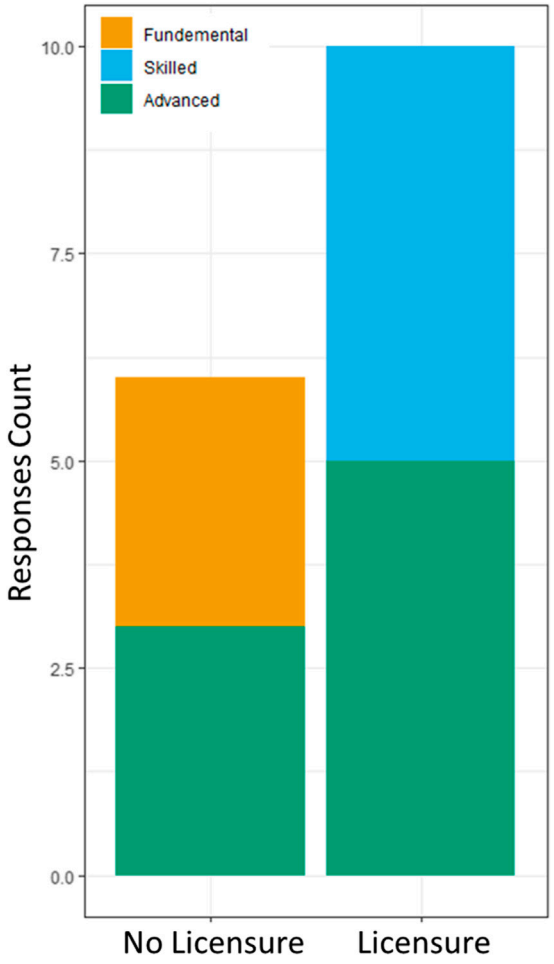

FIGURE 3
Domain 7 (leadership and professionalism) response count by licensure.

paper examined the contributory factors of the CRP workforce reduction and response efforts across professional and organizational levels at a large healthcare organization in the rural northwest. Using the JTF Framework allows organizations to build necessary research skill sets transferable to frontline healthcare workers in the rural healthcare setting. Employees are encouraged to adapt their behaviors and mindset to ensure patient safety, career growth, and collaboration between those in the field. Similar to the current literature, albeit limited, our survey findings suggest that although healthcare workers interact with clinical research participants, they are unlikely to ask the patient to participate in a research study and work with the research team. As suggested by MacQueen et al., 2018, rural healthcare and research sites continue to struggle to maintain and retain adequately trained staff with researchers. Although only 21 participants completed the survey in our study, this suggests that our research teams could better educate the community about available research opportunities. In a qualitative study by Schmidt et al. (2020), there was an overall lack of knowledge and training due to organizational system structures, further impeding effective change management. Outreach efforts should be investigated further as a solution to building awareness and trust in the rural healthcare setting. The advancement of CRP talent among rural populations would aid in all aspects of decentralized trials and could strengthen the field by ensuring capable research staff are prepared to address the unique complexities inherent in rural healthcare. With the increase of technology in studies, there is an opportunity to engage more with our rural communities, although limitations present themselves due to access issues to modern-day technologies.

Based on the results of this study, the authors recommend further investigation of the competency domains relative to rural decentralized trials and discussions on updating and/or adapting the JTF framework to accommodate rural CRPs who manage decentralized trials. Currently, there is not a risk-based management component that is separated as a priority in the framework as it pertains to decentralized trials in rural areas. As highlighted in the results of this study, providers are not asking patients if they are participating in a clinical trial or evaluating medical devices for their integration in clinical care. This is concerning, especially without the integration of the risk management component. For example, any patient on any given trial could seek care at the organization and be from a different group and/or trial site. Another area to consider is integrative, effective communication via technology. Specifically, how is the organization consistently and accurately messaging the significance of clinical research as a care option or its impact on clinical care delivery? We recommend expanding Domain 8 and potentially creating a separate domain for decentralized/hybrid trials because

they necessitate different skillsets and competencies given the variability of resourced environments. Without attention given to this domain, the decentralized model does not work in rural areas. This is because there is a lack of awareness of potential trial participants, no communication, and no adaptation of remote-task skillsets among CRPs. In conjunction with the JTF Core Competency Framework, the lens of classical risk management modeling using Rasmussen's Framework can glean insight into how competency level may influence the organizational approach to risk associated with clinical research programs or departments. Given the emphasis on clinical trial participant safety in the community setting, adverse event reporting, and shared information exchange of research information pertinent to clinical care, the augmentation of the framework to that of a risk-based organizational model particularly in rural or low-resource settings will aid in the development of responsible trial portfolio expansion and workforce development.

Limitations

Given the exploratory nature of this initial, formative study, there were noted limitations. While clinical research is an aspect of the organization's mission, there is no mechanism during the orientation of clinical staff about research opportunities and necessary behaviors that are protective towards research participation in the clinical milieu. The sample size for this study was not statistically powered. However, future research and current activities that amplify awareness of trial opportunities to the enterprise at large will permit statistical analysis generalizable to the region and other rural institutions. Missingness of responses was observed given the voluntariness of each question should the respondent wish not to answer. Given the small number of research-dedicated staff, we could not describe competency by CRP designation (i.e., coordinator, nurse, manager). However, future research will entail focus groups that permit the examination of role-specific competencies and insights. Results from this initial study inform the line of questioning for the focus groups and the educational materials and training necessary for the research portfolio expansion at this healthcare organization.

Implications for industry sponsors and clinical research workforce

The expanded use of decentralized trial elements and models of research delivery bring a heightened need to evaluate workforce allocation and labor optimization to ensure responsible, compliant conduct outside the traditional research site. In the wake of the COVID-19 pandemic, the site-based clinical research workforce, which includes clinical research nurses (CRNs) and nurse researchers, showed signs of significant contraction (Johnson, 2022). The overall high turnover rate of CRPs, compounded with retirements and increased demand, requires a critical pause and evaluation of how best not only to retain and recruit CRPs but also establish standardization in core competencies, particularly in regions with a reduced pool of candidates (Freel et al., 2023). While sites may conduct a mix of decentralized, hybrid, and traditional research designs, 81.9% of protocols between 2019 and 2020 had at least some decentralized elements about data collection (de Jong et al., 2022). The inclusion of monitoring remote technologies, managing multiple sources of data collection, and mitigating any issues that arise with the technologies requires an expanded CRP skillset. In rural areas where sparse Internet connectivity and potential mistrust of novel technologies may be evident, CRPs must be additionally agile in their appraisal of resources local to the participant to maintain data integrity and device validity.

Recruitment of participants is a costly endeavor that rests on the shoulders of site CRPs. Without a solid organizational structure supporting research activities, recruitment slows and amounts to generalized trial sponsor financial losses of upwards of USD 8 million per day (Thakur and Lahiry, 2021). Financial evaluation of decentralized and traditional trial design has demonstrated that the core factor to cost reduction and participant recruitment success has been the efficiency gained over time from experienced CRPs with the organizational structure in place to promote maintainable, sustainable research portfolios (DiMasi et al., 2023). With 77% of trial sponsor executives incorporating DCT elements or fully decentralized trials in the next coming years (up from 59% when surveyed in 2021), the time is now to adapt the JTF Core Competency framework to reflect the decentralization of trial activities, organizational system influence on core competencies, and approach CRP skillset through the lens of risk management and safety (LaHucik, 2021).

As demonstrated in this formative study, local clinical providers must be acknowledged and included as partners in trial delivery for participants to be provided research opportunities and for their safety when receiving clinical care. However, suppose providers do not have the skillsets or awareness congruent to those of the CRPs. In that case, challenges will persist with research delivery in communities where trial participation is not the norm. For example, while providers reviewing the patient chart ahead of encounters is a fundamental skill, an advanced skill is identifying that patient as a trial participant. Cultivating provider skillsets as they relate to research is equally important to those of CRPs in rural and frontier areas, given their established trust with the participants as community members but also being the ultimate line of defense related to preventable adverse events (safety) and clinical monitoring. Developing the association of clinical care integration with research activities can be accomplished through enterprise-level leadership and socialization of research programs through grand rounds, organization town halls, and physician-investigator peer mentorship opportunities.

Conclusion

The call for inclusivity and access equity among rural, frontier, and other under-represented populations also, in turn, means a call to support the recruitment and retention of the clinical research workforce in these areas. The variance in resources, training, and skillsets of CRPs and research program culture across multiple locations necessitates a critical review of organizational culture in clinical care regarding awareness of research activities and their

impact on clinical decision-making or risk to patients. The heightened focus on decentralized trial model utilization in rural and frontier areas warrants additional examination and augmentation of the JTF Core Competency Framework to include cultural and resource-contextual considerations aligned to the U.S. Food and Drug Administration decentralized trial guidance. As the results of this formative study highlight, rural research programs need to be integrated with clinical operations to promote awareness and education and foster adaptability across an enterprise as participant and workforce need adjust during this period of rapid change in the industry.

Data availability statement

The raw data supporting the conclusion of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by the Montana State University IRB; Billings Clinic Privacy and Exemption Committee. The studies were conducted in accordance with the local legislation and institutional requirements. The ethics committee/institutional review board waived the requirement of written informed consent for participation from the participants or the participants' legal guardians/next of kin because Consent was implied upon completion of the electronic survey; respondents were not identified and therefore, it would have compromised participant privacy to obtain informed consent forms. The MSU IRB and Billings Clinic Privacy and Exemption Committee granted an exemption for full IRB review.

Author contributions

JB: Conceptualization, Investigation, Writing–original draft, Writing–review and editing, Funding acquisition, Resources, Supervision. EJ: Conceptualization, Writing–original draft, Writing–review and editing, Funding acquisition, Methodology, Resources, Visualization. JM: Formal Analysis, Writing–review and editing. BK: Writing–review and editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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References

Baer, A. R., Zon, R., Devine, S., and Lyss, A. P. (2011). The clinical research team. *J. Oncol. Pract.* 7 (3), 188–192. doi:10.1200/jop.2011.000276

Baquet, C. R., Commiskey, P., Daniel Mullins, C., and Mishra, S. I. (2006). Recruitment and participation in clinical trials: socio-demographic, rural/urban, and health care access predictors. *Cancer Detect Prev.* 30 (1), 24–33. doi:10.1016/j.cdp.2005.12.001

Bharucha, A. E., Wi, C. I., Srinivasan, S. G., Choi, H., Wheeler, P. H., Stavlund, J. R., et al. (2021). Participation of rural patients in clinical trials at a multisite academic medical center. *J. Clin. Transl. Sci.* 5 (1), e190. doi:10.1017/cts.2021.813

Brady, A., and Naikar, N. (2022). Development of Rasmussen's risk management framework for analysing multi-level sociotechnical influences in the design of envisioned work systems. *Ergonomics* 65 (3), 485–518. doi:10.1080/00140139.2021.2005823

Chacon, J. A., and Janssen, H. (2021). Teaching critical thinking and problem-solving skills to healthcare professionals. *Med. Sci. Educ.* 31 (1), 235–239. doi:10.1007/s40670-020-01128-3

de Jong, A. J., Grupstra, R. J., Santa-Ana-Tellez, Y., Zuidgeest, M. G. P., de Boer, A., Gardarsdottir, H., et al. (2022). Which decentralised trial activities are reported in clinical trial protocols of drug trials initiated in 2019-2020? A cross-sectional study in ClinicalTrials.gov. *BMJ Open* 12 (8), e063236. doi:10.1136/bmjopen-2022-063236

DiMasi, J. A., Smith, Z., Oakley-Girvan, I., Mackinnon, A., Costello, M., Tenaerts, P., et al. (2023). Assessing the financial value of decentralized clinical trials. *Ther. Innov. Regul. Sci.* 57 (2), 209–219. doi:10.1007/s43441-022-00454-5

Donovan, S.-L., Salmon, P. M., and Lenné, M. G. (2015). The leading edge: a systems thinking methodology for assessing safety leadership. *Procedia Manuf.* 3, 6644–6651. doi:10.1016/j.promfg.2015.11.004

Freel, S. A., Snyder, D. C., Bastarache, K., Jones, C. T., Marchant, M. B., Rowley, L. A., et al. (2023). Now is the time to fix the clinical research workforce crisis. *Clin. Trials* 20 (5), 457–462. doi:10.1177/17407745231177885

Goodson, N., Wicks, P., Morgan, J., Hashem, L., Callinan, S., and Reites, J. (2022). Opportunities and counterintuitive challenges for decentralized clinical trials to broaden participant inclusion. *npj Digit. Med.* 5, 58. doi:10.1038/s41746-022-00603-y

Ibrahim, S., Guerrero, M. M., and Goos, L. M. (2022). Adapting the Joint task Force core competency framework for clinical research professionals: a Canadian paediatric research perspective. *J. Res. Adm.* 53 (2), 85–102.

Iglehart, J. K. (2018). The challenging quest to improve rural health care. *N. Engl. J. Med.* 378 (5), 473–479. doi:10.1056/NEJMhpr1707176

Johnson, E. (2022). Trouble for trials - the worrying state of the research nurse workforce. *Contemp. Clin. Trials* 120, 106878. doi:10.1016/j.cct.2022.106878

Kelley, K., Clark, B., Brown, V., and Sitzia, J. (2003). Good practice in the conduct and reporting of survey research. *Int. J. Qual. Health Care* 15 (3), 261–266. doi:10.1093/intqhc/mzg031

LaHucik, K. (2021). About 77% of clinical research execs expect to run decentralized trials in next 12 months: survey. Available at: https://www.fiercebiotech.com/cro/nearly-80-clinical-research-execs-expect-to-run-decentralized-trials-next-12-months-survey.

Lintern, G. (2010). A comparison of the decision ladder and the recognition-primed decision model. *J. Cognitive Eng. Decis. Mak.* 4 (4), 304–327. doi:10.1177/155534341000400404

MacQueen, I. T., Maggard-Gibbons, M., Capra, G., Raaen, L., Ulloa, J. G., Shekelle, P. G., et al. (2018). Recruiting rural healthcare providers today: a systematic review of training program success and determinants of geographic choices. *J. Gen. Intern Med.* 33 (2), 191–199. doi:10.1007/s11606-017-4210-z

Mansaray, H. E. (2019). The role of leadership style in organisational change management: a literature review. *J. Hum. Resour. Manag.* 7 (1), 18–31. doi:10.11648/j.jhrm.20190701.13

Quilliam, C., Glenister, K., Ervin, K., and Weller-Newton, J. (2022). Revisiting rural healthcare access through held's ethics of care. *Soc. Theory Health* 21 (2), 178–193. doi:10.1057/s41285-022-00181-9

Rasmussen, J. (1986). "Information processing and human-machine interaction," in *An Approach to Cognitive Engineering: an approach to cognitive engineering* (New York: North-Holland).

Rasmussen, J. (1997). Risk management in a dynamic society: a modelling problem. *Saf. Sci.* 27 (2), 183–213. doi:10.1016/S0925-7535(97)00052-0

R Core Team (2013). *R: a language and environment for statistical computing*. Vienna, Austria: R Foundation for Statistical Computing.

Schmidt, D., Reyment, J., Webster, E., Kirby, S., and Lyle, D. (2020). Workplace-based health research training: a qualitative study of perceived needs in a rural setting. *Health Res. Policy Syst.* 18 (1), 67. doi:10.1186/s12961-020-00580-2

Seidler, E., Keshaviah, A., Brown, C. L., Wood, E., Granick, L., and Kimball, A. (2014). Geographic distribution of clinical trials may lead to inequities in access. *Clin. Investig.* 4, 373–380. doi:10.4155/cli.14.21

Sonstein, S. A., and Jones, C. T. (2018). Joint task Force for clinical trial competency and clinical research professional workforce development. *Front. Pharmacol.* 9, 1148. doi:10.3389/fphar.2018.01148

Sonstein, S. A., Kim, L. P., Ichhpurani, N., Padbidri, R., White, S. A., Aldinger, C. E., et al. (2022). Incorporating competencies related to project management into the Joint taskforce core competency framework for clinical research professionals. *Ther. Innov. Regul. Sci.* 56 (2), 206–211. doi:10.1007/s43441-021-00369-7

Sonstein, S. A., Namenek Brouwer, R. J., Gluck, W., Robert Kolb, H., Aldinger, C., Bierer, B. E., et al. (2020). Leveling the Joint task Force core competencies for clinical research professionals. *Ther. Innov. Regul. Sci.* 54 (1), 1–20. doi:10.1007/s43441-019-00024-2

Thakur, S., and Lahiry, S. (2021). Digital clinical trial: a new norm in clinical research. *Perspect. Clin. Res.* 12 (4), 184–188. doi:10.4103/picr.PICR_278_20

U. S National Library of Medicine (2023). Trends, charts, and maps. Available at: https://clinicaltrials.gov/ct2/resources/trends.

Walker, B., and Soule, S. A. (2017). *Changing company culture requires a movement, not a mandate*. Brighton, MA: Harvard Business Review.

Winter, S. S., Page-Reeves, J. M., Page, K. A., Haozous, E., Solares, A., Nicole Cordova, C., et al. (2018). Inclusion of special populations in clinical research: important considerations and guidelines. *J. Clin. Transl. Res.* 4 (1), 56–69. doi:10.18053/jctres.04.201801.003

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EDITED BY
Jacqueline G. Bloomfield,
The University of Sydney, Australia

REVIEWED BY
Michael J. Wolyniak,
Hampden–Sydney College, United States
Peter David Stonier,
Kings College, United Kingdom

*CORRESPONDENCE
Denise C. Snyder
✉ denise.snyder@duke.edu
Jessica R. Cranfill
✉ jessica.cranfill@duke.edu

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Development and implementation of an on-demand competency-based onboarding program for clinical research professionals in academic medicine

Jessica R. Cranfill[1,2,3]*, Christine E. Deeter[1,2,3], Deborah Hannah[1,2,3], Denise C. Snyder[1,2,3]* and Stephanie A. Freel[1,2,3]

[1]Duke Office of Clinical Research, Duke University, Durham, NC, United States, [2]School of Medicine, Duke University, Durham, NC, United States, [3]Clinical and Translational Science Institute, Duke University, Durham, NC, United States

Over the past 7 years, Duke has implemented competency-based job classifications for clinical research professionals (CRPs) with a defined pathway for career advancement. The workforce is defined specifically as the collection of staff employed across the clinical research enterprise to operationalize clinical research and human participatory protocols through the hands-on conduct of protocol activities including participant enrollment, regulatory coordination, study documentation, data collection and management, and sponsor engagement. The competency framework for this critical workforce laid the foundation for a centrally developed on-demand onboarding program at Duke. The self-paced program is designed to engage learners through competency-based learning modules, guided mentor/manager discussions, and applied learning activities. Consisting of an initial E-Learning orientation to clinical research at Duke, called Express Start, followed by a 90-day role-based Onboarding Learning Plan, our onboarding program includes training in foundational pre-defined core competency areas and customizable learning paths. Associated Engagement Activity Packets for many clinical research competencies encourage mentor and/or manager involvement and hands-on learning for the employee through suggested enrichment activities. The program has been widely adopted for CRPs within the Duke University Schools of Medicine and Nursing, and newly hired CRPs and their managers have expressed satisfaction with these centrally offered tools. In this paper, we describe the methods used to develop and implement our competency-based onboarding program. We will share an evaluation of the program and planned next steps for expanding the suite of onboarding resources.

KEYWORDS

clinical research professional, clinical research coordinator (CRC), competency-based training, onboarding program, E-learning, workforce development, professional development, instructional design

1 Introduction

Coordination and management of clinical research projects and programs within academic medicine has become increasingly recognized as a profession over the past decade (1, 2). As study conduct has become more complex, a growing number of tasks (informed consent, regulatory submissions, addressing privacy and data, engaging diverse community populations for recruitment, etc.) are delegated to these clinical research professionals (CRPs) (3). Yet, academic medical centers (AMCs) often struggle to identify, train, and develop this critical workforce within their institutions due to several factors including limited resources for staff-level managers and poorly defined clinical research workforce structure (4, 5). The consequent nebulous workforce is difficult to identify and oversee, ultimately impacting site quality. A multi-institutional task force convened to address the burgeoning complexity and lack of job standardization across CRP workforces resulting in the Joint Taskforce for Clinical Trial Competency framework, published in 2014 (6). Further efforts under Duke's Workforce Engagement & Resilience Initiatives (WE-R) to standardize clinical research jobs and career ladders at Duke with distinct JTFCTC competency-based roles have reduced attrition and created a CRP identity across twelve jobs (1, 2, 5–11). Consequently, the WE-R initiatives housed within the Duke Office of Clinical Research (DOCR) laid the necessary groundwork for developing competency-based onboarding for newly hired CRPs. The WE-R team began aligning CRP training opportunities with the JTFCTC framework (6) in 2018 and incorporating competency learning into the onboarding process to strategically propel CRPs toward competency-based thinking. This enables them to consistently progress within the established leveled framework, allowing for the enhancement of their competencies through continuing educational opportunities and positioning them to take advantage of advancement opportunities (7, 8, 11). We believe that onboarding programs with a foundation in this widely recognized competency framework will fill a critical gap in CRP development at many AMCs.

Through our work with the Association for Clinical and Translational Science (ACTS) Clinical Research Professional Taskforce (CRPT) Special Interest Group, including professional partners from the Association of Clinical Research Professionals (ACRP) and Clinical and Translational Science Award (CTSA) institutional networks, it is evident that effective onboarding and training paradigms remain a significant need in CRP workforce development (5). Onboarding in this context is the development of fundamental competencies that allow CRPs to perform their job successfully. The onboarding period for a new hire often aligns with a 3 to 6-month evaluation period and may be a constant endeavor for some teams due to a combination of portfolio growth and staff turnover. This can be a costly process; estimates for the cost of turnover for one employee can top $50 K or more, not including lost revenue related to study pauses, and can lead to manager burnout (8, 11). Importantly, poor onboarding may contribute to an unsupportive research culture and leave new staff without the ability to demonstrate necessary competency skills leading to more turnover early in the new hire period. We initiated our WE-R Onboarding Program to standardize CRP onboarding using established competencies and to ameliorate the onboarding burden faced by study teams and managers of new CRPs.

