Addressing the Clinical Research Workforce Crisis:
A Call for Collective Action

WHITE PAPER

ACRP

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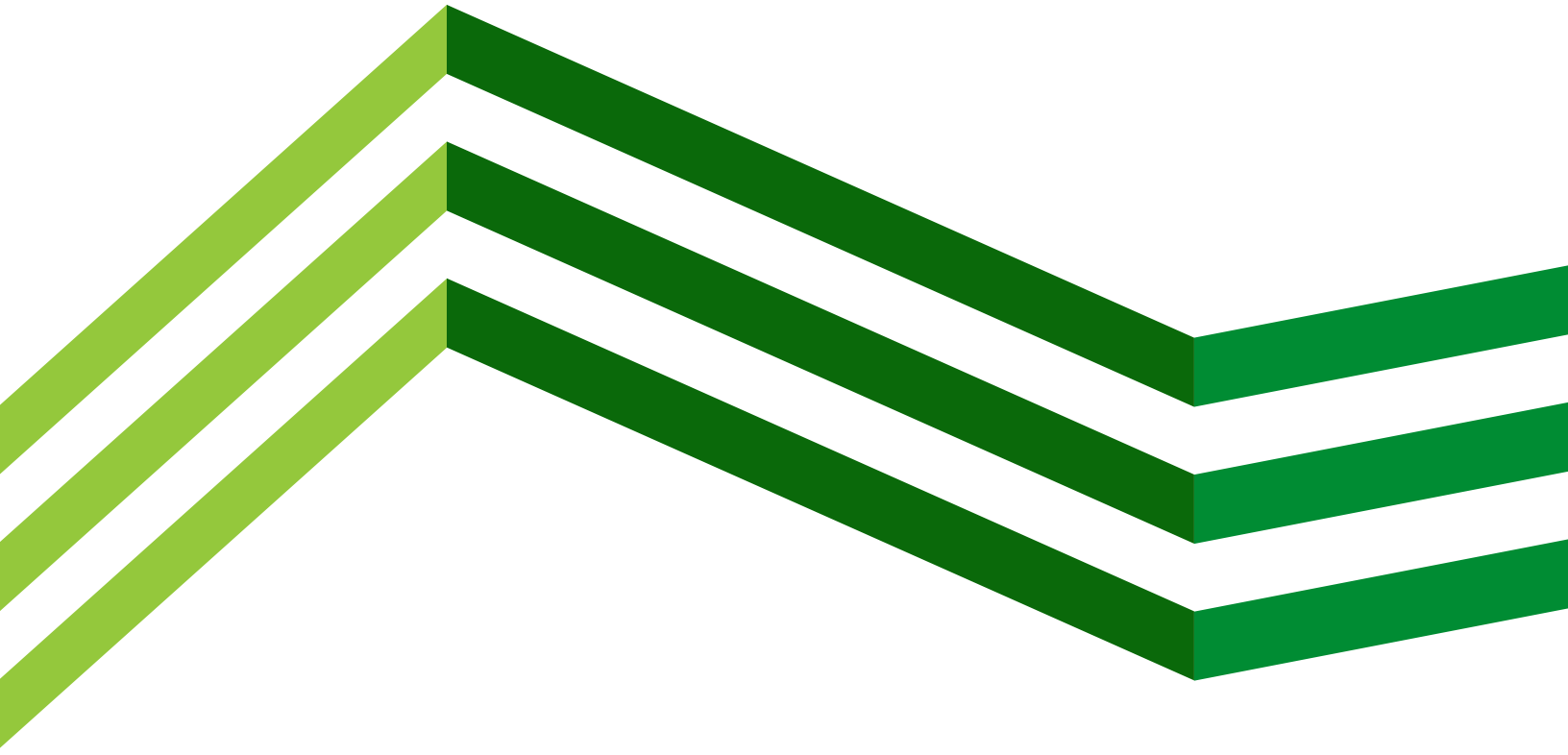


EXECUTIVE SUMMARY

Across the life sciences ecosystem, thought leaders are devising bold new missions to transform the design and conduct of clinical research. To keep up with accelerations in discovery science, clinical research—the "evidence generation system" that brings innovative treatments to people who need them—must achieve new heights of quality, speed, and participant diversity. Largely overlooked is an area that may make or break the success of these missions: the global clinical research workforce itself. Currently, this workforce is profoundly depleted, unable to meet escalating demands, and poorly representative of the patient communities it serves. Unless the workforce crisis is addressed as a matter of priority, all the grand ambitions and aspirations for the future of clinical research will simply keep stalling.

