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Author for correspondence:
H. Robert Kolb, RN, MS, CCRC, Director, Clinical Research Professionals' Programming, Clinical Translational Science Institute – Workforce Directorate, JHMHC PO Box 100322 – Gainesville, FL 32610-0219, USA.
Email: kolbhr@ufl.edu

Academic medical center clinical research professional workforce: Part 2 – Issues in staff onboarding and professional development

Jacqueline M. Knapke[1,2], Michelle Jenkerson[3], Peg Tsao[4], Stephanie Freel[5], Jessica Fritter[6,7], Shirley L. Helm[8], Penelope Jester[7], H Robert Kolb[9], Angela Mendell[1], Megan Petty[10] and Carolynn T. Jones[7,11]

[1]University of Cincinnati, Center for Clinical & Translational Science & Training, Cincinnati, Ohio, USA; [2]University of Cincinnati, Department of Family & Community Medicine, Cincinnati, Ohio, USA; [3]Washington University – St. Louis, Center for Clinical Studies, St. Louis, Missouri, USA; [4]Stanford University, Spectrum, School of Medicine, Palo Alto, California, USA; [5]Duke University, School of Medicine, Duke Office of Clinical Research, Raleigh, North Carolina, USA; [6]Nationwide Children's Hospital, Clinical Research Services, Columbus, Ohio, USA; [7]The Ohio State University, College of Nursing, Master of Clinical Research Program, Columbus, Ohio, USA; [8]Virginia Commonwealth University, C. Kenneth and Dianne Wright Center for Clinical and Translational Research, Richmond, Virginia, USA; [9]University of Florida, Clinical Translational Science Institute - Workforce Directorate, Gainesville, Florida, USA; [10]University of Rochester Medical Center, Center for Leading Innovation and Collaboration, Rochester, New York, USA and [11]The Ohio State University, Center for Clinical Translational Research, Columbus, Ohio, USA

Abstract

Background: Defining key barriers to the development of a well-trained clinical research professional (CRP) workforce is an essential first step in identifying solutions for successful CRP onboarding, training, and competency development, which will enhance quality across the clinical and translational research enterprise. This study aimed to summarize barriers and best practices at academic medical centers related to effective CRP onboarding, training, professional development, identify challenges with the assessment of and mentoring for CRP competency growth, and describe opportunities to improve training and professionalization for the CRP career pathway. *Materials/Methods:* Qualitative data from a series of Un-Meeting breakout sessions and open-text survey questions were analyzed to explore the complex issues involved when developing high-quality onboarding and continuing education opportunities for CRPs at academic medical centers. *Results:* Results suggest there are several barriers to training the CRP workforce, including balancing foundational onboarding with role-based training, managing logistical challenges and institutional contexts, identifying/enlisting institutional champions, assessing competency, and providing high-quality mentorship. Several of these themes are interrelated. Two universal threads present throughout all themes are the need for effective communication and the need to improve professionalization of the CRP career pathway. *Conclusion:* Few institutions have solved all the issues related to training a competent and adaptable CRP workforce, although some have addressed one or more. We applied a socio-technical lens to illustrate our findings and the need for NCATS-funded academic medical centers to work collaboratively within and across institutions to overcome training barriers and support a vital, well-qualified workforce and present several exemplars from the field to help attain this goal.

Introduction

Clinical and translational research (CTR) is conducted by academic medical center scientific communities who seek to improve the public's health through discovery, research, and translation. The rapid emergence of the COVID-19 pandemic and the challenges of understanding and managing this new virus highlighted the need for highly functional, agile, and effective AMC research teams to conduct robust clinical research [1–3]. An established, well-trained clinical research professional (CRP) workforce that is able to pivot quickly to changing clinical research needs is critical for ensuring the conduct of high-quality, ethical research. However, AMCs experience significant and costly challenges to building such a workforce [4]. Because of this, AMCs must have mechanisms to efficiently onboard new staff, while also providing existing staff with professional development opportunities needed for progression and retention.

Defining CRPs

AMCs employ a large number of CRPs; yet often these professional roles are invisible[5] and disconnected due to silos and institutional human resources (HRs) and communications

constraints. CRPs working in AMCs have lacked professional identification as a community of practice, yet are essential to the quality and success of clinical trials, the institution's research mission, and revenue stream [6]. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), Good Clinical Practice guidelines (GCP) E6 R2, states that persons who are "involved in conducting a (clinical) trial should be qualified by education, training, and experience to perform his or her respective task(s)" [7]. More recently, the National Center for Advancing Translational Science (NCATS) defined Clinical Translational Science Teams as inclusive of principal investigators (PIs), co-investigators, clinical researchers, research nurses, pharmacists, administrators, coordinators, consultants, data managers, quality assurance managers, regulatory affairs managers, or educators in clinical trial management [8]. The focus of this paper is on CRPs, who we define as those non-faculty staff at all levels (novice to expert) who are managing and operationalizing all aspects of CTR studies, inclusive of study coordinators, CTR managers, research nurses, clinical research managers, biobank coordinators, laboratory personnel, regulatory affairs coordinators, and data management professionals. CRPs at AMCs work within the broader landscape of practice in healthcare and CTR.

