Addressing the Global Clinical Research Workforce Crisis

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About ACRP

With more than 13,000 members, the Association of Clinical Research Professionals (ACRP) is the only non-profit organization solely dedicated to representing, supporting, and advocating for clinical research professionals.

Advancing People Advancing Health™

ACRP is moving the people and practice of clinical research forward™ by:

- Being the Most Passionate Advocate for the Clinical Research Profession
- Providing the Tools Clinical Research Professionals Need to Build Their Own Career Journeys
- Creating Connections through Community
- Giving Employers the Confidence to Know They’re Hiring the Best of the Best
- Leading the Way for Workforce Development in Clinical Research

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Clinical Research
Global Workforce Crisis

“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.”
AN INDUSTRY IN CRISIS

For over 15 years, a shortage in the clinical research workforce has been a looming threat\textsuperscript{1-3} - one that has now reached crisis point.

**Unprecedented staff turnover**

In 2022, the resignation rate among experienced clinical research professionals was \textbf{60\% higher than in 2020}.\textsuperscript{4}

As many as 95\% of cancer centers report staffing issues and oncology clinical trial accrual rates are down 20\% from January 2020 levels.\textsuperscript{5}

**Major shortfall in applicants**

In July 2022, 6.6 million clinical research jobs were publicly posted in the US, but there were only 5.7 million available hires, highlighting a \textbf{shortfall of almost one million}, with a particular shortage among experienced patient-facing roles.\textsuperscript{6}

**Lack of diversity**

Diversity among site staff leads to a more diverse clinical trial participant population. This is critical for addressing the long-recognized concern of under-represented demographic groups in clinical trials.

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\textsuperscript{1} https://www.religiamedia.com/articles/111576-shortage-of-nurses-docs-hurts-or-staff-hiring-retention-rates-2
\textsuperscript{2} https://www.clinicalleader.com/doc/clinical-staff-shortage-growing-plague for-pharma-cross-0001
\textsuperscript{3} https://www.actalentserices.com/en-gb/insights/articles/the-staffing-crisis-in-clinical-trials-and-the-drive-for-permanent-staff
\textsuperscript{4} https://teckro.com/resources/blog/clinical-research-staff-resignation-burnout
\textsuperscript{6} https://myscrs.org/resources/sites-now/exploring-the-current-clinical-workforce/

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A More Diverse Staff Improves Clinical Trial Participant Diversity

**Practical Implications**

- There is a statistically significant association between the presence of a Centralized CT Office, Unconscious Bias SOPs, and Inclusive Behavior SOPs, and the staff diversity profiles of sites in the industry dataset. This finding suggests that companies are encouraged to continue to work and collaborate with sites in the development and implementation of diversity-focused SOPs and efforts to streamline trial execution.

- Continued support for the use of communication tools and platforms (i.e., SMS, WebEx, and Zoom, among others) is expected to support an increase in staff diversity across clinical research sites, globally.

- A strong association was identified between the presence of technologies supporting clinical trial execution and higher staff diversity. These technologies include Electronic Data Capture, Clinical Data Management Software, Patient Management Systems, Digital Imaging and Communications, and Web-based medical image viewers. With increased use and implementation of these technologies, sponsors and professional associations are encouraged to continue to support the training of site staff in these areas.

- Approximately half of staff at clinical research sites globally believe that SOPs for Diversity & Inclusion, Unconscious Bias, and

**This study shows that there is a statistically significant relationship between staff diversity and patient diversity; however, only 22% of respondents in this study believe that staff diversity is a major factor to the success of clinical research. This suggests an opportunity to educate site staff about the importance of staff diversity in the successful completion of clinical studies.**

Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY
Transformation Depends on a [Trained] Workforce
“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.”

2023
Pressure On Workforce To Intensify

Growing number of trials
The number of clinical trials registered worldwide has risen exponentially (from 2,119 in 2000 to 433,207 in 2022) and shows no signs of slowing.¹

Increasing protocol complexity
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.

In addition, for all trial phases, an increase in the mean number of protocol deviations and substantial amendments, which are notoriously labor-intensive.²,³

Increasingly specialized roles
Surging expectation for trials powered by innovative technology (e.g., telemedicine, internet-enabled patient wearables) has created new requirements for specialist skills.