The ACRP Partners for Advancing the Clinical Research Workforce™ (PACRW) is a multi-disciplinary, cross-sectoral consortium that aims to promote and nurture the development of a robust, diverse, sustainable, and research-ready workforce, equipped to meet expectations for quality and efficiency in clinical research, now and in the future. Member organizations—including sponsors, contract research organizations (CROs), investigator sites, academic institutions, regulatory agencies, and more—provide strategic direction and support for breaking down barriers and building bridges for entry into the clinical research profession through key initiatives.

ACRP's 2022 white paper, *"Barriers to Bridges,"*[1] called for "revolutionary re-thinking." This was followed in 2023 by an academic publication *"Now is the time to fix the clinical research workforce crisis,"*[2] (referred to from now on as *"Time to Fix,"*) which quantified the problem, provided a forensic analysis of its root causes, and called for systemic, multidisciplinary collaboration to address it.

The aim of this new white paper is to build on our previous publications with a strong focus on solutions. It sets out a vision of how to integrate a constellation of solutions into a coherent, holistic framework, comprising a blueprint for collaborative effort. Significant foundational work has already been done, tactical models have been piloted, and momentum is building. The opportunity is ripe for industry stakeholders to join forces and get on board, for the benefit of the entire clinical research enterprise.

KEY IMPERATIVES ARE:

- **Skills-first hiring:** Embrace a new hiring model for aspiring clinical research professionals based on skills and competences, rather than on academic degrees or years of experience.
- **Access and advancement:** Support access into, and advancement in, a clinical research career.
- **Site support:** Support sites—the bedrock of clinical research and de facto training ground for clinical research professionals—by finding ways to make them rewarding places to work.

Without urgent collective action, clinical research will rapidly become an unsustainable bottleneck in research and development (R&D) agendas and a roadblock to medical progress.

EXPECTATION—AND REALITY

Scientific innovation is on a phenomenal upward trajectory. In the past year alone, transformative medical breakthroughs were made in several areas of significant unmet need facing previously intractable challenges. As drug discovery opens yet more leads, the demand for clinical trials will escalate. In a seminal paper published in early 2023, then U.S. Food and Drug Administration (FDA) Commissioner Robert M. Califf highlighted that, while discovery science is in its ascendency, the clinical research enterprise lags, requiring "a major reformation" to efficiently translate invention into implementation.[3]

In June 2023, the FDA released draft guidance aimed at modernizing the design and conduct of clinical trials in order to improve speed, efficiency, patient centricity, cost-effectiveness, and the incorporation of technological innovation, including digital wearables and artificial intelligence (AI).[4] The European Medicines Agency (EMA) has articulated similar objectives with the launch of its bold new venture, ACT EU (Accelerating Clinical Trials in the European Union).[5]

These new initiatives—and many others springing up across the industry (several examples for the U.S. alone are shown in the chart below)—highlight universal recognition of the urgent need to revolutionize the clinical research "machine" to minimize bench-to-bedside latency and propel new scientific advances into the clinic.

These ambitious imperatives still appear to take it for granted that, in the brave new world of clinical research, there will always be enough qualified, motivated people available to run studies. Yet, as things stand, nothing could be further from the truth. As we state in *"Time to Fix,"* "…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."[2]

TABLE 1. Examples of Recent U.S. Initiatives Designed to Accelerate and Modernize Clinical Research