Competency-Based Education for CRPs

Clinical trials have become more complex and are subject to ever-expanding regulations. In fact, clinical trials are the highest globally regulated enterprise [9]. As a result, increasing clinical research regulations and guidelines led to the development and wide adoption of the Joint Task Force (JTF) Clinical Trial Core Competencies [10]. JTF defines clinical trial competencies as the knowledge, skills, and attitudes necessary for conducting safe, ethical, and high-quality clinical research [11]. These have served as the basis of CTR training and academic curricula, certification exam updates, SOPs, quality improvement plans and job descriptions, and role progression [12–17].

Training the CRP workforce can be problematic for AMCs for many reasons as identified in the literature [6,14]. Often, AMCs cannot easily identify CRPs or track their training activities and needs. This is primarily due to intra- and cross-institutional variability of job titles and communication barriers [18]. This missing career professionalization across and within institutions hampers planning and management of onboarding and continuing education (CE) to effectively prepare the workforce to meet institutional research needs. Another barrier is a lack of institutional policies that require onboarding training and mentoring for CRP roles. Individual CRPs report the continued dilemma of "on-the-job training" as they commence their roles [15]. This dated model is counter to the professionalization of the role, hampers CRP growth, and hinders the ability to respond resiliently to pressing CTR needs, as experienced during the COVID-19 pandemic. This is compounded by a lack of awareness of needed training by administration or efficient access training by the CRPs. Another barrier is financial, specifically a lack of personnel and budgetary resources that limit the capacity to create and sustain robust training curricula. Furthermore, institutions often conduct silo-based training within departments or divisions. A large number of AMC CRPs are not employed in centralized departments (e.g., cancer centers or other central research offices) and thus represent a large cohort that are without access to onboarding and CE. This also leads to inconsistency across curricular content. Finally, creating training that is metacognitive as opposed to passive or simple task orientation is imperative for CRPs. Structured mentoring programs, pairing experienced CRPs with those CRPs needing new task and skill development, can lead to a collaborative network of skilled professionals or communities of practice [19–21]. However, implementing a mentoring program requires intention, organizational stakeholder buy-in, experienced CRPs with mentor training, protected time, and mentoring responsibilities incorporated into job descriptions. Moreover, similar to current methods of developing the clinical translational scientist workforce, the use of individualized development plans (IDPs) coupled with mentoring can support growth, performance quality, and job satisfaction, leading to improved CRP retention in the institution [22].

As we consider the current and future state of the CRP workforce at AMCs and the increasing complexity of CTR, we must explore how to maximize education and experiences to guarantee excellence and sustainability of the CRP workforce [23]. Furthermore, assessment of competency acquisition is limited. A short self-assessment for CRP clinical trial competence has been developed and shows potential as pre-test and post-test measures for staff undergoing training, or perhaps as a self-assessment tool during periodic needs assessments for CE [24–26]. Additionally, the value of CE should be coupled with evaluation of methods and outcomes [27]. Having well-defined, competency-based job descriptions that outline a tiered approach to knowledge, skills, and ability acquisition can assist larger institutions to find, train, and retain the workforce as well as save the institution the cost of staff turnover [4,18,28,29].

In this study, we sought to explore and summarize barriers and best practices related to effective CRP onboarding, training, and professional development at AMCs. The focus of our paper is two-fold: describing challenges to effective onboarding and CE of CRPs at AMCs, as well as solutions to overcoming these challenges in order to improve CRP competency development and retention using a systems thinking approach.

Methods

Participants and Study Setting

In 2019, several individuals at different CTSA hubs developed a collaborative to explore and address key issues in workforce development of CRPs. The hubs included representatives from the University of Washington, University of Florida, The Ohio State University, and University of Rochester, with administrative support from the Center for Leading Innovation and Collaboration (CLIC). Additionally, the Association of Clinical Research Professionals (ACRP) was included in the collaborative. The collaborative designed a series of Un-Meetings called "Collaborative Conversations: The Critical Need for Professional Workforce Development at Academic Medical Centers." The Un-Meeting series was promoted through a variety of email listservs and websites, geared primarily towards individuals involved in CRP workforce development, at CTSA institutions, IdEA networks, and aligned private clinical translational research organizations. Participants registered for Un-Meetings all at once, but attendance was tracked for each Un-Meeting. This study was reviewed by the university Institutional Review Board (IRB) and determined exempt from full review (IRB #2020E0066).