In 2022, there was a 28% increase in demand for decentralized clinical trials (DCTs) vs 2021.⁴

In July 2022, close to 30% of all new postings for CR roles didn’t fit a traditional job description.⁵,⁶


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A ‘Perfect Storm’ of Issues

<table>
<thead>
<tr>
<th>Professional Identity</th>
<th>Lack of a clear professional identity, and lack of recognition as a profession by the US Bureau of Labor &amp; Statistics.</th>
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<tbody>
<tr>
<td>Infrastructure</td>
<td>No standardized pathway into the profession and baseline terminology for industry roles, no centrally funded training programs or continuing education, and no mandatory qualifications.</td>
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<td>Recognition</td>
<td>‘Hidden in plain sight’: non-faculty clinical research professionals are generally overlooked as key stakeholders in the clinical research ecosystem.</td>
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<td>Remuneration</td>
<td>In contrast with the biotech industry and CROs, pay ceilings at academic medical centers, dictated by static research grants, act as a deterrent to recruiting and retaining staff.</td>
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<tr>
<td>Recruitment</td>
<td>Highly varied hiring requirements and barriers to recruitment, often based on number of years of experience rather than competencies, are further stalling an already strained recruitment process.</td>
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Professionalizing The Clinical Research Profession

The process model of professionalization

Later processes continuously influence and alter already established processes.

Stage 1: Full-time occupation identified
Critical mass of workers performing similar work activities established

Stage 2: Training or education programs provided
Key knowledge and key skills are identified

Stage 3: Professional associations established
Qualifications (certifications and licenses) are developed

Stage 4: Code of ethics established
Rules are developed and accepted by professionals

Competency Domains for the Clinical Research Professional

1. Ethical and Participant Safety Considerations
2. Scientific Concepts and Research Design
3. Investigational Products Development and Regulation
4. Clinical Study Operations (Good Clinical Practice)
5. Study and Site Management
6. Data Management and Informatics
7. Leadership and Professionalism
8. Communications and Teamwork

Adapted from Curnow and McConville.


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“The industry has the opportunity to address the workforce issue in a way that it has never looked at it before.”

FDA
Partners Advancing The Clinical Research Workforce
ACRP Partners Program - Mission

To ensure a diverse, research-ready and sustainable clinical research workforce to sustain the advancement of therapies that improve global human health.
Barriers To Bridges Thought Leadership

“...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

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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 EMBRACE 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. 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 attract and retain talent into 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.
Ready, Set, Clinical Research

Objectives and Audience

Boost the number of people interested in embarking on a career in clinical research and to enhance their diversity; showcase the benefits of a career in clinical research.

The toolkit aims to inform, motivate, and inspire the broad spectrum of individuals who may be eligible to enter a career in clinical research, including:

- **Entry-level** (high school and college leavers, including those from historically black colleges and universities)
- **Lateral movers** (people with relevant experience and/or professional qualifications in another field)

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We Agree…

- Workforce issue is a crisis that must be addressed with a shared responsibility among all industry stakeholders
- Majority of organizations have allocated funding for the purpose of addressing the workforce crisis and have created partnerships outside of their organizations to raise awareness for the clinical research profession
- Representatives attending believe that the industry should support the professionalization of the clinical research workforce through education grants for training for new entrants to the workforce

“Solve difficult problems with great people.”
Where Do We Start?

...From the CRO perspective, it would be client requirements for CRAs assigned to their study (min 2 years, etc.)...

...It is difficult to meet the minimum qualifications for entry-level positions (many ask for experience)...

...Sponsors only looking for experienced CRAs to work on projects. Not enough resource and effort is being put into hiring and training of those naive to clinical research...

...There are a significant number of individuals at a mid-career level who are interested in coming over ...but there are only a few avenues/entry points, so lack of entry points for both entry level and mid-career individuals...

...Overworked and underpaid — it can be difficult at academic medical institutions ...to remain competitive salary-wise...

...Identifying and addressing the primary reasons for the workforce shortage. Where are the gaps? Is it in entry-level roles, mid-career roles, or higher up? Then, how do we fix it?...

...agreeing to encourage entry level and non-traditional backgrounds across many of our roles...