Advanced Research Project Agency for Health (ARPA-H)	To improve the U.S. Government's ability to speed up biomedical and health research
The Consolidated Appropriations Act 2023 (H.R. 2617)	An omnibus appropriations bill, which includes the Food and Drug Omnibus Reform Act of 2022 (FDORA), with several provisions intended to promote representation in clinical trial enrollment, encourage the growth of decentralized clinical trials, and streamline clinical trials
The NIH Clinical Trial Diversity Act 2023	Legislation that sets out requirements to increase the representation of clinical trial participants and requires other activities to foster participation in clinical trials
NASEM'S "Envisioning a Transformed Clinical Trial Enterprises for 2023"	Vision for a transformed clinical trials enterprise for 2030 with key priorities
The U.S. FDA Digital Health Technologies for Remote Data Acquisition in Clinical Investigations Guidance (Dec 2023)	Recommendations on the use of digital health technologies to acquire data remotely from participants in clinical investigations that evaluate medical products
The Clinical Trial Modernization Act 2024	Introduced in May 2024 by Congressman Raul Ruiz, MD (D-CA) and Congressman Larry Bucshon, MD (R-IN) to improve participation in clinical trials by underrepresented populations
The Communities Advancing Research Equity (CARE) for Health	A $30 million initiative launched by NIH for fiscal years 2024 and 2025 which aims to improve health outcomes by integrating research into primary care settings

THE GLOBAL CLINICAL RESEARCH WORKFORCE CRISIS

Across the world, a shortage of qualified clinical research professionals—particularly those who are site-based—has become more and more evident. The shrinking workforce has created a fierce "war for talent," characterized by overt poaching of staff and unsustainable levels of turnover.[2] In a nationwide survey of oncology clinical research professionals, 80% reported staff shortages at their centers, which were negatively impacting virtually all aspects of clinical research. The authors of the study comment that, unless these challenges are resolved, people with cancer will find access to clinical trials delayed or restricted, which, they state, would "be a stark and preventable inequity."[6]

The symptoms and underlying causes of the crisis are analysed in detail in *"Time to Fix."*[2] In essence, the clinical research profession has, for decades, lacked identity, recognition, and public awareness, with no centrally funded training programs, no mandatory educational qualifications, and no established pathways for career entry or advancement. Site-based staff are expected to devote almost 100% of their time to billable studies, leaving no opportunity for personal professional development or mentoring. The responsibilities involved in these roles also closely reflect the types of job that, according to a recent survey, are most likely to lead to burnout.[7] With regard to career entry, an archaic hiring preference for two (or four) 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.[2] Where experience is not mandated, it is often replaced by a requirement for a four-year academic degree, even if in an unrelated field, overlooking candidates who have undertaken an educational course specifically for aspiring clinical research professionals.

This crisis—which is already having a profound impact—is likely to intensify. The number of clinical trials registered worldwide is escalating sharply and shows no signs of slowing. In addition, trial designs are becoming more complex and there is a surging expectation for decentralized and hybrid models powered by innovative new technology, such as telemedicine and patient wearables, which has created new requirements for specialist skills.[2]

Figure 1. The Clinical Research Workforce Crisis: Scale of the Problem and Why It's Set to Get Even Worse

THE SCALE OF THE PROBLEM

Unprecedented rates of experienced staff leaving the profession

- For clinical research professionals with a 5- to 10-year tenure, the resignation rate in 2022 was 60% higher than in 2020.

Demand for new applicants vastly outstripping supply

- Clinical research coordinators: 7x more vacancies than jobseekers
- Clinical research nurses: 10x more vacancies than jobseekers
- Regulatory affairs professionals: 35x more vacancies than jobseekers

Unsustainable levels of turnover

- Compared to only a few years ago, staff turnover at site networks has approximately doubled reaching 35% to 61%

Lack of diversity

- Low percentage of traditionally under-represented demographic groups.

WHY IT WILL INTENSIFY

Exponential growth in registered clinical trials

- The number of clinical trials registered worldwide has risen exponentially in the last 25 years, from approximately 2,000 to almost 500,000.

Increasing protocol complexity

- Data points collected in Phase III trials have risen threefold over the past decade.

Increasing expectation for familiarity with latest technology

- In 2022, demand for decentralized clinical trials rose by 28% compared to previous year and almost 30% of new job posting deviated from traditional clinical research roles.

Twenty years ago, an academic paper about the role of clinical research coordinators (CRCs) was given the title: *"The invisible hand of clinical research."*[8] One of its authors, Benjamin Wilfond, a professor at the University of Washington School of Medicine, recently commented that, since CRCs clearly play a vital role in the conduct of trials, it's imperative that the "invisible hand" must now be made visible.[9]

To rejuvenate the depleted workforce and equip it to meet the challenges of the future, the clinical research professional enterprise must be elevated into the spotlight and transformed into a desirable and rewarding career choice. Critically, the workforce must also reflect its community members. Strong evidence shows that study sites with diverse personnel do a better job of recruiting trial participants from underrepresented groups, helping to ensure that trial populations truly represent their real-world counterparts.[10] In turn, this enhances the validity and generalizability of research findings. However, only 22% of site staff understand the importance of a diverse clinical research workforce,[10] and site hiring criteria—which focus on fulfilling urgent needs rather than an intentional model of workforce development—generally don't reflect this imperative.

