

FROM CAREER BY CHANCE TO PROFESSION BY DESIGN

*Building a Research-Ready Clinical Research
Professional Workforce in the U.S.*



Association of Clinical Research Professionals (ACRP)



This paper was developed from a multi-stakeholder workforce development symposium convened by the Association of Clinical Research Professionals (ACRP), with support from the National Center for Advancing Translational Sciences (NCATS) of the National Institutes of Health (NIH) under Award Number R13TR005703. Symposium participants represented a broad cross-section of the clinical research ecosystem, including sponsors, clinical research organizations (CROs), sites, academic thought leaders, educators, regulators, and professional organizations. The reflections synthesized here capture an emerging cross-sectoral consensus about the cultivation and sustainability of the clinical research workforce of the future.

“There is no greater leverage point to advance clinical trial quality for tomorrow than a deep and strategic investment in the clinical research workforce of today.”

– **David Burrow**, PharmD, JD, U.S. Food and Drug Administration

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INTRODUCTION

Clinical research has become more technologically sophisticated, operationally complex, and heavily scrutinized than at any point in its history. Expectations surrounding participant protection, digital literacy, trial execution, data integrity, and audit readiness continue to intensify.¹ In June 2026, the U.S. Department of Health and Human Services reinforced the strategic importance of the sector through the launch of Operation Trialblazer,² a cross-agency initiative designed to accelerate U.S. clinical trials in response to growing global competition, especially from China. Against this backdrop, it is striking that the workforce responsible for delivering U.S. clinical research continues to develop in a comparatively informal and inconsistent manner.

Too often, careers in clinical research are shaped by chance and circumstance, with many professionals reflecting that they “fell into it” rather than purposefully choosing it. In essence, clinical research has functioned less like a recognized profession with defined pathways into practice and more like a hidden labor market dependent upon transferability, improvisation, and experience accumulated opportunistically over time.

This scenario is becoming increasingly unsustainable. The sector continues to face significant workforce shortages and escalating turnover, with serious implications for research capacity, quality of practice, and regulatory compliance.³ Despite years of warnings from independent research sites and academic thought leaders, most employers within the clinical research enterprise continue to compete for a finite pool of experienced personnel rather than investing in a new talent pipeline through rethinking and modernizing hiring strategies. Essentially, talent is being continuously re-distributed, rather than expanded and cultivated.

The situation is reminiscent of the U.S. manufacturing workforce crisis of the early 2000s, where serious capacity issues received inadequate attention, ultimately contributing to a growing dependence on manufacturing capability abroad, particularly in China.⁴ While clinical research operates within a different context, the cautionary lesson is clear: talent pipelines cannot be rebuilt overnight once they have been allowed to erode.

CAREER ENTRY vs RESEARCH-READINESS

Currently, employers routinely seek “research-ready” candidates without acknowledging the absence of explicit pathways through which aspiring professionals may become research-ready in the first place—or even considering what “research readiness” may mean for the role in question. In many organizations, hiring has become less an exercise in identifying future professionals than in locating individuals who can immediately absorb operational pressure. This creates a structural tension between short-term operational demands and the long-term developmental needs of a maturing profession.

Professions are not built solely in response to operational need. They are built through shared identity, professional standards, intentional developmental pathways, and a common sense of purpose. The notion that the Clinical Research Coordinator (CRC) role, for example, is primarily transactional or task-based is increasingly outdated. Today’s CRCs require not only technical proficiency, but also foundational knowledge, critical thinking, sound judgment, interpersonal skills, adaptability, and resilience.

Recognizing these realities, the Association of Clinical Research Professionals (ACRP) and its Partners Advancing the Clinical Research Workforce™ (PACRW) are spearheading a multi-stakeholder, cross-sector collaboration to define

clear and accessible pathways into clinical research careers. The collaboration seeks to cultivate individual potential, minimize unnecessary barriers to entry and progression, and strengthen the professional identity of the workforce, with the ultimate aim of safeguarding clinical research for those who take part in it and for society as a whole.