When job classifications are not standardized, it can be difficult to estimate how many CRPs are hired each year nationally or globally (12). Our twelve standardized job classifications combined host between 800–900 staff at a time and include entry-level Clinical Research Specialists, Clinical Research Coordinators, Regulatory Coordinators, Clinical Research Nurse Coordinators, Research Program Leaders, and senior-level and CRU management positions. Such standardization has allowed us to track attrition and hiring metrics over time, showing that in 6 years between FY2017 through FY2022, we have hired more than 1,200 new CRPs into Duke (11). Duke has over 24 clinical research units (CRUs) that are largely defined by clinical therapeutic area (e.g., Population Health, Pediatrics, Oncology, etc.) and vary in size of workforce based on research portfolio. Across all of our CRUs, we identified two essential problem areas relating to the onboarding of new CRP staff: (1) lack of standard and up-to-date onboarding tools for specific CRP positions, and (2) lack of alignment with established CRP competency domains. A series of "Un-Meetings," hosted by the ACTS and led by the CRPT Special Interest Group has uncovered the pervasiveness of these two critical deficits across both AMCs and Contract Research Organizations (CROs) (5). At Duke, we found that the onboarding tools used within the CRUs were inconsistent, quickly became outdated, and lacked a clear connection to an established professional competency framework. This lack of competency alignment created the potential for performance inequities across defined roles and unmet expectations for employees working across CRUs and therapeutic areas. Moreover, fully decentralized onboarding multiplied the effort required for managers to maintain onboarding processes and materials. The existing tools, developed and maintained by individual managers or units, did not align with the JTFCTC competency framework, resulting in knowledge gaps that might only be discovered later when CRPs needed to apply their skills. By centralizing and standardizing CRP onboarding tools at Duke, we provided managers with a structured onboarding plan that covered all the essential competency areas for their new employees' roles, with training materials that were kept up to date. This method allowed us to leverage the expertise of a dedicated instructional designer who specializes in adult learning to create an effective learning framework. Furthermore, by defining job-based core competencies that transcend research area, as well as distinct competency paths that align with more research area-specific requirements, we have created a foundational learning platform that can be tailored to, and grow with, the employee's career. Although our tools were developed in the context of Duke's CRP career structure, the transcendency of work roles, onboarding challenges, and the JTFCTC competency framework allowed us to create an onboarding program that can be easily adapted and widely implemented across clinical research sites and AMCs.

Abbreviations: ACRP, association for clinical research professionals; AMCs, academic medical centers; CRC, clinical research coordinator (job title); CRNC, clinical research nurse coordinator (job title); CRP, clinical research professional; CRPT, clinical research professional taskforce; CRS, clinical research specialist (job title); CTSA, clinical and translational science awards; CRU, clinical research unit; DOCR, Duke office of clinical research; JTFCTC, joint task force for clinical trials competency; OLP, onboarding learning plan; RC, regulatory coordinator (job title); RPL, research program leader (job title); WE-R, workforce engagement and resilience.

2 Pedagogical framework

We intentionally crafted our onboarding program to be flexible for CRPs and their managers and incorporated key elements for self-paced adult learning. These elements included a digital learning strategy with online modules to present new information and guided applied learning tasks. We reviewed onboarding models across the field, seeking a balanced approach that promotes competency-based learning retention while remaining flexible and feasible for our small, centralized team to manage. During our assessment of onboarding models, ranging from boot camps to fully centralized, training-intensive programs, we observed that boot camps—intensive training over a short period—are commonly provided (13). While this option provides significant and often competency-aligned training, this accelerated method may not be as conducive to information retention as more gradual, on-the-job onboarding options, due to the absence of experiential learning and hands-on practice (14).

To evaluate options that might better promote competency-based learning retention, we engaged collaborators across CTSA CRPT Special Interest Groups to understand onboarding programs being offered among our peer institutions. The challenges of implementing a fully centralized program, such as that written by Musshafen et al. (15), include both the significant training effort and expense needed to run the program (multiple dedicated full-time staff for 200+ new hires each year) and the amount of time new employees spend away from their projects during the onboarding period. We aimed to create and broadly share a hybrid approach that capitalizes on the most effective strategies from each of these successful models. While not a factor when we began program development, the need to accommodate onboarding during the remote and hybrid environments of the COVID-19 pandemic quickly became an important influence in program design and remains advantageous for the growing number of decentralized research teams. To our knowledge, there are no published or disseminated tools from other institutions for a similar on-demand and competency-based onboarding program for the CRP workforce.

Program development relied on partnerships between the central WE-R team, CRU leaders, and individual managers. To ensure the program was both impactful and acceptable across CRUs, we explored needs with CRU leaders and considered the versatility of tasks and work locations. Using our existing competency framework, we developed a semi-centralized onboarding program for each of our CRP job classifications which includes several components (see Figure 1). Due to the decentralized and federated CRU structure at Duke, direct supervisors and managers are responsible for the supervision and mentorship of newly hired CRPs, implementation of the onboarding program and tools into their CRU's onboarding practices, and management of competency acquisition and advancement for their CRPs. While the use of this program is currently not required across the institution, it is a step toward standardizing training for clinical research staff and preparing them for recurrent competency development and career advancement. The following sections describe our work to centrally develop, implement, and evaluate this onboarding program for CRPs at Duke University.

3 Learning environment

The competency-based CRP onboarding program at Duke is driven by employees and their managers and includes several components that work together to prepare CRPs for their careers at Duke. We used an iterative process to develop each component and sought input from members of the research community throughout the process.

3.1 Mapping existing training to competencies

Before developing centralized onboarding, our first step was to map existing relevant training into the competency framework at

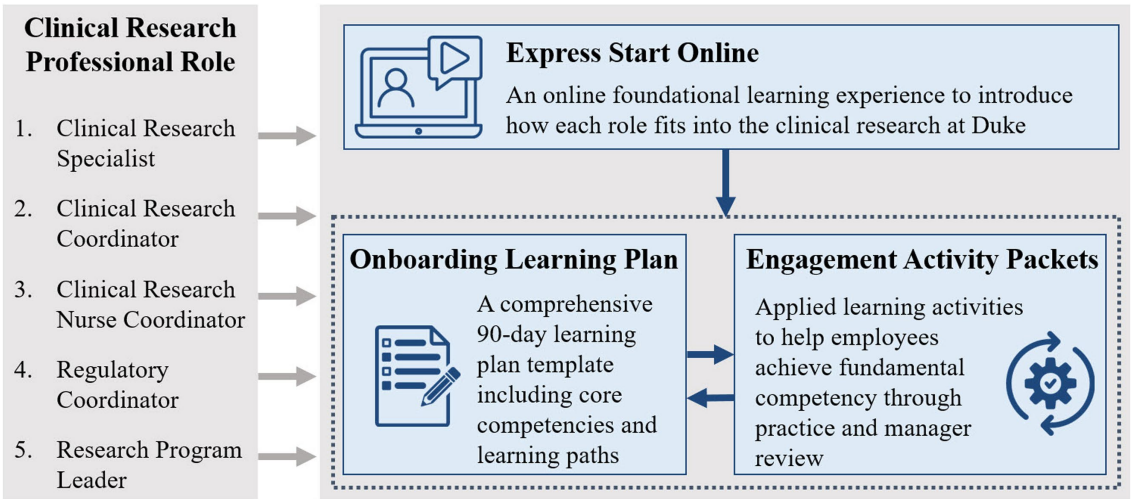

FIGURE 1
The clinical research professional onboarding program at Duke consists of 3 parts: (1) Express Start is an online foundational learning experience to introduce how each role fits into clinical research at Duke, (2) the Onboarding Learning Plan is a comprehensive 90-day learning plan template including core competencies and learning paths, and (3) the Engagement Activity Packets include applied learning activities to help managers guide the onboarding process and help employees achieve fundamental competency through practice and manager review.

Duke. This allowed us to understand existing resources, identify training gaps, and begin to frame a competency-based training structure. A total of 97 existing courses were mapped to clinical research competencies. Mapped trainings were developed by the Duke Office of Clinical Research (DOCR), Duke Clinical and Translational Science Institute, Duke Office of Physician Scientist Development, Duke Office of Scientific Integrity, Duke Occupational and Environmental Safety Office, Duke Office of Regulatory Affairs and Quality, the Collaborative Institutional Training Initiative, and the Society of Clinical Research Sites (16, 17). The process of mapping training to clinical research competencies was useful to (1) identify currently available training in each competency area, (2) organize courses appropriately for staff to easily identify training needed for skill growth, (3) pinpoint gaps and prioritize opportunities for new course development, and (4) inform competency-based onboarding development.

3.2 Engaging the Duke clinical research community and leadership

Buy-in and engagement from the clinical research community and executive leadership were essential in developing an onboarding process applicable across all Duke CRUs. To achieve this, we assembled a steering committee including our DOCR WE-R team, Duke School of Medicine Human Resources, and colleagues from CRUs of various sizes and therapeutic areas. The committee's goal was to contribute to an onboarding program that represented Duke as an entity yet easily tailored to meet specific CRU needs.

To capture specific needs across every CRU, we surveyed CRU leadership via REDCap (an electronic data capture tool described in detail in the Acknowledgments section of this paper) (18). The survey queried which of the JTFCTC competencies CRU leaders considered necessary for a given job role within their unit, what they desired in a centrally developed onboarding program, and how they onboarded new CRPs at the time. Consistent themes included the need for onboarding tools that: (1) introduced the competency framework and promoted competency development, (2) were centrally maintained and regularly updated, (3) were standardized for each CRP job role, yet flexible and customizable for unit-specific functions, (4) could be available on-demand for new staff to begin immediately upon start, (5) included a manageable and adjustable timeline for completion, and (6) encouraged application of concepts on the job with intentional manager involvement.

3.3 Addressing the heterogeneous academic research environment

As expected, survey results showed variability regarding which competencies were considered essential across CRUs. However, follow-up interviews with CRU leaders to further discuss the survey identified several common competencies for each job role despite differences in research areas and project types. One essential goal was, therefore, to develop a tool that was both standardized for these core job competencies and flexible for our varied research areas. To address this, we created an onboarding framework with required "core competencies" and elective "learning paths" for each CRP role.

- **Core competencies:** competencies deemed necessary for all individuals in the job classification across all research areas.
- **Learning paths:** chosen by the hiring manager based on an individual CRP's job responsibilities and research environment. Individuals are likely to have multiple paths based on the job functions they need to learn.

To ensure universally applicable categorization, the WE-R team interviewed each survey respondent individually to discuss the initial survey results and achieve consensus on the defined cores and learning paths. During these interviews, the team also gathered the current onboarding plans and checklists used across units to further compare consistency and variations in onboarding across the units. Finally, core competencies and learning paths were presented at CRU leadership meetings to obtain consensus for the Clinical Research Coordinator (CRC) and Regulatory Coordinator (RC) roles. We attribute much of the voluntary uptake of standardized onboarding to the engagement of CRU leadership and CRPs throughout the development of the program.

At the end of fiscal year 2022, the CRC job classification accounted for 40.89% of the Duke CRP workforce. The greatest number of annual hires are also in CRC jobs. Clinical Research Specialist Srs. and Clinical Research Specialists (CRS) combined accounted for 17.18% of the CRP workforce. Therefore, we began by developing onboarding tools for CRCs and then modifying them for CRSs. Table 1 is a visual representation of the core competencies and learning paths defined for each role's onboarding.

3.4 Onboarding program components

To meet the described needs of our CRUs, including the hybrid work environment required during the COVID-19 pandemic, the WE-R team started developing three primary onboarding components that are available on demand. The components include (1) Express Start Online, (2) Onboarding Learning Plan, and (3) Engagement Activity Packets.

3.4.1 Express start

Express Start is a series of self-paced E-Learning modules for each role that serves as an introduction to clinical research and the competency framework at Duke. This introduction is meant to provide context for all additional training tasks a new employee will complete, allowing them to relate what they learn to their understanding of their role within the institution. These modules include an overview of the clinical research competencies, activities, regulations, and workflows specific to their role, and provide a sense of what other members of their team may be responsible for. Refer to Supplementary Table S1 for a list of the modules included in Express Start for each role.

3.4.2 Onboarding learning plan templates

The Onboarding Learning Plan (OLP) template for each role provides a curated list of technical online (and limited in-person) training to develop fundamental skills in the CRP competencies. Core competencies and customizable learning paths are organized within the easily personalized template, refer to Table 1 for cores and paths mapped to each CRP role. Adult learning motivation stems from

TABLE 1 This table shows the competencies included in the Onboarding Learning Plan (OLP) template for each clinical research professional job described in this paper.

Job title	Core competencies: foundational learning applicable to everyone in the role	Learning paths: competencies chosen by the manager based on responsibilities
Clinical Research Specialist (CRS)	1. Express Start for CRS 2. Electronic Management of Participants* 3. Participant Level Documentation* 4. Data Security and Provenance* 5. Institutional Regulatory Policies and Procedures*	6. Recruitment* 7. Databases 8. Adverse Events* 9. Contracts and Agreements 10. Study Closeout*
Clinical Research Specialist, Senior (CRS Sr.)	1. Express Start for CRS Sr. 2. Electronic Management of Participants* 3 Participant Level Documentation* 4. Data Security and Provenance* 5. Institutional Regulatory Policies and Procedures*	6. Consent Procedures* 7. Recruitment* 8. Databases 9. Adverse Events* 10. Contracts and Agreements 11. Study Closeout*
Clinical Research Coordinator (CRC)	1. Express Start for CRC 2. Electronic Management of Participants/Protocols* 3. Consent Procedures* 4. Participant & Study Level Documentation* 5. Data Security and Provenance* 6. Institutional Regulatory Policies and Procedures*	7. Recruitment and Screening* 8. Databases 9. Adverse Events* 10. Regulatory Cores* 11. Investigational Products* 12. Specimen Handling 13. Study Closeout* 14. Financial-Related Training
Clinical Research Nurse Coordinator (CRNC)	1. Express Start for CRNC 2. Duke Health Nursing Orientation & Nursing Competency Checkoffs 3. Electronic Management of Participants/Protocols* 4. Consent Procedures* 5. Participant & Study Level Documentation* 6. Data Security and Provenance* 7. Institutional Regulatory Policies and Procedures*	8. Recruitment and Screening* 9. Databases 10. Adverse Events* 11. Regulatory Cores* 12. Investigational Products* 13. Specimen Handling 14. Study Closeout*
Regulatory Coordinator (RC)	1. Express Start for RC 2. Electronic Management of Protocols* 3. Development of Informed Consent Documentation and Plan* 4. Navigating the Ethics Review Process 5. Institutional Regulatory Policies and Procedures* 6. Data Security and Provenance* 7. Sponsor/Regulatory Reporting	8. Participant and Study Level Documentation* 9. Databases 10. Adverse Events* 11. Contracts and Agreements* 12. Study Closeout* 13. FDA Regulatory Submissions*
Research Program Leader (RPL)	1. Express Start for RPL 2. Electronic Management of Participants and Protocols 3. Operational Leadership *(Institutional Regulatory Policies and Procedures, Leading Project/Program Staff, Budgeting and Resource Management*)* 4. Project Management *(Project Initiation and Scope*, Project Planning*, Stakeholder Management*, Task Management*, Milestone Tracking and Reporting)* 5. Intellectual Contribution and Scientific Concepts* *(Proposals, Grants, Manuscripts, and representing the program)* 6. Leadership and Professionalism *(Professional Development, External Awareness, Organizational Agility, Resilience and Adaptability, Subject Matter Expertise and Problem Solving, Communication and Teamwork)*	7. Contracts and Agreements 8. Investigational Products* 9. Study Documentation* 10. Recruitment* 11. Participant Retention 12. Monitoring and Audits 13. Adverse Events* 14. Informed Consent* 15. Navigating the Ethics Review Process 16. Sponsor/Regulatory Reporting 17. Data Security and Provenance* 18. Data Collection and Entry 19. Coordination with Sponsor/CRO 20. Study Closeout*

The OLP template for each job title includes core competencies that are relevant to anyone new to the role as well as learning paths that are chosen by the manager based on individual responsibilities. Competencies with an asterisk (*) have an associated Engagement Activity Packet.

understanding how learning will be applied and valuing learning outcomes (19). Therefore, we provide a 90-day week-by-week plan that can be aligned functionally and temporally with work activities. The OLP templates include core learning for everyone in the role, learning paths that may be relevant to the role, and space for the manager to add any additional study or unit-specific training requirements for the employee. The core competencies for each position set the stage for foundational job activities in clinical research that are necessary to

perform a CRP job and apply across all therapeutic areas. The inclusion of customizable learning paths in the Onboarding Learning Plan recognizes the diverse responsibilities CRPs may have in different therapeutic areas and allows for tailored learning experiences while maintaining standardization to the JTFCTC competency area. This flexibility ensures that the onboarding program caters to the specific needs of individual CRPs, acknowledging the varied competencies required across research areas.

The OLP templates have a customizable week-by-week timeline with a checklist structure so the employee can check off training items upon completion. Each week includes training for one to two clinical research competencies and an estimated time to complete certain tasks. Weekly goals provide the employee with a sense of structure, space out learning over time, and allow the employee allotted time to do hands-on activities related to each competency. Managers are encouraged to review the timeline and organize the plan in a way that aligns training with the employee's opportunity to practice certain tasks.

The OLP includes a description for the CRP of each learning element listed. This description provides necessary context that helps orient them by clarifying the purpose for specific tasks and workflows. Courses that are required by institutional policy are marked as such. While this context can help ensure employees only complete courses that apply to their responsibilities, the manager is expected to review the template and tailor it to the needs of the specific employee before providing it to them.

3.4.3 Engagement activity packets

Engagement Activity Packets are available for many of the clinical research competencies and are linked within the OLP. This tool is used by managers to guide supervision of the onboarding process and mentoring of new employees as they work to acquire each competency. The Engagement Activity Packets include the following elements to help the employee achieve fundamental competency through application, practice, and manager review:

1. **Knowledge objectives and fundamental skills:** A description of expected knowledge and skill after 90-day onboarding. These are tied to the established fundamental skill level for the competency (8).
2. **Recommended guidance, policies, and additional courses**: A list of recommended guidance (websites, resources, etc.), policies, and courses to supplement those included in the OLP as needed.
3. **Manager review questions:** Guided questions to review with a manager or mentor. These are intended to engage the manager in the learning process and keep them informed of progress and opportunities for clarification.
4. **To-do items and suggested shadowing activities:** Suggested activities to help the employee make the connection between E-Learning courses and their daily work. These provide a means for meaningful team interactions and experiential learning. *The involvement of a manager/mentor in the onboarding process is critical for this piece to be effective.*

The combination of the three onboarding components described above offers a foundational starting point for career competency development and structured reference materials for many job tasks. These tools can be used for new hires to Duke, transfers between units, and staff with limited experience in clinical research. The flexibility of the onboarding toolkit as a whole allows managers to personalize the onboarding process depending on an employee's existing strengths and experience.

3.5 E-learning course development and rationale for on-demand training

It is important to note that many of the courses included in this onboarding program are asynchronous E-Learning modules. Most of the modules were developed by an instructional designer on the DOCR WE-R team using Storyline and Rise authoring software, which are both included in the Articulate 360 E-Learning development platform's suite of tools used for instructional design (4). Subject matter experts from CRUs and DOCR were consulted in the design, development, and review of each module. Modules include an engaging combination of reading, narration, video, interactivity, practice, and assessment.

The shift to on-demand E-Learning modules rather than live, instructor-led courses occurred for several reasons. The volume of new hires in clinical research positions has led to an overwhelming demand for training (roughly 200 annually). At the same time, CRPs are located across hospitals, clinics, and in the community with limited time or ability to attend in-person training. E-Learning modules are a solution for training that does not require an in-person observation of competency. On-demand modules afford CRPs the ability to learn at their own pace, intersperse study-specific training as needed, and spend more time upfront practicing job-specific tasks with their study team. Additionally, the ability to access content within these modules at any time has allowed for more just-in-time training and guidance for the whole clinical research community.

The creation of E-Learning modules is a time-intensive endeavor up front, but centrally maintaining, hosting, and tracking training completion is more simplified and less effort-intensive in the long term. The limitation to exclusively using E-Learning in the complex clinical research environment is the need for hands-on practice to retain skills in many competencies (20). As described above, the Engagement Activity Packet component of our onboarding program addresses this pitfall by providing a means for applying the competencies on the job.

4 Implementation of the onboarding program

Institutions that are interested in accessing the onboarding program tools described above may request access to our repository of licensed materials and an Onboarding Toolkit Implementation Plan. There is a request form publicly available on the Duke Office of Clinical Research Onboarding and Training for Clinical Research Professionals website.[1] The implementation plan further details the

1 https://medschool.duke.edu/research/research-support/research-support-offices/duke-office-clinical-research-docr/workforce-0#toolkit

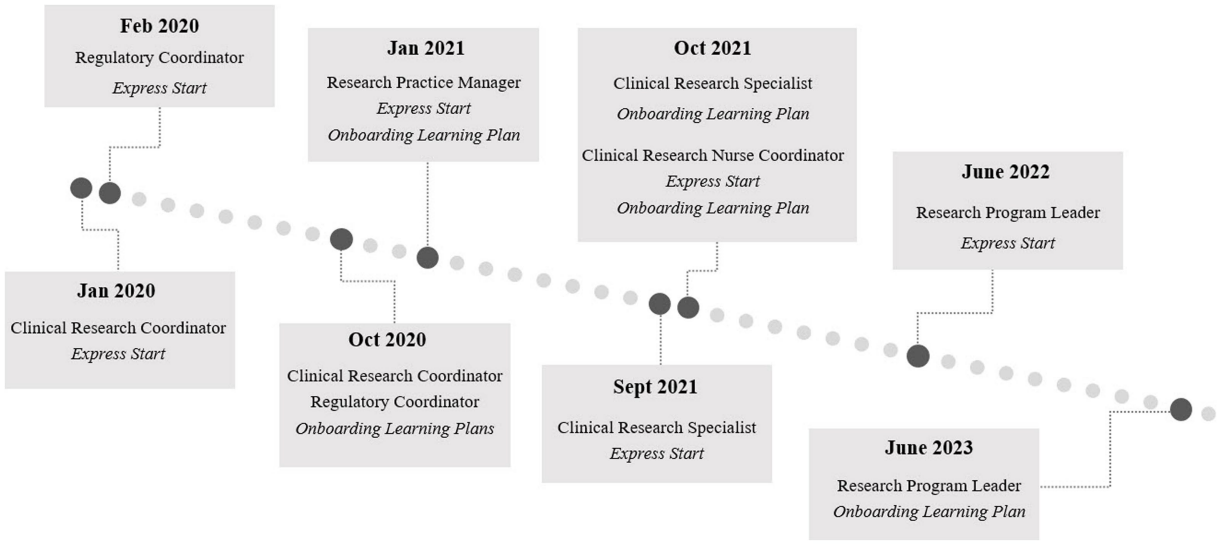

FIGURE 2
Onboarding program implementation and launch timeline for each component of the Duke onboarding program for clinical research professionals by role. Engagement Activity Packets launched in October 2020 and June 2023 along with the Clinical Research Coordinator and Research Program Leader Onboarding Learning Plans, respectively. The phased development and launch of the tools spanned from 2020 to 2023 and iteration will continue.

program components, audience, competency-based jobs foundation, program intention and goals, program team, software used, description of program components and materials, program implementation steps, challenges and solutions, manager guidance, and a full implementation timeline.

4.1 Phased launch

Implementation of the full suite of onboarding tools for all CRP jobs at Duke occurred in phases, with tools for each role launching as development concluded. The full timeline for the launch of each element from 2020 to 2023 is illustrated in Figure 2.

We initially planned a soft launch of the full suite of onboarding tools in mid-2020 with 43 staff in CRC and Regulatory Coordinator roles across nine volunteer CRUs. Those in this phase would receive a survey at 30, 60, and 90 days about the program and their comfort with the competencies covered. However, several weeks into the soft launch, as more CRPs were hired, we began receiving requests from additional managers who were not participating in the first phase of the rollout to receive the tools. As teams were managing COVID-19 demands during this time, the increasing need for an online, standard solution for managers to onboard and train staff was apparent. We discontinued the pilot evaluation phase to focus on disseminating and training all interested managers to use the tools. We later reconvened to assess the program as described in the Program Assessment.