ATTITUDES TOWARD THE WORKFORCE CRISIS

The workforce crisis is still failing to attract the attention it deserves within academic literature, at congresses, and at high-profile industry events. However, it's undoubtedly a hot topic in boardrooms. Some observers appear to interpret the crisis as merely a headache for Human Resources (HR) units, a hangover from the pandemic, or an issue that can be solved by technology. Others recognize its much more deep-rooted and far-reaching nature but, so far, the search for solutions has been based on "every company for itself."

Change may be coming though. At a ACRP Global Workforce Roundtable, FDA's Jan Hewett stated: *"We can't have high-quality data and adequate protection for subjects without an adequately staffed, properly trained, knowledgeable, and experienced research staff. The FDA may only regulate the clinical investigator and sponsor, but the clinical research staff are the beating heart of the industry—and to the extent we may be able to support the continued development of clinical research staff, we are also going to be supporting the quality conduct of clinical research."*

It's also encouraging that the National Academies for Science, Engineering, and Medicine (NASEM), whose Forum on Drug Discovery, Development, and Translation held a public workshop in October 2023,[9] is now focusing on key imperatives for establishing a workforce ready to deliver its vision of "a transformed clinical trials enterprise by 2030."[11] Co-chair Jonathan Watanabe, of UC Irvine's School of Pharmacy & Pharmaceutical Sciences, stated that, in order to support the evolving needs of discovery, development, and translation, the next-generation workforce must be "resilient, interdisciplinary, inclusive, culturally aware, and reflective of the communities it serves."[9]

In addition, a high-profile collaboration between NASEM, MRCT (the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard), CTTI (the Clinical Trials Transformation Initiative), and Faster Cures (Milken Institute), is focused on achieving representation in clinical trials.[12]

ADDRESSING THE CRISIS: CREATING AN INTEGRATED SOLUTIONS FRAMEWORK

Transforming the disjointed, homegrown clinical research professional workforce from "the invisible hand" to a highly visible fleet of motivated, diverse professionals engaged in a purposefully chosen career may seem a daunting task. However, guiding principles are available. In their *Good Jobs Initiative*, the U.S. Departments of Commerce and Labor aimed to identify what a "good job" looks like.[13] Alongside job security, pay, and benefits, the report highlights the following defining features:

- In *Good Jobs*, applicants are evaluated using relevant, skills-based requirements. Unnecessary educational credentials and experience requirements are minimized.
- All workers have transparent promotion or advancement opportunities.
- All workers are valued, contribute meaningfully to the organization, and are engaged and respected, especially by leadership.
- All workers have the opportunity to contribute to decisions about their work, how it is performed, and organizational direction.

These themes were taken up by a 2023 White House report on *"Building the Bioworkforce of the Future,"* which sets out recommendations for expanding and diversifying the talent pool for biotechnology and biomanufacturing careers.[14] The report highlights the need to channel the skills and talents of all students and workers and strongly encourages skills-based hiring, an approach to hiring that reduces employers' reliance on degrees as a way to screen out candidates, and instead asks them to evaluate whether a candidate has the knowledge, skills, and abilities to succeed in the role." It advises that the perceived value of skills should not depend on whether they were learned in a classroom or on the job.

In our vision for the future of the clinical research professional workforce, there will be:

- Increased awareness of clinical research as a distinct profession at high schools and colleges, with pipelines to training programs, internships, and apprenticeships
- Globally recognized entry-level competencies, harmonized across employers
- A universal commitment to skills-based hiring
- Explicit career pathways that clearly articulate the training and experience required to advance
- Active efforts to recruit candidates that reflect the communities they serve
- Recognition of the value of clinical research professionals as part of interprofessional teams

Since the problems underlying the workforce crisis are multifaceted, ACRP's PACRW Consortium sees the need for a constellation of solutions. Although many "barrier busters" have already sprung up, they are fragmented.[2] Solutions in silos won't have sufficient power to turn the wheels of change at a systemic level, so it's critical that such initiatives are integrated into a cohesive framework. The creation of this framework should enable momentum through multiplicity and the harnessing of synergies. Ultimately, each individual solution will become part of a robust, holistic entity capable of driving meaningful and sustainable progress.

