Perspective

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Now is the time to fix the clinical research workforce crisis

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Abstract

The clinical and translational research enterprise is recognized by many as the "evidence generation system." While there have been several calls to revolutionize this enterprise to more effectively deliver the fruits of biomedical science to patients and society, significant issues across the clinical research workforce are pervasive. Perhaps the most visible sign is the widening gap between supply and demand for competent staff. Underpinning this, is a perfect storm of complex issues. Now reaching crisis point, this problem is far bigger than a staffing issue and ultimately jeopardizes the "engine" of drug and device development. With the current perilous state of the workforce, proposed enterprise fixes are likely to languish far out of reach, given that even "business as usual" is under threat. In fact, a glaring disconnect is evident between the visionary discourse on how to revolutionize the clinical research enterprise and the sober recognition that operationalization of any such vision rests on the shoulders of a workforce that's in dire straits. In this article, we provide a brief forensic analysis of the workforce problem and an initial indication of where solutions may lie.

Keywords

Clinical research, translational research, workforce development, clinical research professional, clinical research coordinator, research nursing, drug development, recruitment, retention, clinical research workforce

"Now is the time to fix the evidence generation system" US Food and Drug Administration (FDA) Commissioner Robert M. Califf wrote in this journal in January 2023.[1] While discovery science is in its ascendency, the clinical research enterprise lags behind, requiring, in Dr Califf's view, "a major reformation" to efficiently translate invention into implementation. The reformation proposed is far-reaching and multidimensional. However, a fundamental pillar is the clinical research workforce itself, which is currently anything but robust.

In the wake of the COVID-19 pandemic, the stark contrast between supply and demand for essential functions erupted across news outlets. Notably absent from this spotlight was the clinical research workforce, for which the ensuing "Great Resignation"—apparent across so many critical professions—merely served to magnify a profound, pre-existing problem. A workforce shortage in clinical research has been a looming threat for over a decade.[2–4] It has now reached crisis point, with the potential to curtail medical advances for years to come.

This article examines the clinical research workforce crisis through a US lens, although the problem is undeniably global and growing steadily worse.[5,6] The crisis is most apparent among site-based clinical research staff, on whom the rest of this article focuses. Here, our use of the terms "clinical research professionals" (CRPs) and "clinical research workforce" excludes principal investigators (PIs), whose primary occupation is typically not clinical research.

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The scale of the problem

Nationwide, for every experienced clinical research coordinator seeking work, there are 7 jobs posted. For clinical research nurses, the ratio is 1:10 and, for regulatory affairs professionals, 1:35.[7] Demand is set to increase further, with the US job market for clinical research coordinators predicted to grow by 9.9% between 2016 and 2026.[8] The prevailing CRP shortage is alarming in itself but also bodes ill for the current workforce, which is already overburdened. For CRPs with a 5- to 10-year tenure, the current resignation rate is 60% higher than in 2020.[9] The shrinking pool of qualified CRPs has created a fierce "war for talent," characterized by overt poaching of staff and culminating in unsustainable levels of turnover.[10–12]

Among patient-facing CRPs, the turnover rate has risen to 35%–61%.[10] A National Cancer Institute site in Michigan reported a $> 40\%$ turnover rate among clinical research nurses from 2019 to 2021, the highest level in the program's history.[13] In many cases, site-based staff are lured away to contract research organizations or biotech industry posts which offer better pay and better prospects. But, just as clinical research is the bedrock of drug and device development, sites are the bedrock of clinical research operations so, when sites cannot perform, the entire industry suffers.

What is at stake?

The ability to offer patients a clinical trial is often an integral part of care pathways. Beyond the impact on individuals, the slowing of clinical research has massive implications for medical progress. Management of the COVID crisis was fundamentally dependent on CRPs operationalizing the development of vaccines and treatments at record speed. And, in the face of more everyday life-threatening and quality-of-life-threatening conditions, the turning wheels of clinical research represent a constant source of hope.