The "Collaborative Conversations" Un-Meeting series was comprised of six virtual meetings, held via Zoom. Table 1 provides a summary of Un-Meeting dates and topics [30]. Each virtual Un-Meeting was two hours in length and consisted of a brief

Table 1. *Un-meeting series dates & topics*

Date	Topic
September 16, 2020	Kick-Off and NCATS Keynote (Dr M. Kurilla)
October 28, 2020	Job Titles and Descriptions
November 18, 2020	Competency-Based Onboarding & Training
December 9, 2020	Competency-Based Continuing Education
January 27, 2021	Issues in Retention, Attrition, Role Progression
February 17, 2021	Pipeline, Diversity, Equity & Inclusion

presentation to introduce the topic and agenda, followed by interactive activities and brainstorming.

This study's emphasis was on training and competency development issues within the CRP workforce, and so the study team focused only on the Un-Meetings that occurred on November 18 and December 9, 2020. A second study occurred simultaneously that focused on recruitment and retention issues affecting the CRP workforce, using data from the meetings that occurred on October 28, 2020, and January 27, February 17, 2021.

Data Collection

Each Un-Meeting was recorded in Zoom, including all breakout sessions. The introductory session was brief, typically between 15 and 30 minutes, followed by approximately 45 minutes in small group breakout rooms. All sessions were recorded. In addition to the main session and breakout recordings, each breakout room had a scribe who took notes on the small group discussion and reported back to the full group upon conclusion of the breakouts. Finally, for the purpose of brainstorming, an electronic survey was distributed at each Un-Meeting. The surveys were conducted via Qualtrics by placing the survey URL in the Zoom chat, and participants were given time to complete the survey. The surveys were comprised of open-ended questions designed to generate discussions of issues and possible solutions related to the topics of interest for each Un-Meeting. Participant survey responses were captured and shared in the breakout rooms to help guide and augment small group discussions. This study utilized the qualitative data generated by the Un-Meeting Zoom recordings, any available chats and scribe notes from the main session and breakout rooms, and Qualtrics survey responses.

Data Analysis

A research team of 11 coders used an interpretive, inductive approach to analyze the qualitative data generated at the November and December 2020 Un-Meetings. We identified one team member as the qualitative lead. This individual was trained in qualitative methods at the doctoral level and guided the group through each step of the analysis process, collating notes and moderating each analysis discussion. The team met for three months from August to October 2021. Each coder analyzed the data independently at first, and the team met bi-monthly to refine interpretations and reach inter-coder agreement. Prior to each team meeting, two volunteers were identified to serve as lead analysts. The lead analysts were responsible for bringing their codes with themes to the meeting for the rest of the team to respond to and discuss. The lead analysts rotated for each meeting so that no individual led an analysis discussion more than once. The research team reviewed all qualitative data for one Un-Meeting at a time; that is, the research team maintained a loose timeline of analyzing the November 2020 Un-Meeting data in August 2021, and the December 2020 data were analyzed in September 2021, with final data analysis occurring in October 2021.

Table 2. *Participant demographics*

Demographic Information	Detail	n (%)
Highest Degree Earned	• *Bachelor*	10 (16%)
	• *Master*	36 (57%)
	• *Doctorate*	13 (21%)
	• *Unspecified*	4 (6%)
Professional Role	• *Faculty*	11 (17%)
	• *Manager*	23 (37%)
	• *Administrator*	20 (32%)
	• *Clinical Research Professional*	4 (6%)
	• *Educator/Trainer*	5 (8%)
CTSA Affiliation	• *Clinical Translational Science Award Hub*	30 (73%)
	• *Non-Clinical Translational Science Award Entity*	11 (27%)
CTSA Size	• *Small (<$4.5M direct costs)*	12 (40%)
	• *Medium ($4.5–$6M direct costs)*	3 (10%)
	• *Large (>$6M–$7.5M direct costs)*	15 (50%)

Results

Participants and Study Setting

In total, 63 participants attended these two Un-Meetings, representing 41 institutions or organizations (both CTSA and non-CTSA) and a diverse spectrum of professional appointments within the CRP workforce development domain. Table 2 provides details on study participants.

Data Collection

This study analyzed the qualitative data generated by the Un-Meeting Zoom recordings, any available chats and scribe notes from the main session and breakout rooms, and Qualtrics survey responses. In total, the dataset included approximately 735 minutes of audiovisual data, or 12.25 hours, 11 conversations captured by Zoom chat, 13 summary note documents recorded by breakout room scribes, and 75 responses to Qualtrics surveys. Table 3 summarizes the survey questions, data sources, and data details for each Un-Meeting included in the dataset.

