

Barriers to Bridges:

Addressing the Urgent Need for a
Diverse, Research-Ready Workforce
Within the Clinical Research Profession



WHITE PAPER

ACRP⁺

A Call to Action

INTRODUCTION

The clinical research profession is in the midst of a serious workforce shortage, and the problem is getting worse. This was the focus of a forum sponsored by the Association of Clinical Research Professionals (ACRP), in which thought leaders from across the clinical research spectrum came together to consider the likely reasons for this deeply concerning situation and how best to turn barriers into bridges.

“The projected growth of the clinical research industry is demanding a diverse, research-ready workforce that doesn’t exist today,” Susan Landis, Executive Director of ACRP, told the gathering of Partners Advancing the Clinical Research Workforce, an industry consortium established by ACRP to confront this formidable challenge. Right now, the clinical trial workforce is not keeping up with the workload, ultimately threatening to delay delivery of innovative treatments to patients who need them. “Now is the time to spotlight the key barriers and encourage radical ideas for change,” Landis stated.

So, what exactly underpins the struggle to boost the workforce? Lack of awareness of the clinical research profession as a career option is certainly one reason. However, the Partners group unanimously highlighted a second incontrovertible barrier: the default prerequisite for a specific number of years of experience—very frequently two years—in entry-level job descriptions. In essence, it’s a one-two punch or a double whammy: even if significant efforts are made to raise awareness of the profession—and the fulfilling career it offers—many of those who have been enticed by this prospect will end up falling at the first hurdle.

Put simply, entry level is often not really entry level. The paradox of “how can I get any experience until I get a job that gives me experience?” is the ultimate Catch-22 scenario. Of course, it is not unique to the clinical research profession, as others have illustrated.¹

When a profession is crying out for more people—and the consequences of a workforce shortage are potentially dire—the onus should not be on candidates themselves or their advocates to come up with strategies to play the system. Instead, the system should be fixed.

The urgent need for a fundamental “system fix” is further highlighted by the impact on those already in the profession and the organizations that employ them. When entry restrictions are too tight, there is a tug-of-war over existing employees, with employers offering more and more competitive packages and trying to outdo one another in the race to secure human resources. The result has been an alarming rate of churn in the profession, with serious adverse effects on organizational productivity, operational continuity, team building, and morale. Clinical research sites are reportedly experiencing the greatest drain on talent, as it’s well acknowledged that these providers function as the industry’s training ground for entry-level employees. In fact, the Society for Clinical Research Sites recently published an Open Letter highlighting this predicament.²

BARRIERS: A CLOSER LOOK

Lack of Awareness of Clinical Research as a Profession

Participants in the Partners gathering, who represent pharmaceutical sponsors, contract research organizations, sites, and leaders from clinical research support industries, noted that clinical research is generally not well known as a career option, especially among younger people about to enter the workforce. Although the COVID-19 pandemic—and the global mission to develop vaccines at record speed—raised awareness of the ability of science to solve big public health problems, the role played by the clinical research industry is still under-recognized.³ “Clinical research is not part of the STEM discussion,” said Danielle Coe, Founder and CEO of Black Women in Clinical Research, who called for a “big shift” to put clinical research firmly on the career radars of students and college advisers.

Other participants echoed Coe’s concern, calling for increased community outreach, new educational materials, and an overarching campaign designed to encourage new professionals and “lateral movers” (those considering a change of profession) to consider clinical research as a stimulating, rewarding, and versatile career choice.

Alongside the imperative to grow the workforce is the equally vital need to diversify it. Recent research from the Tufts Center for the Study of Drug Development⁴ found a statistically significant relationship between staff diversity and clinical trial participant diversity but reported that only 22% of respondents to a survey believed that staff diversity is a major factor for the success of clinical research. Education is needed throughout the profession about how staff diversity builds trust with under-represented demographic sub-groups whose participation in clinical research is imperative for understanding potential safety and efficacy differences in real-world populations. For this reason, initiatives specifically designed to attract particular ethnic groups into the profession should be actively pursued.

Ultimately, both strengthening and diversifying the workforce are imperative to the sustainability, quality, and reliability of clinical research now and in the future.