4.2 Implementing the program components

The primary mechanism for delivery of the program components is the Duke Office of Clinical Research WE-R website where managers can locate all information associated with using these tools. Each tool is either housed in Duke Box[2] (secure cloud-based storage and collaboration service), the Duke Learning Management System (online system for training management and completion tracking), or can be requested directly from the WE-R team. The website and materials are maintained by the DOCR Manager of Education and Outreach/Instructional Designer.

When a new hire is identified, their manager downloads the most recent version of the plan from the WE-R website and adjusts the template as needed to align with opportunities for hands-on application and onboarding timeline needs. This includes choosing relevant learning paths for the employee, indicating a goal week for completion of each competency, and removing any learning paths that are irrelevant to the employee's research focus. For onboarding to be most effective, we recommend managers meet regularly with the new employee throughout the 90-day onboarding period to review the Engagement Activity Packets, keep up with progress, and adjust timelines or learning paths as needed.

4.3 Communication and support

Availability of the new onboarding tools for CRPs was initially communicated to CRU leadership who relayed information about the program and provided their expectations for use to managers in their unit. Announcements to the full community occurred via our Clinical Research Update Newsletter, targeted email announcements from clinical research leadership, and presentations at Duke clinical

2 http://box.com/

research community events. Currently, the community is continuously updated on new tools and new versions.

To make it as smooth as possible for managers to incorporate the new tools into their onboarding processes, the WE-R team launched an on-demand training module, a Clinical Research Onboarding Manager Guide webpage, and no-cost onboarding consultations. Information about these is publicly available on the DOCR Onboarding and Training for Clinical Research Professionals website. Managers can request the onboarding consultation with DOCR to discuss their current onboarding process, review the central onboarding tools, and receive guidance on incorporating the program into their CRU's current onboarding practices. The WE-R team provides continuous support as needed and managers can request as many consultations as they need.

4.4 Tracking program use

Because CRUs independently manage hiring and oversight of their CRP employees, we do not require the use of our centralized tools for all new CRP employees. Instead, expectations for use are set by the leadership within each CRU. With the decentralized nature of our workforce, tracking the use of each element requires unique strategies. Completion of the Express Start modules is tracked via the Duke Learning Management System. Onboarding Learning Plan use is more difficult to ascertain. Upon receiving the OLP from their manager, employees first engage with a link to a REDCap survey to manually "Register Use" of the plan. For the Engagement Activity Packets, we track use via the number of downloads of each packet from Duke Box.

5 Program assessment

Two years following the initiation of the phased launch, and adaptation as described in section 4.1, we employed a new evaluation strategy. To evaluate satisfaction with the suite of tools, three separate surveys were disseminated to managers and staff who reportedly used the tools between August 2021 and July 2022. An Express Start Employee survey was sent to employees who completed the Express Start modules in the Duke Learning Management System. Managers and staff received a role-specific OLP and Engagement Packet survey if they reported the use of an OLP. Survey totals and response rates have been provided below for all three surveys.

- Express Start Employee Survey: 53% response rate (sent 185/ responded 98 – CRC, 44; CRNC, 18; CRS, 21; RC, 8; RPL, 5)
- Onboarding Learning Plan and Engagement Packet Employee Survey: 56% response rate (sent 102/ responded 57 – CRC, 30; CRNC, 15; CRS, 8; RC, 3; RPL, 1)
- Onboarding Learning Plan and Engagement Packet Manager Survey: 71% response rate (sent 52/ responded 37)

Survey respondents represented 21 of the 23 Duke CRUs in operation during the assessment period as well as each of the included CRP jobs, with a majority of respondents in the CRC role that makes up the largest percentage of our workforce. As displayed in Figure 3, 70% or more respondents either agreed or strongly agreed that they were satisfied with the onboarding tools they used. 30 out of the 57 respondents confirmed completion of the Engagement Activity Packet component with 25 of those 30 agreeing or strongly agreeing that they were satisfied with them. All 30 employees agreed or strongly agreed that the engagement activities included were useful for their role and 28 of the 30 employees agreed or strongly agreed that the engagement activities helped them apply what they have learned on the job. When compared, those employees who answered agree or strongly agree to "my manager played an active role in my onboarding activities" or "my manager and I thoroughly reviewed the engagement packets together" more often reported satisfaction with onboarding tools than those who did not feel that their manager was engaged.

In addition to expressing overall satisfaction with the tools, managers overwhelmingly agreed or strongly agreed that the tools were easy to find (92%), clear and easy to use (100%), and saved them time preparing for and onboarding their new employees (95%). Most managers agreed or strongly agreed that the central onboarding tools closely matched the roles they were onboarding (90%).

Manager satisfaction with the tools is evident in their use across CRUs despite the absence of any central requirement to use them. Table 2 captures information about employee completion of each onboarding component during the assessment period. From August 2021 to July 2022, 305 employees were hired, transferred, or reclassified into one of the CRP positions. Of those 305 employees, 190 (62.3%) completed all of the Express Start modules for their role, and 120 (39.3%) registered their use of an OLP. The completion percentages are higher when we consider only hires who are brand new to Duke. Of the 145 total hires new to Duke, 110 (75.9%) completed Express Start, and 64 (44.1%) registered the use of an OLP. These data do not include Research Program Leaders, because an OLP and Express Start were not yet available for the role during this period. The higher uptake of the Express Start modules may stem from the Learning Management System which automatically tracks and records completion. Data about OLP usage, on the other hand, is tracked via voluntary submission of a REDCap registration form by the employee or manager and numbers may underrepresent usage if downloaded and used without registration.

A few themes emerged from the analysis of 19 employee qualitative comments. Comments were mainly constructive, and themes were consistent regardless of stated satisfaction with the learning plan received. Themes included document issues (e.g., redundancy and broken links) (6), uninvolved/unprepared managers (12), and lack of and/or need for shadowing (6). Comments around the need for shadowing, lack of manager involvement, and not customizing templates indicate mismanagement of the process by managers and failure to use the tools as intended. This emphasizes the importance of additional manager training, which we have prioritized developing since the assessment. The OLP template, by itself, does not provide everything an employee needs to be successfully onboarded. Manager or mentor involvement in tailoring the onboarding experience is an essential element that can only be supplemented by any training tools.

Manager comments were overwhelmingly positive. Among the available comments from 15 managers, themes included general appreciation of the tool (10), customizability (3), helpfulness of engagement activities (3), and comprehensiveness of the tools (2). Constructive comments included the need for a plan that caters to senior-level roles and the lack of time available to them for effective

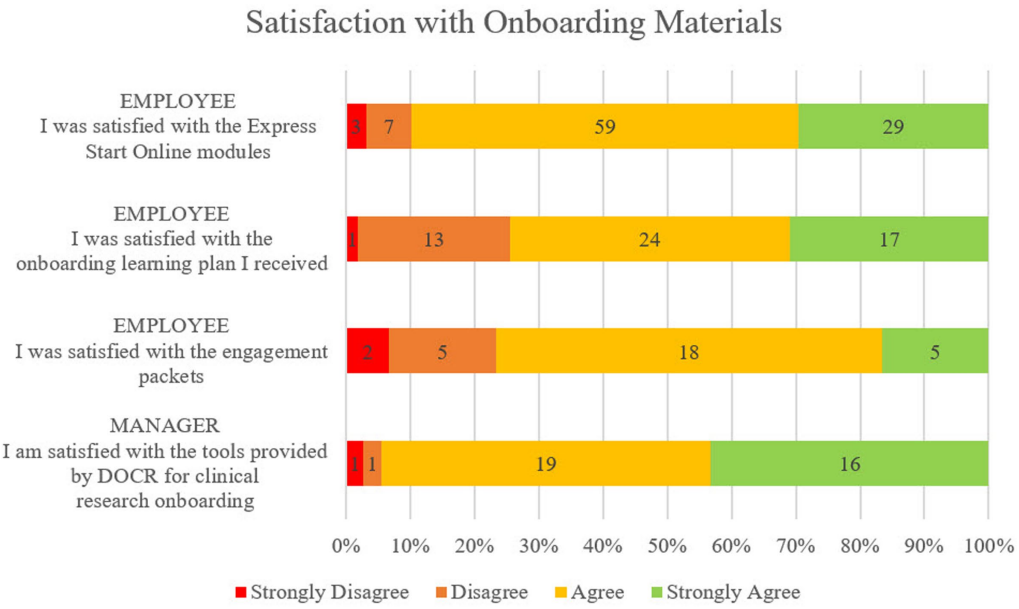

FIGURE 3
Satisfaction with onboarding components from the employee perspective and the manager perspective on a 4-point scale from Strongly Disagree to Strongly Agree. Employees recorded satisfaction with Express Start, Onboarding Learning Plan, and Engagement Activity Packets. Managers recorded satisfaction with the full suite of tools provided for their use.

TABLE 2 The count (*N*) of clinical research professionals (CRPs)* who joined the workforce at Duke within the assessment period (August 2021 – July 2022).

Type of Hire	*N*	Completed express Start	Registered onboarding learning plan
Hires new to Duke	145	110 (75.9%)	64 (44.1%)
Transfers and reclassifications within Duke	160	80 (50%)	56 (35%)
All	305	190 (62.3%)	120 (39.3%)

The rightmost columns illustrate the number and percentage of those hires who completed Express Start and/or registered use of an Onboarding Learning Plan for their role.
*This table does not include hire data for research program leaders because the onboarding tools for this role were in development during the assessment period.

onboarding. A few managers indicated the need for something that was already included in the toolkit (e.g., shadowing ideas and a customizable timeline), further confirming the need for additional manager training on using these tools effectively. Only two managers disagreed that they were satisfied with the tools and neither provided comments, therefore a thematic analysis of dissatisfaction was not possible.

6 Reflections, challenges, and future opportunities

6.1 Reflections

The program assessment described above illustrates the utility of a centrally offered, standardized onboarding program in meeting the needs of newly hired CRPs. Survey results indicate a high degree of satisfaction with the centrally offered onboarding tools from both new employees and their managers. A majority expressed that the competency-based onboarding tools aligned with their job duties and prepared them to be successful in their work, emphasizing their clarity, ease of use, and time-saving benefits. Managers indicated a high level of satisfaction with the tools, and their positive feedback aligns with their proactive use of the onboarding resources despite the lack of requirement.

The completion rates for the Express Start modules and Onboarding Learning Plans reveal a noteworthy initial adoption among new hires. Despite the voluntary nature of the program and the constraints on their time, both managers and employees actively opt to use these tools. This underscores the motivation of CRPs to undergo comprehensive training, emphasizing their commitment to succeeding in their roles and delivering high-quality work. At the same time, it reflects managers' need for effective onboarding tools to facilitate the integration of new hires into their teams. Taken together our data indicate that a competency-based centralized onboarding program can be standardized for clinical research job classifications while still accommodating the unique requirements of distinct research areas.

6.2 Challenges and opportunities

Because of our federated research structure, we have limited ability within the central WE-R team to control how the program tools are used within each CRU. There is a clear need for ongoing manager

training and outreach about the availability of the tools themselves and onboarding best practices. We have implemented onboarding consultations to help managers apply our tools and are expanding manager training opportunities. However, manager time may continue to be a barrier to effective onboarding for some, given general competing priorities for time and effort. Although we are encouraged that the onboarding tools are saving managers' time and reducing burden, we are cautious that this may reflect inappropriate use of the tools, replacing meaningful manager engagement rather than enhancing and fostering mentoring relationships with new staff. Because of this, we are continuing outreach across CRU leadership and management communities to promote manager engagement during the onboarding process and to identify remaining educational gaps.

Another challenge is the time-intensive maintenance of tools. While relatively low maintenance compared with labor-intensive fully centralized onboarding models, this program requires one full-time employee to develop and at least 50% effort to maintain post-implementation. During the start-up phases, an instructional designer/project manager FTE as well as 10%–20% effort from the steering team was needed. For sites that have fewer resources, we offer the use of our publicly available toolkit without cost so that resources can be minimized to those required for adapting and implementing the educational framework at their site.

Finally, because we strove to produce a low-technology program that could be widely adopted without technology-related costs, our tracking mechanisms for some components of the program are limited. To reflect more directly on whether this onboarding program contributes to employee competency development and career advancement over time will require additional tracking mechanisms and partnerships with CRUs.

6.3 Leadership and manager onboarding and training

As a next step for the onboarding program, we will focus on building out tools for CRPs hired into senior-level positions. The study conduct competencies required of these positions are captured in the existing tools; however, there is a need for additional content to be added for team lead and manager roles. Future offerings for managers will cover use of onboarding and training tools for their employees, best practices in hiring and professional advancement, and critical management and leadership skills. Introducing the onboarding tools and best practices during onboarding for senior staff, who will primarily manage and onboard future CRPs, will help improve awareness and alleviate some of the program implementation challenges presented above.

6.4 Adding a social component to onboarding: new hire cohorts and mentoring

There are three main components of successful onboarding; organizational, technical, and social (21). Express Start and CRU-specific training address the organizational component by showing employees how Duke functions and where they fit into clinical research. Technical aspects are covered within the Onboarding Learning Plans and competency-based Engagement Packets that help establish fundamental competency and allow employees opportunities for practice. In a new labor era where CRPs work in many different settings, including their homes and community settings, the social component is inherently important. To supplement our existing onboarding tools, we have begun piloting a New Hire Cohort and Mentoring Program that includes 6 months of bi-weekly group meetups with an experienced mentor to facilitate discussions and monthly foundational live training sessions. Our intention with this program is to provide a social element to onboarding, build a collaborative community across clinical research positions and units, and provide a professional growth opportunity for experienced clinical research staff.

6.5 Final thoughts

The alignment of the CRP onboarding program at Duke with the Joint Task Force for Clinical Trials Competency (JTFCTC) framework, has provided a structured approach to introduce CRPs to competency-based thinking early in their career (6). This alignment allows for consistent growth within the established framework, promoting continuous competency-based educational opportunities and facilitating competency-based career advancement (8).

At this time, we believe there are no published or disseminated tools from other institutions for a similar on-demand and competency-based onboarding program aligned with the JTFCTC framework for CRPs. However, since launching our Onboarding Toolkit[3] in August 2023 for other institutions to access and download, 35 different Academic Medical Centers have requested access to the tools described in this paper. This, alongside our collaborative Un-Meeting findings (5), demonstrates that there is a critical need for standardized, competency-based, on-the-job training to develop early talent among newly hired site CRPs. Readily available, easily adaptable, and broadly accessible tools, such as ours bridge a critical gap toward improving study quality and building a stronger CRP workforce.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Author contributions

JC: conception and design of work, data acquisition and interpretation, and publication draft and revision. CD: conception and design of work, analysis and interpretation of data, and publication revision. DH: conception and design of work and publication draft. DS: conception of work, interpretation of data, and publication revision. SF: conception and design of work, data

3 https://medschool.duke.edu/research/research-support/research-support-offices/duke-office-clinical-research-docr/workforce-0#toolkit

acquisition and interpretation, and publication draft and revision. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

Supplementary material

The Supplementary material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fmed.2023.1249527/full#supplementary-material

References

1. Speicher LA, Fromell G, Avery S, Brassil D, Carlson L, Stevens E, et al. The critical need for academic health centers to assess the training, support, and career development requirements of clinical research coordinators: recommendations from the clinical and translational science award research coordinator taskforce. *Clin Transl Sci*. (2012) 5:470–5. doi: 10.1111/j.1752-8062.2012.00423.x

2. Stevens EJ, Daemen E. The professionalization of research coordinators. *Clin Res*. (2015) 29:26–31. doi: 10.14524/CR-15-0035

3. Sung NS, Crowley WF, Genel M, Salber P, Sandy L, Sherwood LM, et al. Central challenges facing the national clinical research enterprise. *JAMA*. (2003) 289:1278–87. doi: 10.1001/jama.289.10.1278

4. Articulate (2016). The World's best Creator platform for online workplace learning. Available at: https://articulate.com/ [Accessed November 27, 2023].

5. Knapke JM, Jenkerson M, Tsao P, Freel S, Fritter J, Helm SL, et al. Academic medical center clinical research professional workforce: part 2–issues in staff onboarding and professional development. *J Clin Trans Sci*. (2022) 6:e81. doi: 10.1017/cts.2022.412

6. Sonstein SA, Seltzer J, Li R, Silva H, Jones CT, Daemen E. Moving from compliance to competency: a harmonized core competency framework for the clinical research professional. *Clin Res*. (2014) 28:17–23. doi: 10.14524/CR-14-00002R1.1

7. Brouwer RN, Deeter C, Hannah D, Ainsworth T, Mullen C, Hames B, et al. Using competencies to transform clinical research job classifications. *J Res Admin*. (2017) 48:11–25.

8. Deeter C, Hannah D, Reyes C, Mack ME, Stroo M, Freel SA, et al. Professional development for clinical research professionals: implementation of a competency-based assessment model. *J Res Administr*. (2020) 51:15–40.

9. Snyder DC, Brouwer RN, Ennis CL, Spangler LL, Ainsworth TL, Budinger S, et al. Retooling institutional support infrastructure for clinical research. *Contemp Clin Trials*. (2016) 48:139–45. doi: 10.1016/j.cct.2016.04.010

10. Sonstein SA, Namenek Brouwer RJ, Gluck W, Robert Kolb H, Aldinger C, Bierer BE, et al. Leveling the joint task force core competencies for clinical research professionals. *Ther Innov Regul Sci*. (2020) 54:1–20. doi: 10.1007/s43441-019-00024-2

11. Stroo M, Asfaw K, Deeter C, Freel SA, Brouwer RJ, Hames B, et al. Impact of implementing a competency-based job framework for clinical research professionals on employee turnover. *J Clin Trans Sci*. (2020) 4:331–5. doi: 10.1017/cts.2020.22

12. Bocchino E., Joseph M., Butler E., MS Joan, Harper M., BS Beth (2020). A perspective on the current state of clinical research education and training. Clin Res. Available at: https://acrpnet.org/2020/11/10/a-perspective-on-the-current-state-of-clinical-research-education-and-training/.

13. Association of Clinical Research Professionals (2023). CRC boot camp. Available at: https://acrpnet.org/business-solution/business-solutions/crc-boot-camp/ [Accessed June 21, 2023].

14. Merriam SB, Bierema LL. *Adult learning: Linking theory and practice*. San Francisco, CA: Jossey-Bass, A Wiley Brand (2013).

15. Musshafen LA, Poger JM, Simmons WR, Hoke AM, Hanson LN, Bondurant WW, et al. Strengthening the clinical research workforce through a competency-based orientation program: process outcomes and lessons learned across three academic health institutions. *J Clin Trans Sci*. (2021) 5:e178. doi: 10.1017/cts.2021.852

16. Society for Clinical Research Sites (2023). Site Management Modules nm. Available at: https://myscrs.org/learning-campus/site-management-modules-nm/ (Accessed June 28, 2023).

17. The CITI Program (2017). The CITI program. Available at: https://about.citiprogram.org/ (Accessed June 28, 2023).

18. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform*. (2009) 42:377–81. doi: 10.1016/j.jbi.2008.08.010

19. Lombardozzi C. *Learning environments by design*. lexandria, VA: ATD Press (2015).

20. Stavredes T, Herder T. *A guide to online course design: Strategies for student success* San Francisco, CA: Jossey-Bass, A Wiley Brand (2013).

21. Carucci R. To retain new hires, spend more time onboarding them. *Harv Bus Rev*. (2018):1–5.

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EDITED BY
Carolynn Thomas Jones,
The Ohio State University, United States

REVIEWED BY
Bernadette Capili,
The Rockefeller University, United States
Barbara DeMarco,
Rutgers, The State University of New Jersey, United States

*CORRESPONDENCE
Diana Lee-Chavarria,
leeachar@musc.edu

†These authors have contributed equally to this work

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Supporting clinical research professionals through educational innovations

Diana Lee-Chavarria[1*†], Tammy L. Loucks[1,2†], Rechelle Paranal[1†], Royce Sampson[1,3,4†] and Carol Feghali-Bostwick[5†]

[1]South Carolina Clinical and Translational Research Institute, Medical University of South Carolina, Charleston, SC, United States, [2]Academic Affairs Faculty and Department of Obstetrics and Gynecology, Medical University of South Carolina, Charleston, SC, United States, [3]Office of Clinical Research, Medical University of South Carolina, Charleston, SC, United States, [4]Department of Psychiatry and Behavioral Sciences, College of Medicine, Medical University of South Carolina, Charleston, SC, United States, [5]Department of Medicine, College of Medicine, Medical University of South Carolina, Charleston, SC, United States

Clinical Research Professionals (CRPs) are essential members of the Clinical and Translational Research Workforce. Many academic medical institutions struggle to recruit and retain these vital team members. One strategy to increase job satisfaction and promote the retention of CRPs is through educational initiatives that provide training and professional development. The South Carolina Clinical and Translational Research (SCTR) Institute Workforce Development (WD) team at the Medical University of South Carolina (MUSC) developed several trainings as part of our larger educational portfolio for CRPs. In 2022 WD implemented a digital badge micro-credential for SCTR's Core Clinical Research Training (CCRT) course in collaboration with institution-wide education and technology offices. Beginning in January 2023, individuals were able to earn the CCRT Certified Digital Badge upon successful completion of the CCRT course.

KEYWORDS

micro-credential, digital badge, clinical research professional, research, training, professional development

1 Introduction

Clinical Research Professionals (CRPs) are essential members of the clinical and translational research workforce at Academic Medical Centers (AMCs). These professionals include clinical research coordinators, data managers, regulatory affairs specialists, clinical trial monitors, research nurses, and others (Sonstein and Jones, 2018; Knapke et al., 2022a). While the Principal Investigator (PI) has the final oversight of the study, many important tasks are often entrusted to CRPs as front-line workers. The role of a CRP has grown beyond solely participant management to encompass additional responsibilities including quality assurance, budgeting, regulatory compliance, database management, HIPAA compliance, and IRB submissions. CRPs also serve as the study's central point of contact for research participants, clinicians, institutional research support offices, investigators, sponsors, and others (Speicher et al., 2012). The roles CRPs play in clinical research studies are both vast and essential.

Unfortunately, many AMCs struggle to recruit and retain these vital team members. There are various theories to explain challenges with CRP recruitment and retention, including compensation, a lack of professional recognition for their complex job functions, the absence of role-specific training and/or professional education, and expanding duties

FIGURE 1
CCRT certified digital badge.

without the benefit of the previous two resources (Sonstein and Jones, 2018; Knapke et al., 2022b). As study protocols and regulations guiding research become more expansive, so do the roles of CRPs (Speicher et al., 2012). An increase in the breadth and scope of responsibility in the absence of additional training or job support can lead to job dissatisfaction and even burnout. Burnout may cause CRPs to depart from their roles or the entire clinical research workforce, leaving study teams ill-equipped to meet research study timelines and deliverables (Knapke et al., 2022a). A revolving door of novice CRPs can create a vacuum of institutional knowledge causing newly hired CRPs to learn on the fly, potentially slowing study efficiency and inadvertently jeopardizing compliance with study protocols, reporting, and regulatory requirements. The loss of experienced CRPs can have numerous ill effects on the conduct of clinical research at AMCs.