Cardiovascular disease and cancer continue to impact countless lives, and their increased survival rates—largely attributable to past successes of clinical research—have illuminated other healthcare challenges associated with longer lifespans. The complications of COVID infections have created new unmet needs. Mental illness in its various guises has escalated alarmingly, especially among the young. Demographic disparities in health—recently brought into sharper focus by COVID—continue to emerge and grow. As the baby boomer generation ages, the strain on the healthcare system threatens to bankrupt the nation.[14] Notably, Alzheimer's Disease and related dementias cost the United States an estimated $355 billion in 2021, a sum that will rise to $1.1 trillion in 2050 unless a breakthrough treatment is found.[15] While the news that Eisai and Biogen's lecanemab met its Phase 3 primary endpoint in early Alzheimer's disease[16] is encouraging, further investigation is urgently needed to elucidate its safety profile and clarify its role. It is imperative that clinical research keeps forging ahead in all these areas, which ultimately depends on a buoyant workforce.

Staffing challenges have already slowed down the ability to run clinical trials. As many as 95% of cancer centers have reported staffing issues and trial accrual rates are down 20% since January 2020.[17] In response to President Biden's recent re-launch of the Cancer Moonshot initiative—which aims to reduce the cancer death rate by at least 50% in the next 25 years—an editorial published in *The Hill* warned that the declining ability to deliver cancer trials "could delay by years the introduction of those exciting new treatments and prevention strategies referred to in the administration's initiative."[18] Alongside these costly delays, the workforce crisis imperils the quality of clinical research, including compliance with good clinical practice and the integrity of the data generated.

Origins and reasons for the workforce crisis

Latent clinical research workforce issues were fomented ~15 years ago when outsourcing in the field began to boom. Reliance on transient freelance contractors set in motion a vicious cycle of supply-and-demand conflicts and "BandAid" solutions.[3,4] It's clear today that the crisis in the clinical research workforce goes far deeper than the staff shortage. Unlike PIs, CRPs are generally overlooked as key stakeholders in the clinical research ecosystem. A weighty report from the National Academies of Science, Engineering and Medicine entitled *"Envisioning a Transformed Clinical Trials Enterprise for 2030"* includes a mere three paragraphs about the workforce and these are solely about PIs.[19] At the heart of the problem is the fact that the clinical research workforce has no clear professional identity. Clinical research is not recognized as a profession by the US Bureau of Labor & Statistics, rarely mentioned as a possible career path in undergraduate coursework for nursing and related disciplines[20] and nowhere to be found within supply-and-demand projections for healthcare occupations reported by the National Center for Health Workforce Analysis.[21]

Most CRPs find their way into the profession by chance. In high schools and colleges, an evident lack of awareness of clinical research as a career prevails. The 10th grader who aspires to "find a cure for cancer" sees themselves either as a drug discovery scientist in a futuristic lab or a top doctor in a leading hospital, caring for patients and making medical breakthroughs on the side. They know nothing of the vast network of dedicated professionals whose names are never up in lights but who play such an integral part in driving

medical knowledge forward. Intentional pursuit of the clinical research profession is an imperative. For too long, this profession has been ill-defined, poorly represented in STEM curricula and lacking in the hallmarks and "brand recognition" of other pivotal professions, even though clinical trials are the world's most globally regulated enterprise,[22] requiring highly specialized knowledge to conduct. Moreover, patient recruitment and retention critically depends on trusting and enduring relationships with CRPs and is jeopardized by high staff turnover.

The author of a 2018 letter to *The Lancet* wrote: 'Having worked in clinical trials for 25 years, I have no doubt that the part that determines success or failure is the part between protocol development and data analysis."[23] It is CRPs, more so than PIs, who represent the human face of the trial for participants and caregivers, shouldering responsibility for critical success factors such as patient identification, recruitment, retention, data capture, protocol adherence and regulatory compliance. Yet, despite the significant intellectual and skill requirements of their roles, there remains a lack of career infrastructure, no centrally funded training programs, no mandatory educational qualifications and no established pathways for career advancement.[12,22] The Association of Clinical Research Professionals notes that it is not even possible to capture reliable statistics about the clinical research workforce, due to cross-institutional inconsistency of job titles and varying role definitions.