Data Analysis

Qualitative analysis of Un-Meeting data led to identification of several themes that hinder the effectiveness of training and the professional development of CRPs. Five challenges that emerged from the data were as follows: 1) balancing foundational onboarding and role-based competency training, 2) CRP training policies and

Table 3. *Participants, survey questions, and data sources/details for each un-meeting*

Un-Meeting Date	Survey Open-Ended Questions	Data Sources	Data Details
November 18, 2020	What are the components of an effective and inclusive Onboarding program?	*Main session recording, plus chat*	~75 minutes
		Breakout recordings	n = 8 ~40 minutes each
		Breakout scribe notes	n = 7
		Main session/ Breakout chats	n = 7
		Qualtrics brainstorming survey	~40 responses
December 9, 2020	1. How can we accurately assess competency and evaluate for success? 2. How can we obtain buy-in and support from the institution? 3. Should continuing education be offered through a centralized mechanism or at the departmental/study level training? 4. How do we overcome the "lack of time" defense for poor attendance?	*Main session recording, plus chat*	~60 minutes
		Breakout recordings	n = 7 ~40 minutes each
		Breakout scribe notes	n = 6
		Main session/ Breakout chats	n = 4
		Qualtrics brainstorming survey	~35 responses

logistics, 3) the need for champions, 4) mentorship, and 5) competency assessment. Data analysis also identified two universal threads that underlie these five themes: communication skills, particularly as they relate to interdisciplinary team science, and the need to support professionalization of the CRP as a career path and professional identity through training.

Study participants described the first challenge, balancing foundational onboarding with role-based competency development, using the following codes: differentiating between foundational topics in which every CRP needs training (e.g., Collaborative Institutional Training Initiative (CITI), GCP training certificates) to more role-specific training that should be provided as needed, enabling CRPs to pivot from one study to the next as needed with baseline knowledge in place, connecting onboarding to continuous education in a step-wise fashion that allows new CRPs to quickly undertake study coordination but also maximizes knowledge retention, filling in gaps not covered by foundational onboarding (e.g., behavioral health, community-engaged research, or specific software), tailoring foundational training to variable job responsibilities, and finally providing educational opportunities in a proactive manner rather than reactive. Included in this theme were the more straightforward challenges of maintaining content that is updated and correct, and creating and maintaining one-stop resource libraries that included updated checklists, standard operating procedures (SOPs), and key contacts.

The second challenge identified in the dataset was logistics and policy of offering training to CRPs, from onboarding to continuous education. Participants discussed the difficulty of requiring training for a workforce that is fragmented and decentralized, monitoring completion and training timelines, and simple identification of individuals who are CRPs and should be informed of, and enrolled in, training opportunities, and requirements. Participants described how CRPs span many job titles, units, and sometimes organizations, and so coordinating with HR is difficult. Another code within this theme was the difficulty silos introduce when trying to coordinate, share, and track CRP training. Participants suggested many of these issues could be solved by centralizing training in one office, but such a structure was highly uncommon within this study population, and this solution was deemed challenging given the silos that are common at AMCs. Other concerns regarding logistical coordination within this theme included the mode of offering CRP education, with participants discussing the merits and concessions of offering training online vs. in-person versus multi-modal. Onboarding individuals during the COVID-19 pandemic when much of the workforce was remote often used webinar technology to allow interaction and the ability to ask questions. In contrast, more passive reading and consuming educational content on one's own was another method used.

The third theme in the dataset described the need for champions who understand the facets of the CRP workforce, including the variable job duties and career ladder, and can advocate for the significance of high-quality training and competency development. Participants stated that champions play an important role in conveying the urgency of the need for CRP training to leadership when so many other issues can take priority. Such champions must also have the capacity to describe the resource commitment up front and the return on investment over time – both in quality and efficiency of research and in employee satisfaction and retention. One code within this theme was the need to translate poor staff outcomes (e.g., turnover, rehiring costs, lost productivity) into measurable factors of research productivity (e.g., number of studies delayed, number of dollars spent on recruitment, retention rates compared to other research organizations) as a way of garnering support from advocates. Participants described several types of champions who can contribute to the effort to improve CRP training: PIs, research managers, administrators, and CRPs themselves.

The fourth theme identified in this study was the important role mentorship plays in the development of a highly competent CRP workforce. Participants agreed mentoring should be a key element of an onboarding program and that mentors should be well-trained and high-quality. However, participants discussed the difficulty of matching mentor pairs because of different job duties (e.g., social/

behavioral research vs. drug development), lack of mentor training opportunities dedicated to staff, and low bandwidth of senior CRPs to serve as mentors. Additionally, the decentralization of the CRP workforce contributes to the challenges of instituting an effective mentorship program.

The fifth theme participants discussed was the difficulty of assessing CRP competency. One code within this theme was the difficulty of assessing knowledge vs. competency. Here, participants described pre-, post-, and longitudinal follow-up testing as one method of CRP evaluation, but many noted that this method may be a weaker measure of competency. As an alternative, observational assessment could help to assess competency, but most participants agreed observational assessment is not a feasible or sustainable method in the current AMC climate. Another challenge related to competency assessment was tracking competency over time, including external training and certification obtained by CRPs. Participants suggested competency assessment should align with performance evaluation and promotion, possibly with the requirement of CE units. All of these challenges are exacerbated by the lack of a centralized clinical translational research office, which could facilitate competency training and assessment as a condition of employment and track it over time. Most participants reported this organizational structure did not exist at their home institutions.

