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Is There A Solution To The CRA Shortage Problem?



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If you are involved with clinical trials, you are aware of the shortage of qualified CRAs. Numerous reports have noted the continuous increase in turnover and salaries for these clinical professionals. If you have been in the industry long enough, you have likely experienced it firsthand, when your Trial Lead or Project Manager at a CRO opted to leave the company mid-study.



Carolyn Stroud knows something about the problem and even has firsthand experience with it. Her career in clinical trials began in 1993 when she joined ClinTrials Research as a Clinical Research Associate. She later joined Resource Solutions (acquired by Constella in 2002) where she worked as a Sr. CRA, Project Manager, and as a Manager of Clinical Operations. She also spent three years working for a large CRO in clinical operations before starting her own consulting firm, and later founding VIGOR BIOPHARMA SOLUTIONS, a niche clinical research staffing firm where she serves as CEO.

I recently spoke to Stroud about the problem, its origins, where we currently stand, and where we go from here.

Ed Miseta: At one time clinical research was performed in-house. In recent years, pharma companies started outsourcing to CROs to cut costs and become more efficient. Is this when the problem started?

Carolyn Stroud: No, not exactly. During that time, the demand and supply for CRAs was better balanced. This was a growth period for CROs so CRA training programs were in place and constantly developing the CRA workforce in accordance with their client's demand. During this time the entry level CRA was fully embraced. When pharma began to outsource their trials, they retained



a workforce that oversaw and managed their partnering CRO. Many of these individuals simply became Project Managers. At the same time, CROs increased their need for CRAs to monitor their client's trials. As a CRO grew and took on more projects, the demand for more CRAs increased. If you were in the industry at that time, you saw this change coming and I along with many of my colleagues at the time embraced this growing change. When I think back to my days as a CRA, after 6 months we were considered "experienced" and were Mentors to newly hired and trained CRAs.

Miseta: If pharma companies were not getting rid of many of their CRAs, who were the CROs hiring at that time?

Stroud: CROs were recruiting individuals with allied healthcare degrees and/or with some type of a science discipline. These were established professionals who were hired, provided several weeks of classroom training on the fundamentals of clinical research, federal regulations and GCP guidelines and the role and responsibilities of a CRA. Over the years, PPD has been known to have one of the best CRA training programs in the industry, because of its Clinical Foundation Program and its CRA Academy. PPD, along with Quintiles and ClinTrials Research, have been recognized as the top three CROs worldwide and have been credited for consistently developing CRAs. As outsourcing by pharma became even more popular, staffing agencies were in a growth spurt and able to add value to project demands more quickly. Wolf, Trio, and RSI were some of the more popular ones in the RTP area during this growing season. They provided CROs and pharma with a more experienced and seasoned individual than the traditional entry-level CRA. This option was very appealing to the client because these individuals could be onboarded onto a team and hit the ground running and often had the therapeutic experience the client was seeking. Providing such talent to a client obviously brought the opportunity to negotiate at a higher rate and allowance to work more in a regional capacity which was also appealing in that it began to cut travel cost. These more seasoned CRAs popped up everywhere. Some were placed inside pharma companies as contractors, worked remotely, or were independent of an agency altogether and I believe that this is when we first started to see the surge in salaries.

Miseta: Are the staffing firms still active in this space?

Stroud: Yes, of course, but CRAs are smart. CRA independence continued to grow during that time and many began to realize that they did not need a staffing firm and could set the terms of their own contract. They began to contract with pharma directly and established relationships, some of which we can attribute to why we now have so many independent contractors still working in the industry. Presently, the tide has turned in favor of staffing firms again as pharma and CROs work more directly through them now rather than directly with an Independent contractor. The idea is better control on CRA rates and the staffing firm's ability to accurately vet and confirm the authenticity of the CRA. Some of the larger CROs also rely on their own Talent Acquisition groups to provide quality CRAs and use staffing firms to supplement their needs.

Miseta: Are universities doing more to train qualified CRAs?

Stroud: Yes. Technical schools such as Durham Tech were the first to start a certification program for CRAs along with an internship with a local CRO. It was generally a two-year program, and although students graduating from these programs had classroom training and an internship with a local CRO, they had limitations not necessarily experienced by those who were trained directly through a CRO's training program. Universities such as Campbell University are now more involved with offering degrees in clinical research. I am aware of their master's degree which is an option for someone already working in the field. These types of programs can also be obtained online which is attractive for the person who is unable to participate in a classroom setting.