Pathways into the profession are also unclear. Despite the increasing number of academic programs developed to prepare aspiring CRPs, an archaic hiring preference for 2 years of experience blocks many promising candidates, creating a Catch-22 situation where experience is needed to get a job, but a job is needed to gain experience. In addition, lack of consistency in defining roles contributes to unusually long searches for applicants. A 2021 study at an academic medical center in Georgia showed the time-to-fill for a clinical research coordinators ranged from 55 to 75 days[24]– notably higher than the national average for a healthcare position (49 days), which in turn is higher than the average across other US industries (36 days).[25] The length of the search may also be influenced by unrealistic expectations. In the Georgia study, one PI's list of requirements for an entry level clinical research coordinator position was deemed "champagne taste on a beer budget"—a memorable description for a common phenomenon.[24]

This situation contrasts starkly with related careers like nursing, where routes into the profession, training and career advancement pathways are explicit.[26] It also contrasts with the wide range of initiatives intended to grow and retain the PI workforce,[12] whose involvement accounts for less than 10% of the total hours invested in a typical trial.[27] In addition, while the biotech industry and clinical research organizations may be able to pay competitively, the same is not true of academic medical centers – the linchpin of clinical trial conduct –where salaries are dictated by complex funding mechanisms.[12] The monetary value of an National Institutes of Health (NIH) research grant has remained unchanged for 15–20 years,[28] leading to pay ceilings at sites that act as an obvious deterrent to staff retention. When staff members quit, commercial sponsors react by parachuting in high-paid temps, an irony that's not lost on struggling site teams. Ultimately, the cost to replace a clinical research coordinator has been estimated at $50K–$60K based on hiring costs and employee onboarding time,[24] a sum that does not include the loss of study productivity during the hiatus and the potential costs of loss or burnout of other staff forced to take up the slack in the interim. A recent pre-COVID survey among CRPs at academic medical centers identified that, apart from remuneration, the most important factor driving job satisfaction and retention was a sense of being valued.[29] Thus, visible recognition of CRPs as contributing members of an interprofessional team is a prerequisite for retaining high quality staff.

Why the crisis is likely to intensify

Worryingly, the pressure on the clinical research workforce is set to intensify even further. First, the number of clinical trials registered worldwide has risen exponentially and shows no signs of slowing.[30] Second, an overall rise in the complexity of trials is evident and measurable.[31] A study by the Tufts Center for the Study of Drug Development noted a threefold rise in the number of data points collected in Phase 3 trials over the past decade[32] and, for all trial phases, an increase in the mean number of protocol deviations and substantial amendments, which are notoriously labor-intensive.[33] Third, a surging expectation for trials powered by innovative new technology, such as telemedicine and patient wearables, has created new requirements for specialist skills. The demand for decentralized clinical trials in particular was massively catalyzed by the pandemic, rising by 28% in 2022 versus 2021.[34] The Association of Clinical Research Professionals anticipates that the decentralized clinical trials "revolution" will necessitate an unprecedented transformation of the workforce[35,36] already evidenced by the fact that, in July 2022, almost 30% of new job postings deviated from traditional clinical research roles.[37] Critically, the clinical research profession is faced not only with a workforce shortage but a diversity shortage too. Diversification of the patient-facing clinical research workforce has been increasingly recognized as essential for improving recruitment of hard-to-reach demographic sub-populations whose participation is so important for applicability of trial

findings to heterogenous real-world populations.[38,39] Although dependable data on the current demographic profile of the workforce are hard to secure—a symptom of the lack of official recognition of the profession—it can be anticipated that adequate, let alone optimal, diversity and inclusivity is still a long way away.

In summary, the clinical research workforce is required to meet rising expectations for quality, safety, speed, study complexity, novel technologies, and diversity—all amid rapidly shrinking human resources and lack of professional infrastructure.

Where do solutions lie?

Although a range of innovative models and partnerships have sprung up across the United States to try to address these formidable challenges,[40] efforts have so far remained highly fragmented. Systemic solutions are urgently needed. In recent years, the culmination of a series of special interest groups, roundtables, and collaborative ventures involving academic medical centers, clinical research organizations, sponsors and professional associations[12,22,41,42] has led to the identification of six key imperatives for workforce regeneration and invigoration (Table 1).