At the heart of this initiative is a shared conviction that Clinical Research Professionals should be defined and developed as members of a distinct profession. It also recognizes that the future sustainability of clinical research depends upon separating two concepts that have too often been conflated: suitability for entry into the profession and readiness to perform specific research functions. This distinction is pivotal.

Historically, prior experience has been the dominant gatekeeper into clinical research roles. Experience is frequently treated as shorthand for competence, reliability, and professionalism. Yet experience alone is an increasingly unsuitable hiring standard. It privileges those who have already found a way into the system, excludes individuals who may possess exceptional potential or valuable transferable skills, and perpetuates a labor market that simply recycles existing talent. Moreover, experience is an unreliable proxy for future performance. Measured in

years of tenure rather than demonstrated competence, it offers little assurance of adaptability, learning agility, or long-term success. Indeed, experienced hires may also require an element of “unlearning” as they adapt established habits acquired in different organizational or operational environments. As clinical research continues to evolve rapidly, the qualities that matter most increasingly include the capacity to learn, adapt, and grow.

The conversations underpinning this work repeatedly returned to the idea that the profession should recruit primarily for potential and cultivate technical competence through structured development. In this model, entry into clinical research should be based upon a combination of human attributes, transferable skills, and developmental potential. Attributes such as integrity, accountability, intellectual curiosity, critical thinking, adaptability, empathy, professionalism, communication, and resilience are fundamental. Equally important are transferable skills acquired through education, employment, or lived experience, including project coordination, customer or patient engagement, problem-solving, digital literacy, and teamwork. These capabilities frequently translate successfully into the requirements of clinical research roles.

This distinction between “on-ramping” and “research readiness” is central to the emerging philosophy of workforce development. On-ramping concerns an individual’s suitability for entry into the profession, based on the attributes, transferable capabilities, and potential to grow successfully within it. Research readiness, by contrast, concerns the development of the knowledge, skills, and confidence required to perform research responsibilities competently.

The implications are significant. A profession that hires only those who are already fully formed inevitably narrows its own future. Such individuals risk being anchored to their past experiences and not ready for field led by dramatic medical and technological innovation. By contrast, professions that intentionally identify potential and cultivate competence create sustainable pipelines, broader accessibility, more robust workforce composition, and greater adaptability for a fast-moving future.

MULTIPLE PATHWAYS INTO THE PROFESSION

“This is a profession we need to care for and nurture. It needs and deserves explicit pathways for aspiring new members that map out both entry and progression, so it is truly seen as a career.”