One strategy to address problems with CRP readiness and retention at AMCs are initiatives that provide job training and professional development to support this vital workforce. The SCTR Institute Workforce Development (WD) team develops and refines trainings as part of a large educational portfolio for all members of the research team. SCTR is the NIH-funded Clinical and Translational Science Award (CTSA) Hub at the Medical University of South Carolina (MUSC) and serves the entire state. CTSAs are funded by the National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH) to cultivate research from the laboratory into functional therapies for patient populations (National Center for Advancing Translational Sciences, 2023)[1].

SCTR provides a portfolio of research training and professional development opportunities for staff, students, faculty, and investigators as part of its CTSA activities. Core Clinical Research Training (CCRT) is SCTR's primary CRP training offering and has been embedded in the WD program for more than 10 years. CCRT provides foundational clinical research training for study team members to be effective in their jobs. CCRT focuses on the resources, processes, and regulations supporting clinical research conduct at MUSC. It is offered to MUSC employees and students who work in clinical research and collaborating institutions that partner with SCTR, including an associated Veteran's Affairs (VA) Hospital. CCRT is considered a core element of training and orientation, and many new CRPs take the course as part of their introduction to conducting research at MUSC, although it is not part of mandatory onboarding training at the institution. SCTR WD debuted a digital badge for CCRT in 2023 [Figure 1].

Digital badges are micro-credentials in the form of an electronic symbol that document achievement or skills mastered through a specific training or coursework. Digital badges verify that the obtainer has achieved a certain level of knowledge and/or met a specific set of criteria to be awarded the badge (Stefaniak and Carey, 2019). Micro-credentials can be shared across digital platforms, including LinkedIn and social media, and on email signatures. Information about these required criteria, when the user completed the course/content, the date the badge was issued, and other relevant information from the issuer is embedded in an online platform and visible to outside users (Yu et al., 2015; Galindo, 2023).

This manuscript describes our experience to develop and obtain a digital badge micro-credential for the CCRT course. The CCRT Certified Digital Badge was predicated on the converging factors of new education technology resources at MUSC and the revision of CCRT's content and format.

2 Opportunity

In 2019, the SCTR WD team conducted an institution-wide survey of research staff and faculty via REDCap to identify their research-related training needs and challenges. Respondents were asked about their preferences for learning environment (e.g., online, in-person), the value of specific research-focused learning topics (e.g., recruitment, research administration, research processes), and any barriers to utilizing existing trainings. More than half of respondents (52.9% of faculty and 58.0% of staff) reported a preference for attending online trainings (it should also be noted that this survey was conducted before the COVID-19 pandemic and implementation of remote work policies). Additionally, multiple responses indicated a need for additional training on internal and external research processes (Loucks et al., 2021).

1 https://ncats.nih.gov/ctsa

TABLE 1 CCRT course modules.

Part	Module title	Learning objectives
I	Introduction to Core Clinical Research Training	• N/A
	SCTR Services	• explore resources available through SCTR Institute
		• distinguish between SCTR fee-based and free services
II	Evaluating Study Feasibility	• identify the key components of a comprehensive feasibility analysis
		• list the 3 self-service patient count tools that can be used to obtain patient count data for a feasibility assessment
		• identify the aspects of each component of a comprehensive feasibility analysis
	Recruitment Planning and Development	• name at least 3 factors that can influence recruitment strategies for a particular study
		• identify the web-based resources for recruitment that MUSC supports and the distinguishing features between them
		• list the ways MUSC patients can opt-out of research contact
		• identify best practices for recruitment messaging
	Inclusion of Special Populations in Research	• differentiate between the concepts of equality and equity
		• identify who are special populations in clinical and translational research
		• identify barriers to special populations participating in research
		• identify ways to integrate special populations into research
III	SPARCRequest	• review elements of the SPARCRequest system
		• describe how it is used in conducting research at MUSC
	Research Billing Compliance—Prospective Reimbursement Analysis (PRA)	• summarize the rationale for a PRA process
		• identify which studies require a PRA and which are exceptions
		• understand how to initiate and submit a PRA and PRA Amendment
	Understanding a Corporate Clinical Research Budget	• recognize the steps involved in the budgeting process
		• identify key components of a corporate clinical research budget
		• describe the importance of invoicing communication and how that results in money for the study team
	Overview of Epic	• describe EPIC and how it relates to research studies at MUSC
IV	Good Clinical Practice	• understand the errors previously made by investigators
		• name and understand the principles of the Belmont Report
		• understand the importance of regulations and guidelines in clinical research
	Institutional Review Board (IRB)	• define the role of the IRB
		• identify the types of IRB review
		• describe what information gets reviewed by the IRB
	Informed Consent and HIPAA	• differentiate between the different types of informed consent
		• describe the consent process including the key elements
		• explain HIPAA requirements in relation to research
V	Principal Investigator Roles and Responsibilities	• identify the regulatory bodies and guidelines that define PI responsibilities in the conduct of clinical trials
		• identify common problems in obtaining appropriate informed consent
		• distinguish to whom study activities may be delegated by the PI
	Regulatory Files	• determine what comprises regulatory files for research studies

(Continued on following page)

TABLE 1 (*Continued*) CCRT course modules.

Part	Module title	Learning objectives
		• identify the reasons why maintaining a regulatory binder is important to the success of your research study
		• identify organizational techniques that are beneficial for certain types of research and regulatory file organization
	Procedural Documentation for Clinical Research Operations	• identify the differences between Policies, SOPs, and MOPs
		• identify the benefits of developing SOPs, MOPs, and site-specific protocol plans
		• demonstrate basic knowledge of the 8-steps to write an SOP
	Investigational Drugs and Devices	• identify the FDA regulations regarding investigational drugs and devices
		• describe the institutional policies regarding studies utilizing investigational drugs
		• discuss best practices for managing investigational drugs
VI	Adverse Events, Protocol Deviations and Unanticipated Problems	• identify terms related to reportable events
		• differentiate between an AE and an SAE
		• apply reporting requirements related to safety reporting
	Overview of ClinicalTrials.gov	• identify the differences between ClinicalTrials.gov and the CT.gov Protocol Registration System
		• identify the purposes and beneficiaries of trial registration/results reporting
		• identify examples of the types of studies that need to be registered on CT.gov and report results
		• identify the timeframe in which a study needs to be registered on CT.gov per federal requirements and for ICMJE-affiliated journal publication
	Creating a Compliant Research Program	• examine ethical responsibilities and identify methods of reporting non-compliance activities
		• provide researchers and study teams with practical techniques to identify, monitor, and resolve compliance issues
		• demonstrate proactive behaviors to help safeguard against non-compliance
	Research Misconduct	• define what constitutes research misconduct
		• identify the steps MUSC takes toward preventing research misconduct
		• recognize the process for addressing an allegation of potential research misconduct
		• describe the protections affirmed for “whistleblowers"

Prior to 2020, CCRT included both in-person sessions (twice annually) and bi-monthly online sessions that were video recordings of presentations from the live course. Attendees received paper Certificates of Completion that were signed by the course director; these certificates were not able to be shared on digital platforms and did not verify achievement of skills but rather course participation. CCRT moved fully online during the COVID-19 pandemic to meet the needs of CRPs who were working remotely during that time. Considering the widespread adoption of remote work and feedback obtained from the 2019 survey, SCTR WD evaluated our existing portfolio and determined that an update of CCRT into a fully online, asynchronous course was necessary. During this same time frame, members of the WD team had been introduced to the idea of digital badging and MUSC was evaluating new learning management systems that could support a digital badge.

In 2022 SCTR WD began to refresh the existing course material and add new content with the goal of attaining a digital badge micro-credential for the course. As part of this refresh, all content and learning modules were revised. This initiative involved input from the SCTR regulatory staff and institutional offices, and an instructional designer who was versed in course design and adult learning principles. The instructional designer used Articulate 360 to create new modules for CCRT that were interactive, engaging, met MUSC’s digital accessibility requirements, and could be deployed using MUSC’s learning management system (LMS) for continuing education (Desire to Learn D2L, Brightspace).

The revised CCRT consists of 20 distinct modules and 15 required quizzes. These modules are broken down into Parts I-VI with relevant modules grouped together along the research project life cycle [Table 1]. Each instructional module begins with learning objectives and relevant terminology and acronyms. Modules are comprised of brief video segments followed by knowledge checks to allow the learner to reflect on the material they have learned and test their knowledge before moving to the next section. Depending on the number of subsections covered in each topic, there are three to six video segments each followed by a knowledge check. Modules are intended to be taken in the order which they are presented. The course is self-paced, and participants have 8 weeks to complete the course modules and quizzes. The course also includes a “Start Here” module that provides

important information on how to navigate the learning management system.

There is no cost to participate, and personnel can self-enroll in the course through REDCap one of the four times a year it is offered—January, April, July, and October. Announcements about course registration are distributed through various institution-wide research-focused electronic newsletters and on the SCTR webpage.

Prerequisites include completing and passing the CITI MIAMI courses for Basic Human Research or Social and Behavioral Research and Good Clinical Practice and ICH prior to enrolling in CCRT. MUSC requires these courses to be taken by any personnel involved with the conduct of human subjects research prior to engaging in any research. CCRT builds on the foundations in the CITI courses and including these as a prerequisite also ensures that all participants have the same baseline level of knowledge before starting the course. Participants must complete all modules and receive an overall average of 80% or higher on the quizzes to earn the CCRT Certified Digital Badge.

2.1 Pedagogy

Both revised and new CCRT content was based around the process of conducting clinical research at MUSC. Content was also informed by the Joint Taskforce (JTF) for Clinical Trial Competency core competency domains (Multi-Regional Clinical Trials, 2023)[2]. The JTF competencies are widely accepted and broadly utilized across the CTSA consortium and the clinical research community. Two national organizations focused on the professional advancement of clinical research personnel, the Association of Clinical Research Professionals (ACRP) and the Society of Clinical Research Associates (SOCRA), have harmonized their training and certification exams to the JTF competencies (Sonstein and Jones, 2018).

2.2 Innovation

In 2022, MUSC initiated a new LMS with the capability to support digital badging, Brightspace by D2L, that had separate platforms for students and staff/professional development. CCRT and other non-credit courses were moved to the Endeavor platform on Brightspace and inherited the badging capability. The Brightspace/Endeavor platform can automatically issue digital badges to users who meet the set criteria. At the same time the MUSC Education Cabinet developed a digital badging policy that included a process to vet and award micro-credentials.

Taking into consideration this new institutional innovation and the ongoing revision of CCRT into a fully asynchronous online format, it was decided to proceed with implementing a digital badge for the course. The badge was developed in collaboration with institution-wide education and technology offices. The WD team, led by the SCTR Science Development Officer, prepared a proposal and sought approval from the MUSC Education Cabinet for the digital badge. An official application and the revised CCRT topics, instructors, and learning objectives were submitted for review as part of this proposal. Once the proposal was approved, the team worked with SCTR's in-house graphic designer to create the badge's visual element on an institutionally approved template that was established by the MUSC Brand Center in the Office of Communications and Marketing. Four options of badges were created, and the final design was selected by the full WD committee and then submitted to the MUSC Brand Center for approval. Once approved, the WD team worked with MUSC's Office of Instructional Technology and Faculty Resources (ITFR) to add the badge to the course in the LMS and set the criteria for attainment. SCTR WD employs a full-time program coordinator who also collaborates regularly with the ITFR office to set the criteria for award dispensation and enroll and unenroll participants in the course.

Beginning in January 2023, individuals were able to earn the CCRT Certified Digital Badge upon successful completion of the CCRT course. Announcements about the inclusion of a digital badge in the updated CCRT course were made through the usual communications channels, including institutional research newsletters and on the SCTR website. The CCRT Certified Digital Badge is accredited and stored on the digital credentialing platform Canvas Credentials (formerly known as Badgr). Using Canvas Credentials, managers and other supervisory personnel can view the criteria required for obtaining the digital badge as well as evidence that the learner met the criteria.

3 Results

Between January and September 2023, 152 people registered for the CCRT course and 135 MUSC and associated VA personnel took the revised CCRT course. Participants' "primary reason for taking the CCRT" is asked during course registration; 53.9% of registrants responded their primary reason was "Professional Development," 34.2% stated that the course was required by their supervisor, and 5.9% responded that it was required by their training program. Participants' "length of time in the field of research" was also collected during course registration; over half of respondents (57.1%) indicated that they had only been in research 12 months or less, with 34.2% noting that they had only been involved in research for 0–3 months. Of the 135 participants, 104 (77%) earned the CCRT Certified Digital Badge.

CCRT course evaluations are conducted at the end of every 8-week cohort. Participants who successfully completed the course received a link to a REDCap survey to evaluate their overall training experience and provide input for continuous quality improvement. This survey is optional and confidential as no identifying data is collected, although respondents are asked to select their primary role in research. The majority (72%) of respondents from January-September 2023 (n = 77) self-identified as program coordinators (n = 32), program assistants (n = 13), or research assistants (n = 10) [Figure 2]. Participants are asked about their research experience, their overall thoughts on the course, and to provide input on future CCRT modifications.

Aggregate course evaluation results (n = 77) since January 2023 show the value of CCRT to the research learning environment at MUSC. 97% agree or strongly agree that CCRT provides a solid foundation for conducting clinical research at

2 https://mrctcenter.org/clinical-trial-competency/framework/domains/

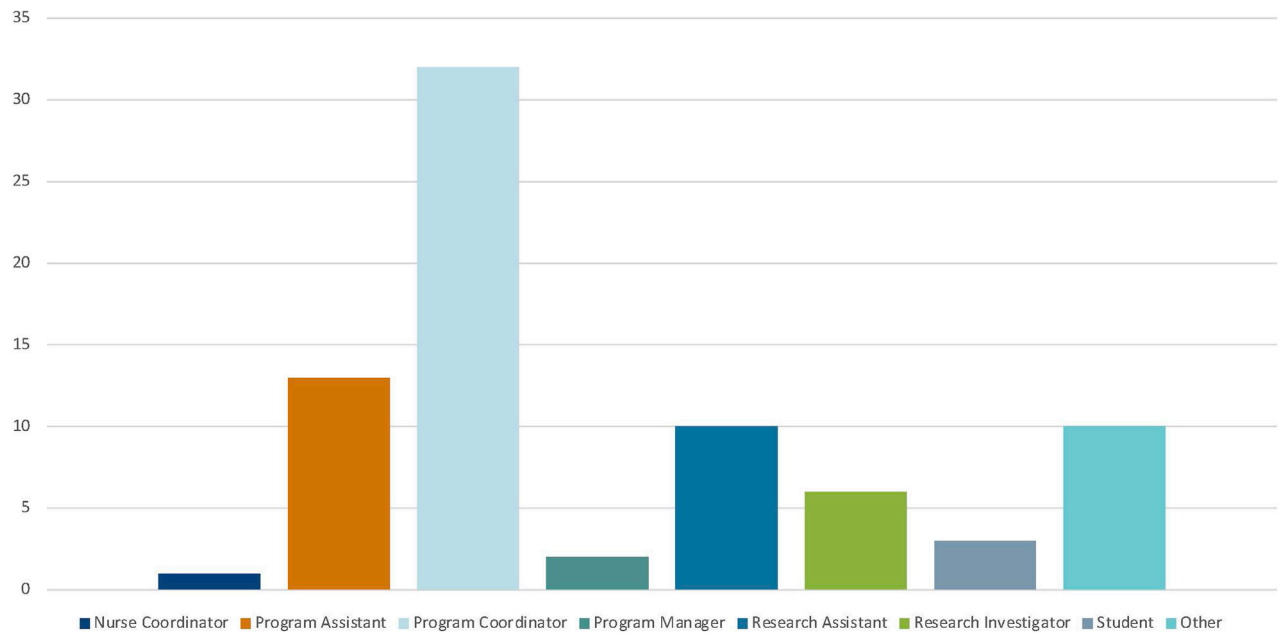

FIGURE 2
CCRT attendees—primary role in research.

MUSC and 95% agree or strongly agree that CCRT was useful to their role in clinical research [Figure 3]. It is relevant to note that there are no questions specifically pertaining to the digital badge included in the overall course evaluation as this survey was developed prior to 2022. VA personnel provided feedback that some of the content was MUSC-focused and not directly relevant to them, but they still gave overall high marks to the course as a valuable learning opportunity.

When asked what they liked best about CCRT, numerous responses indicated the ability to complete the course at their own pace. This speaks to the importance of flexibility with online learning opportunities:

> "The format of the course was easy to use and allowed for learning at one's own pace."

> "Ease and flexibility in completing the course."

> "That it was self-directed."

> "It gave me a good foundation for conducting clinical research at MUSC."

Responses indicated overwhelmingly that CCRT was perceived to be a valuable learning experience:

> "The course was a good overview of clinical research at MUSC and provided a strong basis for a variety of research topics that are applicable to my job."

> "I think continuing education is helpful in minimizing mistakes."

> "Being that I'm new in research, I feel like by taking this course I have a great foundation on the research sector, and I will be able to continue to build upon that foundation as I learn and grow more professionally."

> "CCRT breaks down the core development that is needed to succeed in this role."

Moving forward, SCTR's Evaluation and Quality Improvement (EQI) team will conduct a focused evaluation on the CCRT Certified Digital Badge. They will convene a focus group for a one-year follow up to gather data on the value of the digital badge from CCRT participations who have obtained the micro-credential. This will begin in early 2024 to facilitate data collection 1 year after the first cohort received their badges and will enable the evaluators to get a better sense of how the badge was used and/or perceived as beneficial. EQI also plans to do six-month follow-up surveys beginning in 2024 to continuously gather quality improvement data for the badge. These surveys will include questions about the prior awareness and anticipated incentive of the CCRT digital badge, the overall perceived value and utilization of the badge, and applicability of the badge to participants' current roles at MUSC. These plans will also allow the team to identify how many participants—stratified by primary research position—are still at MUSC. As digital badging becomes more established at the institution, it may also be useful to add a question to the course evaluation asking if the digital badge was a factor in taking and/or completing the course. Additionally, SCTR WD and EQI are exploring ways to share this strategy and the opportunity to earn the CCRT Certified Digital Badge with our state-wide collaborators to increase interest and engagement in CRP career development.

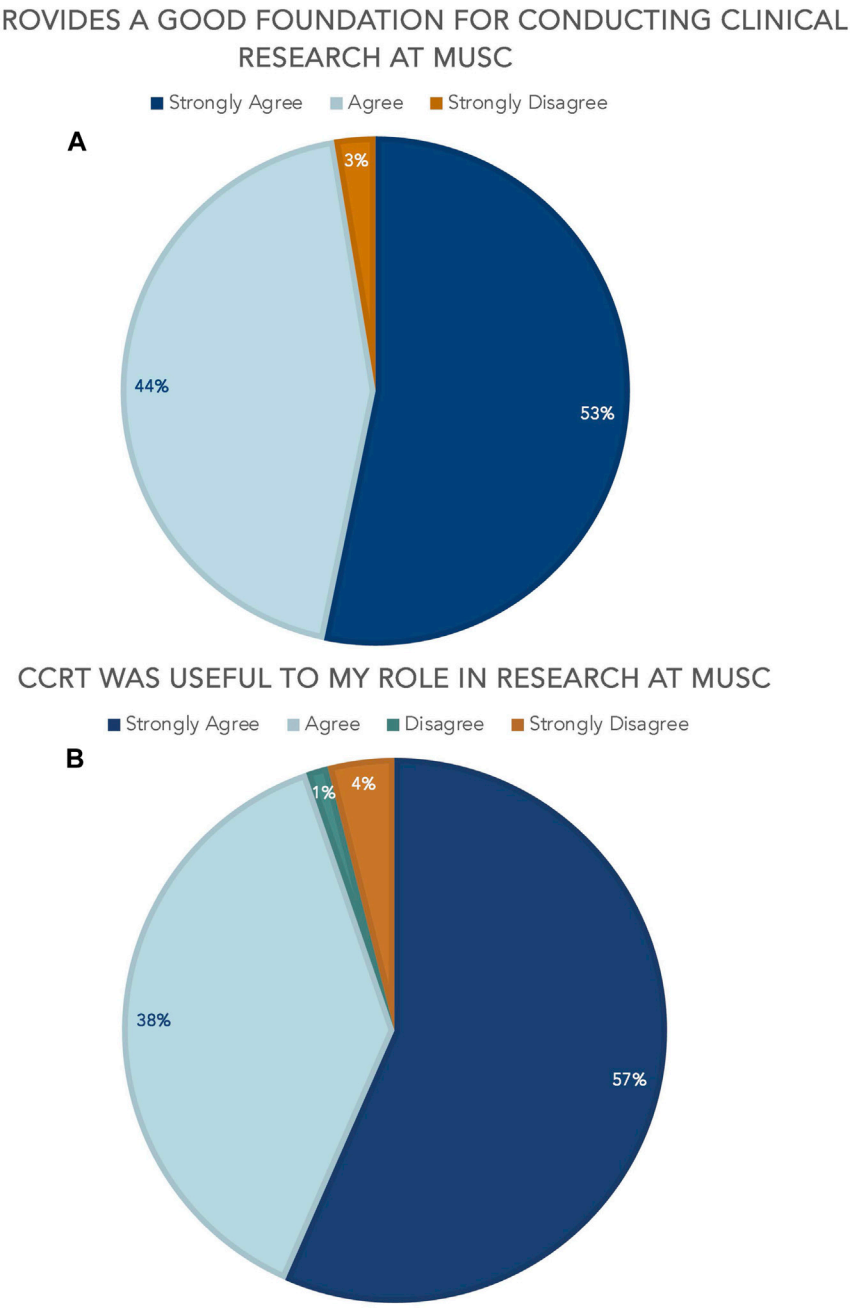

FIGURE 3
CCRT aggregate course evaluation results **(A)** CCRT provides a good foundation for conducting clinical research at MUSC **(B)** CCRT was useful to my role in research at MUSC.

4 Discussion

There is a general acceptance that CRPs are integral to the conduct of clinical research, and "provision of adequate training and support to the research coordinator is critical to the overall goal of human subject protection at a given institution" (Speicher et al., 2012). CRPs serve numerous vital roles in the conduct of clinical research studies, both patient-facing and behind the scenes. One global survey of CRPs conducted in 2014 found that the increased job complexities and responsibilities of clinical research personnel requires additional skills (Sonstein and Jones, 2018). However, increasing responsibilities without commensurate skills training is not a sustainable practice and could lead to adverse study outcomes. In addition, a 2008 study found that 42% of CRPs surveyed worked more than their scheduled 40-h/week completing their study tasks (Speicher et al., 2012). Results such as these make it easier to understand how a CRP could feel overextended without time to pursue continuing education or job training and underappreciated in their roles.