Finally, the research team identified two universal threads that underlie all of the themes presented above: communication (skills and methods) and the need to support professionalization of the CRP as a career path and professional identity. The first, communication, indicates the significance of communication as a means of overcoming all the barriers described by the themes: communication of training needs, challenges, and outcomes to champions, communication of training requirements and opportunities to CRPs, communication of foundational topics and role-based training to HR administrators, and communication externally to organizations across the CTR field. Inclusive in the theme of communication is team science training. Second, all the above themes point to the need to professionalize CRP as a career track. Accomplishing this would have the dual effect of communicating the importance of education and training preparation for the field to all key stakeholders, as well as supporting the self-actualization of individuals as they conceive the CRP career path as their professional identity. This internalization of disciplinary norms is often achieved through peer-to-peer interactions, emphasizing the need for effective onboarding and mentorship programs.

Discussion

Our findings suggest five thematic areas for improvement that will strengthen the CRP workforce. Additionally, the research team identified two universal threads underlying all the themes presented above: communication (skills and methods) for team-based work and the need to support professionalization of the CRP as a career path and professional identity. Figure 1 summarizes the five themes and two universal threads.

CRP Workforce Development as a Socio-technical Ecosystem

To develop and retain a resilient and competent CRP workforce supporting CTR, we must explore how the identified challenges are not separate from the dynamic context of the institutions where they are manifested. Conceptualizing the CRP workforce as embedded in a socio-technical ecosystem offers a lens to view the challenges related to training competent and adaptable CRPs at AMCs. When seen in this light, our findings should compel collaborative and intentional action from NCATS-funded AMCs working within and across institutions to harmonize a vital and well-qualified workforce.

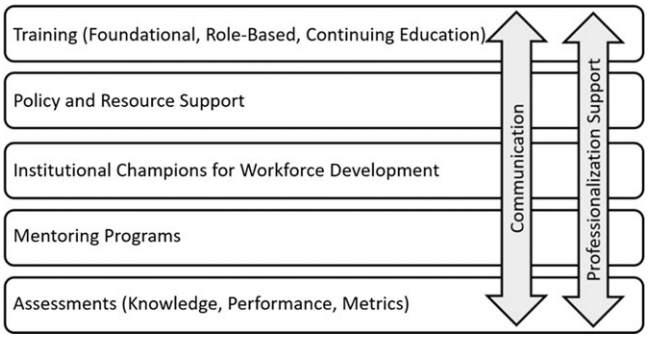

Fig. 1. Five themes and universal threads for clinical research professional workforce development at academic medical centers.

As originally devised, socio-technical systems theory had a historical application from studies investigating worker behavior and new technology during the mechanization of coal mining [31]. Those researchers understood that in order to improve productivity, careful consideration of the social ecology of the workplace superseded simply reengineering upper management [31–34]. These researchers explored elements of the overlapping webs of social systems (power structure, values, individuals, communication, rewards, and behavioral styles) and technical systems (equipment, capability, arrangement, flexibility, and sequence). A socio-technical systems thinking approach is described as an opportunity to identify, design, and evaluate systems, especially in light of evolving technology, practices, and work, not only in the IT community but also in nursing and other health-related systems [35,36]. Therefore, this approach can be applied to CTR in the complex AMC socio-technical ecosystem with social interactions and professional work shaping and being shaped by the system. As a socio-technical system, AMCs have an interactive nature and interdependency of six key components (goals, people, buildings/infrastructure, technology, culture, and processes/procedures) and structural influences such as financial/economic circumstances, regulatory frameworks, and stakeholders. We illustrate those elements in Fig. 2, adding AMC silos as an additional structural influence. The interdependence of each of these components and structural influences offer opportunities to recognize the dynamic, ever-evolving nature of AMCs and opportunities to co-evaluate systems leading to diffusion of innovations and improvements [37].

A systems thinking approach can aid in solution-finding for CRP education and role development. The Un-Meeting series provided a venue for CTR managers and educators from a wide variety of CTSA hubs to have focused contributory discussions on key AMC workforce issues. The qualitative results reveal an AMC social ecosystem out of balance. Our study provides in-depth perspectives of the needs, facilitators, and barriers for CRP onboarding training, professional development, and mentoring in the AMC CTR environment. These data revealed the continued ad hoc nature of CRP training, though some CTSA hub sites have recently developed research training initiatives. In addition, disconnects in pedagogical methods for task-based (capability) and skill-based (trait) and assessments of performance competence for the CRP workforce are fraught with complexities and practicable logistics [38].

