

# Clinical Researcher™

The Authority in Ethical, Responsible Clinical Research

November 2020 (Volume 34, Issue 9)

PEER REVIEWED

## A Perspective on the Current State of Clinical Research Education and Training

Joseph M. Bocchino, EdD; Joan Butler, EdD, MS; Beth Harper, MBA, BS (OT)



The following review of the literature addressing the current state of education within the clinical research profession was undertaken to ascertain directions in which the profession and its supporting educators may be moving in order to further develop clinical research workforce capacity. The in-depth review elucidated a number of key factors that impact clinical research education, including: a) defining who comprises the clinical research professional; b) the role of medical education in clinical research

education and training; c) the focus on competency-based education in the profession; and d) the recent rise of the translational research paradigm and its impact on clinical research education.

This article will discuss the first three factors and introduce questions for further study related to education and training in clinical research.

## **Background**

Over the past four decades, the domain of clinical research has been defined by heavy emphasis on the development of therapeutic interventions through the use of clinical trials. In more recent years an emphasis on public health, including behavioral and epidemiologic studies, has emerged, broadening the common view of clinical research to embrace the full scope of the U.S. National Institutes of Health (NIH) definition of activities encompassed by the field.{ 1 }

It is important to fully understand the current state of education and training in the clinical research profession, in order to more fully engage the direction of the future. This paper strives to provide a current state perspective. Our focus in this review is not to assess and describe the variety of programs and venues; instead, we will discuss the three key factors impacting clinical research education, as identified through our review of the literature.

## **Methodology**

We conducted a review of more than 3,800 abstracts and articles in our initial search, the majority of which focused on specific clinical research studies and findings, rather than education and training. The review identified 76 articles and documents for further, in-depth study. Deeper analysis of the 76 articles and documents yielded four important considerations for informing the future direction of clinical research education and training, with the first three being addressed in this paper:

- Clinical research roles and identity
- Medical education and clinical research
- The role of competency-based education in clinical research
- The relationship between translational and clinical research

## **Clinical Research Profession: Roles and Identity**

The clinical research profession has been characterized as an “umbrella” that incorporates a number of roles and subcomponents supporting an entire field of work.{ 2 } Viewed through a

different lens, clinical research represents a series of competencies, each spanning a continuum of varying levels of expertise necessary to fulfill the stated role of the position holder.

Within the workforce, the profession is often characterized as a series of position titles and job descriptions that tend to focus on specific clinical research domains{3} or professional disciplines.{4} Remarkably, we were not able to find a credible estimate of total employees engaged in clinical research globally. This fact underlies some of the challenges in defining the scope of the clinical research “profession.”

The challenge for educators and trainers supporting the clinical research profession is to identify appropriate learning objectives{5} when the individuals making up its workforce range from scientifically trained clinicians and seasoned researchers to newly minted, inexperienced individuals just entering the profession. That being said, learning and training objectives have focused heavily on the responsibilities associated with monitoring trials on behalf of their sponsors, the protection of human subjects, and the tenets of Good Clinical Practice, as these domains apply in some manner to the largest populations of the “clinical research profession.”{6}

Several relationships emerge in the literature that are characterized by distinct professional credentials and clinical research roles. For example, the relationship between the nursing profession and the role of clinical research coordinator (CRC) is well recognized across study sites and sponsors.{7} In a similar fashion, medical doctors distinctly fulfill the role of principal investigator (PI) more often than not.

Beyond the most well-known roles of the field, defining who the clinical research professional is—as well as the full scope of those who make up the profession—takes on more complexity. Nevertheless, it is easy to understand how both the medical education literature, which we will discuss in the next section, and the nursing education literature influence the education and professional development of “clinical researchers” from these two health disciplines. The education tradition of each discipline influences what elements of clinical research training are emphasized within each profession.