Inspired by the well-known framework created by the Joint Task Force for Clinical Trial Competency (JTF)[15,16] and—more recently—the framework of *Toward a National Plan for Achieving Diversity in Clinical Trials*[11], ACRP has aimed to create a solutions "wheel" (Figure 2) for addressing the clinical research workforce crisis, based on a number of clear domains.

These domains represent the macrostructure, or conceptual blueprint, which can then be translated into a range of tactical models of varying size, scope, and reach, designed to meet situational needs. Our ambition is that this construct will be cited and deployed industry-wide, as a navigational device to show where each individual solution fits.

In this paper, we will focus on the foundational work needed for the Identity, Awareness, and Pathway domains.

Figure 2. ACRP's Solutions Framework of Six Domains for Building a Research-Ready Clinical Research Workforce

FOUNDATIONAL WORK FOR THE "IDENTITY" DOMAIN: CAPTURING BASELINE DATA ON THE CURRENT WORKFORCE

Alongside the curation of tactical models for the solutions framework, foundational work is needed for a number of the domains. The first of these efforts focuses on the "identity" domain. A prerequisite for establishing professional identity—a cornerstone of a robust workforce—is capturing baseline data on the current workforce. This is a challenging prospect, not least because clinical research is currently not recognized as a profession by the U.S. Bureau of Labor Statistics (BLS).

In 2024, ACRP applied to the BLS for a specific occupational code for clinical researchers; if accepted, this would be a significant step forward but would only come into force in 2028. As things stand, minimal insight is available on the make-up of the global clinical research workforce, its demographics, the qualifications and backgrounds of its members, their various entry points into the career, their roles and responsibilities, and their career prospects. Characterizing the workforce transcends HR; it is a macro-economic concern because it also showcases the risks and implications of not having a robust and well-qualified workforce to conduct clinical research.

Capturing accurate data on the workforce would serve several purposes. It would:

- highlight the size, scope, and remit of the clinical research workforce, demonstrating its value to healthcare innovation and enhancing its visibility
- clarify the distinct roles, responsibilities, and competencies of clinical research professionals, supporting ACRP's application for a dedicated BLS occupation code
- identify shortages, skills gaps, and opportunities for targeted training and recruitment
- provide a solid foundation for industry, academia, and policymakers to invest in clinical research workforce training and professional growth.

The PACRW has engaged experts in healthcare workforce to devise a quantitative and qualitative survey that will provide these baseline data. The richer the data, the more they can help shape a professional identity.

FOUNDATIONAL WORK FOR THE "AWARENESS" DOMAIN: ESTABLISHING CLINICAL RESEARCH AS A DISTINCT CAREER OPTION

To raise awareness of clinical research as a career choice among school and college learners, ACRP has developed a toolkit ("Ready, Set, Clinical Research")[17] for hirers and careers advisors. Beyond this, it's important to provide exposure to the clinical research workforce as an integral part of high school and college education by embedding it in Science, Technology, Engineering, and Mathematics (STEM) and Career and Technical Education (CTE) curricula. This will require the buy-in of stakeholders across the educational ecosystem, including high schools, colleges, universities, the U.S. Department of Education, and state governments. There should be linkages across programs and clear high-level visibility.

As shown in the "train tube" diagram below, it's also important to remember that clinical research as an occupation consists of many types of jobs, from patient-facing roles to data managers, statisticians, and regulatory coordinators. Site-based roles themselves split out into "recruiter," "CRC," and "study manager" personas where the skillsets differ.

At an industry conference, ACRP captured views on the attributes and personality traits that seem a good match for a career in clinical research, in the absence of any "official" experience. Parallels were drawn with the attributes needed for occupations such as educators, paralegals, computer scientists, firefighters, engineers, and architects. Descriptors of suitable personality types included "problem solver," "multi-tasker," "critical thinker," "team player," and "people person," along with qualities such as "honesty," "curiosity," and "attention to detail." Such personality types can be found not only among students, but also among potential lateral movers, such as social workers, clinic staff, medical assistants, and those looking for a change from academia. With the right training and opportunities, nontraditional entry routes into clinical research can prove fruitful–and broadening our view of who could make up the future workforce is critical.