“Clinical research is not part of the STEM discussion.”

— **Danielle Coe**, Founder and CEO,
Black Women in Clinical Research



The “Two Years of Experience” Entry Requirement

Turning its attention to the requirement for two years of experience (or a similar specific number), the Partners group agreed that the urgent need for new recruits, juxtaposed with routine blocking of large numbers of applicants by this “tick box” prerequisite, is nothing short of sabotage. “We have to address this disconnect,” Leslie Wolfe, MHA, Director of US-Early Talent Program & Clinical Trial Coordinator Organization for Merck, asserted.

Many indications already exist that college graduates who have taken programs of study in clinical research and/or undergone dedicated internships would be eminently suitable entry-level candidates, whose experience and training could be further enhanced “on the job.” Yet, in the current hiring culture, they are often rejected and it’s very difficult to break through.

Notably, no robust evidence exists to show that the 2-year requirement *actually* produces a more effective clinical research workforce. It appears to be based on a supposition that has been perpetuated for decades without scrutiny. That’s not an acceptable situation at the best of times but, in the midst of an escalating workforce shortfall, it becomes truly pernicious.

- Questioning the justification for the requirement, Sarah Holloway, PhD, formerly with Kelly Science and Clinical and a co-chair of the Partners gathering, asked, “What is the purpose of the 2-year rule? What are we seeking to de-risk?”
- Calling it a “rigid, exclusionary barrier,” Sharleen Traynor, PhD, MPH, Fieldwork Coordinator/Instructor with the Clinical Trials Research Associate (CTRA) Program at Durham Technical Community College, said the self-imposed requirement means “we’re seeing a lot of well-qualified candidates not being considered.” She added that the simultaneous requirement for a bachelor’s degree further excludes potentially promising people, especially those with fewer financial resources. As in many other fields, communities of color tend to be impacted most.
- Jeanne Hecht, MBA, PMP, CEO of JTH Consulting, LLC, agreed. “We are leaving out some of the most innovative minds with this arbitrary minimum requirement,” she said. “Our industry must evolve and re-examine some of its archaic practices.”

“We are leaving out some of the most innovative minds with this arbitrary minimum requirement. Our industry must evolve and re-examine some of its archaic practices.”

— **Jeanne Hecht, MBA, PMP**
CEO, JTH Consulting, LLC



The group further noted the clinical trial industry’s lack of standardization and consistency with job titles, skill requirements, career paths, onboarding, and training represents yet another barrier for prospective candidates, and one that doesn’t always get much easier for those who manage to enter the profession. Jessica Fritter, MACPR, ACRP-CP, Clinical Instructor of Practice at The Ohio State University (and formerly with Nationwide Children’s Hospital), described the situation at entry-level as “horrendous” and Danielle Coe asked, “Can’t we manage to make this profession more welcoming?”

Where to Go from Here

Participants agreed that industry leaders must address the two key barriers—lack of awareness about clinical research as a profession and the 2-year experience stipulation—simultaneously in order to move the needle as quickly and effectively as possible.

**Raise awareness
of the profession**
+ address the diversity
challenge

**Rethink the 2-year
experience
requirement**

GROW & DIVERSIFY THE WORKFORCE

Of the two barriers, rethinking the 2-year requirement is by far the more challenging. In theory, there are two choices here:

- **EITHER:** research must be undertaken to justify the 2-year requirement—and if it proves justifiable, a highly visible and accessible pathway by which candidates can gain those two years of experience should be established;
- **OR:** the unproven 2-year requirement should be replaced with a valid and credible alternative, underpinned by objective evidence.

With the workforce crisis escalating rapidly, the group was unanimous that doing neither of these is not an option. When it came to choosing which of the two routes is the better one, they were united in their view that measuring experience in purely quantitative terms is outdated. Just as the credentials of a writer are never judged simply on the number of words or pages they produce, experience should be measured qualitatively, based on a set of well-articulated standards and competencies.