Recently, other disciplines such as biostatistics and data management have become more evident in their influence on the clinical research profession. Historically viewed as auxiliary within clinical research, both biostatistics and data management have emerged as equally significant as more commonly recognized contributors in terms of their overall impact on the successful conduct of clinical research. As clinical research emerges as a more interdisciplinary profession, these two disciplines further expand the breadth of expertise recognized within the profession. {8–10}

However, key questions arise that are not clarified by the literature, including:

- What relative priority do incumbents engaged in clinical research place on their original field of study (e.g., medicine, nursing, biostatistics, etc.) when compared to their assigned roles in the conduct of clinical research (e.g., PI, CRC, or statistician as examples)?
- What role does the practice of clinical research play in the assumption of professional identity by those engaged in this work? (Education and training typically have served a primary purpose in developing identity across the professions.) {7,11}
- How does interdisciplinary work like clinical research impact professional identity in the traditional health related professions?

A closer look at medical education and its impact on clinical research training provides some insight on these questions.

### **Medical Education: Impact on Clinical Research Training**

Lurie {12} points out that up until the past 15 years, medical education relied heavily on written test outcomes to measure physician competence. However, a wide variation still exists across educational institutions of what constitutes competence in medical education. {13}

Carraccio et al. {14} describe a 21st century “Flexnarian revolution” necessary to move medical education from a then “current structure and process-based curriculum” to one that is competency based.” As such, over the past 20 years medical education moved to adopt a more competency-based educational model. For example, in 1999, the Accreditation Council for Graduate Medical Education (ACGME) and the American Board of Medical Specialties

(ABMS) jointly agreed upon six competencies for the certification and maintenance of certification of physicians.{15}

The ACGME/ABMS move specifically targeted graduate medical education and generated a major shift in medical education and training over the next 10 years, as elucidated by Frank in a 2010 systematic review of the literature.{13} That review also revealed widespread heterogeneity in characterizing the variation in medical education programs across the country. Albanese et al.{15} undertook an effort to define competency for medical education, pointing out that variation was global and that it was unclear whether the differences were semantic or substantive.

In the same time period, Cook et al.{16} specifically called for competency-based education and standards to address issues of patient safety and accountability on the part of medical professionals in service to the general public. Lurie{12} elucidates a number of shortcomings associated with competency-based medical education, among them the absence of humanistic attributes and the lack of assessment tools for higher order skills like critical thinking and judgment. Gunderman et al.{17} describe learner perspectives that interpret competency-based medical education as a mechanism for ensuring a minimum required level of competence, as opposed to maximizing individual higher potential. Gonsalves and Zaidi{11} report on a study in which medical trainees describe the negative impact of competency-based education on “professionalism,” as the trainees interpret directors’ emphasis on step scores as overriding trainee professionalism, a reminder of Lurie’s{12} claim of heavy reliance on test scores in medical education.

Clinical research training and education have developed in a similar manner into a competency-based discipline defined by a set of core areas of expertise.{18} It is not fully clear whether the emphasis on competency-based education in medicine drives the trend toward the same approach in clinical research. Quite possibly it was an Institute of Medicine report from 2002, which called for all health professions to adopt a core set of competencies,{19} which led to this progression. What is clear, though, is that the health professions in general have all adopted a competency-based educational approach and continue to refine it.{20,21}

Much of the current clinical research education in medical schools is now focused on translational research. Despite this shift in academic medical research, it is noteworthy that the recently issued “core Entrustable Professional Activities” by the Association of American Medical Colleges, defining 13 required activities that all medical students be able to perform upon entering residency, makes no mention of clinical research. This makes sense, given the primary focus of medical education at the undergraduate level.

However, at the graduate level, ACGME common program requirements state that curricula must advance a resident’s knowledge of the basic principles of research, including “how research is conducted, evaluated, explained to patients, and applied to patient care.” The program requirements leave to each medical discipline the approach and specifics of what content is to be taught, resulting in much variation even within disciplines, as evidenced in a review of 38 hematology/oncology fellowship programs by Safa and Jazieh.{22} Rangan et al.{23} calls for standardization of research training for all specialty medical trainees, to address broad variation across 62 medical specialty research curricula analyzed.

### **Competency-Based Education in Clinical Research**

Competency-based education is described in detail by del Bueno,{24} and may be synthesized as the educational focus on predetermined outcomes or “competencies” along with an evaluation method. Outcomes are stressed over process; however, as del Bueno points out, it may not be one over the other. Since 1978, education within the health professions has focused heavily on competencies, as we can see within the clinical research profession. Overall, we can say that we do not have reliable research that documents clearly the effects of outcome or competency-based clinical education.{25,26} Within clinical research we continue to strive for relevant standards and metrics for assessment.

