DRUG DISCOVERY & DEVELOPMENT

Are Delays in Clinical Trials Due to a Lack of Experienced CRAs?

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By Craig Morgan

CNN Money recently ranked Clinical Research Associates (CRAs), professionals whose main function is to monitor clinical trials, as one of the 10 best careers in America in terms of job growth rate, worker pay, and satisfaction. Despite this, the clinical research industry has experienced a concerning global shortage of experienced CRAs. Currently, there are over 14,000 open positions for CRAs on Indeed.com alone. And demand for CRAs is expected to grow annually by 1.52 percent (5,590 new positions) by 2018. This shortage is having a significant impact across the pharmaceutical industry, contributing to higher costs and extending drug development timelines for sponsors. As a result of the highly competitive job market, many clinical trial sponsors and contract research organizations (CROs) are finding themselves in a never-ending recruitment cycle for qualified CRAs.

In an industry plagued by rising development costs and increasing complexities, to what extent is the CRA shortage to blame for the delays in clinical trials? It is fair to say that it is a contributing factor, but it is equally important to point out that well documented bottlenecks in starting clinical trials, such as, protocol amendments, contract and budget negotiations, IRB approvals, and others, contribute to significant trial delays and these are not the primary responsibility of the CRA.

According to Maria Ladd, Senior Manager, Global Study Start Up, inVentiv Health, “The CRA/site relationship is a critical factor in the overall clinical trial process. In an industry with ever-increasing demands to ‘beat the clock,’ the face-to-face, human connection between the CRA and site staff can bridge the gaps in site moral potentially created by the pressures to speed activation, enroll the contracted number of appropriate subjects, and maintain complete and clean data. The right CRA can keep site staff grounded and engaged, ultimately serving to meet the goals of both the CRO and the sponsor.”

Causes of CRA Workforce Shortage

One of the biggest factors contributing to the global shortage is lack of training opportunities for clinical professionals to begin their careers as CRAs. Many pharmaceutical companies have tabled their new CRA training programs, requiring instead that CROs have experienced CRAs on staff. The experience requirements that sponsors are placing on CROs are in turn limiting the CROs' ability to grow new CRA talent for the industry.

Sponsors only want CRAs that have years of trial monitoring experience assigned to their projects. As part of their service contracts with CROs, sponsors usually 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. But how can CRAs who are just starting their careers ever become experienced enough to satisfy sponsors requirements without actually working on clinical trials? This is a classic 'catch 22' situation that also serves to discourage potential new CRAs from even pursuing employment opportunities, further exacerbating the situation.

The high numbers of unfulfilled CRA positions has caused a strain on the current CRA workforce with large increases in workload, responsibilities, and challenges. A 2015 CenterWatch/ACRP survey of CRAs found more than one-third reported a "significantly increased" workload over the past three to five years. Some 60 percent of the survey respondents cited increased workload and increased responsibilities as two of their top three professional challenges. A third of respondents said they were considering a job change in the next 12 months due to lack of a work/life balance.

Experienced CRAs that opt to move into management and leadership roles are also contributing to the deepening CRA shortage.

"The CRA shortage means that sites are sometimes faced with absent or under-qualified CRAs," said Christine Pierre, President of the Society for Clinical Research Sites (SCRS). "Consequences of this reality are sites report negative impact on study operations, timelines and even quality. Collectively, this reality ultimately impacts all stakeholders."

Consequences of CRA Workforce Shortage

The consequences of the global shortage of CRAs for clinical research are significant.

Rising costs: Experienced CRAs are taking home larger paychecks, and forcing companies to move some studies and/or jobs to low income countries. Given the competitiveness of the current market, CRAs turnover represents a constant brain drain for research organizations.

Limited career growth for experienced CRAs: Some CRAs who might have otherwise advanced to a more senior role have become trapped in their current role, as companies can't afford to lose them to promotion. This leads to increased frustrations and potentially resignations, as CRAs conclude that the only way to advance their careers is to transfer to a different company.

Extended timelines and lost revenue for sponsors: CRA shortages can impact study cycle times, increasing operational costs and lost revenue due to delayed market entry, as well as, ultimately delaying the delivery of critical therapies to patients.

Solutions

A number of potential solutions to this problem are beginning to emerge:

The Association of Clinical Research Professionals (ACRP), whose mission is to promote excellence in clinical trials, is forming a multi-stakeholder task force charged with defining the core competencies required of entry-level CRAs.

ACRP believes the root cause of the CRA shortage is equating the 2-year experience requirement with validated competence. Instead of focusing on an applicant's skill set and core competencies, companies are judging potential applicants solely on time served. According to Jim Kremidas, ACRP Executive Director, this false equivalency is hurting the clinical trials industry by preventing talented and competent people from entering the CRA workforce, as well as by keeping incompetent CRAs from being identified. As Kremidas notes, "There is a major shortage of CRAs in the workforce. As a result, sponsors and CROs are battling CRA turnover and substantial compensation increases. At the same time, it's clear from our own data and continued FDA inspection findings that there is an insufficient level of knowledge, skills, and abilities in the CRA workforce."

Another potential solution involves CROs investing in effective new CRA training programs. 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 usually only done in response to a particular sponsor's upcoming study needs. To begin to address the global CRA shortage, these training programs must become proactive and ongoing. They must also address the human element by promoting high levels of collaboration with peers and comradery between mentors and trainees.

ACRP has also developed an intensive 8 week CRA Onboarding Program that is available to sponsors and CROs to rapidly develop competent entry-level CRAs for sponsors and CROs. ACRP's CRA Onboarding Program blends online training with in-person training and exercises to ensure CRAs can immediately and effectively contribute to sponsor and CRO operations. A fully online CRA training program is also offered by The CRA Training Institute.

Finally, a number of universities are now offering master's programs in clinical research management, and a company called CRA Assessments is offering web-based simulations that fully reproduce the site environment, and can be used during interviews to assess CRA monitoring skills and competency.

Conclusion

There is little doubt that trials have been hampered by the vast shortage of qualified CRAs to monitor studies. Though sponsors largely outsource the CRA role to CROs, the challenge is ultimately a shared one. The CRA shortage has inevitably lead to higher costs and delays at a time when clinical trials are under enormous pressure to deliver on-time and on-budget. It's critical, however, that we look at this issue holistically and understand that many of the challenges the industry is facing are completely unrelated to the CRA shortage. We know that protocols are increasing in complexity, competition for patients is on the rise, and regulatory mandates continue to proliferate across the globe. These trends are in turn driving the demand for more senior CRAs with the appropriate experience to handle these uncertainties. Taken together, these issues make the CRA shortage all the more painful.

In the race to bring new therapies to market, we have to invest in innovative approaches to fill the talent gap, while finding ways to promote retention of existing CRAs, which are familiar with these issues and are on-hand to minimize execution risks and ultimately speed the delivery of new medicines to patients.

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