The increasing breadth and depth of their roles, combined with inadequate role-specific training and professional recognition, have

contributed to problems with CRP recruitment and retention. These are not the only issues affecting CRP careers, but the only addressed in this manuscript; factors such as wages and job flexibility are not always easy to address and can be dependent on institution or state policies (Knapke et al., 2022a). While the authors do not suggest that educational innovations such as digital badges can solve all issues around CRP job satisfaction and retention, we do feel that they are one tool that can be used to support employees. This idea appears to be gaining acceptance in the clinical research workforce; ACRP, an organization dedicated to CRP advancement, awards a digital badge to those who obtain certification (Association of Clinical Research Professionals, 2017)[3]. Attaching digital badges to courses used as foundational training for CRPs is one step towards recognizing the body of knowledge and scope of practice required for CRPs at AMCs.

Digital badges have several advantages for both AMCs and CRPs. Online training with the inclusion of a sharable, verified micro-credentials can provide validation of the standards met and skills achieved that can be shared both inside and outside of the institution (Stefaniak and Carey, 2019; Galindo, 2023). This is responsive to an issue identified from an evaluation conducted as part of the "Collaborative Conversations" Un-meeting series in November and December 2020; CRPs reported problems in demonstrating competency and recording completed certifications and trainings (Knapke et al., 2022b). First, badges enable employees to have a permanent and visible record of skills attained to demonstrate their professional achievement and career development. Second, employees can build their professional online presence through the ability to share the micro-credential on sites such as LinkedIn or on professional e-portfolios (Pakstis, 2019)[4]. Similarly, the inclusion of badges on email signatures allows for broader distribution of the accomplishment than could be achieved by a paper certificate of completion. Third, digital badges serve as a visual token of skill attainment rather than merely course participation. The promise of a tangible reward may provide an incentive for taking and/or completing trainings (Yu et al., 2015), especially if the CRP has little free time and must choose carefully between continuing education opportunities.

The inclusion of digital badges in continuing education and/or training content may also substantiate the institution's commitment to their employees and an interest in supporting their professional development. Theoretically, an employee who is recognized for their achievements may be more motivated to stay in their role which could enforce recruitment and retention (Pakstis, 2019)[4]. The use of digital badges can also reduce the administrative burden of managing a course. The time needed to verify a learner's scores, ensure they completed all requirements, create a personalized certification of completion (or similar), and send the certificate to each learner (via email or regular mail) can be time-consuming. Because of time constraints, training opportunities for professional development that are not in traditional credit courses may not receive any type of formal certification of completion (Yu et al., 2015). This administrative burden is alleviated by the automated processes involved in issuing electronic micro-credentials and providing learners with a digital badge, allowing CRPs and others to demonstrate competency even in courses targeted at professional development.

It is apparent that continuous learning is necessary as job complexities increase and new innovations arise. CRPs and those responsible for the conduct of studies must be able to prove their competence and knowledge around these issues. Continued fluency in new skills is compulsory for career advancement and to support CRP professional development (Pakstis, 2019)[4]. As previously discussed, one solution to these concerns is continuing education and training that is accessible to CRPs. In this terminology, "accessible" means being available in both a place and time convenient for CRPs; training that cannot be taken is not useful for anyone. Learning and professional development opportunities must be applicable to the participants' roles, or they will not find it beneficial. SCTR WD was thoughtful in revisioning CCRT to make it as accessible to CRPs as possible. This includes the course being asynchronous and online to enable CRPs to complete the work at the times that best work for them, as well as eliminating course fees to prevent financial barriers. It is reasonable to conclude that incorporating a digital badge into a course that is broadly utilized by CRPs would be valuable to the same group. When deciding where to integrate a digital badge, the WD team felt confident in selecting CCRT since evaluation responses show that the course has a high perceived value. The CCRT Certified Digital Badge recognizes CRPs at the enterprise who have attained foundational knowledge in conducting compliant clinical research.

The broad acceptance of online learning has increased the opportunity for micro-credentialing and was vital in our digital badge development. Beginning in 2019, MUSC acquired four hospitals in various parts of South Carolina. These sites did not have a robust clinical research infrastructure, but planned to start conducting research after affiliating with MUSC. Online learning such as CCRT enable CRPs at both the main campus in Charleston and the regional hospitals in rural areas across the state to access continuing education and training opportunities. Another factor that was vital to the development of the CCRT Certified Digital Badge was the addition of an instructional designer who was versed in online learning principles to the WD team. Their expertise enabled us to move from a video recorded presentation format and create new interactive and engaging learning modules to improve the online learning experience.

The authors also wish to acknowledge some constraints on the outcome responses. First, the data is from a small sample size of CRPs ($n = 77$) and only a small percentage of CRPs at the institution have received a badge thus far. Additionally, the revised course with the digital badge has only been active since January 2023, so we do not have longitudinal data showing the impact/effects of the badge. This is why continuous quality improvement evaluations and focus groups will be important; focus groups will begin in January 2024.

Data availability statement

The raw data supporting the conclusion of this article will be made available by the authors, without undue reservation.

3 https://acrpnet.org/wp-content/uploads/dlm_uploads/2017/04/Digital-Badging-FAQs-1.pdf

4 https://www.harvardbusiness.org/for-organizations-and-learners-the-benefits-of-badging-are-clear/

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Conflict of interest

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References

Association of Clinical Research Professionals (2017). Academy of clinical research professionals digital badge FAQs. Available at: https://acrpnet.org/wp-content/uploads/dlm_uploads/2017/04/Digital-Badging-FAQs-1.pdf (Accessed August 8, 2023).

Galindo, M. (2023). 'How designing personalized micro-credentials can support adult learners' journeys', digital promise. Available at: https://digitalpromise.org/2023/09/06/how-designing-personalized-micro-credentials-can-support-adult-learners-journeys/ (Accessed September 26, 2023).

Knapke, J. M., Jenkerson, M., Tsao, P., Freel, S., Fritter, J., Helm, S. L., et al. (2022b). Academic medical center clinical research professional workforce: Part 2 - issues in staff onboarding and professional development. *J. Clin. Transl. Sci.* 6 (1), e81. doi:10.1017/cts.2022.412

Knapke, J. M., Snyder, D. C., Carter, K., Fitz-Gerald, M. B., Fritter, J., Kolb, H. R., et al. (2022a). Issues for recruitment and retention of clinical research professionals at academic medical centers: Part 1 - collaborative conversations Un-Meeting findings. *J. Clin. Transl. Sci.* 6 (1), e80. doi:10.1017/cts.2022.411

Loucks, T. L., Harvey, J., Lee-Chavarria, D., Paranal, R., Lenert, K. A., Bonilha, H. S., et al. (2021). Clinical and translational research workforce education survey identifies needs of faculty and staff. *J. Clin. Transl. Sci.* 6 (1), e8. doi:10.1017/cts.2021.875

Multi-Regional Clinical Trials (2023). Joint task force for clinical trial competency. Available at: https://mrctcenter.org/clinical-trial-competency/framework/domains/ (Accessed August 10, 2023).

National Center for Advancing Translational Sciences (2023). Clinical and translational science awards (CTSA) program. Available at: https://ncats.nih.gov/ctsa (Accessed August 8, 2023).

Pakstis, S. (2019). *For organizations and learners, the benefits of badging are clear.* China, Harvard Business Publishing. https://www.harvardbusiness.org/for-organizations-and-learners-the-benefits-of-badging-are-clear/ (Accessed August 8, 2023).

Sonstein, S. A., and Jones, C. T. (2018). Joint task force for clinical trial competency and clinical research professional workforce development. *Front. Pharmacol.* 9, 1148. doi:10.3389/fphar.2018.01148

Speicher, L. A., Fromell, G., Avery, S., Brassil, D., Carlson, L., Stevens, E., et al. (2012). The critical need for academic health centers to assess the training, support, and career development requirements of clinical research coordinators: recommendations from the Clinical and Translational Science Award Research Coordinator Taskforce. *J. Clin. Transl. Sci.* 5 (6), 470–475. doi:10.1111/j.1752-8062.2012.00423.x

Stefaniak, J., and Carey, K. (2019). Instilling purpose and value in the implementation of digital badges in higher education. *Int. J. Educ. Technol. High. Educ.* 16, 44. doi:10.1186/s41239-019-0175-9

Yu, L., Dyjur, P., Miltenburg, J., and Saito, K. (2015). "Micro-credentialing: digital badges in faculty professional development," in *Proceedings of the IDEAS: designing responsive pedagogy conference*. Editors P. Preciado Babb, M. Takeuchi, and J. Lock (Calgary, Canada: Werklund School of Education, University of Calgary).

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EDITED BY
Andrei Mocan,
University of Medicine and Pharmacy Iuliu Hatieganu, Romania

REVIEWED BY
Marc Henri De Longueville,
UCB Pharma, Belgium

*CORRESPONDENCE
Carolynn T. Jones,
jones.5342@osu.edu

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Education and training of clinical research professionals and the evolution of the Joint Task Force for Clinical Trial Competency

Stephen A. Sonstein [1], Honorio Silva [2,3], Carolynn T. Jones [4]* and Barbara E. Bierer [1,5]

[1]Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard, Boston, MA, United States, [2]Academy of Global Medicines Development Professionals, New York, NY, United States, [3]King's College London, London, United Kingdom, [4]College of Nursing, and Center for Clinical Translational Sciences, The Ohio State University, Columbus, OH, United States, [5]Division of Global Health Equity, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, MA, United States

Clinical research professionals play a critical role in the design, conduct, and oversight of clinical trials, and they must have the knowledge, skills, and abilities to ensure that trials are conducted ethically, safely, and in accordance with regulatory requirements. As clinical research has evolved from being a necessary activity for the development and regulatory approval of new medicines to an accredited academic discipline and, more recently, to a globally recognized profession, the methods of education and training of professionals have also evolved. Initially, on-the-job informal coaching and specialized training organizations led to formalized and accredited academic degree programs and, more recently, to international competency standards and competency maintenance through continuous professional development. The Joint Task Force (JTF) for Clinical Trial Competency is a multidisciplinary, international group of experts who came together to aggregate and refine competency standards for clinical research professionals, first published in 2014. The 8 domains and 49 specific core competencies of the JTF Framework have become a globally recognized standard upon which education and training programs, role descriptions, and upward mobility criteria for professionals are now based. The JTF meets regularly and, through its workgroups, continues to evolve in response to the changing needs of the profession. The JTF is committed to continuous improvement to ensure that clinical research professionals have the competence necessary to conduct safe, ethical, and high-quality clinical research.

KEYWORDS

Joint Task Force for Clinical Trial Competency, accreditation, academic programs in clinical research, clinical research professional, clinical research workforce, pharmaceutical physician

1 Introduction

Clinical research is the bedrock of advancements in diagnosis, treatments, and procedures to improve the public health. Beginning with early discovery work, leading to human trials and, ultimately, to regulatory marketing approvals of products to the public, the teams that assemble to accomplish this work constitute a complex network of experts

and professionals. Professional pathways for basic, translational, and clinical sciences have been defined for principal investigators, doctoral trainees, and pharmaceutical physicians (Nathan, 2002; Meyers et al., 2012; Silva et al., 2013). However, the professional pathways for the large number of staff that support the various activities required for operationalizing and managing clinical research studies are generally less defined and vary with the local definition of the role. At a clinical research site, such clinical research professional (CRP) staff roles include clinical research assistants, clinical research coordinators, or specialized areas such as data managers, quality compliance officers, and regulatory affairs specialists. At the sponsor level, pharmaceutical physicians may lead research and regulatory strategies for the development of new potential targets. Individuals working as CRPs for pharmaceutical sponsors or contract research organizations may perform roles such as site monitors, data managers, safety officers, and project leads. CRP staff may have a wide variety of educational backgrounds with associates degrees, diplomas and graduate degrees, and specific competency-based training or additional academic education in clinical research. A pharmaceutical physician is a medicine development role that requires a baccalaureate degree, an MD and licensure, or a PharmD, who has an additional diploma education in pharmaceutical medicine (Silva et al., 2013). Advancement pathways for these individuals working at the research site and in the pharmaceutical industry are beginning to be better defined; however, in today's workforce climate, severe staff shortages threaten to slow clinical research progress (Freel et al., 2023). The professionalization of the clinical research workforce is dependent on the early recognition of the professional roles and their importance and competency standards defining the work, educational pathways, and professional development paths so that the pool of individuals interested in this work are aware of the opportunities in this field.

1.1 Defining competency standards

The United States National Institutes of Health (NIH), National Center for Advancing Translational Sciences (NCATS), has focused their efforts on expanding the clinical research workforce (Committee et al., 2013). The United States National Academies of Science, Engineering, and Medicine (NASEM, formerly the American Institute of Medicine) called for innovation in the clinical trial enterprise, suggesting the closer integration of healthcare delivery with clinical trials (Califf et al., 2012). Early publications on clinical research skills began to emerge, and publications on competencies for clinical research nurses were published by the United Kingdom Royal College of Nursing (UK Clinical Research Collaboration Subcommittee for Nurses in Clinical Research, 2011), the United States National Institutes of Health Clinical Center (CRN, 2010 Domain of Practice Committee, 2009), and the Oncology Nursing Society (Oncology Nursing Society, 2010). The Association of Clinical Research Professionals (ACRP) began to build a set of targeted trainings; NCATS published competencies for investigators (NCATS. Core, 2011), and knowledge, skills, and abilities (KSAs) for pharmaceutical physicians were also published by the International Federation of Associations of Pharmaceutical Physicians (IFAPP) (Silva et al., 2013). A collaboration among these groups and others initially came together to synthesize the available literature and consolidate skillsets into a set of KSAs that would strengthen the educational curricula for CRPs (Jones et al., 2012). Subsequently, several organizations, many of which included individuals who directed and taught in academic programs in clinical research and had extensive experience working across multiple sectors of the clinical research enterprise, began to outline the standards necessary to perform clinical research. This working group consisted of members from the ACRP, Association of Pharmaceutical Physicians and Investigators (APPI), Consortium of Academic Programs in Clinical Research (CoAPCR), United States NIH Clinical Translational Science Award (CTSA) program, Global Health Network (GHN), IFAPP, Multi-Regional Clinical Trials Center (MRCT Center) of Brigham and Women's Hospital and Harvard, and TransCelerate BioPharma.

1.2 Launching the JTF framework

In 2013, a meeting was organized by the MRCT Center in collaboration with 18 other organizations and institutions to address issues related to the training of clinical research professionals. At the meeting, several individuals noted that there were no defined and globally recognized competency standards for clinical research professionals, despite the definition by the International Council on Harmonisation (ICH) of Technical Requirements for Pharmaceuticals for Human Use of good clinical practices (GCPs) and the expectation of appropriate training and competencies by global regulatory agencies. This diverse group of representatives from the pharmaceutical industry, academic educational programs, clinical sites, and contract research organizations agreed to review the literature concerning competency standards for the various clinical research roles and to align them to a global set of competency standards to reflect the needs of the clinical research enterprise. The group named itself the Joint Task Force (JTF) for Clinical Trial Competency, and members aligned and harmonized the many role-based competencies from the published literature into the JTF Clinical Trial Core Competency Framework (JTF Framework) Version 1.0, which represented the competencies of the entire clinical research workforce. The framework consisted of eight domains: 1) Scientific Concepts and Research Design; 2) Ethical and Participant Safety Considerations; 3) Investigational Product Development and Regulation; 4) Clinical Study Operations; 5) Study and Site Management; 6) Data Management and Informatics; 7) Leadership and Professionalism; and 8) Communication and Teamwork. Each domain included multiple harmonized and related competencies (51 competencies in all). The framework was first published in 2014 (Figure 1) (Sonstein et al., 2014).

The publication of the JTF Framework was supplemented by presentations and other forms of dissemination, describing the multiple ways in which the JTF Framework could be applied. In 2015, the JTF conducted a global survey of the clinical research workforce, including investigators, clinical coordinators, regulatory affairs professionals, research managers, data managers, and clinical trial monitors to validate the applicability of the JTF Core Competency Framework to assess the self-perceived competency level across the JTF domains by role and to inform the enterprise of the education and training needs for each role. Significant gaps were revealed in domain 1 (Scientific Concepts and Research Design) and

FIGURE 1
Competency domains for the clinical research professional.

domain 3 (Investigational Products Development and Regulation), a finding that contributed to future academic and training initiatives (Sonstein et al., 2016). The JTF Competency Framework was adopted by clinical research professional associations, ACRP, and the Society of Clinical Research Associates (SoCRA) and incorporated into revised certification examination content and training programs. These competencies were also adopted by academic researchers who later expanded the JTF Framework to include competencies for investigators and coordinators conducting not only clinical trials but also social, behavioral, and community research (Calvin-Naylor et al., 2017; Murphy et al., 2018). NCATS funded a multi-institutional effort to collect trainings relevant to each of the competencies, culminating in a freely available portal that enabled access to those educational opportunities (Ianni et al., 2020). Version 2.0 of the JTF competencies was the result of an editorial review that combined redundant competencies resulting in a total of 47 competencies for the 8 original domains. At the clinical site level, Duke University revised their job titles and job descriptions around the JTF competencies, and onboarding programs were redesigned to align with the JTF competencies (Brouwer et al., 2016; Saunders et al., 2017). Academic programs in clinical research through the CoAPCR endorsed the JTF competencies, incorporated them into educational curricula, and applied them to develop accreditation standards for educational programs in clinical research. Subsequently, the Commission on Accreditation of Allied Health Education Programs (CAAHEP) agreed to utilize the JTF Framework as the basis for formal academic program accreditation and supported the formation of the Committee on Accreditation of Academic Programs in Clinical Research (CAAPCR) (Commission on Accreditation of Allied Health Programs, 2012; Sonstein and Jones, 2018). In tandem with these educational initiatives, IFAPP further developed KSAs of core competencies and proposed the alignment of those to educational content for pharmaceutical physicians, among others involved in medicine development (Silva et al., 2015; Stonier et al., 2020).

1.3 Leveling the JTF Framework: calibrating experience, understanding, and expertise

The JTF recognized that professional competency evolved with experience and education. A working group was formed that consisted of advanced clinical research professionals who were leaders across site- and sponsor-related sectors and included international representation. The group agreed to align the specific competencies by experience and expertise as 1) fundamental, defined as can perform the task/and exhibit the knowledge at an essential or fundamental level; may require some coaching or supervision; 2) skilled, defined as can perform task or skill

independently, navigate resources, and use tools well; and 3) advanced, defined as demonstrates advanced skills and knowledge and the ability to teach, coach, or supervise others; consistently applies critical thinking and problem solving (Sonstein et al., 2020). The working group was divided into five smaller sub-groups that were charged with creating a first-round set of leveled and measurable competency statements, with examples. Using a modified Delphi approach, these competency statements and examples were rotated amongst the other sub-groups, whereby they determined whether to keep the leveled competencies and examples and if so, edit them. When the leveled competencies and examples for each of the eight domains completed the cycle, the groups did a second-level cycle, making track-change edits. Ultimately, the chairs of each sub-group conducted the final synthesis and edits for publication. The resulting leveled competencies were presented as a new version 3.0 of the JTF Clinical Trial Competency Framework, one that maintained the 8 domains but expanded the numbers of measurable competencies, with each competency having an average of 3–5 additional measurable, leveled skillsets (Sonstein et al., 2020). Some institutions relied on this work to develop institutional job descriptions that were consistent in their expectations with respect to experience and salary grade, contributing to the development of a tiered career progression pathway for clinical research professionals that helped improve CRP turnover rates (Stroo et al., 2020).

1.4 Expanding clinical research roles reflected in the JTF Framework

In 2019, members of the project management communities in clinical research noted that the original JTF Framework did not specifically include project management competencies. A new JTF working group was charged with the task of suggesting appropriate additions to reflect the competencies of the project and program managers. This led to the addition of two additional core competencies, bringing the number of core competencies to 49 (Sonstein et al., 2022a). This current version 3.1 of the framework can be found on the MRCT JTF website (Joint Task Force for Clinical Trial Competency, 2022).

1.5 International reach of the JTF Framework

The awareness and relevance of the JTF Framework has continued to expand internationally. Increasingly, educational programs, onboarding programs, and professional development efforts have been based upon and incorporated into the JTF Framework. Moreover, as the JTF Framework has become a globally recognized resource, new translations of the framework into Spanish, Japanese, French, Thai, Bahasa Indonesia, Italian, Vietnamese, Chinese, and Korean have been made publicly available (Joint Task Force for Clinical Trial Competency, 2022). Additional translations are in progress.

2 Discussion

This manuscript summarizes the decade-long evolution and impact of the JTF Framework on the education and professionalization of CRPs, investigators and their study teams, pharmaceutical, and other professionals involved in medicine development and clinical research. Professionalizing the workforce is a strategic goal for the clinical research enterprise as shortages in the workforce threaten operations and clinical trial progress (Freel et al., 2023). The basic content for clinical research professional academic curricula, training curricula, job titles, professional advancement, ePortfolios, professional certification, research, team science competencies for CRPs, competency assessments, and international applications are all influenced by the adoption and application of the JTF Framework (Association of Clinical Research Professionals, 2018; Stonier et al., 2020; Ivey, 2021; Jones et al., 2021; Society of Clinical Research Associates; Sonstein et al., 2022b; Glaettli et al., 2022; Ibrahim et al., 2022; Mendell et al., 2023). A CTSA working group has conducted a leveled approach to define CRP team science competencies, which provides more granularity to JTF domains 7 and 8 covering Leadership, Professionalism, Communication, and Teamwork (Mendell et al., 2023). Additionally, because of the emerging technology and requirements in data management (Ittenbach, 2023), future work is underway to address expanding data management competencies, leveled by necessary skills, for today's digital era. In conclusion, having attained global recognition, the JTF Framework is an important resource to educators, trainers, and clinical research leadership and management. The JTF Framework will continue to evolve in response to the rapidly changing clinical research enterprise and will continue to be integrated into international clinical research structures. The JTF Framework will contribute to strengthen the workforce, enhance clinical research operations, and empower a professional identity that is essential for public health.

3 Scope statement

This perspective article meets the special topic collection entitled Building the Clinical Research Workforce: Challenges, Capacities, and Competencies. Here, we summarize the decade-long contribution of the JTF Clinical Trial Core Competency Framework that defined the educational standards and competencies for the clinical research workforce, especially clinical research professionals working at clinical research sites, contract research organizations, and sponsors. The application of this framework has had broad and international impact. As a living competency framework, the JTF competencies continue to adapt to emerging trends in clinical research.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary Material; further inquiries can be directed to the corresponding author.

Author contributions

SS: conceptualization, project administration, supervision, visualization, writing–original draft, and writing–review and editing. HS: funding acquisition, writing–original draft, and writing–review and editing. CJ: conceptualization, funding acquisition, project administration, validation, writing–original

draft, and writing–review and editing. BB: conceptualization, funding acquisition, project administration, validation, visualization, writing–original draft, and writing–review and editing.

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Conflict of interest

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References

Association of Clinical Research Professionals (2018). *CRC certification alexandria*. VA: ACRP. Available at: https://www.acrpnet.org/certifications/crc-certification/.

Brouwer, R., Moen, R., Hannah, D., Mullen, C., Ainsworth, T., McKellar, T., et al. (2016). *Competency-based job classifications for research professional*. Washington, DC: Association of Clinical and Translational Science.