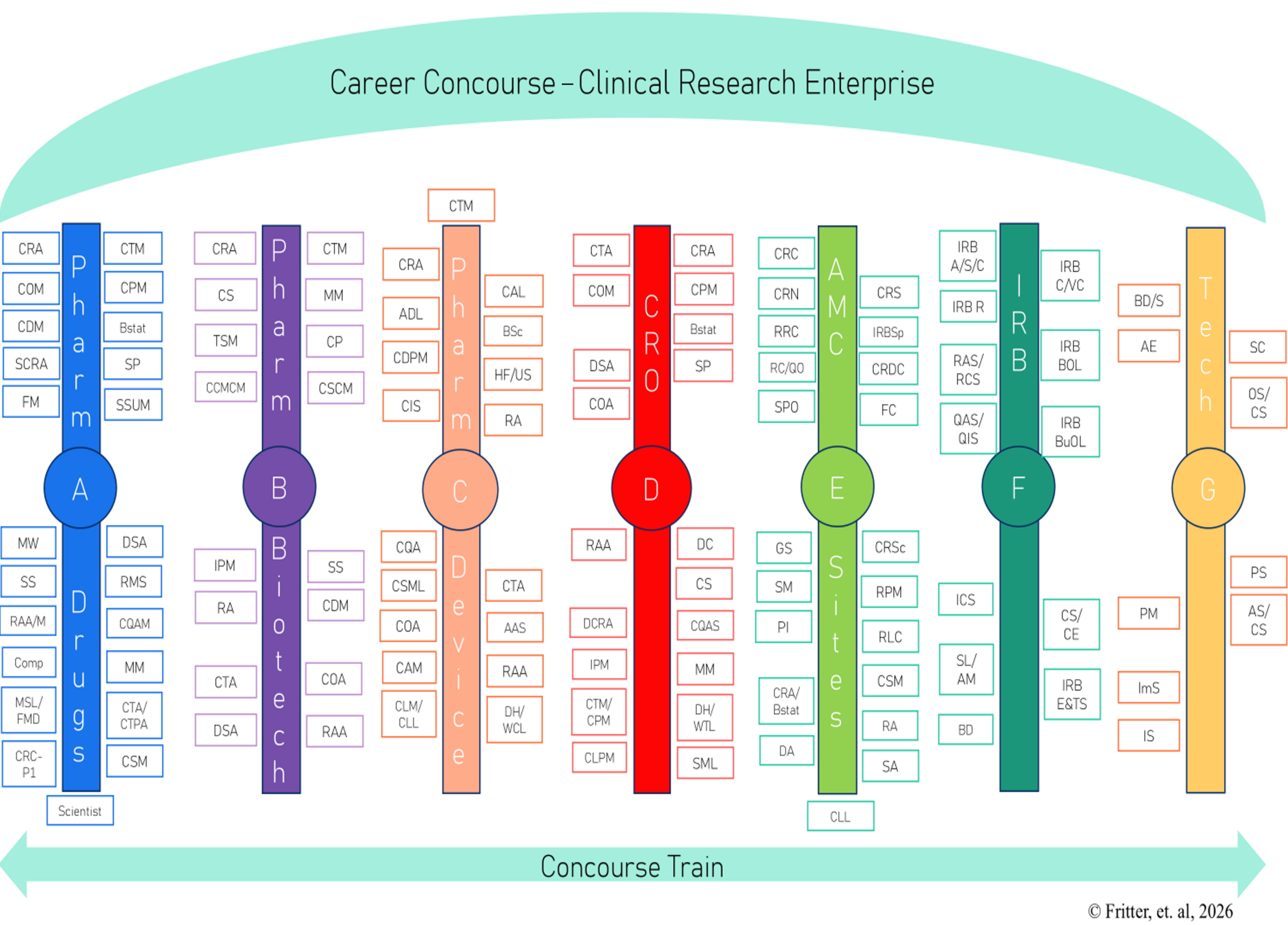
– **Barbara Bierer, MD**, Harvard School of Medicine; Harvard Clinical and Translational Science Center; Multi-Regional Clinical Trials Center of Brigham and Women’s Hospital

This way of thinking also changes how entry into clinical research is imagined. Rather than assuming a single linear pathway, the profession begins to recognize multiple legitimate routes into practice. Some individuals may enter directly from high school or college with curiosity, discipline, and growth potential but little practical exposure. Others may transition laterally from healthcare professions such as nursing or medical assisting, bringing patient-centered experience and operational maturity. Still others may arrive from

technology, data science, or operational backgrounds as digital systems and artificial intelligence increasingly reshape the infrastructure of clinical research. What unites these individuals is not sameness of background, but suitability for the profession.

This perspective reframes the profession as intentionally pursued rather than discovered by chance. It also challenges the assumption that professional identity must begin only after technical specialization has occurred. For many participants in the discussions informing this paper, medical assistants emerged as particularly strong examples of individuals whose existing capabilities translate naturally into clinical research coordination and participant-facing work. Similarly, early-career entrants often demonstrated precisely the adaptability, curiosity, and growth orientation required for long-term development within the field, even when they lacked formal research exposure. The profession therefore benefits not from narrowing entry, but from recognizing transferable human capability across diverse backgrounds.

Figure 1: The Clinical Research Career Concourse Model⁵



Rather than a single linear ladder, clinical research careers may be envisaged as a transport network or airport concourse system (Figure 1).

The “concourse train” under the “career airport” is the way individuals may travel forward in their careers from one concourse to the other, or within a concourse.

Factors that influence progression from one job category or within a job category include: education, experience, specialized training, certifications, individualized development planning, mentoring, passion drivers, and scholarship.

