
TALENT MANAGEMENT SOLUTIONS TO THE CRA SHORTAGE: Investing in a Global Talent Pool

Over the past few years, the field of clinical research has been hampered by a shortage of qualified Clinical Research Associates (CRAs) to monitor studies of investigational drugs in mature and emerging markets. Even though sponsors have largely outsourced the CRA role to Clinical Research Organizations (CROs), the problem, ultimately, is a shared one. Labor shortages for CROs inevitably drive up costs and extend timelines for sponsors in their race to bring research studies in on time and on budget.

The difficulty is not in finding people eager to, and capable of, filling monitoring positions. Rather, it's that sponsors want CRAs with extensive monitoring experience assigned to their projects. This is a classic paradox, for how can CRAs who are beginning their careers ever become experienced enough to work on trials, without actually working on trials?

To meet the CRA talent shortage, the situation calls for an investment in building a global talent pool in innovative ways. Here we discuss one solution that is a win for all: clinical professionals interested in the CRA role, existing CRAs (who can now advance in their careers), sponsors, and ultimately patients.

AN ATTRACTIVE FIELD

By all accounts, the CRA role is a promising one for clinical professionals, with rapid and ongoing growth. In 2013, CNN Money's "Best Jobs in America" report ranked the job of CRA #6 in its list of 100 careers. The listing cited the 10-year job growth rate as 36.4 percent, and the job earned high "quality of life ratings," of "A's" and "B's" for Personal Satisfaction, Benefit to Society, Flexibility, and Stress Levels.

Yet, ask any manager responsible for resourcing CRAs and you'll find that it is increasingly difficult to staff studies—especially in emerging markets (the locale of a growing number of studies) and in key therapeutic areas such as oncology. CareerBuilder reports that at any given point in time, there are at least 1,000 openings in the U.S. for candidates with clinical research experience.

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A WIDENING GAP BETWEEN SUPPLY AND DEMAND

Sponsor companies have been turning to CROs to manage and monitor their clinical trials with increasing frequency over

the past several years. According to a Tufts Center for the Study of Drug Development (Tufts CSDD) survey conducted in 2011 of 4,000 CRAs, 70 % of CRAs surveyed were employed by CROs, as opposed to 26% by sponsor organizations. This number continues to increase as we have seen more outsourced work, including large functional relationships involving site monitoring.

As part of their service contracts with CROs, sponsors may specify preferred qualifications for the CRAs assigned to their studies. Typically, they require that CRAs have a minimum of two to four years of monitoring experience, often with expertise in specific therapeutic areas. In the not-too-distant past, CROs could easily comply with sponsors' personnel requests. However, increased growth in the marketplace and a lack of CRA talent development activity across pharma caused the number of qualified CRAs relative to industry need to dwindle.

Any active or ongoing CRA development efforts were targeted, limited, and focused on specific program needs and did not address the larger resourcing gap. As CRA professionals advanced their careers out of the monitoring role, the replacement ratio continued to decline. This lack of ongoing early CRA talent development resulted

in compression of existing resources in the market. CareerBuilder reports that only a small portion (11%) of CRAs in the workforce have five or fewer years of experience.

This widening gap between experience expectations and the current labor pool has created a number of related problems:

- Limited career growth for experienced CRAs.** Many CRAs who might otherwise be promoted to other positions within their organizations have been “stuck” in their roles because they are too valuable where they are. The inability to identify suitable replacements within a reasonable time frame leads to increased frustration and attrition. Some CRAs may feel that the only way to advance their careers is to leave their organizations.
- Rising employment costs with disproportionate ROI.** CROs have seen increased hiring costs, wage inflation, and longer times-to-fill for CRA openings. Unfortunately, these increased costs have not yielded proportionate returns on the investments with respect to process improvements or efficiency gains, since most of these expenses relate to getting staff in the door or to retaining them.
- Extended timelines for sponsors.** Labor shortages could ultimately delay delivering key drugs to patients. The cumulative impact of these “resourcing gaps” over time could be quite substantial to a pharma company, simultaneously increasing the timeline of a compound in the drug development phase while potentially shortening its commercial lifespan.

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AN INNOVATIVE, YET PRACTICAL SOLUTION

One answer to closing the labor gap is for CROs to invest in developing their own CRA talent. To meet growing study and portfolio needs, such programs must not only train CRAs, but provide them with best-in-class mentorship and an opportunity to gain valuable field experience at investigative sites. These “hands-on” experiences are critical in developing the right

skills and knowledge to conduct independent monitoring visits effectively.

One proven approach involves a lengthy, intensive development program that includes a mixture of training formats and multi-faceted support network for CRAs to ensure their long-term success. (See Figure 1.) This entails several steps and multiple training modalities:

- Rigorous candidate screening.** “There is no shortage of candidates out there,” noted Michael Jimmink, Vice President Strategic Resourcing with inVentiv Health Clinical, “but the long-term success of any program relies on selecting the right candidates. Hiring managers must look beyond education and clinical experiences to identify proactive, highly motivated candidates with critical thinking skills.” “The best candidates are those who demonstrate a passion for the mission,” John Avender, Associate Director, Clinical Operations at inVentiv Health, continued. “They see advancing science as an honor and improving patient health and quality of life as a noble calling.”