Califf, R., Filerman, G. L., Murray, R. K., and Rosenblatt, M. (2012). "Appendix D: discussion Paper- the clinical trials enterprise in the United States: a call for disruptive innovation," in *Institute of medicine, editor. Envisioning a transformed clinical trials enterprise in the United States: establishing an agenda for 2020* (Washington, DC: National Academies Press).

Calvin-Naylor, N., Jones, C., Wartak, M., Blackwell, K., Davis, M., Divecha, R., et al. (2017). Education and training of clinical and translational study investigators and research coordinators: a competency-based approach. *J. Clin. Transl. Sci.* 1 (1), 16–25. doi:10.1017/cts.2016.2

Commission on Accreditation of Allied Health Programs (2012). CAAHEP commissioners special meeting. Available at https://www.caahep.org/CAAHEP/media/CAAHEP-Documents/Commissioner-Meeting-Minutes-October-2012.pdf.

Committee (2013). in *Committee to review the clinical translational science awards program at the national center for advancing translational sciences policy; Institute of medicine. The CTSA program at NIH: opportunities for advancing clinical and translational research. Leshner AI*. Editors S. F. Terry, A. M. Schultz, and C. T. Liverman (Washington, DC: National Academies Press).

CRN 2010 Domain of Practice Committee (2009). Building the foundation for clinical research nursing: domain of practice for the specialty of clinical research nursing: national Institutes of health clinical center, nursing and patient care services. Available at http://www.cc.nih.gov/nursing/crn/DOP_document.pdf.

Freel, S. A., Snyder, D. C., Bastarache, K., Jones, C. T., Marchant, M. B., Rowley, L. A., et al. (2023). Now is the time to fix the clinical research workforce crisis. *Clin. Trials* 0 (0), 457–462. doi:10.1177/17407745231177885

Glaettli, M., di Petto, L., Fayet-Mello, A., Fila, C., Kalin, S., Kohlmaiaer, S., et al. (2022). *Clinical research core competencies framework basel*. Switzerland: Swiss Medical Weekly. Available at: https://smw.ch/index.php/smw/announcement/view/55.

Ianni, P. A., Perorazio, T. E., Samuels, E. M., Eakin, B. L., Jones, C. T., Bigelow, V. J., et al. (2020). The DIAMOND portal: an innovative platform for sharing translational research workforce training and assessment resources. *J. Clin. Transl. Sci.* 4 (6), 480–484. doi:10.1017/cts.2020.507

Ibrahim, S., Guerrero, M. M., and Goos, L. M. (2022). Adapting the joint task force core comptency framework for clinical research professionals: a Canadian paediatric research perspective. *JRA* 53 (2), 85–102. ISSN-1539-1590

Ittenbach, R. F. (2023). From clinical data management to clinical data science: time for a new educational model. *Clin. Transl. Sci.* 16 (8), 1340–1351. doi:10.1111/cts.13545

Ivey, A. (2021). *Opinion: adoption of clinical research comptencies can set the state for research success*. Philadelphia, PA: NRG Oncology. Available from: https://www.nrgoncology.org/Home/News/Post/opinion-adoption-of-clinical-research-competencies-can-set-the-stage-for-research-success.

Joint Task Force for Clinical Trial Competency (2022). JTF core competency framework mrctcenter. Available at: https://mrctcenter.org/clinical-trial-competency/framework/domains/.

Jones, C. T., Parmentier, J., Sonstein, S., Silva, H., Lubejko, B., Pidd, H., et al. (2012). Defining competencies in clinical research: issues in clinical research education. *Res. Pract.* 13 (3), 99–107.

Jones, C. T., Tornwall, J., Plahovinsak, J., Fritter, J. S., and Neidecker, M. V. (2021). Key ePortfolio features and strategies for student success in a competency-based clinical research program. *Curr. Pharm. Teach. Learn* 13 (7), 826–834. doi:10.1016/j.cptl.2021.03.007

Mendell, A., Fritter, J., Summerside, N., Capili, B., Exe, N., Hildreth, L., et al. (2023). 444 Team science competencies for clinical research professionals: determining skills and leveling through a modified delphi approach. *J. Clin. Transl. Sci.* 7 (132), 132. doi:10.1017/cts.2023.471

Meyers, F. J., Begg, M. D., Fleming, M., and Merchant, C. (2012). Strengthening the career development of clinical translational scientist trainees: a consensus statement of the clinical translational science award (CTSA) research education and career development committees. *Clin. Transl. Sci.* 5 (2), 132–137. doi:10.1111/j.1752-8062.2011.00392.x

Murphy, S., Samuels, E. M., Kolb, H. R., Behar-Horenstein, L. S., Champagne, E., Byks-Jazayeri, C., et al. (2018). Best practices in social and behavioral research: a multisite pilot evaluation of the good clinical practice online training course. *J. Clin. Transl. Sci.* 2 (2), 95–102. doi:10.1017/cts.2018.27

Nathan, D. G. (2002). Careers in translational clinical research-historical perspectives, future challenges. *JAMA* 287 (18), 2424–2427. doi:10.1001/jama.287.18.2424

NCATS. Core (2011). Competencies for clinical and translational research NCATS: NCATS. Available at https://clic-ctsa.org/sites/default/files/CTSA_Core_Competencies_final_2011.pdf.

Oncology Nursing Society (2010). Oncology clinical trials nurse competencies. Available at: http://www.ons.org/media/ons/docs/publications/ctncompetencies.pdf.

Saunders, J., Pimenta, K., Zuspan, S. J., Berent, R., Herzog, N., Jones, C., et al. (2017). Inclusion of the joint task force competency domains in onboarding for CRCs. *Clin. Reseacher* 31 (6), 32–37. doi:10.14524/CR-17-0007

Silva, H., Sonstein, S., Stonier, P., Dubois, D. J., Gladson, B., Jones, C. T., et al. (2015). Alignment of competencies to address inefficiencies in medicines development and clinical research: need for inter-professional education. *Pharm. Med.* 29 (2), 131–140. doi:10.1007/s40290-015-0097-3

Silva, H., Stonier, P., Buhler, F., Deslypere, J.-P., Criscuolo, D., Nell, G., et al. (2013). Core competencies for pharmaceutical physicians and drug development scientists. *Front. Pharmacol.* 4, 105. doi:10.3389/fphar.2013.00105

Society of Clinical Research Associates Certification program overview 2018. Available at: https://www.socra.org/certification/certification-program-overview/introduction/.

Sonstein, S., Brouwer, R. N., Gluck, W., Kolb, R., Aldinger, C., Bierer, B., et al. (2020). Leveling the joint task force core competencies for clinical research professionals. *Ther. Innov. Regul. Sci.* 54 (1), 1–20. doi:10.1007/s43441-019-00024-2

Sonstein, S., Silva, H., Jones, C. T., Calvin-Naylor, N., Halloran, L., and Yrivarren, J. L. (2016). Global self-assessment of competencies, role relevance, and training needs among clinical research professionals. *Clin. Reseacher* 30 (6), 38–45. doi:10.14524/CR-16-0016

Sonstein, S. A., and Jones, C. T. (2018). Joint task force for clinical trial competency and clinical research professional workforce development. *Front. Pharmacol.* 9 (1148), 1–6. doi:10.3389/fphar.2018.01148

Sonstein, S. A., Kim, L. P., Ichhpurani, N., Padbidri, R., White, S. A., Aldinger, C. E., et al. (2022a). Incorporating competencies related to project management into the joint taskforce core competency framework for clinical research professionals. *Ther. Innov. Regul. Sci.* 56 (2), 206–211. doi:10.1007/s43441-021-00369-7

Sonstein, S. A., Samuels, E., Aldinger, C., White, S. A., and Bierer, B. E. (2022b). Self-assessed competencies of clinical research professionals and recommendations for further education and training. *Ther. Innov. Regul. Sci.* 56 (4), 607–615. doi:10.1007/s43441-022-00395-z

Sonstein, S. A., Seltzer, J., Li, R., Jones, C. T., Silva, H., and Daemen, E. (2014). Moving from compliance to competency: a harmonized core competency framework for the clinical research professional. *Clin. Res.* 28 (3), 17–23. doi:10.14524/CR-14-00002R1.1

Stonier, P. D., Silva, H., Boyd, A., Criscuolo, D., Gabbay, F. J., Imamura, K., et al. (2020). Evolution of the development of core competencies in pharmaceutical medicine and their potential use in education and training. *Front. Pharmacol.* 11, 282. doi:10.3389/fphar.2020.00282

Stroo, M., Asfaw, K., Deeter, C., Freel, S. A., Brouwer, R. J. N., Hames, B., et al. (2020). Impact of implementing a competency-based job framework for clinical research professionals on employee turnover. *J. Clin. Transl. Sci.* 4 (4), 331–335. doi:10.1017/cts.2020.22

UK Clinical Research Collaboration Subcommittee for Nurses in Clinical Research (2011). in *Developing the best research professionals: qualified graduate nurses: recommendations for preparing and supporting clinical academic nurses of the future* (London, United Kingdom: UKCRC).

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EDITED BY
Sudip Bhattacharya,
All India Institute of Medical Sciences, Deoghar (AIIMS Deoghar), India

REVIEWED BY
Marjorie Neidecker,
The Ohio State University, United States

*CORRESPONDENCE
Denise C. Snyder,
denise.snyder@duke.edu

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Enhancing the clinical research workforce: a collaborative approach with human resources

Denise C. Snyder[1,2,3]*, Heather Gaudaur[4], Mark Marchant[5], Laura Viera[6], Andrea McCubbin[7], William Verble[8], Angela Mendell[9] and Christine Gilliam[10]

[1]Duke Office of Clinical Research, Duke University, Durham, NC, United States, [2]School of Medicine, Duke University, Durham, NC, United States, [3]Clinical and Translational Science Institute, Duke University, Durham, NC, United States, [4]Rewards and Recognition, Office of Human Resources, Duke University, Durham, NC, United States, [5]Clinical Trials Administrative Offic, University of Alabama at Birmingham (UAB), Birmingham, AL, United States, [6]North Carolina Translational and Clinical Sciences Institute, University of North Carolina at Chapel Hill (UNC-CH), Chapel Hill, NC, United States, [7]Office of Research, College of Medicine, University of Kentucky (UK), Lexington, KY, United States, [8]Human Resources, University of Kentucky (UK), Lexington, KY, United States, [9]Center for Clinical and Translational Science and Training (CCTST), College of Medicine, University of Cincinnati (UC), Cincinnati, OH, United States, [10]College of Medicine Human Resources, University of Cincinnati (UC), Cincinnati, OH, United States

Jobs for clinical research professionals (CRPs) have grown increasingly complex over the past 20+ years. This is due largely to additional administrative burden for investigators, study teams, sponsors, Clinical Research Organizations (CROs), and sites, particularly Academic Medical Centers (AMCs). Furthermore, National Institutes of Health (NIH) has reduced capacity to effectively fund research recognizing this is dependent on the overall congressional budget, which creates greater pressure for clinician scientists to secure external support. It is widely known clinical research will continue to become increasingly more complex for clinician scientists. This manuscript explores adoption of a clinical research competency-based job classification framework from the Joint Task Force for Clinical Trial Competency (JTFCTC) across several AMCs and the role of Human Resources (HR) in facilitating this process. This collaboration focuses on fostering successful projects tied to the business case in order to address equity and improve support for the clinical research enterprise.

KEYWORDS

clinical research professional (CRP), clinical research coordinator (CRC), clinical research nurse (CRN), human resources (HR), workforce development, academic medical center (AMC)

1 Introduction

In today's rapidly evolving landscape, clinical research sites, particularly those in AMCs, need to revitalize job descriptions and establish career pathways (Brouwer et al., 2017). Such efforts aim to reduce turnover, increase employee engagement, and improve clinical trial quality (Stroo et al., 2020). Staff supporting the research for clinician scientists are asked to do more than recruit participants and complete study visits, while also facing an increased regulatory burden and a fragmented infrastructure (Sung et al., 2003). Although job responsibilities have evolved, the job titles, essential skills, and salaries held by individuals performing these tasks have not (Knapke et al., 2022). In addition, training demands have soared and resources for professional development remain limited.

Associated costs with training are already substantial (Deeter et al., 2020). However, with ill-defined jobs, it is often arduous to garner how many clinical research professionals (CRPs) are hired (Bocchino et al., 2020), thus actual costs of training have likely been underestimated. These CRP jobs are in high demand, with increasingly documented shortages related to a workforce in crisis (Freel et al., 2023).

Beginning in 2014, the Association for Clinical and Translational Science (ACTS) Clinical Research Professional Taskforce issued recommendations advising AMCs to assess the training, support, and career development needs of CRPs (Speicher et al., 2012; Sonstein et al., 2014; Stevens and Daemen, 2015; Knapke et al., 2022). Competency-based job frameworks provide a foundation to integrate and enhance recruitment, development, performance management, and career progression (Benayoune, A. 2017). To affect change, a deep dive is needed by AMCs with representation by stakeholder groups requiring engagement across the institution for departments, faculty, staff and administrators (Snyder et al., 2016). Critical partnerships and relationships must be established between institutional clinical research leadership and leaders in Human Resources (HR) (Brouwer et al., 2017). Successful competency-based job models for clinical research professionals have been demonstrated by several institutions (Furtado et al., 2015; Brouwer et al., 2017; Deeter et al., 2020; Ibrahim et al., 2022). In this paper, we will describe elements of successful institution-wide partnerships focusing specifically on the importance of engaging HR in both private and public AMCs. We will provide key recommendations spanning various phases of competency-based job framework adoptions highlighting areas of success, challenges, and lessons learned.

2 How to get started

Revamping job descriptions and creating career ladders in any industry is daunting. Doing it in a traditional AMC clinical research setting where teams have operated in a decentralized, siloed manner may seem impossible. Despite the challenges, endeavors to standardize the CRP positions and career pathways exist using the Joint Task Force for Clinical Trial Competency framework https://mrctcenter.org/clinical-trial-competency/ (Sonstein et al., 2014; Kolb et al., 2018; Sonstein et al., 2018; Musshafen et al, 2021) and are well-documented by Duke University (Brouwer et al., 2017; Deeter et al., 2020; Stroo et al., 2020), and further instantiated at the University of Alabama at Birmingham (UAB) in March 2020. More recently, various efforts are underway at other AMCs, several included in this perspective. There are likely other implementations by AMCs in-part, or in-whole that are not known or documented.

To initiate the competency-based job classification project, organizations must make an effective business case to institutional leadership, clearly articulating the benefits of revising job descriptions and career pathways to attract, retain and motivate staff. This involves demonstrating how a project of this caliber directly aligns with organizational goals including increased research funding, high quality staff support, long-term reduced administrative costs and improved competitiveness in the clinical research industry, spanning both jobs and funding. This step may vary slightly across institutions, however, to fully understand the institutional landscape, an assessment of the existing clinical research workforce is needed. This assessment may include the following: 1) Define the CRP role and identify existing jobs supporting clinical research; 2) Review current job descriptions and corresponding salary ranges; 3) Solicit feedback from CRPs, managers, and clinician scientists on the current tasks and competencies needed to perform CRP jobs; 4) Identify deficits in current workforce management process; and 5) Review literature and attend sessions on existing competency-based clinical research job frameworks. This data-driven approach sets the stage for success by providing the foundation for future conversations with key stakeholders.

The next step includes buy-in and partnership from key stakeholders, including (but not limited to, given differences across organizations): Clinical research leadership, School and departmental leadership, HR (including Compensation and Recruitment), Faculty, and Staff (See Figure 1). At Duke, in the second and successful attempt at job classification revision and implementation, buy-in and partnership was sought from top leadership. This began with Vice Deans for Clinical Research, Finance, and HR before proceeding to leadership in each clinical research unit (24 units align with clinical areas). UAB's approach mirrored Duke's by initiating conversations initially with senior leadership within the Heersink School of Medicine, where the majority of the affected staff's positions resided, before making the pitch to the Chief HR Officer for the institution. Once approval was garnered at those levels, the campaign to disseminate high level information about the upcoming effort commenced with the University's institutional-wide Clinical Trials Administration Committee and then diffused from there. Similarly, at University of North Carolina at Chapel Hill (UNC-CH), a survey of School of Medicine (SOM) CRPs revealed that the area of lowest job satisfaction among respondents related to lack of clear career pathways and highlighted the importance of such an initiative to SOM and HR leaders. At the University of Kentucky (UK), leadership buy-in was initially achieved by the College of Medicine (COM) Office of Research establishing a Research Professionals Network encompassing CRPs in COM and the Center for Clinical and Translational Sciences (CCTS). CRPs were invited to share challenges and barriers to carry out daily tasks responsibly and effectively. Feedback included non-competitive salary ranges, misaligned job responsibilities, lack of training opportunities, and lack of a defined career pathway. Using this feedback as the catalyst for redefining the CRP job architecture demonstrated COM's commitment and alignment with the institution's strategic plan principle to "Take Care of our People" (https://pres.uky.edu/strategic-plan). At the University of Cincinnati (UC), there were narrowly focused efforts to address compensation while battling increased turnover with little focus on other factors contributing to retention. For example, clinical research leaders were aware of shortcomings in the CRP job classification framework, but little work had been done to evaluate competency-based job models and career advancement. UC took a team science approach to addressing these issues. Team science brings together people from different fields and utilizes their expertise in a collaborative manner to tackle projects or issues (NIH, National Cancer Institute Division of Cancer Control and Population Sciences, 2021). UC's approach was to form a CRP workgroup in which membership had a cross-section of contributors from UC's CCTST, College Human Resources, CRP

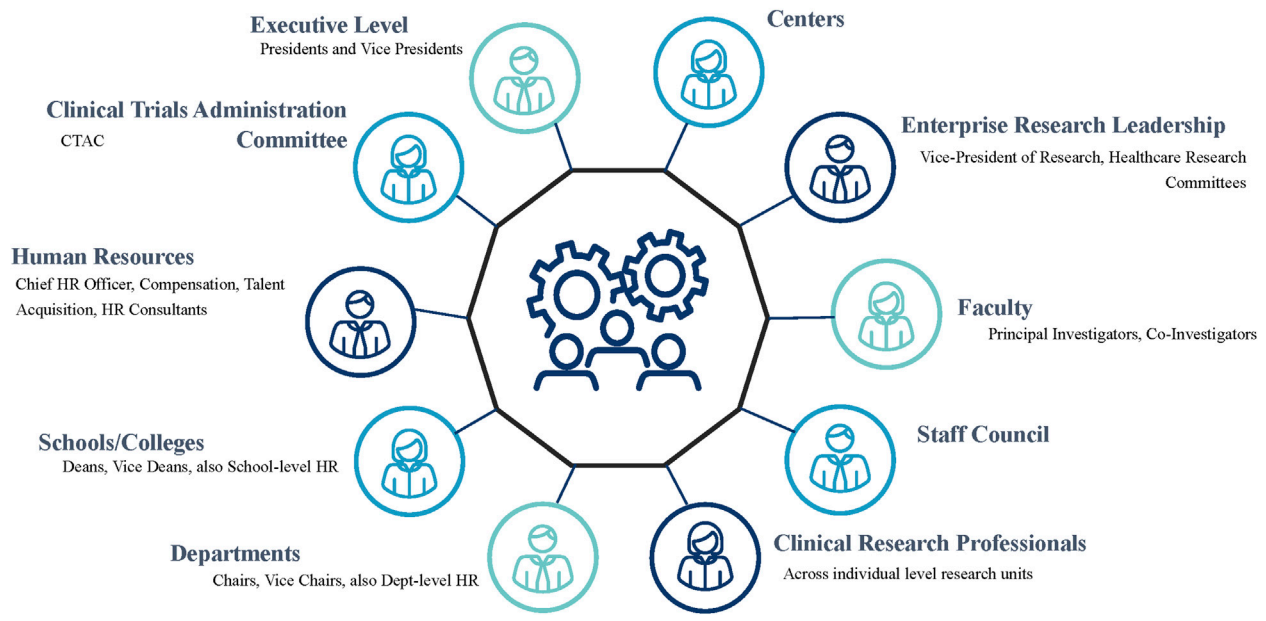

FIGURE 1
Organizational buy-in is needed across key institutional stakeholders.

leaders, and faculty. This group was charged by its Sr. Associate Dean of Clinical Research. UC's approach is 3-pronged exploring Education, Recruitment and Retention. Each group is focusing on specific initiatives within an area and is functioning independently, yet collaboratively, to improve each of these areas. A major endeavor of the CRP workgroup is to incorporate competency-based job descriptions and create career advancement pathways for CRPs.

Identifying the "win-win" reasons for establishing a competency-based framework was a key to success in prior implementations. Duke reduced staff turnover by 30% (Stroo et al., 2020) and improved professional development and career advancement (Deeter et al., 2020). This structure allows the organization to capitalize on the data associated with these jobs, while attracting more diverse faculty expertise and increasing the institution's clinical research portfolio. Prior to UAB's implementation in 2020, it was not able to identify, much less track, its CRP workforce given the more than 80 job titles used across the institution. Now, the University is able to monitor its growth in the workforce, which has shown a 20% increase over the past year. Likewise, UAB is now able to monitor its retention rate of CRPs and ensure communications and training opportunities reach their target audience.

3 The importance of a human resources (HR) collaboration

An overhaul of clinical research job classifications requires a vital HR partnership. HR professionals play a crucial role in talent management and workforce planning and engaging them early and often throughout the process facilitates a smooth implementation. Establishing a strong rapport involves educating HR about the unique job requirements of the clinical research field, cost of turnover, including lengthy time to fill positions and subsequent training, and workload demands for managers. In addition, this partnership ensures HR professionals understand the institutional infrastructure for oversight and support, fosters open communication channels, and helps them understand the similarities and differences for clinical research staff compared to jobs in private industry and patient care. In turn, the CRP workgroups learn about HR-related themes such as market analysis for compensation, salary transparency, equity across and within institutional organizations, as well as practices that may relate to recruiting and compensating staff outside the landscape. The workgroup collaborates on understanding the organization's processes. Each institution has its own policies and processes related to job design and compensation practices. Working in partnership with HR ensures compliance, efficiency, and equity to meet project timelines. Engaging HR early during the needs assessment phase allows the HR team to identify potential barriers to proactively address.

Building on the assessment of the institutional landscape as the foundation to engage key stakeholders, HR partners can assist greatly. This step includes identifying clinical research facilities or departments across the various areas within the project's scope and determining how many staff are in those areas along with respective titles. This can be achieved by reviewing multiple sources of HR data (University, School, and/or Department). Duke started with a list of employees named as key personnel in protocols submitted to its University Health System's Institutional Review Board (IRB), and then reviewed employees in frequently used positions. For UAB, this meant reaching out to the HR and administrative officers in each School to confirm or deny that clinical research was being conducted there and provide the staff names along with corresponding title, organization, and supervisor. At UNC-CH, early data was obtained using a custom-developed *Profile and*

Training System (*PaTS*) in which all employees engaged in clinical research were asked to indicate their primary role. This identified significant variance in roles compared to job classifications, further emphasizing the need for standardization. A combination of self-reported data from PaTS, job classification data from HR, study role information from IRB submissions, and supervisor-reported data will be used for the final, comprehensive identification of CRPs. UK accomplished this by defining a "clinical research professional" and then identifying job titles likely to have associated responsibilities. HR consulted with the project advisory group, comprised of COM leadership, CRPs, CCTS, and Cancer Center representatives, to identify which job titles and employees were in scope for the project. UC's existing structure had all CRPs identified, but the job descriptions and career framework were lacking. UC CRP leaders suspected missing job classifications (i.e., Nurse Research, Regulatory) and HR assisted with reviewing these prior to the career pathway work.