Sonstein et al.{27} point out that clinical research has progressed over the past two decades from a regulatory compliance–driven activity to one focused on competency. They go on to point out that even the global standards that guide training for clinical research are, at best, vague. Early on, professional organizations like Association of Clinical Research Professionals (ACRP) and the Regulatory Affairs Professionals Society (RAPS) began developing and have listed

competencies associated with various clinical research roles. More recently, a consortium of clinical and translational research centers has developed and published through the National Center for Advancing Translational Sciences (NCATS, part of NIH) a set of core competencies for translational researchers which includes traditional components of clinical research.

Of importance for this discussion, representatives from a broad-based assembly of constituencies in clinical and translational research came together in 2013 as the Joint Task Force for Clinical Trial Competency, in an effort to harmonize core competencies for clinical research professionals. Kohara et al. {28} chronicle the development of competencies attributed specifically to the role of CRCs. While quite extensive, the list was derived from a review of presentations and interviews conducted with thought leaders in the field of clinical research.

This raises a question as to who determines “needed competencies” and for which domains. Furthermore, we are compelled to ask how we integrate competencies across professional roles like the CRC, the clinical research associate, or the PI to ensure that we are able to address the overall goals of clinical research through the designated workforce. {29}

In this regard, Sonstein et al. {2} through a review of self-assessments elucidate the need to differentiate between “competency” and “proficiency” as we think about expertise in clinical research. The implication of this differentiation is to recognize that a purely competency-based training and educational model may not achieve the overall goals needed for a proficient clinical research workforce.

Morcke, Dornan, and Eicke {25} point out that the progression of outcomes-based education, heavily linked to contemporary competency-based approaches, was heavily criticized in the 1970s for reducing focus and development of skills associated with values, judgment, and insight. Lurie {12} discusses the humanistic shortcomings that may emerge from a purely competency-based education model. Taken together, these researchers may ultimately be facilitating a broader move to a more blended approach to developing the clinical research workforce by integrating outcomes and competency.

It is important to note for all reading this paper that the literature supports all the efforts put forth to identify and differentiate competencies in clinical research; the question raised here is whether

we have gaps in our training and education that can't be met through competency-based education. As an example, Alsumidaie{30} describes findings that do not correlate experience with performance outcomes in clinical research, and furthermore raises questions about the relevance of surrogates or benchmarks for assessing competence in certain areas of clinical research.

Hartl et al.{31}, looking at how a specific medical education program utilized longitudinal blocks to develop competence, elucidate the complexity associated with thinking of the temporal nature of experience and automatically linking it to acquisition of competence or expertise.{32} Calvin-Naylor et al.{33}, as many other authors also do, describe in detail the process for identifying and developing domains and associated assessments, but does not elucidate the “thinking” behind the selection of such choices.

Dauphinee et al.{34} question directly whether we can validly assess competence in medicine, raising that same specter for our discussions of clinical research. Finally, Hodges and Akroyd{35} illustrate the lack of connection between PI certification and actual performance outcomes, as measured through reported site deviations. These examples suggest that we have gaps in our understanding of, and capacity to, leverage competency-based education fully to achieve our workforce development goals within clinical research and that this will require further exploration.

Finally, a critical consideration for our understanding of competency-based education in clinical research is to recognize the emergent nature of requirements to conduct clinical research. Innovation and technological advancements are redefining roles{5}; as such, competency may be evolving as a “situational” construct depending on the nature of the workplace, the specific requirements of specific sponsors, and/or the capabilities of their partners supporting the clinical research efforts. In this vein, Sargeant, Wong, and Campbell{36} delineate a wide range of considerations that may lead us to consider the intersections between competency-based education, continuing professional development, and even implementation science as pathways to addressing the educational needs of the future workforce.