Individuals may enter the profession at different points depending on their backgrounds, experiences, and transferable capabilities. Some may begin with foundational learning and gradually develop specialization over time. Others may arrive with existing healthcare, technical, or operational expertise and therefore “board farther along the route.” What matters is not the starting point but shared professional foundations. The wide variety of roles and settings within this profession also provides numerous opportunities for career development within and between role categories.

Learn more about this model in “From Mapping Your Pathway to Traversing a Career.” Job descriptions for all roles found in this model can be found [here](#).

FOUNDATIONAL EDUCATION

Table 1: Key components of role-agnostic foundational education in clinical research

Ethics • Ethics principles and human subject protection • International Council for Harmonization—Good Clinical Practice (ICH-GCP)
Science • Medicines development • Disease understanding • Scientific method • Statistics
Data and Operations • Health Insurance Portability and Accountability Act (HIPAA) • Data integrity principles such as ALCOA (Attributable, Legible, Contemporaneous, Original, Accurate) • Operational concepts including specimen handling and transport (e.g., International Air Transport Association (IATA))

Importantly, this perspective does not diminish the importance of education and training. On the contrary, it elevates them. If the profession is to reduce unnecessary barriers to entry, it must also assume greater responsibility for the intentional development of competence. Research readiness cannot simply be demanded from the workforce; it must be cultivated. The discussions also highlighted that responsibility for workforce development cannot rest with any single stakeholder group. Sponsors, CROs, sites, academic institutions, and professional organizations all benefit from a stable and capable workforce, yet investment in early talent development remains unevenly distributed across the ecosystem. Sustainable workforce formation will likely require more explicit models of shared responsibility and shared investment.

There was broad recognition throughout the development of this paper that, across the enterprise, individual sponsors, CROs, academic medical centers, independent sites, and technology organizations all operate within different realities and maintain different expectations of incoming staff. Even identical job titles frequently conceal substantial differences in responsibility and scope. Nevertheless, considerable alignment emerged around the value of role-agnostic foundational learning that can support entry into the profession without becoming a rigid prerequisite or exclusionary gatekeeping mechanism. Exposure to the

key principles of ethics, medicines development, scientific method, Good Clinical Practice, therapeutics, data and statistics, and quality management can provide important conceptual grounding even before role-specific specialization begins.

Table 1 shows a more detailed list of the ideal components of foundational education.

Such preparation should be understood not as a professional ceiling, but as a springboard. The underlying principle repeatedly articulated throughout the discussions was one of “opportunities, not barriers.” Costly pre-employment credentials, inflexible educational expectations, or excessive standardization may ultimately narrow rather than expand the pipeline. Clinical research cannot solve one workforce problem by creating another. The more sustainable model is therefore one in which foundational education serves not as a pre-requisite, or filter, but as an enabler. Academic credentials specific to clinical research should be recognized by employers as a meaningful indicator of commitment, capability, and preparedness. There is little logic in valuing an unrelated four-year academic degree more highly than a focused clinical research qualification that provides directly relevant preparation for the profession.

DEFINING THE CLINICAL RESEARCH PROFESSIONAL

This understanding was also shaped by reflection upon how mature professions define themselves. Inspiration was drawn from the manner in which the American Nurses Association defines nursing—not as a collection of technical tasks, but as a professional practice grounded in ethical responsibility, scientific knowledge, advocacy, and societal contribution. The significance of that model lies not in its wording alone, but in its philosophy. It defines a profession through purpose, accountability, and human responsibility rather than operational function. Clinical research increasingly requires a similarly mature articulation of identity.

The following working definition emerged from this effort:

A Clinical Research Professional is a qualified professional who, through the application of specialized knowledge, ethical principles, and professional judgment, protects the rights, safety, and well-being of research participants; ensures the ethical and scientifically rigorous conduct of clinical studies; and contributes to the generation of trustworthy evidence to advance health for individuals and populations.*

*Ancillary roles like receptionist, interpreter, and patient navigator are not included in this definition.