A cornerstone of this mission is the establishment of a global standard for training and qualification of clinical research professionals. Robust foundational work to underpin this goal was undertaken a decade ago by the Joint Task Force (JTF) for Clinical Trial Competency, spearheaded by the Multi-Regional Clinical Trials Center of Brigham & Woman's Hospital and Harvard. The JTF Core Competency Framework—a matrix of competency domains that objectively define the knowledge, skills, and attitudes necessary for conducting safe, ethical, and high-quality clinical research[43,44]–has been assimilated by the two main bodies representing U.S. clinical research professionals (Association of Clinical Research Professionals and Society of Clinical Research Associates) and adopted by many academic medical centers and research institutions. At Duke University, for example, the core competencies were utilized to transform job classifications and establish a career ladder[45,46] enabling a 30% reduction in employee turnover.[47]

It is critical that a competency-based infrastructure for the clinical research profession is universally adopted across industry and academia and used to harmonize roles and entry paths into the profession from across diverse communities, as well as constructing a basis for professional development, career prospects, and remuneration. These pathways require new paradigms of onboarding and mentorship of early career professionals and new financial models to promote staff retention and workforce sustainability. At the same time, a clear identity for the clinical research profession must emerge: one that enables future generations to readily identify clinical research as a chosen career path and which recognizes the value of clinical research workers within site-based interprofessional teams. Each of these areas will require significant thought leadership, advocacy and financial support that can no longer be driven entirely from within. Before we can "fix the evidence generation system,"[1] we have to fix the workforce crisis, a top-down and grassroots mission which demands nothing short of multidisciplinary, enterprise-wide cultural change.

Table 1. Key areas for workforce regeneration.

Imperatives
• Prioritize the creation of a strong and clear identity for the clinical research professional and promote visibility, recognition, and value of CRPs in interprofessional collaboration
• Establish a baseline global standard of excellence in training and qualification for CRPs
• Elevate and standardize clinical research roles across all the enterprise to support salary equity and ensure funding keeps pace with workforce growth
• Raise awareness of the clinical research profession as a distinct career goal for both future generations and professional lateral movers
• Establish universal, competency-based definitions of clinical research roles to support equitable assessment of workforce readiness among entry-level applicants and professional advancement throughout clinical research careers
• Ensure a diverse workforce by providing access and advancement in training for historically underserved communities

CRP: clinical research professionals.