To address the identified barriers, the leaders of the Partners Advancing the Clinical Research Workforce consortium proposed four key strategic imperatives:

GRASSROOTS OUTREACH TO RAISE AWARENESS

In the absence of a well-funded national workforce development campaign, pursue a grassroots outreach effort to build awareness of clinical research as a profession through educational materials and motivational messaging.

DEFINE AND EMBED A NEW MEASURE OF EXPERIENCE

Define a new composite measure of experience to replace the 2-year requirement, building on the groundbreaking efforts of the Multi-Regional Clinical Trials Center's Joint Task Force for Clinical Trial Competency.⁵ This new measure of experience should also capture transferable skills for those making a lateral move from other professions.

ESTABLISH COMPETENCY-BASED TRAINING

Build upon the existing repository of clinical research training with a proven, competency-based educational program accessible to all in the industry that will help accelerate early talent onto study teams without sacrificing the quality or integrity of clinical trials.

SUPPORT NOVEL RECRUITMENT AND RETENTION INITIATIVES

Support organizations that are implementing novel and innovative methods to recruit new and diverse talent into the industry, including professionals whose skills align with the needs of clinical research who may be seeking a new career. In addition, share best practices regarding retention, including professional development opportunities such as certification.

EXISTING INITIATIVES UPON WHICH TO BUILD

“Ready, Set, Clinical Research!™” Awareness-Raising Toolkit

To address the need for awareness-raising about the clinical research profession, ACRP has launched a new toolkit entitled “Ready, Set, Clinical Research!™” with tailored versions for entry-level and “lateral movers.” The toolkit is designed for flexible use by career advisors, recruiters, employers, and other stakeholders with a vested interest in the growth and diversification of the clinical research workforce. The toolkit content showcases the “who,” “what,” “why,” and “how” of a career in clinical research, using carefully crafted, impactful messaging intended to influence both hearts and minds. Emotive, personal stories from patients and clinical research professionals are featured to emphasize the people-centered nature of clinical research, while a bold, contemporary design aims to foster a sense of excitement, inspiration, and curiosity. The toolkit also showcases the numerous routes into the profession and the wide spectrum of potential roles.



[Learn more at acrpnet.org/rscr](https://www.acrpnet.org/rscr)

Establishment of Competency Domains as a Basis for Measuring Experience

The Joint Task Force for Clinical Trial Competency, an international team of investigators, educators, and clinical research professionals spearheaded by the Multi-Regional Clinical Trials Center of Brigham & Woman’s Hospital and Harvard, has developed an authoritative framework of competency domains that objectively define the knowledge, skills, and attitudes necessary for conducting safe, ethical, and high-quality clinical research. These have been adopted and assimilated by ACRP as “core competencies” and represent a robust foundation for the collaborative development of a new, composite measure of experience to replace the 2-year requirement.

Once defined and validated, it will be imperative to achieve (a) recognition and buy-in across the industry; and (b) alignment on what this measure means in practice and how to implement it when assessing candidates. To minimize discrepancies in understanding and interpretation, ACRP is well placed to develop a comprehensive guide that reframes the principles for recruitment of clinical research professionals, alongside a “playbook” and user-friendly template for talent acquisition professionals and hiring managers that simultaneously encompasses the need for inclusivity and diversity.

This will comprise a major undertaking in its own right, but it will only be the beginning. Success will depend entirely on the collective commitment of the industry to adopt and embed these new principles. “The clinical research industry is in a workforce crisis which can only be solved by an immense collaborative effort,” ACRP’s Susan Landis stressed. “We need to harness the power of all your organizations. Core principles, standards, and tools can be provided, but you are the ones who understand how things work within your own organizations, where the pain points are, and what needs have to be addressed in order to drive adoption.”

“The clinical research industry is in a workforce crisis which can only be solved by an immense collaborative effort.”

— **Susan Landis**, Executive Director, ACRP



CASE STUDIES: BUILDING BRIDGES

The following section describes a range of innovative models and approaches that are enabling and facilitating the growth and diversification of the clinical research workforce. For more details, visit acrpnet.org/mmd

Training the Next Generation of CRCs

Angela Griffiths, PhD, Education Program Manager at the UC Davis Clinical and Translational Science Center’s Clinical Trials Office, shared a successful program that piloted an innovative and scalable clinical research coordinator (CRC) training program to grow and diversify the clinical research workforce and provide a re-training opportunity to under-resourced communities. This unique program combines classroom learning with workplace exposure to clinical research in order to train next-generation CRCs.