The importance of this definition lies not simply in the language itself, but in what it attempts to establish. It avoids limiting the profession to specific job titles or employer settings and instead recognizes the broader responsibilities that unite the workforce across sectors. It seeks to balance scientific rigor with human responsibility while framing clinical research as work performed in service of participant welfare, public trust, and the advancement of health.

A profession cannot mature without a coherent understanding of who belongs to it and what obligations accompany that identity. Defining the Clinical Research Professional therefore becomes more than a semantic exercise. It becomes an act of professional recognition.

REIMAGINING CLINICAL RESEARCH PROFESSIONALIZATION

This thinking ultimately gave rise to a new conceptual framework for clinical research professionalization (Figure 2).

- At the base of the pyramid sits the profession itself, anchored by shared ethical responsibility, scientific integrity, participant protection, and public trust.
- From this foundation emerge the human attributes, characteristics, and transferable skills that make individuals well suited to a career in clinical research.
- Aspiring professionals with the right attributes may arrive via different entry points and career stages.
- Where available, access to role-agnostic foundational education in clinical research serves as an important enabler, providing both conceptual grounding and career focus.
- Only after this common foundation does the model narrow toward role-specific specialization and advanced training, much of which may be best acquired in the workplace.

The order is significant: the profession comes first; roles come later. Like a tree with shared roots, a common trunk, and many specialized branches, clinical research is a single profession encompassing a multitude of roles.