## Summary

We have developed a comprehensive understanding of the factors and dynamics that are influencing the direction of clinical research education. This paper was undertaken well before, and essentially completed prior to, the emergence of the coronavirus pandemic of 2020, which will undoubtedly influence education in the clinical research discipline. It is premature to anticipate where this influence will lead. Our review clearly elucidates the changing nature of clinical research practice, how roles are defined, and how competencies define the field.

As a result, we have identified a number of discussion points that may help guide future inquiry on this subject:

- As more professional disciplines fall under the umbrella of clinical research, how will we leverage educational programs for those disciplines to integrate the core tenets of clinical research early in professional and academic training?
- The goal to be striven for is that clinical research education not be treated as an “add-on,” and that it would help situate the individual’s learning to recognize clinical research as part of his or her professional identity.
- We may need to move clinical research education “upstream” in the development of the health professions.
- How do we foster a truly interdisciplinary clinical research workforce?
- More work is necessary to fully explicate the relationships between stated clinical research competencies, actual job performance, and methods for assessing both to derive value for both employers and each clinical researcher.
- How will our currently stated clinical research competencies facilitate innovation and professional success within the field?
- We need to look more closely at the relationships between stated clinical research competence and the actual outputs and outcomes of clinical research activity.

## References

1. National Institutes of Health. Glossary of Terms for Human Subjects Protection and Inclusion Issues. <http://grants.nih.gov/grants/glossary.htm#ClinicalResearch>
2. Sonstein S, et al. 2016. Global self-assessment of competencies, role relevance, and training needs among clinical research professionals. *Clinical Researcher*. <https://acrpnnet.org/2016/12/01/global-self-assessment-of-competencies/>
3. World Health Organization. 2016. Using the TDR global competency framework for clinical research. <https://www.who.int/tdr/publications/year/2016/competency-framework-clinical-res/en/>
4. Brouwer R, et al. 2017. Using competencies to transform clinical research job classifications. *Journal of Research Administration* 48(2):12–25.
5. Smailes P. 2016. Data-Tech Connect: Improving technology training to facilitate competency for the clinical research professional. *Clinical Researcher*. <https://acrpnnet.org/2016/10/01/data-tech-connect-improving-technology-training-facilitate-competency-clinical-research-professional/>
6. Arango J, et al. 2016. Good clinical practice training: Identifying key elements and strategies for increasing training effectiveness. *Therapeutic Innovation & Regulatory Science* 50(4):480–6.
7. Behar-Horenstein LS, et al. 2018. Advancing the practice of CRCs: Why professional development matters. *Therapeutic Innovation & Regulatory Science*. <https://journals.sagepub.com/doi/abs/10.1177/2168479017750128>
8. Zozus MN, et al. 2017. Analysis of professional competencies for the clinical research data management profession: Implications for training and professional certification. *Journal of Informatics in Health and Biomedicine* 24(4):737–45.
9. Valenta A. 2016. Core informatics competencies for clinical and translational scientists: What do our customers and collaborators need to know. *Journal of the American Medical Informatics Association* 23:835–9.
10. Ameredes BT, et al. 2015. The Multidisciplinary Translational Team (MTT) model for training and development of translational research investigators. *CTS Journal.com* 8(5):533–41.

11. Gonsalves C, Zaidi Z. 2016. Hands in medicine: Understanding the impact of competency-based education on the formation of medical students' identities in the United States. *Journal of Educational Evaluation for Health Professionals* 13(31).
12. Lurie S. 2012. History and practice of competency-based assessment. *Medical Education* 46:49–57.
13. Frank J, et al. 2010. Toward a definition of competency-based education in medicine: A systematic review of published definitions. *Medical Teacher* 32:631–7.
14. Carraccio C, et al. 2002. Shifting paradigms: From Flexner to competencies. *Academic Medicine* 77(5):361–7.
15. Albanese M, et al. 2008. Defining characteristics of educational competencies. *Medical Education* 42:248–55.
16. Cook M, et al. 2006. American medical education 100 years after the Flexner report. *New England Journal of Medicine* 355:1339–44.
17. Gunderman R, Gasparis P. 2012. Learners' perspectives on competency-based education. *Academic Radiology* 19(5):630–1.
18. Jones CT, et al. 2012. Defining competencies in clinical research: Issues in clinical research and training. *Research Practitioner* 13(3):99–107.
19. Nahrwold D. 2005. Continuing medical education reform for competency-based education and assessment. *Journal of Continuing Education in the Health Professions* 25:168–73.
20. Moriates C, et al. 2015. Defining competencies in education for health care value: Recommendations from the University of California. *Academic Medicine* 90(4):421–4.
21. Sohlberg L, et al. 2018. Ensuring representativeness in competencies for research coordinators. *Clinical Researcher*. <https://acrpnet.org/2018/05/15/ensuring-representativeness-competencies-research-coordinators/>
22. Safa M, Jazieh A. 2006. Lack of a uniform approach to clinical research training for hematology oncology fellows. *Journal of Cancer Education* 21(3):166–8.
23. Rangan A, et al. 2017. Standardization of delivery and assessment of research training of specialty trainees based on curriculum requirements: Recommendations based on a scoping review. *BMJ Open* e013955.
24. Del Bueno D. 1978. Competency based education. *Nurse Educator* May-June:10–4.

