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Academic Preparation in Clinical Research: *Experience from the Field*

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In 2012, the Institute of Medicine published a seminal work outlining an approach to transform the clinical trials landscape in the United States. This work emphasized a greater need for education and training for all levels of clinical researchers, inclusive of investigators and the wide range of professionals employed across the enterprise.

Why is this important? In clinical decision making, the number of facts considered in the treatment of a patient has steadily increased from an estimated 25 facts per decision in 2000, to 80 facts per decision in 2010, to an amazing 1,000 facts per decision by 2020, mostly due to the exponentially increasing amount of data and decision-points in genomics, genetics, and proteomics.[1,2] These decision factors are in keeping with published literature on the complexities of clinical trials in the current decade.[3]

THE NEW REALITY

Complexity is our new reality, and innovations in clinical trial design, development, and implementation will require a workforce that is able to keep pace. The harmonization of overall clinical and translational science competencies with those defined by the Joint Task Force (JTF) for Clinical Trial Competency will ensure this workforce is well prepared for the challenges ahead in the next decade of clinical research.[4]

Some professional organizations are embracing the formal structuring of current and emerging roles to reflect core competencies for clinical research professionals.[4,5] In response, academic and formal training programs and policies have emerged to fill this need.

TABLE 1: Clinical Research Site Role Opportunities

Role Category	Sample of Job Titles
Regulatory Affairs	• Regulatory Coordinator
	• Senior Regulatory Coordinator
	• ClinicalTrials.gov Coordinator
	• Regulatory Affairs Compliance Officer
Study Coordinator	• Clinical Research Specialist
	• Senior Clinical Research Specialist
	• Clinical Research Coordinator
	• Senior Clinical Research Coordinator
	• Research Program Leader
	• Associate in Research
	• Project Coordinator
	• Project Manager
	• Clinical Research Nurse
	• Senior Clinical Research Nurse
Data Management	• Data Entry Operator
	• Data Coordinator
	• Senior Data Coordinator
Grants and Contracts	• Data Processing Specialist I and II
	• Programmer Analyst
	• Sponsored Programs Analyst
	• Budget Analyst
	• Research Billing Associate
	• Contract Analyst
	• Program Manager I and II
	• Grants and Contracts Specialist
	• Grants and Contracts Officer
	• Conflict of Interest Administrator
	• Associate Director of Sponsored Projects
	• Director of Sponsored Projects
IRB Administration	• Protocol Analyst I and II
	• IRB Regulatory Specialist
	• Regulatory Compliance Manager
	• Assistant Director of IRB
	• Director of IRB

Note: This is an abbreviated sampling of job titles per role category derived from a search of research positions at several AMC sites, and is not intended to be an exhaustive list.

However, an individual with a goal of working in the clinical research field has many pathways from which he or she can choose.[6] Most position postings in clinical research prefer an applicant to have earned a bachelor's degree and have the requisite years of "experience." This is a challenge for those new to the profession, who are faced with the necessity of gaining experience in order to enter the field.

Individuals considering the clinical research profession may ask, "Are there ideal paths to success?" and "How have others advanced in this profession?" Academic programs and clinical research internships can help open doors to new opportunities.

This article introduces competency-based approaches for clinical research education, training, and progression, and shares vignettes about the career paths of a variety of clinical research professionals.

THE CLINICAL RESEARCH SITE

Clinical research sites employ a wide spectrum of individuals. In the mid-1980s, academic medical centers (AMCs) were structured such that principal investigators (PIs) would hire nurses and data entry clerks to manage their clinical trials. Back then, it was common for administrative assistants or PIs to submit protocols and informed consent forms to the relevant institutional review boards (IRBs), and sometimes to serve as the study coordinator. Even IRBs were supported by only a few staff members.

To be sure, clinical research studies were once far less complex. Notably, at that time few clinical research sites operated outside AMCs, and very few contract research organizations (CROs) were in existence.

Today's AMC research sites employ a broad range of clinical research staff (see Table 1), and IRBs have expanded with a wide range of positions. Moreover, companies in the private sector now have staff holding positions and responsibilities in the field that are very similar to those found in AMC-based study sites.

However, a significant problem exists in the current research environment; two job postings with the same title may have very different requirements and responsibilities. Further, there is a lack of training consistency and progression plans for these roles. These gaps burden human resource departments, whose staff may have a general lack of understanding about the value of research operations and the role of clinical research as the lifeblood of an AMC.

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STORIES FROM THE FIELD

The vignettes presented here highlight the journeys taken by some of the authors of this article in their clinical research careers. The stories explore how these individuals broke into the clinical research field, their education and training experiences, and how their roles progressed.

A CLINICAL RESEARCH NURSE STORY

Carolynn J. became a clinical research nurse coordinator after working for two years in a coronary care unit at a university hospital in the mid-1980s. Prior to a clinical research role, she had no prior knowledge of or coursework related to clinical research as a professional pathway. As she received training in an on-the-job fashion, her coordinator job duties changed from those of a clinical research nurse to a research nurse coordinator, and later from those of a study coordinator to a program manager.