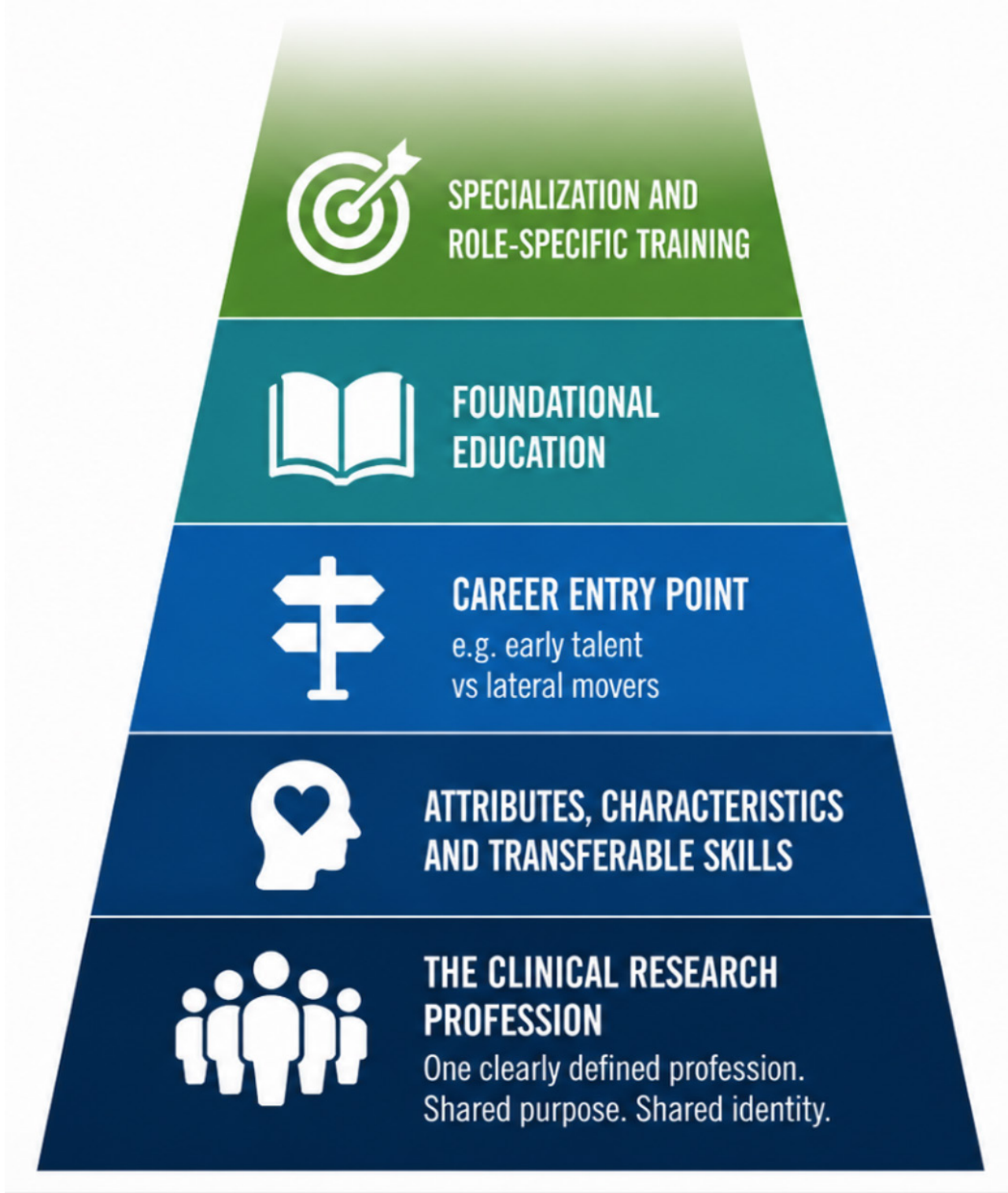


Figure 2: Conceptual framework for clinical research professionalization

This concept represents a meaningful departure from the historical approach to workforce development in clinical research. Individuals do not begin as isolated operational functions. They begin as future professionals who subsequently develop specialization within a broader professional identity.

CONCLUSION

Ultimately, the future of clinical research depends not only upon technological advancement, operational efficiency, or regulatory sophistication, but upon the people entrusted to carry out the work. The enterprise will continue to evolve. Artificial intelligence will reshape workflows. Roles will shift. Organizational structures will continue to fragment and reform. Yet the profession will still depend upon individuals capable of ethical judgment, scientific reasoning, adaptability, accountability, and human connection to evaluate the safety, efficacy, and risk/benefit profiles of potential new medical therapies.

The challenge ahead is therefore not simply to fill vacancies, but to build a profession: one with visible pathways, intentional development, shared standards, and a stronger sense of identity than the field has historically possessed. Creating such a profession requires a fundamental shift in how workforce development is understood. Rather than relying primarily upon prior experience as a proxy for competence, the sector must become more deliberate in identifying potential, recognizing transferable skills, valuing relevant education, and cultivating research readiness through structured development.

Emerging workforce development models underscore the critical contribution of academia as a foundational partner: not only universities and colleges but also high schools, where awareness, career identity, and exposure to clinical research as a visible, purposeful, and socially important profession can begin to take root. Importantly, career entry represents only the beginning of professionalization. Career progression—which requires its own explicit pathways—is equally important for ensuring that the clinical research profession can retain and grow the talent it attracts and provide the lifelong learning necessary for a field of rapid innovation.

The question we face today is no longer whether clinical research requires a dedicated, recognizable profession. It is whether the enterprise is prepared to invest—intentionally and collaboratively—in building one.

ABOUT ACRP

From new Clinical Research Professionals just starting out to industry veterans who are looking for ways to move ahead in their career, the Association of Clinical Research Professionals (ACRP) is where success starts—and grows. With more than 22,000 global members, ACRP is the strongest advocate for Clinical Research Professionals—amplifying their voice throughout the research industry and elevating their position by providing gold-standard education, rigorous certification, and strong community connections.

Learn how ACRP’s Partners Advancing the Clinical Research Workforce™ (PACRW) is committed to building a representative, research-ready clinical research workforce that advances therapies to improve global human health.