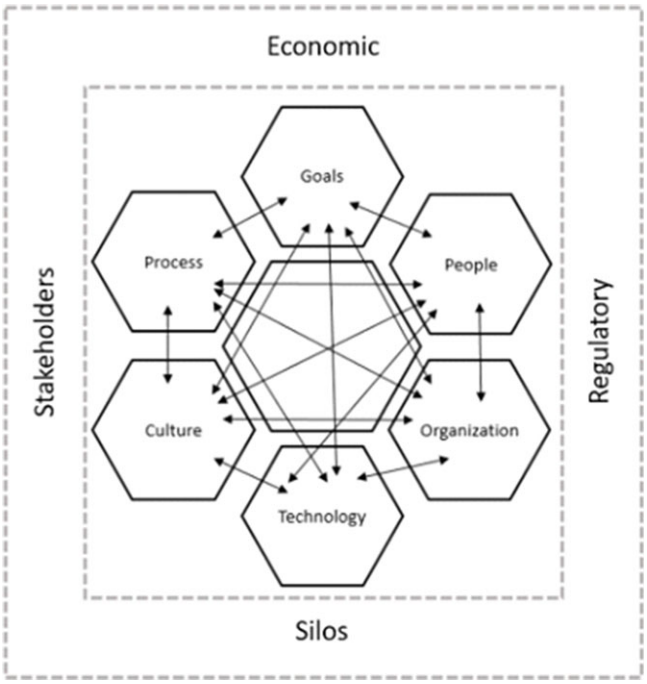

Fig. 2. Academic medical center socio-technical ecosystem.

Applying our study findings to the AMC socio-technical system helps to provide a design and systems thinking approach to solution-finding. Figure 3 illustrates our findings on the challenges for CRP onboarding training, CE, progression planning, and responsiveness to the socio-technical ecosystem complexity and technological challenges in doing the work of CTR in an AMC ecosystem.

Universal Threads: Communication for Interdisciplinary Team Science and Professionalization of the CRP Community of Practice

The first universal thread, communication, indicates the significance of communication as a means of overcoming all of the barriers described by the themes:

- Communication of training needs, challenges, and outcomes to champions
- Communication of training requirements and opportunities to CRPs
- Communication of foundational topics / role-based training to HR administrators
- Communication externally to organizations across the CTR field
- Interdisciplinary team science communication, learning, and collaboration.

Communication is a key component of achieving success in a team-oriented work environment. While there is a breadth of published literature on team science competencies for CTR investigators, trainees, and scientists, team science competencies for CRPs are lacking. This emphasizes a general gap in team science and interdisciplinary training for CRP team members. Creative professional development opportunities in the areas of leadership, professionalism, communication, and teamwork will go a long way to ensuring success when paired with data-driven policy changes that enhance a collaborative orientation.

The second universal thread reported is the need to facilitate professionalization of CRPs as a significant career track and community of practice within the larger AMC landscape of practice. However, unmediated challenges presented by institutional culture can impact CRP professionalization negatively. Principal investigators are dominant stakeholders in the clinical research hierarchy, and it is critical that their perceptions of CRP professional identities support the view that CRPs are full and essential members of CTR interdisciplinary teams. These PI-CRP professional relationships are the key for current and future research growth and success. Research faculty and CRPs represent two cultures that must work collaboratively to fulfill scientific and ethical CTR goals. AMCs need to understand how these interdependent co-cultural groups work together. The development and maintenance of these relationships requires intentionality. Likewise, the CTR team science lens should embrace CRPs as full-fledged team members, resulting in a higher order of ownership and responsibility towards performance and collaborative adaptions in the face of the uncertainty and variability of complex CTR. Furthermore, fostering a culture that values the input of all team members in true partnership will align attitudes and values, thereby strengthening collaboration.

Often CRPs obtain their initial clinical research positions through serendipity. As the field becomes more professionalized, individuals will self-identify as a future CRP with intentions of pursuing education, training, and advancement as key members of CTR teams. Transforming the workforce to be more intentional and fostering the CRP workforce as a community of practice will strengthen institutions and ensure an applicant pool. This may mean that institutions develop outreach programs that target undergraduates, junior colleges, and secondary schools with the intention of making students aware of the CRP career pathway and recruiting them to jobs. This approach could realize workforce diversity goals as well.

Fostering and nurturing the CRP workforce requires an active convergence with the dominant co-culture within the socio-technical ecosystem. This will require reasonable, well-informed choices that transcend outdated and fragmented patterns of pedagogy for CRPs in the current AMC landscape. Our research is timely as it addresses the common issue of CRP workforce development, training needs, and CRP professionalization and retention in the setting of complex AMC CTR institutions. CRPs represent a large cohort of employees at AMCs and have direct impact on the success of CTR operations.

Strengths and Limitations

Though our study focused on only two Un-Meeting events, we collected over 12 hours of discussion data and multiple written responses, leveraging the expertise of 63 individuals who represented a spectrum of CRP workforce development from 41 different institutions. Participants had a strong passion for the subject matter and were eager to share their challenges and work to describe solutions. Collaborations emerged from the encounters as well, with different CTSA hubs agreeing to share their best practices for training policies and outreach to CRP staff. Study participants represented a wide variety of private and public, large, medium, and small CTSA hubs, so these results could be generalized to AMCs with CTSA funding.