Within five years, Carolynn ascended to a role as a research nurse manager and was administrator of a National Institutes of Health (NIH)–funded coordinating center, with duties in project management and monitoring. She also worked as a research director for a private practice group supervising a range of staff.

Carolynn is a member of multiple clinical research professional associations. She added a Master of Science in Public Health (MSPH) degree in epidemiology to her BSN ("because no clinical research degrees were accessible to me at the time") and, in 2014, a Doctorate in Nursing Practice (DNP). She states, "At the beginning of this clinical research journey, I had a thirst for knowledge about the role and sought journal articles to find out more. When I landed upon clinical research professional organizations, I immediately joined. I purposefully sought ascending degrees that would enhance my knowledge of research and mentored many individuals in the role. This is a fantastic area to work in. There are so many directions I could go in this profession, and now I have options to generate and lead research projects and consult, in addition to my teaching role in the university. This way I can contribute to improving our enterprise!"

A CLINICAL RESEARCH TRAINER STORY

Kathryn J. entered the clinical research field at an academic institution 25 years ago, after first attending medical school for a year but having then experienced a change of heart. She had majored in natural science in her undergraduate work with a lifelong goal of attending medical school and becoming a pediatrician. After the first year of medical school, she reconsidered her ultimate career and family goals.

Knowing that she wanted to stay in the healthcare field, Kathryn discovered the wide world of clinical research. She started working in the field as a data coordinator, gaining experience with managing data on paper case report forms. She continued to progress through various research roles, such as a Phase II grant lead site coordinator, a protocol compliance auditor, and a regulatory manager. Each of those roles provided an opportunity to learn about different facets of clinical research, but not necessarily the "why" behind those facets. All of the training came in the form of on-the job experience.

While serving as a clinical research manager, Kathryn had the opportunity to continue to expand her experience with regulatory responsibilities (such as IRB submissions, study registration, study monitoring, etc.) and clinical responsibilities (such as patient recruitment, informed consent, completing data both electronically and on paper, etc.). This position also introduced her to the business side of clinical trials, such as developing study budgets, assisting with clinical trials agreements, and invoicing for study payments. While in this position, a new graduate program in clinical research became available. This provided the opportunity to expand her knowledge about clinical research operations in a formal setting.

Kathryn's journey has been an exciting one, but she acknowledges that, "While hands-on experience is a necessity in the clinical research arena, the evolution of official academic education in this field will lead to better prepared clinical research staff more quickly."

A REGULATORY AFFAIRS PROFESSIONAL STORY

Joe B. is excited by the convergence of scientific challenges, advancement in medicine, and regulation in clinical research. As an undergraduate student in the biological sciences, he entered the profession through diverse research assistant positions at an AMC. His involvement in data and specimen management and clinical activity with research participants fostered his appreciation for the spectrum of good practices.

Joe's career continued at a pediatric hospital, with new regulatory responsibilities. "Interfacing with patients and subjects revealed the broad effects of regulatory activity on medicine and healthcare," he says. "I discovered my passion to help people by working to expedite the process of clinical development and improve medical treatment options. I felt more than excited. I was driven."

Through a regulatory position in oncology, Joe later focused on industry and investigator-initiated clinical trials. He continued to learn by exposure on the job, and through regulatory and clinical research publications. There were many avenues to explore, and he quickly recognized that an advanced degree and professional credentialing in regulatory affairs were key to transitioning into the next phase of his career. Diving in, he earned both over the next few years; the results were tremendous, because they opened doors to new job opportunities in the field.

The curriculum of a graduate degree expanded the scope of Joe's expertise. It spanned across the field of clinical research to incorporate communication, leadership, and management. In global product development, changing regulations and environments require an ability to adapt and effectively communicate. The graduate program accelerated the learning curve and prepared Joe to collaborate across organizational functions. It enabled him to take on responsibilities that are integral to regulatory affairs, but would have otherwise taken years of experience to navigate.

A RESEARCH BILLING AND COMPLIANCE OFFICER STORY

Jennifer L. started her career as a nurse. After a couple of years, she was offered a position as a cardiology clinical research coordinator. Like many in this position, she had no prior knowledge of clinical research as a career and her training came on the job. Fortunately, she loved the job, and she developed a passion for learning about the entire clinical research enterprise.

After becoming a Certified Clinical Research Coordinator (CCRC®), Jennifer developed a regulatory specialist role and eventually became director of her unit. After eight years, she was provided an opportunity to help open a Clinical Research Center focusing on investigator-initiated and NIH-funded studies. This was a great opportunity to round out her experience, which had been mostly pharmaceutical studies to that point, and it allowed her time to obtain her MSPH with a focus on clinical investigation.

After two years as a nurse manager with the research center, Jennifer followed her boss to Columbus, Ohio to manage his clinical research program. Regrettably, her boss was not satisfied with the transition and left Ohio shortly after arriving. With her experience she was able to secure a new position working for a Hospital Billing Office as a manager in research billing and compliance. She developed a Research Billing Office and was promoted to a director position, in which she was able to learn about the revenue cycle while educating researchers and hospital staff about research and research billing.