FOUNDATIONAL WORK FOR THE "PATHWAY" DOMAIN: MAPPING OUT THE PATHWAY

Even though clinical research is one of the most regulated industries in the world (second only to the commercial nuclear industry), there are currently no defined or explicit pathways into the career. Most clinical research professionals say they "just fell into it."

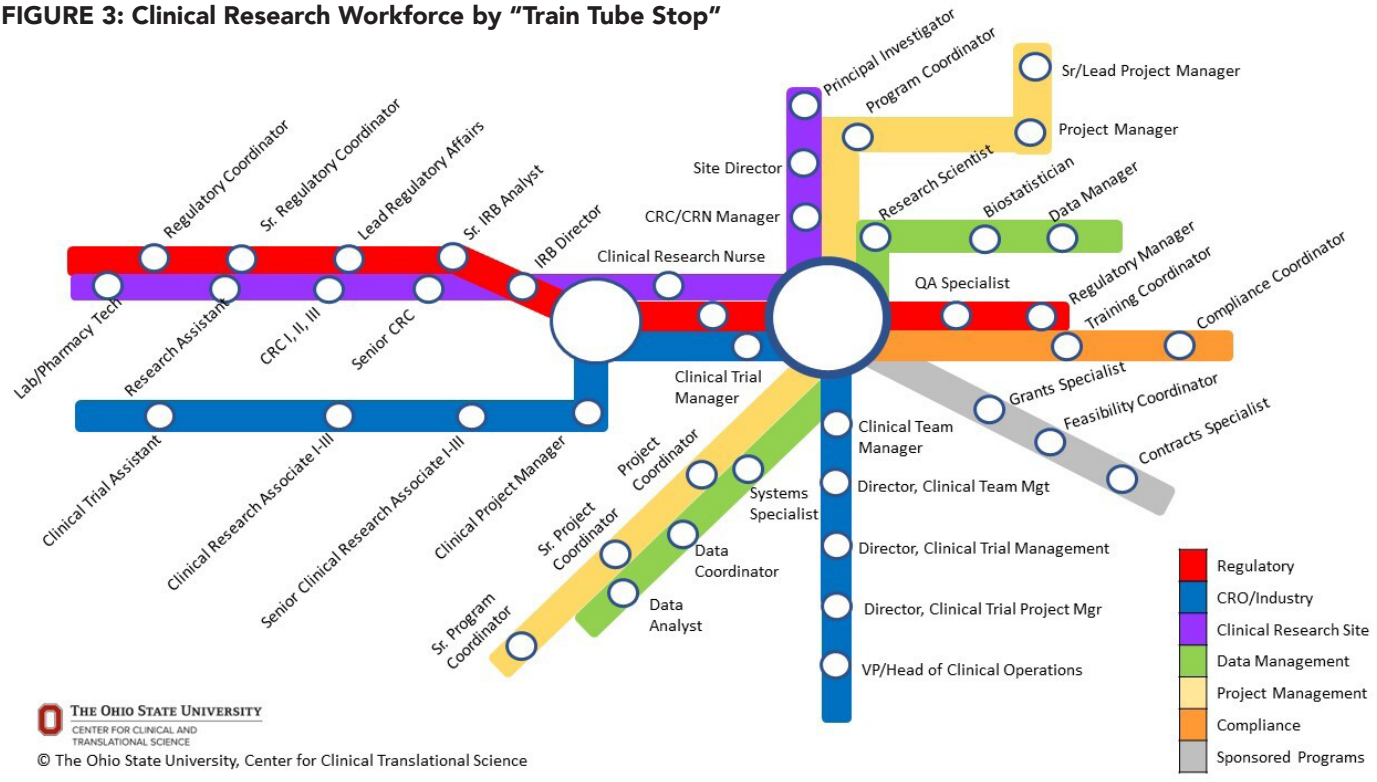
This situation contrasts starkly with other careers that also critically depend on skills and competencies. Consider the aviation industry. Enormous trust is placed in airline pilots to work out the best route using air traffic control data and weather reports, create a flight plan, follow operating procedures, communicate with cabin crew and passengers, and ultimately ensure the safety and security of all on board. Airline pilots don't fall into their career, they choose it. From the start, they understand the pathway and gain the qualifications recognized and required by their employers. This equips them to get hired, take their seats in the flight deck, and fly planes.