Learn more at
acrpnet.org/advocacy

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- **Stephanie Freel**, PhD, Director, Clinical Research Operations, Education & Outreach, Duke Office of Clinical Research (DOCR); Director, Strategy & Innovation, Duke Clinical and Translational Science Institute (CTSI); Adjunct Assistant Professor, Pediatrics
- **Jessica Fritter**, DHSc, MACPR, ACRP-CP, FACRP, Associate Clinical Professor, Director, Master of Clinical Research & Certificate Programs, The Ohio State University
- **Jared Kerr**, JD, MPH, Clinical Associate Professor, Clinical Research Graduate Program Coordinator Clinical Research Program, College of Health and Human Services, University of North Carolina Wilmington
- **Tracie Locklear**, PhD, Research Assistant Professor, Department of Pharmaceutical Sciences; Program Lead, Clinical Research Sciences, Biomanufacturing Research Institute and Technology Enterprise (BRITE), North Carolina Central University
- **Kate Marusina**, PhD, MBA, Director, Research Staff Workforce Development and Resource Innovation, Clinical and Translational Science Center, UC Davis School of Medicine
- **Denise Snyder**, MS, RD, LDN, FACRP, Associate Dean for Clinical Research, Duke Office of Clinical Research (DOCR)

- **Kathleen O’Malley**, RN, BSN, CCRP, Director of Education and Training, Jefferson Clinical Research Institute, Thomas Jefferson University
- **Stephen Sonstein**, PhD, Consultant, MultiRegional Clinical Trials Center, Harvard University
- **Sharleen Traynor**, PhD, MPH, Clinical Research & Public Health Educator; Epidemiologist, Durham Technical Community College

Symposium Attendees

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- **Kara Bastarache**, Senior Manager, Workforce Development, ACRP
- **Catherine Barnes**, MS, Program Manager, Workforce Development, UNC Chapel Hill
- **Ruma Bhaghat**, MPH, Executive Director, Global Health Equity Population Sciences, Roche | Genentech
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- **Elizabeth Edwards**, Senior Vice President, Clinical Operations, Parexel
- **Jessica Fritter**, DHSc, MACPR, ACRP-CP, FACRP, Associate Clinical Professor, Director, Master of Clinical Research & Certificate Programs College of Nursing, The Ohio State University
- **Judy Galindo**, CCRC, MAS, Executive Director/Co-owner; Co-Founder Sun Valley Research Center, Inc.; Latinos in Clinical Research & Save Our Sites
- **Morgan Hanger**, MPP, Executive Director, Clinical Trials Transformation Initiative (CTTI)
- **Karen Hartman**, MSN, Vice Chair, Research Administration, Mayo Clinic
- **Samantha Hayes**, Cluster Head (North America) - Clinical FSP, Fortrea
- **Lesley Heckaman**, Human Resources Director, AMR Research
- **Amy Henderson**, Vice President, Clinical Operations, Paradigm Research
- **Jared Kerr**, JD, MPH, Clinical Associate Professor, Clinical Research Graduate Program Coordinator, UNC Wilmington
- **Susan Landis**, Chief Executive Officer, ACRP
- **Karen Lipworth**, Senior Writer, ACRP
- **Kathleen O'Malley**, RN, BSN, CCRP, Director of Education and Training, Jefferson Clinical Research Institute; Thomas Jefferson University
- **Heather O'Neal**, Director of Learning and Development, AMR Research
- **Tracy Parker**, MBA, EdD, Vice President, Managing Director, IQVIA
- **Debra Pritchett**, Director, Emerging Talent, Merck
- **Kathryn Robison**, Executive Director, Human Resources, Javara Research
- **Erica Rosemond**, PhD, Deputy Director, Division of Clinical Innovation, NCATS
- **Michelle Rowe**, RN, Vice President, Research, HCA Healthcare
- **Jennifer Sheller**, MPH, ACRP-CP, Senior Vice President and Head, Global Clinical Trial Operations (GCTO), Merck
- **Ann Shirriffs**, Vice President, Human Resources, Velocity Clinical Research
- **Denise Snyder**, MS, RD, LDN, FACRP, Associate Dean of Clinical Research, Duke Office of Clinical Research
- **Steven Sonstein**, PhD, Consultant, Multi-Regional Clinical Trials Center, Harvard University
- **Sharleen Traynor**, PhD, MPH, Clinical Research & Public Health Educator; Epidemiologist, Durham Technical Community College
- **Elizabeth A. Williams**, PhD, RN, Assistant Professor, Clinical Research Sciences, Department of Pharmaceutical Sciences, North Carolina Central University

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