4 Revision of jobs and adopting the JTFCTC framework

Using a data-driven assessment, the workgroup evaluates the current job descriptions and information gathered to identify gaps and areas for improvement. This will vary across institutions. At Duke, this was enterprise-wide for Schools of Medicine and Nursing that support biomedical research (Brouwer, et al., 2017). UAB's effort took an institutional-wide perspective by including all seven Schools and Colleges engaged in the conduction of clinical research. In addition to Medicine, this encompassed Dentistry, Optometry, Nursing, Public Health, Health Professions, and Arts & Sciences. At UNC-CH, a public state institution, it was critical to develop the standardized position descriptions in a manner that would align with the existing state of North Carolina career banding profiles. To ensure the standardized positions would be acceptable based on those statewide requirements and standards, individuals from the UNC-CH SOM first worked closely with HR representatives to develop the position descriptions and then reviewed the proposed positions with leaders, managers, and staff from across the SOM to fine-tune the descriptions. At UK, the advisory group formed a workstream specific to each job title [CRC, Clinical Research Nurse (CRN), Regulatory Specialist, etc.] comprised of CRPs in that role to conduct the job description reviews. This ensured a larger span of input and engagement in the review without having too large of an advisory group. HR representatives then provided feedback and guidance on draft job descriptions and compensation impact and considerations. In 2017, UC had identified all clinical research staff with department business leaders and managers where employees were mapped to a general CRP title and job description. UC HR and the CRP Taskforce are incorporating the framework by mapping these competencies to the existing and newly expanded job titles. UC opted to follow UNC-CH's lead and work within the existing framework to create competency-based job descriptions and establish advancement pathways. The retention subgroup at UC is incorporating competencies into job descriptions and tiers using Duke's tier advancement model and integrating with the advancement pathway.

As part of this work, consideration should be given for establishing career ladders, as this has been linked to retention (Stroo et al., 2020). HR can provide guidance on existing job ladders at your institution by aligning the number of levels to other ladders. Understanding the existing HR framework is critical at public institutions where there may be less flexibility due to statewide standards. Mapping career progression opportunities and defining career growth stages using the JTFCTC framework to establish job ladders is a significant step in identifying a clear career pathway for CRPs. Linking the revised job descriptions to the identified career pathways through incorporating competency skills trainings and requirements at each stage will ensure alignment for growth opportunities.

In summary, revising CRP job architecture and adopting the JTFCTC framework requires workgroups to do the following: 1) Update job classifications and titles, working with HR partners to develop associated external market-based and internally aligned salary ranges to accompany job classifications; 2) Map existing positions to revamped job classifications, carefully review the function of the role (not the individual currently in the role) to determine classification; 3) Review financial impact of potential salary adjustments with department business managers, 4) Craft letters that will notify each employee of new position title and associated compensation, 5) Retire old job descriptions, post new job descriptions; 6) Provide resources for questions and assistance (FAQs, Tip sheets, Central email/voicemail box, Town Halls, etc.); and 7) Establish data acquisition plan for tracking the revised jobs framework to measure project successes and to pivot in real-time, if needed (may involve working with data analytics team, recruitment and/or payroll services). All the institutions participating in this manuscript have learned from each other and the extensive resources and tools provided by Duke as part of their Workforce Engagement and Resilience program (https://medschool.duke.edu/research/research-support/research-support-offices/duke-office-clinical-research-docr/workforce-3).

5 Implementation and evaluating changes

During the planning and implementation of any project, communication is paramount. This, in fact, cannot be overstated. Stakeholders must be informed about the data-driven process resulting in revised job classifications and established career pathways to ensure understanding for individual impact, overall project transparency, and the investment of the institution. Providing necessary training to HR professionals and clinical research managers is important to implementation of the new framework. Both managers and HR professionals can assist the project team in fielding questions and triaging any problems that arise. Along with consistent and transparent communication, change management and dealing with expectations for study teams is critical for success. Not all institutions can make all the changes at once. Incremental changes along the way can assist in the longer-term plan to implement career ladders and clearer pathways for advancement. Early, easy wins can provide momentum to tackle the larger goal. For example, tackling clearer roles like nursing and regulatory tracks may provide short-term deliverables and keep institutional

FIGURE 2
High-level steps to implementing competency-based clinical research professional jobs.

buy-in strong. After implementation, regularly assessing the effectiveness of the changes allows for continuous improvements and refinements to the process. A great deal of work goes into aligning clinical research job responsibilities with a competency-based framework; it will not happen overnight, and it will not be perfect for all stakeholders. The idea of perfection can be paralyzing, so best to adhere closely to the timeline, launch, seek and apply feedback, adjust the process, and make improvements. Demonstrating progress in this process communicates value to CRPs.

6 Conclusion

Collaboration between clinical research leadership and HR is critical for establishing and maintaining a strong workforce, and for successfully implementing competency-based job descriptions and creating career pathways. The process does not have to be overwhelming and can be mitigated by leaning on institutions with experience in this space. This paper demonstrates collaborations of five institutions working together to learn from one another and build a stronger research workforce by leveraging partnerships. By investing in this process, organizations can recognize and foster a high-quality clinical research workforce, boost employee engagement, and secure support for the growing number of clinical trials. Figure 2 provides a high-level overview on moving this process forward. Reworking the competency-based job classifications provide an excellent starting point to tie together improved onboarding, training, on the job support, expansion of diversity and inclusion efforts (Cranfill et al., 2022) and professional development (Deeter et al., 2020). Establishing strong collaborations between clinical research leadership and HR will promote building a talented workforce supporting the quality and success of clinical trials.

Data availability statement

No data sets were used in this article, but we do provide access to our tools such as a REDCap data dictionary that contains Code or technology also methodology. This data can be found here. https://medschool.duke.edu/research/research-support/research-support-offices/duke-office-clinical-research-docr/workforce-3.

Author contributions

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

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References

Benayoune, A. (2017). Competency-based framework: the benefits and the challenges. *Int. J. Manag. Appl. Sci.* 3, 6–11.

Bocchino, J. M., Butler, J., and Harper, B. (2020). A perspective on the current state of clinical research education and training. Clinical researcher. Available at: https://acrpnet.org/2020/11/10/a-perspective-on-the-current-state-of-clinical-research-education-and-training/.

Brouwer, R. N., Deeter, C., Hannah, D., Ainsworth, T., Mullen, C., Hames, B., et al. (2017). Using competencies to transform clinical research job classifications. *J. Res. Adm.* 48, 11–25.

Cranfill, J., Freel, S. A., Deeter, C., Snyder, D., Naggie, S., Barrett, N., et al. (2022). Development and evaluation of a novel training program to build study staff skills in equitable and inclusive engagement, recruitment, and retention of clinical research participants. *J. Clin. Transl. Sci.* 6 (1), E123. doi:10.1017/cts.2022.456

Deeter, C., Hannah, D., Reyes, C., Mack, M. E., Stroo, M., Freel, S. A., et al. (2020). Professional development for clinical research professionals: implementation of a competency-based assessment model. *J. Res. Adm.* 51, 15–40.

Framework (2022). Framework for clinical research professionals: a Canadian paediatric research perspective. *J. Res. Adm.* 53, 85–102.

Freel, S. A., Snyder, D. C., Bastarache, K., Jones, C. T., Marchant, M. B., Rowley, L. A., et al. (2023). Now is the time to fix the clinical ResearchWorkforce crisis. *Clin. Trials* 2023 (0), 457–462. doi:10.1177/17407745231177885

Furtado, T., Jule, A., Boggs, L., Van Loggerenberg, F., Ewing, V., and Lang, T. (2015). Developing a global core competency framework for clinical research. *Trials* 16, P191. doi:10.1186/1745-6215-16-s2-p191

Ibrahim, S., Guerrero, M. M., and Goos, L. M. (2022). Adapting the Joint task Force core competency framework for clinical research professionals: a Canadian paediatric research perspective. *J. Res. Adm.* 53 (2), 85–102.

Knapke, J. M., Snyder, D. C., Carter, K., Fitz-Gerald, M. B., Fritter, J., Robert Kolb, H., et al. (2022). Issues for recruitment and retention of clinical research professionals at academic medical centers: Part 1- collaborative conversations un-meeting findings. *J. Clin. Transl. Sci.* 6 (1), e80. doi:10.1017/cts.2022.411

Kolb, H. R., Kuang, H., and Behar-Horenstein, L. S. (2018). Clinical research coordinators' instructional preferences for competency content delivery. *J. Clin. Transl. Sci.* 2 (4), 217–222. doi:10.1017/cts.2018.320

Musshafen, L. A., Poger, J. M., Simmons, W. R., Hoke, A. M., Hanson, L. N., Bondurant, W. W., et al. (2021). Strengthening the clinical research workforce through a competency-based orientation program: process Outcomes and lessons learned across three academic health institutions. *J. Clin. Transl. Sci.* 5 (1), e178. doi:10.1017/cts.2021.852

NIH, National Cancer Institute, Division of Cancer Control and Population Sciences (2021). What is team science? Available at: https://cancercontrol.cancer.gov/brp/research/team-science-toolkit/what-is-team-science August 31, 2023).

Snyder, D. C., Brouwer, R. N., Ennis, C. L., Spangler, L. L., Ainsworth, T. L., Budinger, S., et al. (2016). Retooling institutional support infrastructure for clinical research. *Contemp. Clin. trials* 48, 139–145. doi:10.1016/j.cct.2016.04.010

Sonstein, S. A., Namenek Brower, R. J., Gluck, W., Kolb, H. R., Aldinger, C., Bierer, B. E., et al. (2018). Leveling the joint task force core competencies for clinical research professionals. *Ther. innovation Regul. Sci.* 2168479018799291, 216847901879929. doi:10.1177/2168479018799291

Sonstein, S. A., Seltzer, J., Li, R., Silva, H., Jones, C. T., and Daemen, E. (2014). Moving from compliance to competency: a harmonized core competency framework for the clinical research professional. *Clin. Res.* 28, 17–23. doi:10.14524/CR-14-00002R1.1

Speicher, L. A., Fromell, G., Avery, S., Brassil, D., Carlson, L., Stevens, E., et al. (2012). The critical need for academic health centers to assess the training, support, and career development requirements of clinical research coordinators: recommendations from the Clinical and Translational Science Award Research Coordinator Taskforce. *Clin. Transl. Sci.* 5, 470–475. doi:10.1111/j.1752-8062.2012.00423.x

Stevens, E., and Daemen, E. (2015). professionalization of research coordinators. *Clin. Res.* 29 (6), 26–31. doi:10.14524/CR-15-0035

Stroo, M., Asfaw, K., Deeter, C., Freel, S. A., Brouwer, R. J., Hames, B., et al. (2020). Impact of implementing a competency-based job framework for clinical research professionals on employee turnover. *J. Clin. Transl. Sci.* 4, 331–335. doi:10.1017/cts.2020.22

Sung, N. S., Crowley, W. F., Genel, M., Salber, P., Sandy, L., Sherwood, L. M., et al. (2003). Central challenges facing the national clinical research enterprise. *Jama* 289, 1278–1287. doi:10.1001/jama.289.10.1278

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EDITED BY
Michael J. Wolyniak,
Hampden–Sydney College, United States

REVIEWED BY
Marc Henri De Longueville,
UCB Pharma, Belgium
Jun Hyun Kim,
Inje University Ilsan Paik Hospital,
Republic of Korea

*CORRESPONDENCE
Carolynn Thomas Jones
✉ jones.5342@osu.edu

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The competency index for clinical research professionals: a potential tool for competency-based clinical research academic program evaluation

Carolynn Thomas Jones[1]*, Xin Liu[2], Carlton A. Hornung[3], Jessica Fritter[1] and Marjorie V. Neidecker[4]

[1]Center for Clinical Translational Science, College of Nursing, The Ohio State University, Columbus, OH, United States, [2]Division of Biostatistics, College of Public Health, The Ohio State University, Columbus, OH, United States, [3]Department of Medicine, University of Louisville, Louisville, KY, United States, [4]College of Pharmacy, The Ohio State University, Columbus, OH, United States

Background: Accreditation of graduate academic programs in clinical research requires demonstration of program achievement of Joint Task Force for Clinical Trial Competence-based standards. Evaluation of graduate programs include enrollment, student grades, skills-based outcomes, and completion rates, in addition to other measures. Standardized measures of competence would be useful.

Methods: We used the Competency Index for Clinical Research Professionals (CICRP), in a separate-sample pretest-posttest study to measure self-confidence or self-efficacy in clinical research competency comparing cohorts of students entering and completing a master's degree program in clinical research across three semesters (summer 2021 – spring 2022). CICRP is a 20-item Likert scale questionnaire (0 = Not at all confident; 10 = extremely confident).

Results: The study sample of 110 students (54 in the entry course, 56 in the exit course) showed overall 80.9% entered the program with only a baccalaureate degree and 55.5% had no prior experience in managing clinical trial research. Cronbach alpha for the instrument showed a high level of content validity (range 0.93–0.98). Median CICRP item rating range at entry was [1, 6] and at exit [7, 10]. Mean CICRP total score (sum of 20 items) at entry was 72.7 (SD 41.9) vs. 167.0 (SD 21.1) at exit ($p < 0.001$). Mean total score at program entry increased with increasing years of clinical trial management experience but attenuated at program exit.

Conclusion: This is the first use of the CICRP for academic program evaluation. The CICRP may be a useful tool for competency-based academic program evaluation, in addition to other measures of program excellence.

KEYWORDS

clinical trial competency, program evaluation, competency-based education, academic program in clinical research, clinical research professionals

1 Introduction

Academic programs in clinical research have evolved over the past two decades to provide an educational pathway for clinical research professionals for chosen career paths in clinical research. Academic programs may range from associate degrees, undergraduate or graduate certificates, undergraduate degrees and master's degrees in clinical research management and regulatory affairs. Many of these programs are distance-based and asynchronous, enrolling students nationally and internationally. Other graduate programs also support more advanced clinical translational research and regulatory science education for doctorally prepared clinical translational scientists (e.g., physicians, pharmacologists, and basic scientists).

The Joint Task Force (JTF) for Clinical Trial Competency (JTF Framework) is an international team of investigators, educators, sponsors and clinical research professionals that has developed a framework that defines the knowledge, skills and attitudes necessary for conducting safe, ethical, and high-quality clinical research. This group published core competencies in clinical research, harmonizing evolving work in role-based competencies at the time (1, 2) (Figure 1). Subsequent research on the JTF Framework included a global survey applied to competency relevance to roles and training needs in clinical trials (3). Since that time, the JTF Framework has been updated to include illustrated leveling and project management. The JTF website is maintained by the Multi-Regional Clinical Trials Center at Harvard University (4–6).

In 2018, a factor analysis of the global survey data for non-investigator, clinical research professionals working in the United States and Canada resulted in a short-form 20-item competency index assessment tool called the Competency Index for Clinical Research Professionals (CICRP) (Table 1) that used a 0–10 Likert scale (7). The tool analysis included five empirical domain subscales: I. General Operation and Management of Clinical Trials, II. Medicines Development, III. Ethics and Participant Safety, IV. Data Collection and Management, and V. Scientific Concepts in Clinical Research (CICRP-I). The scale was used in a subsequent study exploring the use of the index to compare self-perceived self-efficacy in performing clinical trial skills among clinical research professionals (CRPs) working at academic medical center settings, other site settings and students of academic programs in clinical research. This study assessed the importance of clinical trial experience and academic education in CRPs (8). This index, known as CICRP-II, measured routine functions and advanced functions of clinical research professionals (8).

The Consortium of Academic Programs in Clinical Research, established an accreditation pathway for academic programs in

FIGURE 1
Joint task force clinical trial competency framework (3).

TABLE 1 Competency Index for Clinical Research Professionals (CICRP) criteria.

CICRP items	JTF competency domain(s)*	CICRP empirical domain(s)**
1 Describe the role and process for monitoring a study.	(4)	I, III
2 Describe the roles and responsibilities of various institutions participating in the medicines development process.	(3)	II
3 Compare and contrast clinical care and clinical management of research participants.	(2)	I, III, V
4 Summarize the process of electronic data capture (EDC) and the importance of information technology in data collection, capture and management.	(6)	IV
5 Explain the elements (statistical, epidemiological, and operational) of clinical and translational study design.	(1)	V
6 Identify the legal responsibilities, issues, liabilities, and accountability that are involved in the conduct of a clinical trial.	(5)	I
7 Explain the medicines development process and the activities, which integrate commercial realities into the life cycle management of medical products.	(3)	II
8 Compare the requirements for human subject protection and privacy under different national and international regulation and ensures their implementation throughout all phases of a clinical study.	(2), (4)	III
9 Describe the significance of data quality assurance systems and how SOPs are used to guide these processes.	(6)	I, IV
10 Critically analyze study results with an understanding of therapeutic and comparative effectiveness.	(1)	V
11 Summarize the legislative and regulatory framework, which supports the development and registration of medicines, devices and biologicals and ensures their safety, efficacy and quality.	(3)	II
12 Describe the ethical issues involved when dealing with vulnerable populations and the need for additional safeguards.	(2)	III
13 Compare and contrast the regulations and guidelines of global regulatory bodies relating to the conduct of clinical trials.	(4)	I, V
14 Describe the specific processes and phases that must be followed for the regulatory authority to approve the marketing authorization for a medical product.	(3)	II
15 Differentiate the types of adverse events which occur during clinical trials, understand the identification process for AEs and describe the reporting requirements to IRBs/IECs, sponsors and regulatory authorities.	(4)	II, III
16 Describe the reporting requirements of global regulatory bodies relating to clinical trial conduct.	(4)	I, IV, V
17 Describe the impact of cultural diversity and the need for cultural competence in the design and conduct of clinical research.	(7)	IV
18 Define the concepts of "clinical equipoise" and "therapeutic misconception" as they relate to the conduct of a clinical trial.	(2)	I
19 Apply management concepts and effective training methods to manage risk and improve quality in the conduct of a clinical research study.	(5)	I
20 Identify and apply the professional guidelines and codes of ethics, which apply to the conduct of clinical research.	(7)	I, IV

*JTF competency domains	**CICRP empirical domains
(1) Scientific concepts and research design	I General operation and management of clinical trials
(2) Ethical and participant safety considerations	II Medicines development
(3) Investigational products development and regulation	III Ethics and participant safety
(4) Clinical study operations (good clinical practice)	IV Data collection and management
(5) Study and site management	V Scientific concepts in clinical research
(6) Data management and informatics	
(7) Leadership and professionalism	
(8) Communications and teamwork	

CICRP, Competency Index for Clinical Research Professionals; JTF, Joint Task Force; SOP, Standard Operating Procedures; AEs, adverse events; IRBs, Institutional Review Boards; IECs, Independent Ethics Committees.

clinical research. Accreditation is offered by Commission on Accreditation of Allied Health Education Programs (CAAHEP) and is administered by the Committee on Accreditation of Academic Programs in Clinical Research (CAAPCR) (9). The CAAPCR accreditation standards incorporate the JTF Competency Framework for competency-based clinical research educational programs. The

self-study process requires gathering numerous student, course, program and institutional evaluation materials and data to address the specific requirements for the CAAPCR standards and guidelines. Program evaluation measures include enrollment; retention and graduation metrics; and student and course demonstration of achieving clinical research competencies by analysis of competency-based course assignments mapped to program goals, course objectives and the JTF Framework.

The authors are reporting on the use of the 20-item CICRP instrument as an evaluation tool in a 100% online asynchronous master's degree program in clinical research (Master of Clinical Research, MCR) with specializations in both clinical research management and regulatory affairs at a midwestern public institution in the United States, with a major academic medical center. Students complete 12 graduate courses (36 credit hours total) consisting of seven core courses, four specialization courses and a culminating project course. Students are accepted into the program three times per year (spring, summer, and autumn) using a holistic admissions method, including required undergraduate GPA of 3.0. Prior clinical research experience is not a pre-requisite to admission. Courses are delivered using a well-established learning management system adopted by the university and taught by faculty with experience in clinical research, clinical trials, pharmacology, bioethics, and biostatistics. The program curriculum is mapped to the JTF Framework with a heavy distribution of JTF competencies across the core courses and more focused JTF competencies across the specialization courses. The final course allows students to select one of five culminating project options: develop an integrative review, develop a research protocol/proposal, develop a manuscript on a clinical research topic, develop and perform a clinical research-related project, or work with a mentor in a focused research opportunity. Another deliverable in the culminating project course is the development of an ePortfolio that included evidence of acquired JTF competency skillsets and an essay on each of the JTF competency domains reflecting on their learning in each domain and future learning and experiential goals as a clinical research professional. We included applied real-world assignments to provide authentic learning for students to enhance the competency-based nature of our asynchronous learning environment. Table 2 provides examples from a subset of applied competency-based assignments found in courses in the curriculum. Furthermore, our courses were structured using program-designed, learner-centric module templates, applying collaborative learning pedagogy including forming a course community, providing opportunities for interactive discussion, and requiring ongoing teacher scaffolding through frequent input. This pedagogy is in keeping with the best practices for online collaborative education (10). The program requires that students maintain a B- or above final grade in all completed courses and an overall GPA of 3.0 to graduate.

While the master's program evaluated competence for clinical research professional roles through students' assignments, ePortfolios and culminating projects, a standardized assessment tool was lacking. The program aimed to supplement the existing measures of competency by including the CICRP questionnaire as a program evaluation tool. The purpose of this study is to describe the results of

TABLE 2 Subset of authentic applied assignments in the master's program core courses aligned to JTF competency domai.

Applied assignment	JTF competency domain(s)
Develop an IND submission for an assigned study	(3) Investigational products development and regulation
Describe and analyze a manuscript's statistical methods, results for an assigned study and dataset	(1) Scientific concepts and research design
Develop a PICOT question and research proposal.	(1) Scientific concepts and research design
Develop a quality management plan for a clinical research site and study.	(5) Study and site management
Demonstrate the correct use of electronic case report form system from perspective of the sponsor, monitor and coordinator.	(6) Data management and informatics
Analyze and discuss bioethical case studies applying regulations.	(2) Ethical and participant safety considerations
Develop an IRB submission and informed consent form for an assigned clinical study.	(2) Ethical and participant safety (4) Clinical study operations (GCPs)
Develop a recruitment analysis and plan for an assigned clinical trial.	(2) Ethical and participant safety (4) Clinical study operations
Work as a team to develop a data management plan for an assigned study.	(6) Data management and informatics (8) Communication and teamwork
Conduct and present a risk analysis of a planned study.	(5) Study and site management (4) Clinical study operations (GCPs)
Generate a CAPA and SOPs based on findings from FDA warning letters.	(4) Clinical study operations (GCPs) (3) Investigational products development and regulation
Create case studies and scripts demonstrating the application of crucial conversations principles in a conflict between parties occurring at a clinical research site.	(7) Leadership and professionalism (8) Communication and teamwork

CAPA, Corrective and Preventive Action; JTF, Joint Task Force; SOP, Standard Operating Procedures; FDA, Food and Drug Administration; IND, Investigational New Drug; IRB, Institutional Review Board; GCPs, Good Clinical Practices; PICOT, population/patient, intervention, comparison, outcome, and time.

entry versus exit course assessments using the CICRP tool for academic competency-based program evaluation.