- Training on the fundamentals.** Through a mixture of self-guided learning and classroom instruction, recruits are introduced to general background information on the pharmaceutical industry and the field of clinical research, pertinent standard operating procedures, an overview of ICH-GCP guidelines and the need to comply with them, and the requisite soft skillsets.
- Associated learning and simulation exercises.** Following explanations of how things are done, the program provides an opportunity to practice in a safe environment—long before recruits are introduced to the field.
- A period of apprenticeship, or carefully supervised on-the-job training.** Once they’ve passed their classroom assessments (after about six weeks of instruction), recruits are given simulation activities and then, eventually, the opportunity to work alongside an experienced CRA, in essence co-monitoring the trial.

- **A pilot work experience.** Upon completion of another assessment following co-monitoring, the trainees are formally assigned to a project and given the opportunity to demonstrate their competence and confidence while still under close supervision.
- **Close ties with mentors and peers.** Throughout the process, recruits are given multiple resources for support, including their line supervisor, training coach, mentor, and class peers who are organized into a buddy system. Communication between the recruit, the assigned coach and line management is frequent to ensure that everyone is on the same page regarding progress. Issues with workload, timelines, and proficiency with course modules, are addressed promptly, before they become major hurdles to completion of the program.

At the end of this six-month orientation and practicum, the recruits have more than book learning at their disposal. They've been able to practice their newfound knowledge in controlled environments where success builds their confidence and mistakes have limited consequences.

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A LONG-TERM PAYOFF

Employers will, of course, want to protect their investment by retaining successful program graduates. This is best accomplished by ensuring that the CRA feels valued, is supported and has growth opportunities.

“This goes far beyond ensuring that CRAs’ compensation is competitive, and speaks to the need for strong bonds between managers and CRAs,” said Jimmink. “Particularly when CRAs reach a career milestone and the impact of the investment the company made in their training has receded in their memory, employees will be more likely to stay if they trust their leadership, know that they can get help when they need it, and see a future for themselves within the company.”

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PROOF OF CONCEPT

Once CRAs graduating from such a program enter the workforce, they're able to ramp up and assume a full workload within a relatively short time frame. What's more, their performance is nearly indistinguishable from CRAs who've been on the job for years; the quality of their site visit reports, volume of completed visits, and number of audit findings are on par with what can be expected from more experienced CRAs.

Figure 1: Program Structure

Stage	Type of Training	Weeks
First Stage	Training – Theory & Practice	Week 1 – Week 10
Second Stage	In-House & On-Site Training	Week 11 – Week 20
Third Stage	Assigned to a Project – Pilot Experience	Week 21 – Week 24

The structure of the program is such that recruits are shown what to do and then given the opportunity to demonstrate their understanding and gain proficiency by practicing what they learned in controlled environments. Recruits must successfully complete multiple assessments at various points along their journey to becoming an independent CRA.

“The surprising finding, though,” said Jimmink, “is that graduates of such programs have had a dramatically improved retention rate over more experienced CRAs.” In comparing retention rates at the two-year mark for CRA graduates, 95% retention is typical compared to high 60% to mid-70% retention for experienced colleagues (defined as 2+ years monitoring experience). This is indicative of the strength of these programs in creating value, camaraderie, and loyalty for its participants, as well as reflective of the increased market demand for experienced talent.

“Any improvement in retention for this key position has far-reaching ramifications for service providers and sponsors alike,” stressed Joe Mills, Senior Director, Global Recruitment Center, inVentiv Health. Employer benefits of improved retention include reduced employment costs, with shorter time-to-fill openings and reduced revenue loss from open positions. Sponsors see these benefits translated into the ability to meet study milestones on schedule, which directly impacts study costs and the product’s speed to market.

Success Factors

To date, many CROs have offered training for newly hired CRA’s, but these efforts have failed to make a significant dent in the CRA shortage because they are sporadic (usually in response to a particular sponsor’s upcoming study needs), rather than proactive and sustained. Generally, they’ve not been sufficiently comprehensive, nor have they been applied on a global scale. In our experience, to succeed on both an individual program basis and to begin to address the broader industry issue, initiatives to develop CRA talent must:

- Entail a long-term investment
- Screen applicants carefully
- Be open to considering applicants with non-traditional backgrounds
- Be proactive and ongoing
- Apply a consistent training philosophy
- Provide ongoing coaching and support to trainees
- Monitor quality metrics continuously

“The successful program is one that attacks the problem at the organizational level,” advised Jimmink. “It must be strategic, holistic and ongoing. It simply won’t work to wait until operations has a need to pull together a class in a particular geography. That ‘ship will have sailed’ by the time a new class of CRAs is ready.”

CONCLUSION

Although the industry is experiencing a shortage of CRAs to support clinical trials, there’s no lack of talent waiting to be trained. With the right investment, innovative programs can fill the gap, providing sponsors with a continuous supply of experienced monitors who can deliver the quality required. When CRA candidates graduate from a carefully designed training program with practical experience, they not only perform on par with their experienced colleagues, but stay with the company longer. This ultimately drives hiring costs down for service providers and improves productivity and delivery for sponsors.

For such training to address the industry’s need for qualified, fully competent CRAs around the world, it must be globally consistent, comprehensive, holistic, and ongoing.

REFERENCES

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About inVentiv Health

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