Clinical research professionals are the pilots of clinical research studies. Like airline pilots, they carry a heavy responsibility: the safety and wellbeing of participants; adherence to Good Clinical Practice, to the protocol, and to ethical principles; the quality and dependability of the data; the prospects of a potential new intervention and its stakeholders; and the lives of future patients.

And yet, as things stand, those in the clinical research flight deck have no mandatory qualifications or explicit career path. Many promising candidates are blocked by simplistic and outdated hiring criteria based on a particular number of years of experience, or on academic degrees, rather than on relevant skills and competencies. This approach to hiring contravenes the guiding principles of "good jobs" according to the U.S. Departments of Commerce and Labor[12] and the tenets enshrined in the recent White House publication on *"Building the Bioworkforce of the Future."*[14]

The PACRW is determined to change this paradigm by working to embed skills-based hiring in clinical research and by constructing a transparent and unambiguous career pathway, understandable to candidates and recognized by employers. In our vision for the future, candidates and hirers will both be guided by a visible checklist of the knowledge and skills needed for clinical research professional roles. The route through which these competencies are achieved—academic courses, industry training programs, or on-the-job training—will not matter. Subsequent hands-on experience should be gained through internships, apprenticeships, and mentorships, for which we aim to formulate standardized definitions and models. If such a pathway is officially embraced and showcased by employers, candidates who follow it can be confident of getting hired.

FIGURE 3: Clinical Research Workforce by "Train Tube Stop"



For CRC roles, ACRP has already created a detailed "roadmap" which articulates the responsibilities of the role and maps each against the competency domains of the gold standard JTF framework.[18] We also have adaptations for other roles, such as clinical research associates (CRAs) and project managers, and are building navigable digital versions that may include digital badges as a trackable way for prospective candidates and would-be employers to monitor the acquisition of relevant competencies.[19]

Thus, extensive foundational work to enable skills-based hiring already exists. By distilling our roadmaps into composite criteria, and adding in desirable personality attributes, we believe a proposed new hiring model for clinical research is well within our reach. This will also build in so-called "soft skills"—common to other industries—which include communication, cultural awareness, implicit bias, and professionalism in the workplace, all of which are essential for today's workers.

Achieving alignment and uptake of a new hiring model will undoubtedly be a significant challenge but evidence already exists that it is possible. A recent academic publication, *"Enhancing the clinical research workforce: a collaborative approach with human resources,"*[20] describes the adoption of a job classification matrix based on the JTF Core Competency Framework across five academic medical centers and the role of HR units in facilitating this process.

The authors rightly assert that collaboration between clinical research leadership and HR units is critical for establishing and maintaining a strong workforce, and for successfully implementing competency-based job descriptions and creating career pathways. They add, "the process does not have to be overwhelming and can be mitigated by leaning on institutions with experience in this space."

Once formulated, our proposed skills-based hiring model will need to be workshopped with all key stakeholder groups. It will need to be tested and piloted. From that point, we hope sufficient buy-in will be achieved for widespread adoption. Ultimately, we plan to develop a hiring toolkit that helps talent managers assess candidates against an agreed-upon checklist. For candidates, a matching Career Guide agreed-upon what they can expect from a career in clinical research and walk them through the pathway.

CONCLUSION AND CALL TO ACTION

We are in a revolutionary moment of immense technological and scientific change. As the clinical research landscape evolves, a "new normal" for the workforce will be defined. Yet any attempts to shape the workforce of the future must first confront the deepening crisis in the current workforce. Before the workforce can be transformed, it must be rehabilitated. This crisis is everyone's problem. For the sake of the entire enterprise, we call upon the pharmaceutical industry to prioritize investment in clinical research workforce development across the whole supply chain. Supporting sites—a vital shared resource—is an objective in its own right. The mission is eminently achievable: the insights, the building blocks, the solutions blueprint, and a range of successful models are already here. All it takes is commitment and collaboration. There is no time to lose.

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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 17,000 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 more at ACRPNET.ORG

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