Effective Outreach to Latin American Populations

Michaele Linden Johnson, MBA, FACHE, Senior Director of Clinical Trials and Business Development for the Medical Center of the Americas Foundation, shared details of a program that effectively reached out to traditionally underserved Latinx populations in and around El Paso, Texas. “We have an opportunity to significantly increase Latino representation in clinical trials if we can grow a competitive infrastructure for tomorrow’s trials,” she told attendees, noting that the Latinx population represents nearly 20% of the US population but accounts for only 7% of the clinical trial patient population.

“We have an opportunity to significantly increase Latino representation in clinical trials if we can grow a competitive infrastructure for tomorrow’s trials.”

— **Michaele Linden Johnson, MBA, FACHE**, Senior Director of Clinical Trials and Business Development for the Medical Center of the Americas Foundation

Welcoming New Entry-Level Workers

Merck’s Leslie Wolfe shared successes from her company’s Early Talent Rotational Program, explaining how the Global Clinical Trial Operations-US organization recruited, trained, and developed inexperienced new graduates to launch careers in clinical research, in part by creating a new entry-level position that didn’t require two years of prior experience as defined by many other organizations.

The program effectively:

- Built a strong clinical research foundation to foster rapid promotion to various pathways and functional roles (e.g., clinical research associate, data manager, clinical scientist, regulatory affairs specialist).
- Expanded candidate recruitment to include non-intern, new graduates to build a more diverse candidate pool.
- Fostered collaboration with other departments to create similar early-talent programs.

Similarly, the Clinical Development Academy team at PPD,⁶ part of Thermo Fisher Scientific, helps recruit, hire, onboard, and develop select college graduates, early career individuals, and mid-level professionals with transferable skills, but who may have limited or no clinical research experience. The program is designed to ensure that these new workforce entrants are the most efficient and effective as possible and offers extensive training and support through a cohort approach, which includes professional networking opportunities, senior leadership mentoring and resources, and cohort collaboration.

Filling Vacancies, Reducing Attrition

Sharleen Traynor shared details of her successful Durham Tech Clinical Trials Associate curriculum, which leverages partnerships with hiring managers to bypass systemic barriers and create alternate paths, enabling more accurate matching of candidates to opportunities and providing education and practical skills training for entry-level roles. In Durham, the results were clear and positive, Traynor said, noting, “Candidates come in with a passion for clinical research and our program’s precision matching of candidates to roles empowered our partners to fill vacancies faster.”

Conclusion

The current approach to recruitment and retention of the clinical research workforce needs revolutionary re-thinking. The status quo is unsustainable. A great innovator, Marie Curie, said, “It is not the practical men, but the dreamers who create new paradigms. While hard facts define today, new value is created only when the impossible becomes possible.” We can only make the impossible possible if we work together. In the interests of a thriving and vibrant workforce—ready to meet today’s high demand for clinical research and ultimately serve the medical needs of millions of people—let’s work together toward a more insight-driven, more modern, more enlightened approach to hiring people in our industry. Let’s start a movement. Let’s do it now.



References

1. <https://www.themuse.com/advice/what-to-do-when-entrylevel-positions-need-two-years-of-experience>
2. <https://myscrs.org/workforce-challenges-letter/>
3. https://acrpnet.org/wp-content/uploads/dlm_uploads/2022/04/COVID-19.pdf
4. <https://medicine.tufts.edu/news-events/news/increase-diversity-clinical-trials-first-increase-staff-diversity>
5. <https://mrctcenter.org/clinical-trial-competency/>
6. <https://vimeo.com/729316336/027768278a>

ACRP established the Partners Advancing the Clinical Research Workforce consortium to convene industry leaders in an unprecedented collaborative effort to identify imaginative and disruptive ways to build the clinical research workforce of the future. Learn more at acrpnet.org/pacrw