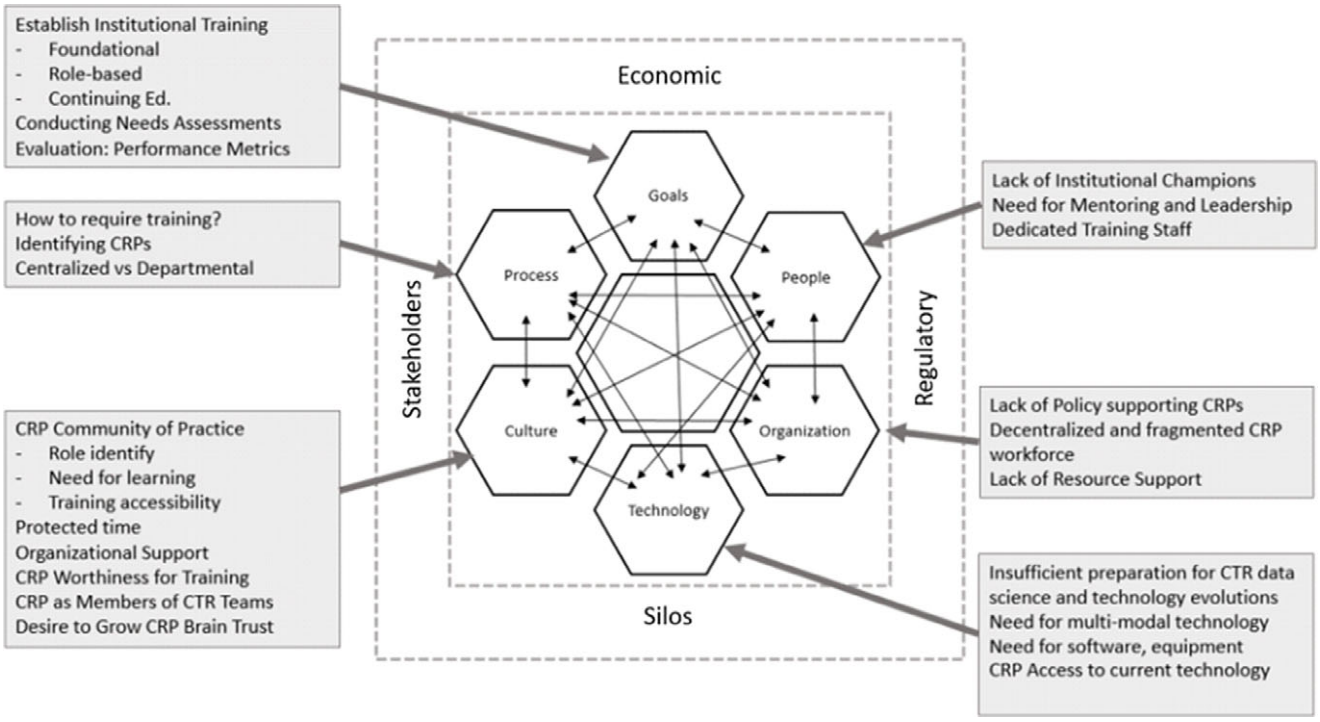

Fig. 3. Addressing clinical research professional (CRP) training and role development needs in the academic medical center socio-technical ecosystem.

Table 4 *Individualized Development Plan for Clinical Research Professionals*

Instructions: Create file folders for each of the 10 categories with sub-folders as needed. Build your IDP and review it every six months.

Personal Information
- Reviewing your job title, job description
- Identify the career paths available for your current job title.
- Determine requirements to advance to the next level in this job title. *(such as: advancing from Clinical Research Assistant to Clinical Research Coordinator, data entry to data management)*
- Determine requirements to move from one job title to the next.
- Developing your CV
  - *Use standard template, update*
  - *Keep a list of all studies you are working on (addendum)*
- Develop your LinkedIn and/or Twitter profile for professional purposes
  - Join groups, update periodically
  - Create or share professional posts
- Get to know yourself better. Who are you? What makes you tick?
  - *Complete a Temperament survey*
  - *Complete a Strengths survey*
  - *Complete a work-life balance survey*
  - *Reflection on findings*
  - *What gives you satisfaction in your job?*

Onboarding/Compliance Training
- Institutional
- General clinical research courses
- Departmental training

Clinical Trial Competencies (complete periodically)
- Long Form JTF Leveled Competency Checklist

Setting SMART goals for Career Success
- Short Term Goals
- Long Term Goals
- Dream Big! Identify one thing (that if there were no obstacles) you want to accomplish.

Professional Development/Training
- Institutional Courses
- Professional Association Courses
- Online Courses
- Readings
- Badges, Certificates, CEUs

Targeting Academic Courses *(Optional)*
- Explore available options
- Curriculum Plan
- Transcripts
- Certificate or Degree

Develop your Team Networks
- What teams are you a member of?
  - What are you learning about team strengths, team struggles?
  - How do you strengthen the team?
- Networking within your department?
- Networking outside of your department?
- Interview someone at a higher job category
- Who can you collaborate with?

Meetings with Supervisor Identifying and Meetings with Mentors Professional Accomplishments
- Certification
- Publications
- Presentations
- Awards
- Certificates
- Licensure
- Leadership
- Memberships

Abbreviations: CV, curriculum vita; JTF, Joint Task Force; CEUs, continuing education units.

