

A photograph of two women in a computer lab. One woman with curly hair and glasses is pointing at a computer monitor. The other woman with straight hair and glasses is smiling and looking at the screen. The image has a blue tint.

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# A New Approach to Developing the CRA Workforce



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This position paper examines the current clinical research associate (CRA) workforce, and calls for elimination of the commonly accepted and practiced two-year experience requirement for entry-level CRAs in favor of competence-based employment practices.

## CRA WORKFORCE SHORTAGE

The clinical research enterprise faces a clear and present personnel shortage. There are at least 10,000 CRA open positions in the United States as of June 2015<sup>1</sup>, and there is no evidence to suggest that number will decline any time soon. The shortage is creating inefficiencies for clinical trial sponsors and contract research organizations (CROs), many of whom find themselves in a constant recruitment cycle for qualified CRAs in a hyper-competitive job market.

A 2013 study by Brookings<sup>2</sup>, lamenting an overall employee shortage throughout the life sciences industry, singled out the CRA as one of the positions most in need of recruitment.

And while a recent CNNMoney<sup>3</sup> survey rated CRA as one of the 10 best jobs in America in terms of growth, pay, and worker satisfaction, warning signs abound that the shortage is negatively impacting the current CRA workforce.

## IMPACTS OF SHORTAGE ON CURRENT WORKFORCE

Strong performers are burning out as more and more CRA positions go unfilled.

A 2015 CenterWatch/ACRP survey<sup>4</sup> of CRAs found more than one-third reported a "significantly increased" workload over the past three to five years. Some 60% cited increased workload and increased responsibilities as two of their top three professional challenges. More than a third of respondents said taking on more responsibilities was their most significant change in their current role. A similar number said they were considering a job change in the next 12 months.

More than half of those considering a job change cited "work/life balance" as a factor, making it the single most-commonly cited reason for seeking a job change.

Looking at the big picture, CRAs gave their current position a roughly 3.5 ranking on a 1 to 5 scale.

While there presently exists no hard evidence to establish a causal relationship between a workforce shortage and the dissatisfaction of many members of the existing workforce, common sense indicates it is a contributing factor worthy of consideration and further study. Given this troubling climate, it is time to assess some current standard operating procedures (SOPs) and examine barriers blocking new talent from filling positions and infusing the talent pool with a new energy.

## TWO YEARS' EXPERIENCE: THE ARBITRARY EMPLOYMENT PRACTICE

Sponsors and CROs routinely require two years' professional experience for entry-level CRAs, which establishes a significant barrier to encouraging interest in job openings among potential new CRAs. The two-year requirement is a seemingly random one, and one whose derivation is unclear. Instead of focusing on an applicant's skill set, potential applicants are to a significant degree judged solely on time served.

Competency based on tenure discourages a talented pool of potential CRAs who lack an industry-imposed, calendar-based requirement from trying to advance and fill the rising number of open positions. The current system in place to train and mentor CRAs is demonstrably inadequate to meet a growing demand for new skills and talents.

It is time to cultivate fresh ways to standardize the processes currently used to develop CRAs.

The most important component of any solution is a willingness to consider new SOPs and philosophies. If we remove the two-year barrier, how do we

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more effectively examine skill sets and base the advancement standards on what is actually needed to perform as an effective CRA? How do we define entry-level competencies? Mid-level competencies? Research experience?

These are not easy questions to answer. Nor are they questions to be treated lightly. However, raising these questions provides the industry with new opportunities to improve quality and provide adequate protection for clinical trial volunteers.

## COMPETENCIES AS A PROPOSED SOLUTION

Any new set of standards and SOPs must be based on real-world data and contributions from the widest possible array of experts and stakeholders. The foundation of decision-driving data must include a close and careful analysis of the skills CRAs truly need and utilize on a daily basis.

The search for answers could begin with ongoing work being carried out by the Joint Task Force (JTF) for Clinical Trial Competency. This consortium of leading voices in the industry was formed to integrate efforts to identify high-level competency domains for clinical research professionals at large, and to then harmonize those requirements<sup>5</sup>. The team is drawn from experts at Harvard's Multi-Regional Clinical Trial Center, Amgen, the Alliance for Clinical Research Excellence and Safety, the Consortium of Academic Programs in Clinical Research, FHI360, Deloitte Consulting, and the Association of Clinical Research Professionals, among others.

ACRP believes the time has come to build on the JTF's work by establishing role-specific competencies, starting with those of the CRA, and for the clinical research enterprise at large to embrace hiring practices that favor professional competence over arbitrary experience requirements.

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## REFERENCES

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