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References

1. Califf RM. Now is the time to fix the evidence generation system. *Clin Trials* 2023; 20(1): 3–12.
2. Clinical Trials Administrator Archives. Shortage of nurses, docs hurts CR staff hiring, retention rates, https://www.reliasmedia.com/articles/111576-shortage-of-nurses-docs-hurts-cr-staff-hiring-retention-rates (2009, accessed 27 March 2023).
3. Miseta E. Clinical staff shortage: "growing plague" for pharma & CROs. *Clinical Leader*, https://www.clinicalleader.com/doc/clinical-staff-shortage-growing-plague-for-pharma-cros-0001 (2016, accessed 27 March 2023).
4. Actalent. The staffing crisis in clinical trials and the drive for permanent staff, https://www.actalentservices.com/en-gb/insights/articles/the-staffing-crisis-in-clinical-trials-and-the-drive-for-permanent-staff (2018, accessed 27 March 2023).
5. Stabile S, Cenna R, Sinno V, et al. Clinical trial units and clinical research coordinators: a system facing crisis? *About Open* (Clin Res) 2023; 10: 1–3.
6. Mitchell EJ, Goodman K, Wakefield N, et al. Clinical trial management: a profession in crisis? *Trials* 2022; 23: 357.
7. SCRS. Exploring the current clinical workforce, https://myscrs.org/resources/sites-now/exploring-the-current-clinical-workforce/ (2022, accessed 27 March 2023).
8. Career Explorer. The job market for clinical research coordinators in the United States, https://www.careerexplorer.com/careers/clinical-research-coordinator/job-market/ (accessed 27 March 2023).
9. Weinberg J and Corcoran L. Tackling the great resignation and burnout in clinical research. Teckro, https://teckro.com/resources/blog/clinical-research-staff-resignation-burnout (2022, accessed 27 March 2023).
10. SCRS. Open letter to sponsor and CRO colleagues regarding the workforce retention and inflationary pressures affecting clinical trial sites, https://myscrs.org/workforce-challenges-letter/ (accessed 27 March 2023).
11. Rose S. Poaching, shallow personnel pool fuel dangerous site "talent drain." *ACRP*, https://acrpnet.org/2022/09/27/poaching-shallow-personnel-pool-fuel-dangerous-site-talent-drain/ (2022, accessed 27 March 2023).
12. Knapke JM, Snyder DC, Carter K, et al. Issues for recruitment and retention of clinical research professionals at academic medical centers: part 1—collaborative conversations un-meeting findings. *J Clin Transl Sci* 2022; 6(1): e80.
13. Pennell NA, Szczepanek C, Spigel D, et al. Impact of workforce challenges and funds flow on cancer clinical trial development and conduct. *Am Soc Clin Oncol Educ Book* 2022; 42: 1–10.
14. Congressional Budget Office. The budget and economic outlook: 2022 to 2032, https://www.cbo.gov/system/files/2022-05/57950-Outlook.pdf (2022, accessed 27 March 2023).
15. Cure Alzheimer's Fund. Stats & costs learn about the rate of occurrence, and costs, impacting the US, https://curealz.org/the-disease/stats-and-costs (accessed 27 March 2023).
16. Van Dyck CH, Swanson CJ, Aisen P, et al. Lecanemab in early Alzheimer's disease. *N Engl J Med* 2023; 388(1): 9–21.
17. Amorosi D. Cancer clinical research in crisis as staffing shortage hits "critical breaking point."*Hemonc Today*, 18 August 2022, https://www.healio.com/news/hematology-oncology/20220818/cancer-clinical-research-in-crisis-as-staffing-shortage-hits-critical-breaking-point (accessed 27 March 2023).
18. Sekers MA. COVID and the Cancer moonshot. *The Hill*, 15 February 2022, https://thehill.com/opinion/healthcare/594199-covid-and-the-cancer-moonshot/ (accessed 27 March 2023).
19. Shore C, Gee AW and Wizemann T. National academies of sciences, engineering, and medicine; health and medicine division; board on health sciences policy; forum on drug discovery, development, and translation. In: Shore C, Gee AW and Wizemann T (eds) *Envisioning a transformed clinical trials enterprise for 2030: proceedings of a workshop*. Washington, DC: National Academies Press (US), 2021.
20. Jones CT, Griffith CA, Fisher CA, et al. Nurses in clinical trials: perceptions of impact on the research enterprise. *J Res Nurs* 2022; 27(1–2): 50–65.
21. Health Resources & Services Administration. Workforce projections, https://data.hrsa.gov/topics/health-workforce/workforce-projections (accessed 27 March 2023).
22. Knapke JM, Jenkerson M, Tsao P, et al. Academic medical center clinical research professional workforce: part 2—issues in staff onboarding and professional development. *J Clin Transl Sci* 2022; 6(1): e81.
23. Roberts I. Women's work in UK clinical trials is undervalued. *Lancet* 2018; 392(10149): 732.
24. Fisher E, Thomas RS, Higgins MK, et al. Finding the right candidate: developing hiring guidelines for screening applicants for clinical research coordinator positions. *J Clin Transl Sci* 2021; 6(1): e20.
25. Ortiz J. Understanding time-to-hire in healthcare. *Apploi*, 14 January 2022, https://apploi.com/blog/hiring-tips/time-to-hire/ (accessed 27 March 2023).
26. National Academies of Sciences, Engineering, and Medicine. *The future of nursing 2020–2030: charting a path to achieve health equity*. Washington, DC: National Academies of Sciences, Engineering, and Medicine, 2021.
27. Baer AR, Zon R, Devine S, et al. The clinical research team. *J Oncol Pract* 2011; 7(3): 188–192.
28. NIH Data Book, https://report.nih.gov/nihdatabook/report/158 (2022, accessed 27 March 2023).
29. Buchanan DA, Goldstein J, Pfalzer AC, et al. Empowering the clinical research coordinator in academic medical centers. *Mayo Clin Proc Innov Qual Outcomes* 2020; 5(2): 265–273.
30. Clinical Trials.gov, https://www.clinicaltrials.gov/ct2/resources/trends (2022, accessed 27 March 2023).
31. ACRP Blog. Clinical trial complexity levels show unrelenting increase, https://acrpnet.org/2021/05/05/clinical-trial-complexity-levels-show-unrelenting-increase/ (2021, accessed 27 March 2023).
32. Passut C. Increasing protocol complexity requires adapting quality metrics tools. *CenterWatch*, 15 March 2021, https://www.centerwatch.com/articles/25462-increasing-protocol-complexity-requires-adapting-quality-metrics-tools (accessed 27 March 2023).
33. Miessler J. No end in sight for trial complexity, CSDD report reveals. *CenterWatch*, 17 January 2022, https://