...Increasing the awareness of this profession and current shortage by addressing the need directly at the source — engaging more community college population...
Top Barriers Identified

Lack of awareness of the clinical research profession & equity in access to training for workforce entry

Widely understood “2 years’ experience” barrier to workforce entry

Lack of shared global baseline for competency standards & training that aligns with a global standard

Entry level is not entry level.

...It is difficult to meet the minimum qualifications for entry-level positions (many ask for experience)

...Not enough resources and effort are being put into hiring and training of those naive to clinical research...
Prioritizing Next Steps

Rank the initiatives below in terms of priority for ACRP to focus its workforce development efforts.

1. Undertake initiatives to build awareness for a clinical research professional identity
2. Generate widespread awareness of the clinical research global workforce crisis
3. Capture industry perspectives on methods and models to incorporate entry-level talent onto trials and studies
4. Encourage CR stakeholders to support acceptance of entry-level and early career talent
5. Provide an alternative perspective and path for the industry "two-years experience" hiring metric
6. Develop programs that support access to training for entry-level talent
7. Establish a global competency-based standard of excellence for assessing CRP talent
3 Strategic Priorities

- Lack of awareness of the clinical research profession
  - Undertake initiatives to build awareness for a clinical research professional identity
  - Generate widespread awareness of the clinical research global workforce crisis

- Equity in access to training for workforce entry
  - Develop programs that support ACCESS TO TRAINING for entry-level talent
  - Early Talent Training Program

- "2 years’ experience" barrier to workforce entry
  - Capture industry perspectives on methods and models to incorporate ENTRY-LEVEL TALENT onto trials and studies
  - Encourage CR stakeholders to support acceptance of entry-level and early career talent
  - Provide an alternative perspective and path for the industry "two-years experience" hiring metric

- Lack of shared global baseline for competency standards & training that aligns with global standard
  - Establish a GLOBAL COMPETENCY-BASED STANDARD OF EXCELLENCE for assessing CRP talent
Strategic Priorities

BUILD AN IDENTITY
Build a powerful brand and professional identity for the clinical research profession

OPEN DOORS TO A NEW CAREER
Ensure access for all to education, training, and professional development in the clinical research industry

CHANGE HOW WE HIRE
Drive industry-wide adoption of a competency-based approach to hiring entry-level clinical research professionals
Building An Identity

Hiring Guidelines for Entry Level Clinical Research Coordinators

ACRP Clinical Research Career Lattice

ACRP + For Learning | For Listening | For Life

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DIA 2023
GLOBAL ANNUAL MEETING
BOSTON, MA
JUNE 25-29
ILLUMINATE
Opening Doors: Scholarship For Access & Advancement

Cycling for Clinical Research Workforce Diversity

Support the 2023 ACRP Ride4DEI
May 15-20, 2023 | Pittsburgh to DC

All funds raised will help increase access to education and training in clinical research for people from underserved communities.

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<th>Make A Donation</th>
<th>Start A Fundraiser</th>
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1. Access for Students to Clinical Research Training Scholarship (ASCRCT)
   - Tuition scholarships for minority students in designated CR curriculum at community college, college, Master’s-level programs, and membership to ACRP

2. ACRP Annual Conference Education & Professional Development Scholarships
   - Individual scholarship for attendance at ACRP’s education summit.

3. ETPR™ Scholarships Funneled Through Collaborations & Chapters
   - Individual scholarships to support entry into the clinical research profession

4. Support Our Sites (S.O.S.)
   - Scholarships awarded to sites for recruiting and retaining clinical research professionals

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Putting Entry Level Training Into Action
A Vision For The Future

- Increased awareness of the profession, career pathways, and how to get the training and experience needed to advance
- Greater collaborations across industry groups (e.g., ACRP, CTTI, SCRC, Avoca, TransCelerate, etc.) to align efforts, share best practices, develop standards
- Globally recognized entry level competencies established with registered site organizations accepting this as their standard
- Pipelines between grade schools, high schools, and colleges or training programs; pipelines between colleges and employers; more internships and mentorship
Do Your Part

- How is your organization supporting entry-level talent?
- Does your organization ensure access to training for those wishing to start a career in clinical research, especially those who may not have the means to get started in clinical research?
- Can your organization partner in its community help build an identity for clinical research and help to fund a training program?
- Is your organization aware of the JTF Competencies as a global standard of excellence in clinical research?
Thank You!

Susan P. Landis
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Your Twitter Handle

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