2 Methods

2.1 CICRP survey instrument

For the purpose of using the CICRP instrument as a program evaluation tool, we used composite scores from the 20-item scale without the CICRP I or II subscale analyses (6, 11). Using a separate-sample pre-post study design, we administered the CICRP questionnaire to students in the entry and exit courses of our clinical research master's degree program during the 2021–2022 academic year. We created a Qualtrics^{XM} (Provo, Utah) survey instrument including the 20 CICRP items asking students to rate their self-efficacy in performing each item (Table 1) using a Likert slider scale from 0 to 10 (0 = not at all confident; 10 = extremely confident) (Figure 2). The survey required a response to each item, and if the respondent intended to select zero, a click or tap on zero was required. Students could participate in the survey on a desktop or a mobile device. We posted links to the survey in the learning management system in course modules and on the course calendar. We also sent reminders to take the CICRP survey through course announcements that generated a notice to their student E-mail inbox.

We included the CICRP Qualtrics^{XM} survey as a required non-graded assessment in the beginning of the students' initial program course (course number MCR 7770) and again at the end of their final program course (course number MCR 7599). We designed this study to measure and compare entering and exiting students to assess whether the CICRP tool had utility for program evaluation. Prior to commencing the survey, students were provided with an informed consent for this study with a prompt to proceed if they consented. The survey study was granted exempt approval by the institution's Institutional Review Board.

2.2 Statistical methods

We describe the two student groups entering and exiting the program by highest degree at program entry, years of clinical research experience, whether being a nurse, and whether holding clinical research certification (12, 13). The Qualtrics^{XM} data set includes the CICRP ratings of the students from the entry course in semesters Summer 2021 (SU21) and Autumn 2021 (AU21) (the entry course is not offered during spring semester). In the exit course, the CICRP survey was conducted with students toward the end of the course during SU21, AU 21 and Spring 2022 (SP22). For each of the 20 survey items we used the Likert scale based on CICRP from zero to 10 (7). *T*he summation of the combined 20 CICRP items is a good tool to evaluate clinical trial core competencies overall (11), which we denote as the CICRP total score *(range 0–200)*.

Because each CICRP item contains 11 categories (0, 1,…,10) it would be reasonable to treat the rating scale as continuous interval data (14, 15). For each item, a higher rating means greater perceived efficacy for that item, *while* a higher CICRP total score *signifies greater perceived competency*.

CICRP total scores were first directly compared between the students taking the program entry course and the program exit course. Students put their student email ID in the tool to ensure no duplicate entries. When the dataset was downloaded, those identifiers were removed before analysis to preserve anonymity. We used linear regression to adjust for these potential confounders such as "semester" and "highest degree at program entry.

3 Results

3.1 Participant characteristics

All students were required to complete the CICRP survey as a non-graded assignment. The number of students in the entry course taking the CICRP was 23 in SU21 and 31 in AU21 (total $n = 54$). The number of students taking the CICRP in the exit course was 27 in SU21, 14 in AU21 and 15 in SP22 (total $n = 56$) (Table 3).

As required in the program, all students had a bachelor's degree; however, in the exit course, a greater proportion of students had entered the program already holding a graduate degree (5.6% in the entry course vs. 32.1% in the exit course, $p < 0.001$). We asked students, "What is your current level of experience in clinical research?" Of the students taking the CICRP in the entry course, 59.3% indicated they had no experience, while 25.9% had more than 2 years of experience. Among students taking the CICRP in their exit course, responses showed more *but statistically* insignificant levels of experience: 51.8% indicated no prior experience, while 33.9% indicated more than 2 years ($p = 0.344$). The program aims to increase its enrollment of nurses to the program so the question, "Are you a nurse" provides data for correlational scores in future analyses.

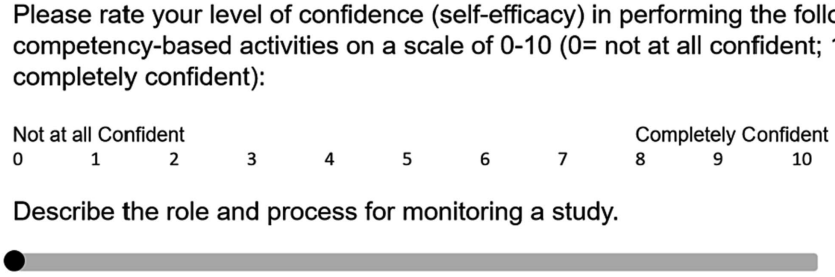

FIGURE 2
Illustration of CICRP question in Qualtrics^{XM} using a slider scale. CICRP, Competency Index for Clinical Research Professionals.

3.2 CICRP total scores

Our analysis explored the question, "Does the Master of Clinical Research program have any significant effect on the improvement of students' self-efficacy in clinical trial core competences in terms of the CICRP ratings." We calculated Cronbach's alpha (16) for each assessment with ratings ranging from 0.93 to 0.98 (Table 4) showing a high degree of content and face validity. The range for combined entry course median item ratings were 0–6, and the range for exit course median item ratings were 7–10.

We conducted parametric and non-parametric two-sample tests to see whether the group of individuals leaving the program have significantly higher mean CICRP total scores compared to the group of individuals entering the program, 167.0 (SD 21.1) vs. 72.7 (SD 41.9), respectfully. Both the Welch's two-sample t-test and Wilcoxon rank-sum test show very significant differences between the group of students entering the program and leaving the program ($p < 0.001$).

Correlations between years of experience and median total scores of each group were difficult to accurately calculate because of the large percentage of students who had no or < 1 year of clinical research experience at the time of the survey. Those in other experience categories were too few to draw meaningful conclusions. However, when combining years of experience into three categories, a significant increase in mean CICRP total score is seen at each experience level between program entry and program exit: no prior experience 54.1 (SD 35.9) vs. 160.7 (SD 21.7), <1 to 2 years 75.2 (SD 33.5) vs. 174.9 (SD 14.8), >2 years 113.9 (SD 28.4) vs. 173.4 (SD 20.3) ($p < 0.001$) (Figure 3).

We further implemented a linear regression of CICRP total scores by course, semester, highest degree at program entry, years of experience, whether being a nurse and clinical research certification to see the effect of course adjusting for other available covariates. The linear regression has a result that, adjusting for available covariates, individuals taking the exit course have a mean CICRP total score 92.690 ($p < 0.001$) higher than individuals taking the entry course. The diagnostic plot of the linear regression does not show signs of fundamental deviation from a normal distribution and generalized variance-inflation factors do not show signs of collinearity. There are significant differences in the variances of different course and semester groups based on Levene's test. Therefore, we used a general linear model (17) allowing different variances for different course and semester groups. The general linear model does produce a better fit in terms of diagnostic plot, but the result is very close to the ordinary linear model with course coefficient 94.750 ($p < 0.001$). We also carried out backward selection of variables based on the change of courses' coefficient and p-values to omit unnecessary adjustment and to improve precision for estimate of courses' coefficient. Though we did not find any noticeable changes in the estimates of the course coefficient. The CICRP total scores for these data demonstrate relatively consistent results for students entering and completing the master's program.

4 Discussion

As clinical research competency-based educational programs prepare for accreditation, having a standardized competency

TABLE 3 Participant education, experience, nursing and certification.

	Entry course		Exit course			Entry course total	Exit course total	Overall	p-value
	SU21	AU21	SU21	AU21	SP22				
	$n = 23$	$n = 31$	$n = 27$	$n = 14$	$n = 15$	$n = 54$	$n = 56$	$n = 110$	
Highest level of education completed before entering master's program									
Bachelor's degree	95.7%	93.5%	63.0%	71.4%	73.3%	94.4%	67.9%	80.9%	<0.001
Master's degree	0.0%	3.2%	25.9%	28.6%	13.3%	1.9%	23.2%	12.7%	
Doctorate degree	4.3%	3.2%	11.1%	0.0%	13.3%	3.7%	8.9%	6.4%	
Years of experience managing clinical trials research									
None	65.2%	54.8%	48.1%	35.7%	73.3%	59.3%	51.8%	55.5%	0.344
< 1 year	13.0%	12.9%	3.7%	7.1%	6.7%	13.0%	5.4%	9.1%	
1–2 years	4.3%	0.0%	7.4%	14.3%	6.7%	1.9%	8.9%	5.5%	
>2–3 years	13.0%	12.9%	18.5%	21.4%	0.0%	13.0%	14.3%	13.6%	
>3–5 Years	0.0%	6.5%	14.8%	7.1%	6.7%	3.7%	10.7%	7.3%	
>5–10 years	4.3%	9.7%	3.7%	7.1%	6.7%	7.4%	5.4%	6.4%	
>10–20 years	0.0%	3.2%	3.7%	7.1%	0.0%	1.9%	3.6%	2.7%	
Nurse									
	4.3%	29.0%	14.8%	7.1%	13.3%	18.5%	12.5%	15.5%	0.437
Clinical research certification									
	0.0%	16.1%	0.0%	14.3%	6.7%	9.3%	5.4%	7.3%	0.485

SU21, Summer 2021 semester; AU21, Autumn 2021 semester; SP22, Spring 2022 semester; n, number.

TABLE 4 CICRP median item ratings and mean total score by semester and course.

CICRP items	Entry course		Exit course		
	SU21	AU21	SU21	AU21	SP22
1 Describe the role and process for monitoring a study.	4	3	9	8	7
2 Describe the roles and responsibilities of various institutions participating in the medicines development process.	3	3	8	9.5	7
3 Compare and contrast clinical care and clinical management of research participants.	4	5	9	9.5	8
4 Summarize the process of electronic data capture (EDC) and the importance of information technology in data collection, capture and management.	4	3	9	10	7
5 Explain the elements (statistical, epidemiological and operational) of clinical and translational study design.	4	2	8	8	7
6 Identify the legal responsibilities, issues, liabilities and accountability that are involved in the conduct of a clinical trial.	3	3	8	9	8
7 Explain the medicines development process and the activities, which integrate commercial realities into the life cycle management of medical products.	3	2	8	9	8
8 Compare the requirements for human subject protection and privacy under different national and international regulation and ensures their implementation throughout all phases of a clinical study.	5	4	9	10	7
9 Describe the significance of data quality assurance systems and how SOPs are used to guide these processes.	4	5	9	10	7
10 Critically analyze study results with an understanding of therapeutic and comparative effectiveness.	4	4	8	9	8
11 Summarize the legislative and regulatory framework, which supports the development and registration of medicines, devices and biologicals and ensures their safety, efficacy and quality.	3	2	8	9	7
12 Describe the ethical issues involved when dealing with vulnerable populations and the need for additional safeguards.	6	6	9	10	8
13 Compare and contrast the regulations and guidelines of global regulatory bodies relating to the conduct of clinical trials.	3	2	8	9.5	7
14 Describe the specific processes and phases, which must be followed in order for the regulatory authority to approve the marketing authorization for a medical product.	3	2	8	9	8
15 Differentiate the different types of adverse events which occur during clinical trials, understand the identification process for AEs and describe the reporting requirements to IRBs/IECs, sponsors and regulatory authorities.	3	3	9	10	8
16 Describe the reporting requirements of global regulatory bodies relating to clinical trial conduct.	3	2	8	8.5	7
17 Describe the impact of cultural diversity and the need for cultural competence in the design and conduct of clinical research.	4	5	9	9.5	9
18 Define the concepts of "clinical equipoise" and "therapeutic misconception" as they relate to the conduct of a clinical trial.	3	1	8	9	8
19 Apply management concepts and effective training methods to manage risk and improve quality in the conduct of a clinical research study.	3	3	9	9.5	8
20 Identify and apply the professional guidelines and codes of ethics, which apply to the conduct of clinical research.	4	4	9	10	8
Cronbach's alpha	0.96	0.98	0.93	0.98	0.94
CICRP total score					
Course semester mean (standard deviation)	72.1 (33.6)	73.2 (47.7)	168.9 (16.7)	171.1 (29.7)	159.8 (18.3)
Course overall mean (standard deviation)*	72.7 (41.9)		167.0 (21.1)		

*$p < 0.001$. SU21, Summer 2021 semester; AU21, Autumn 2021 semester; SP22, Spring 2022 semester; CICRP, Competency Index for Clinical Research Professionals; SOP, Standard Operating Procedures; IRBs/IECs, Institutional Review Boards/Independent Ethics Committees.

evaluation measure such as the CICRP could be a useful program evaluation tool. Competency indexes have been used to evaluate clinical research trainees and educational programs in translational research. The Clinical Research Appraisal Inventory (CRAI) was a 92-item set of competencies for clinical and translational investigators. Robinson et al. created and evaluated a 12-item abbreviated CRAI instrument that was used to evaluate investigator trainees and their acquisition of perceived competence in clinical

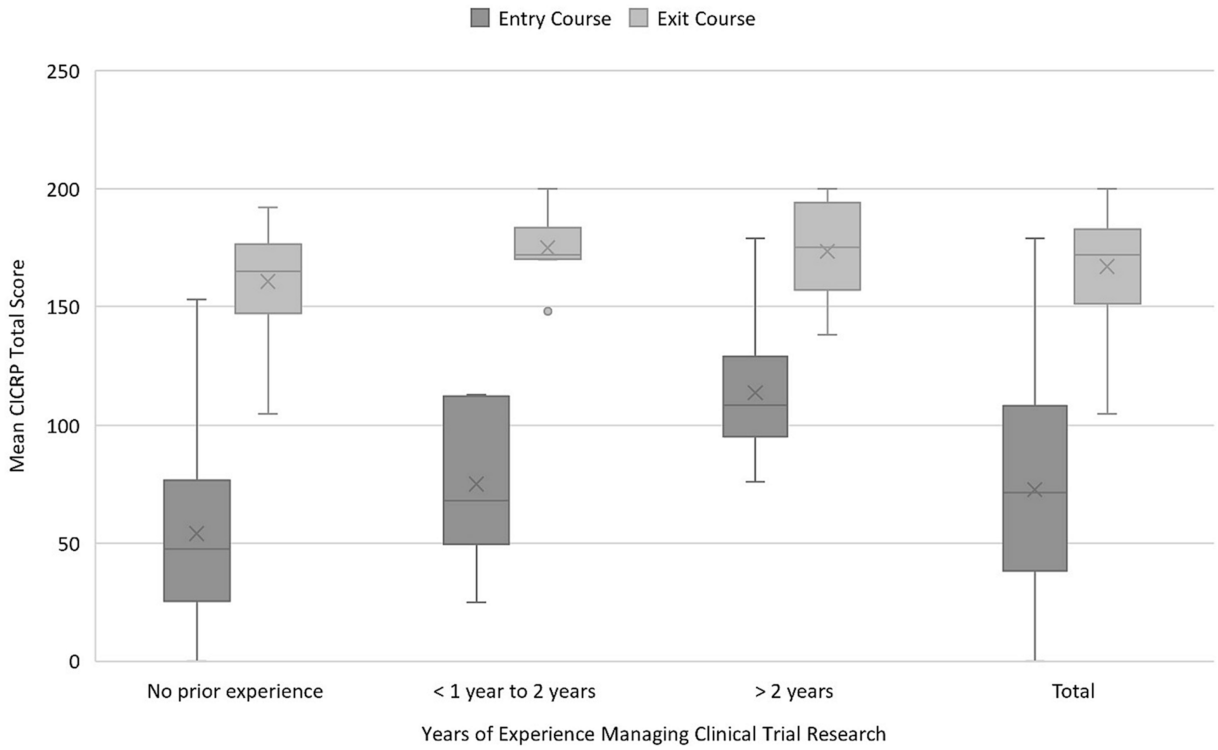

FIGURE 3
Mean CICRP total score by years of experience. CICRP, Competency Index for Clinical Research Professionals.

research (18, 19). Our study presents a potential program evaluation tool for usefulness in assessing whether our competency-based academic program is meeting the JTF Competency needs of students targeting clinical research professional roles. The assessment tool had high Cronbach's alpha demonstrating a high level of internal consistency. Moreover, these data from our program demonstrate acquisition of competence in the areas of scientific concepts and research design and investigational product development, areas that have been shown to be deficits in the field (20).

A limitation of our study is that it did not measure a head-to-head (entry and exit) pre-test and post-test total scores matched to individual students. Rather, we compare entering students as a cohort (those taking entry course) to graduating students (those taking final course) as an initial pilot to determine feasibility of the index for program evaluation. Furthermore, we found that the graduating cohort in our study appeared to have greater levels of clinical research experience than those entering the program. This may be partially because students in our cohort gained employment in clinical research during their tenure as a student. The graduate students enrolled in our professional master's degree vary in their progression through the program. Some may take one to two courses per semester (part-time) or three to four courses per semester (full-time). Moreover, some students take semesters off for professional or personal reasons and return at varying time-points, especially during the COVID-19 pandemic. Ideally, we would have assessed individual students and compare total scores at program entry and exit; however, for feasibility purposes we initially wanted to evaluate the tool for usefulness in program evaluation. Future assessments should match specific individual student pre- and post-CICRP total scores and conduct more in-depth assessments of correlations. Another limitation of this study is that it is applicable to students in a specific United States (U.S.) master's degree program and may not be applicable to students in other U.S. programs or students internationally.

5 Conclusion

The Competency Index for Clinical Research Professionals (CICRP) is a short form (20-item) competency index for the JTF Clinical Trial Competencies. It is a useful tool to measure self-efficacy in clinical trial skillsets for clinical research professionals. Used as a pre-test and post-test for students entering and graduating from a graduate-level clinical research academic program, the tool may contribute to evaluate effectiveness of the program, in addition to other program evaluation criteria such as course deliverables, student e-Portfolios, grade point average (GPA), completion rates and successful employment as clinical research professionals. Future research on the use of the tool in program evaluation is warranted.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by the Ohio State University IRB Columbus, United States. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

CJ: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Supervision, Writing – original draft, Writing – review & editing, Software, Validation, Visualization. XL: Data curation, Formal analysis, Investigation, Methodology, Validation, Writing – original draft, Writing – review & editing, Software, Visualization. CH: Investigation, Validation, Writing – original draft, Writing – review & editing, Methodology. JF: Data curation, Investigation, Project administration, Validation, Writing – original draft, Writing – review & editing. MN: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Software, Validation, Visualization, Writing – original draft, Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

References

1. Jones CT, Parmentier J, Sonstein S, Silva H, Lubejko B, Pidd H, et al. Defining competencies in clinical research: issues in clinical research education. *Res. Pract.* (2012) 13:99–107.

2. Sonstein SA, Seltzer J, Li R, Jones CT, Silva H, Daemen E. Moving from compliance to competency: a harmonized core competency framework for the clinical research professional. *Clin Res.* (2014) 28:17–23. doi: 10.14524/CR-14-00002R1.1

3. Sonstein S, Silva H, Jones CT, Calvin-Naylor N, Halloran L, Yrivarren JL. Global self-assessment of competencies, role relevance, and training needs among clinical research professionals. *Clin Res.* (2016) 30:38–45. doi: 10.14524/CR-16-0016

4. Joint Task Force for Clinical Trial Competency (2020). *JTF core competency framework*. MRCT. Available at: https://mrctcenter.org/clinical-trial-competency/framework/domains/ (Accesed February 26, 2023).

5. Sonstein SA, Palladino-Kim L, Ichhpurani N, Padbidri R, White SA, Aldinger CE, et al. Incorporating competencies related to project management into the joint taskforce Core competency framework for clinical research professionals. *Ther Innov Regul Sci.* (2022) 56:206–11. doi: 10.1007/s43441-021-00369-7

6. Sonstein S, Brouwer RN, Gluck W, Kolb R, Aldinger C, Bierer B, et al. Leveling the joint task force core competencies for clinical research professionals. *Ther Innov Regul Sci.* (2020) 54:1–20. doi: 10.1007/s43441-019-00024-2

7. Hornung CA, Jones CT, Calvin-Naylor NA, Kerr J, Sonstein SA, Hinkley T, et al. Competency indices to assess the knowledge, skills and abilities of clinical research professionals. *Int J Clin Trials.* (2018) 5:46–53. doi: 10.18203/2349-3259.ijct20180130

8. Hornung CA, Kerr J, Gluck W, Jones CT. The competency of clinical research coordinators: the importance of education and experience. *Ther Innov Regul Sci.* (2021) 55:1231–8. doi: 10.1007/s43441-021-00320-w

9. Committee on Accreditation of Allied Health Education Programs. (2023). *Clinical research*. Available at: https://caahep-public-site-5be3d9.webflow.io/committees-on-accreditation/clinical-research-professional (Accessed February 26, 2023).

10. Redmond P, Lock JV. A flexibile framework for online collaborative learning. *Internet High Educ.* (2006) 9:267–76. doi: 10.1016/j.iheduc.2006.08.003

11. Hornung C, Ianni P, Jones C, Samuels E, Ellingrod V. Indices of clinical research coordinators' competence. *J Clin Transl Sci.* (2019) 3:75–81. doi: 10.1017/cts.2019.381

12. Association of Clinical Research Professionals. (2018). *ACRP certification*. ACRP. Available at: https://www.acrpnet.org/professional-development/certifications/ (Accessed 26 February 2023).

13. Society of Clinical Research Associates (2018). *Certification program overview*. SoCRA. Available at: https://www.socra.org/certification/program-overview/ (Accessed February 26, 2023)

14. Boone HN, Boone DA. Analyzing likert data. *J Ext.* (2012) 50:1–5. doi: 10.34068/joe.50.02.48

15. Harpe SE. How to analyze Likert and other rating scale data. *Curr Pharm Teach Learn.* (2015) 7:836–50. doi: 10.1016/j.cptl.2015.08.001

16. Tavakol M, Dennick R. Making sense of Cronbach's alpha. *Int J Med Educ.* (2011) 2:53–5. doi: 10.5116/ijme.4dfb.8dfd

17. Galecki A, Burzykowski T. *Linear mixed-effects models using R: a step-by-step approach*. New York, NY: Springer (2013).

18. Robinson G, Switzer GE, Cohen ED, Primack BA, Kapoor WN, Seltzer DL, et al. A shortened version of the clinical research appraisal inventory: CRAI-12. *Acad Med.* (2013) 88:1340–5. doi: 10.1097/ACM.0b013e31829e75e5

19. Robinson GF, Moore CG, McTigue KM, Rubio DM, Kapoor WN. Assessing competencies in a master of science in clinical research program: the comprehensive competency review. *Clin Transl Sci.* (2015) 8:770–5. doi: 10.1111/cts.12322

20. Sonstein SA, Samuels E, Aldinger C, White SA, Bierer BE. Self-assessed competencies of clinical research professionals and recommendations for further education and training. *Ther Innov Regul Sci.* (2022) 56:607–15. doi: 10.1007/s43441-022-00395-z

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