25. Morcke A, Dornan T, Eika B. 2013. Outcome (competency) based education: An exploration of its origins, theoretical basis, and empirical evidence. *Advances in Health Sciences Education* 18:851–63.
26. Harden R, Crosby J, Davis M. 1999. AMEE Guide No. 14: Outcome-based education: Part 1—An introduction to outcome-based education. *Medical Teacher* 21(1):7–14.
27. Sonstein S, et al. 2014. Moving from compliance to competency: A harmonized core competency framework for the clinical research professional. *Clinical Researcher* 28(3):17–23. <https://acrpnnet.org/crjune2014/>
28. Kohara I, et al. 2017. Core competencies of clinical research coordinators. *International Journal of Bio-science and Bio-technology* 9(2):1–10.
29. Saunders J, et al. 2017. Inclusion of the Joint Task Force competency domains in onboarding for CRCs. *Clinical Researcher* 31(6).  
<https://acrpnnet.org/2017/12/12/inclusion-joint-task-force-competency-domains-onboarding-crcs/>
30. Alsumidaie M. 2018. CRA skills lacking in critical areas. *Applied Clinical Trials*.  
<https://www.appliedclinicaltrials.com/view/cra-skills-lacking-critical-areas>
31. Hartl A, et al. 2017. Development of the competency-based medical curriculum for the new Augsburg University Medical School. *GMS Journal for Medical Education* 34(2):Doc 21.
32. Hinckley T. 2017. Workforce Innovation: Let's focus on competency, not tenure. *Clinical Researcher*. <https://acrpnnet.org/2017/02/01/workforce-innovation-lets-focus-on-competency-not-tenure/>
33. Calvin-Naylor, et al. 2017. Education and training of clinical and translational study investigators and research coordinators: A competency-based approach. *Journal of Clinical and Translational Science* 1:16–25. doi:10.1017/cts.2016.2
34. Dauphinee WD, Boulet JR, Norcini JJ. 2019. Considerations that will determine if competency-based assessment is a sustainable innovation. *Advances in Health Sciences Education: Theory and Practice* 24(2):413–21.  
<https://pubmed.ncbi.nlm.nih.gov/29777463/>

35. Hodges A, Akroyd D. 2018. Does PI certification make a difference? *Applied Clinical Trials*. <https://www.appliedclinicaltrials.com/view/does-pi-certification-make-difference>
36. Sargeant J, Wong B, Campbell C. 2018. CPD of the future: A partnership between quality improvement and competency-based education. *Medical Education* 52:125–35.

**Joseph M. Bocchino, EdD**, ([bocchino.joseph@gmail.com](mailto:bocchino.joseph@gmail.com)) is Chair of the Clinical Management and Leadership faculty at The George Washington University.

**Joan Butler, EdD, MS**, ([joanb@gwu.edu](mailto:joanb@gwu.edu)) is Director of Clinical Research Administration Programs and Assistant Professor at The George Washington University.

**Beth Harper, MBA, BS (OT)** ([bharper@acrpnet.org](mailto:bharper@acrpnet.org)) is the Workforce Innovation Officer for the Association of Clinical Research Professionals.