Jennifer's research experience opened an opportunity to assume additional responsibility over the Revenue Cycle Clinical Support (RCCS) department. RCCS completes clinical pre-certifications and denials, many of which are considered experimental and not medically necessary. Her research education has opened many opportunities—not only in clinical research, but in healthcare in general.

A CLINICAL RESEARCH ASSOCIATE (CRA) AND CONSULTANT STORY

After working as a staff nurse in multiple critical care settings, Beth C. transitioned in 1987 to a clinical research nurse position at an AMC to coordinate a large, global NIH trial. Her training was largely on the job. Over the next decade, she worked as a research nurse coordinator in multiple therapeutic areas, including HIV/AIDS, transplant, and oncology.

During the early 1990s, clinical research certifications emerged along with coordinator training programs. Achieving ACRP's CCRC certification, in tandem with multitherapeutic experience, helped with Beth's career advancement to a research site management position. Meanwhile, pursuing a graduate nursing path in the 1990s did not much aid anyone interested in clinical and translational research, but focused more tightly on nursing research.

"As time passed, the emerging requisite knowledge of complex protocol development and patient safety issues, intensifying competency requirements, and burgeoning local and international regulations often received short shrift in curriculums for medicine, nursing, and allied health programs." Ultimately, pursuing an academic degree in clinical research contributed to Beth's career advancement in site management, pharmacovigilance, project management, and CRA roles.

Beth also had increased opportunities to serve as a consultant on issues related to site development/training needs, operations and quality management, medical data and safety review, and pharmaceutical development. She feels the most significant trend is the demand for high-quality, value-based execution of trials at all levels, saying, "The use of informatics has accelerated quality and pace in the industry. Sponsors in pharma and biotech no longer support 'accident forgiveness' with costly outcomes from untrained investigators/site staff and those actually managing the trials on the sponsor's behalf (CROs, vendors, CRAs, project managers, operations leads, etc.). Highly competent, educated, and well-trained research professionals and those responsible for oversight must produce quality from the first patient first visits to the final analyses."

CLINICAL RESEARCH COMPETENCIES: CURRENT APPLICATIONS

Competency-Based Approach to Academic Education

In an effort to generate an evidence base for clinical research curricula, leaders of the Consortium of Academic Programs in Clinical Research (CoAPCR) conducted a literature search of adopted clinical research core competencies from nursing, physician, and professional association groups. The findings were further discussed and harmonized in a gathering of clinical research stakeholders led by the JTF and culminating in the publication of "Harmonized Core Competencies for Clinical Research Professionals."[4]

Eight competency domains and 51 core competencies have been adopted by CoAPCR, and have become the basis for curriculum development and curriculum restructuring across several academic programs in clinical research. A competency-based accreditation pathway for these academic programs is evolving for a 2017 launch.

Competency-Based Approach to Clinical Research Training

After the JTF disseminated the "Core Competencies" in 2014, the Association of Clinical Research Professionals concentrated its training and development program to focus on competency domains, and has mapped its certification exams to the clinical research core competencies.

Moreover, several AMCs have begun to restructure their training programs using the core competencies as a roadmap for the curricula and assessing content knowledge. A focus group comprised of 62 AMC sites funded by NIH's Clinical and Translational Science Awards (CTSA) program mapped the core competencies for clinical investigator and study coordinator roles.[7] This work led to the establishment of multiple assessments of competence that have been made publicly available at www.ctsa-gcp.org.

Since many individuals continue to enter clinical research roles with no relevant education or training, these proactive contributions to competency-based training can inform site training and policies for onboarding and continuing education of research personnel.

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Competency-Based Approach to Clinical Research Human Resources

Duke University conducted a study to apply a competency-based approach to reconfigure job classifications for clinical research staff. Small working groups of research staff, followed by a widely deployed stoplight evaluation, were used to gain consensus on competencies in each job classification. Agreed-upon competencies were matched to jobs from entry level to leadership levels using a tool they designed in REDCap™. This has resulted in improved definition and organization of job descriptions, and in a competency-based objective approach for progression.

Rebecca Namenek Brouwer, associate director for research operations in the Duke Office of Clinical Research, a unified research support office,[8] reported that mapping under way with more than 700 clinical research staff was expected to be completed by the close of 2016.[9] This groundbreaking work demonstrates that the gaps in job titles, descriptions, and progression can be remedied with a competency-based approach.

CONCLUSION

Individuals pursuing interests in clinical research have multiple doorways by which to enter the field, and many different possible career ladders to climb as they explore it. Competency-based approaches to human resources in clinical research will help to better define the field and mechanisms for advancement.

The professionalization of clinical research careers suggests that the field's educational pathways offer opportunities for expanding knowledge, skills, and attitudes that are based on competencies. Becoming a competent professional would also include such elements as membership in professional associations, dedication to continuing professional education, openness to mentoring, and achievement of certification.

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