cms.centerwatch.com/articles/25921-no-end-in-sight-for-trial-complexity-csdd-report-reveals (accessed 27 March 2023).
34. Parkins K and Hillman A. 2022 forecast: decentralised trials to reach new heights with 28% jump. *Clinical Trials Arena*, 14 December 2022, https://www.clinicaltrialsarena.com/analysis/2022-forecast-decentralised-trials-to-reach-new-heights-with-28-jump/ (accessed 27 March 2023).
35. ACRP Press Release. Rise of technology, decentralized clinical trials requires unprecedented transformation of clinical trial workforce, https://acrpnet.org/2020/08/06/rise-of-technology-decentralized-clinical-trials-requires-unprecedented-transformation-of-clinical-trial-workforce/ (2020, accessed 27 March 2023).
36. Hinkle ET. New jobs, skills needed for trial workforce shifting to decentralized model, experts say. *CenterWatch*, 26 October 2020, https://cms.centerwatch.com/articles/25071-new-jobs-skills-needed-for-trial-workforce-shifting-to-decentralized-model-experts-say (accessed 27 March 2023).
37. SCRS. Exploring the current clinical workforce, https://myscrs.org/resources/sites-now/exploring-the-current-clinical-workforce/ (2022, accessed 27 March 2023).
38. Tufts. To increase diversity in clinical trials, first increase staff diversity. *Tufts University School of Medicine*, 3 December 2021, https://medicine.tufts.edu/news-events/news/increase-diversity-clinical-trials-first-increase-staff-diversity (accessed 27 March 2023).
39. Causey M. NIH affirms importance of diversity in clinical trial workforce. ACRP, https://acrpnet.org/2021/10/19/nih-affirms-importance-of-diversity-in-clinical-trial-workforce/ (2021, accessed 27 March 2023).
40. ACRP. The clinical research profession is in the midst of a serious workforce shortage. *And the problem is getting worse*, https://acrpnet.org/acrp-partners-advancing-the-clinical-research-workforce/models-making-a-difference/ (2022, accessed 27 March 2023).
41. Jones CT, Lane A, Shah A, et al. The Un-meeting approach to stimulate collaborative adult learning: an application for clinical research professionals. *J Clin Transl Sci* 2021; 5(1): e162.
42. ACRP. Barriers to bridges: addressing the urgent need for a diverse, research-ready workforce within the clinical research profession, https://acrpnet.org/barriers-to-bridges-addressing-the-urgent-need-for-a-diverse-research-ready-workforce-within-the-clinical-research-profession/ (2022, accessed 27 March 2023).
43. Sonstein S, Seltzer J, Li R, et al. Moving from compliance to competency: a harmonized core competency framework for the clinical research professional. *Clin Res* 2014; 28: 17–23.
44. Sonstein SA and Jones CT. Joint task force for clinical trial competency and clinical research professional workforce development. *Front Pharmacol* 2018; 9: 1148.
45. Brouwer RN, Deeter C, Hannah D, et al. Using competencies to transform clinical research job classifications. *J Res Admin* 2017; 48(2): 11–25.
46. Deeter C, Hannah D, Reyes C, et al. Professional development for clinical research professionals: implementation of a competency-based assessment model. *J Res Admin* 2020; 51(2): 15–40.
47. Stroo M, Asfaw K, Deeter C, et al. Impact of implementing a competency-based job framework for clinical research professionals on employee turnover. *J Clin Transl Sci* 2020; 4(4): 331–335.