Individualized Development Plans for CRPs

One discussion point mentioned was IDPs for CRPs. During a pre-meeting survey of our Un-Meeting registrants, only 7.6% of respondents indicated that they used IDPs for CRP professional development [39]. In the clinical trial enterprise, contract research organizations and pharmaceutical companies use the IDP as an important career development tool. Academic disciplines utilize IDPs in professional development, particularly with CTR trainees and scholars as a means of facilitating mentorship, personal goal setting, and achievement tracking. We propose an outline for a CRP IDP (Table 4). CRPs should be encouraged to take personal responsibility for collecting and reflecting on their professional development and maintain IDP elements in digital files. One key component of an IDP is goal setting based on self-assessment of clinical trial competencies and the planning for professional development activities. The use of IDPs should not introduce a required burden for CRP supervisors unless formally adopted by the institution for role progression or in a mentoring program. Rather, IDPs can be introduced as a tool used by individual CRPs to embrace professionalism and provide an intentional method of professional development goal setting, CE tracking, and reflection.

Exemplar 1. Two digital applications for CRP professional development

Digital Trello Boards

At _____ University, several departments are successfully utilizing Trello boards (Trello; by Atlassian; 2021) to enhance the onboarding experience with high praise from both new employees and supervisors. Trello is a cloud-based Kanban-style list-making platform providing an interactive tool, which may be used to identify, itemize, and track onboarding activities and tasks as well as provide key contacts and timelines. The cloud-based access for Android and iOS supports collaboration and communication among administrators, supervisors, team leaders/members and the employee all involved with CRP onboarding. This helps to close the gap in tracking CRP training by using a centralized tracking system. "Advantages of Trello Boards are that they are easy to set up and use; very adaptable and flexible; provides interaction between employee and supervisor, particularly in remote and time sensitive environments." Create a master template for use ensuring consistent and uniform essential training and can be customized by role and responsibilities with checklists, timelines, and other elements.

Digital badging

eCredentialing in the form of digital badges have been employed at _____ University to provide recognition of CRP training, education, and competency/skill achievement. We contracted with Association of Clinical Research Professionals to purchase eLearning modules that were aligned and leveled to three _____ University digital badges: CRP Levels I, II, and III representing Foundational, Skilled and Advanced level badging. Digital badges are a web-enabled version of a credential, certification or learning outcome, which are shareable and can be verified in real-time, online. Verified metadata is contained in the digital badge that describes the qualifications and the process required for attaining the digital badge [40].

Shared Exemplars from the Field

During the Un-Meeting, participants shared workforce development initiatives undertaken locally and expressed a willingness to share those for use by other CTSA hubs. Below are exemplars shared by the authors to illustrate novel CRP professional development approaches.

Exemplar 2. Institutional Certificate for CRP Professional Development

The Clinical Research Operations Program at _____ University offers classes specific to clinical research involving human subjects. The goal of the program is to raise the quality of clinical research across _____ University and to enhance the career growth of clinical research personnel through these primary objectives:

- Gain fundamental knowledge related to conducting clinical research in compliance with federal, state and local regulations
- Prepare for Association of Clinical Research Professionals (ACRP) and/or Society of Clinical Research Associates (SOCRA) certification exams
- Enhance career growth and advancement

Certification Eligibility Requirements

- Complete 14 required classes and the associated quiz and evaluation
- Complete 4 elective classes
- Be current with university required trainings for research personnel
- Take exam and a score of 80% or greater

Exemplar 3. CRP Readiness Assessments

_____ University provides a variety of skills-based assessments and role-based readiness tools for CRC, Regulatory Affairs and Program Leader Readiness tools to help CRPs identify current skills and set goals for role progression [41]. This is part of a broader initiative that restructured job titles and role progression developed to enhance CRP hiring and retention [28, 29]. These tools can be used by other CTSA hubs to customize assessments.

Exemplar 4. CRP Co-Mentoring Circles

Authors from two CTSA hubs _____ and _____are engaging in developing and piloting a Collaborative Diversity, Equity and Inclusion (DEI) Co-Mentoring Circle. In this pilot project CRPs of color from the two institutions use recorded DEI-related educational storytelling events as a platform for further discussion on facilitators and barriers to AMC role progression through participant sharing of stories and ideas. A meeting plan with six scripted sessions and evaluations is included. Using Co-Mentoring methods, we included participant agreements to ensure that participation was in a safe place to maximize open sharing and idea generation.

Conclusion

This study describes several challenges and solutions for CRP onboarding and training at AMCs. Study participants from 41 institutions indicated there is a need for improved education and training from onboarding through CE, including establishing mentoring programs and developing resource libraries. Using a socio-technical ecosystems model and exemplars from the field will help champions and other key stakeholders to overcome the challenges identified in this study. This endeavor requires institutional champions that can help break down silos, improve communication, create institutional policy changes, and provide rationale and data around the need for change in support of improving onboarding and professional development for CRPs.

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