Miseta: I have heard CRAs complain about the lack of training opportunities made available to them. Is that a problem?

Stroud: As CRAs have evolved to being more and more independent, it is the responsibility of the CRA to obtain the necessary continuing education needed to do their job more proficiently. Agencies such as the Association of Clinical Research Professionals (ACRP), Society of Clinical Research Associates (SOCRA), Barnett International, and many others provide such training and professional certifications. However, CROs and pharma companies have a different obligation to those who are employed. They are responsible to provide resources that ensure the employee is equipped to do their job proficiently. Project specific training, however, is provided for CRAs whether they are employed or Independent and can be delivered by the CRO and/or the pharma company. This type of training should be customized to ensure understanding of the protocol and the disease which is being investigated. So if a CRA would like more training opportunities, he or she will more likely have better options as an employee rather than an Independent CRA.

As a side note, earlier I mentioned PPD's training program. Most CRAs feel it is quite intense, and agree it is one of the best for equipping CRAs. I am one to agree that there are a number of excellent CRAs out there who obtained their start at a PPD, ClinTrials, etc. and that these CROs were trailblazers for developing a successful "template" for growing and developing CRAs. As is the case with many roles, one issue CROs can face is that once these individuals are trained, after a year or so they may move on to a competing CRO for a more appealing salary. When you invest in developing a CRA, it generally takes 12 months before you see any return on your investment. If that individual leaves after 6 or 12 months, the company can take a loss. It is at this time that the gap in the demand and supply for CRAs broadened since training programs began to wane.

Miseta: Do we have CRAs working in the industry who are not properly trained?

Stroud: We do, and I call those people counterfeits. Most of the larger CROs are putting processes in place to identify these individuals as we know they exist. Sometimes they are identified via a simple background check and following through on the gaps in their CV. Since many CRA managers

are overwhelmed with more responsibilities along with their general workload, occasionally someone will slip through that screening process. When that happens we rely on study sites, co-workers, and peers to inform management of their concerns.

To become a CRA, you are required to have a minimum of a four-year degree. You should go through a two- or three-week training program and provide a credible account of your work history via a CV. Today we refer to training programs as CRA boot camps, and most of the major CROs have this type of a program. However, many sponsor companies are not on board for entry-level CRAs. They remain adamant in having CRAs with experience to monitor their trials. The problem is that no one kept a pulse on the attrition of CRAs over the years. We are losing the more qualified CRAs to career advancement, retirement, burnout, etc. and we will not be able to replace them if we do not start accepting newly trained CRAs and providing them opportunity to gain the experience they need.

Miseta: Most of the CRA training is taking place in North Carolina, since that is where the large CROs are located. CROs are also tapping local colleges and universities for individuals to enter their CRA training programs. Will we be able to spread that talent around the country to where it is needed?

Stroud: Obviously we can't have all of our CRAs saturated in one area. We will somehow need to disperse them across the U.S. and that will take time to ensure they are ready to take on the challenge for working remotely or regionally based. Large box CROs are more than capable in transitioning newly trained CRAs to work regionally, even those young professionals recruited from local colleges and universities. The question is how you convince this young professional, after molding them into a CRA, to move from NC to Maine or California where the cost of living is unreasonably high. Regional CRAs are important and they need to be positioned in areas that do not require an entire day to get to where they need to go. If a CRA is allotted six hours for travel, but delays cause it to take eight hours, the CRA may have to eat two of those hours depending on how the sponsor wrote the contract. That is not a situation any of them would be happy about.

Miseta: In talking to CRAs, I feel that, as a whole, these individuals are not as happy as they were when they were employed by sponsor companies. Do you get that impression?

Stroud: I do, and I think there are a lot of reasons that feed into this dissatisfaction. I think the workload and pace for CRAs is greater now than it has been in years past and with the addition of clinical trials being more complex it requires a broader understanding around the disease and treatment. As an employee, you have greater resources to support you through whatever the situation but as an Independent CRA, your resources are limited particular if you need an advocate. People move from one company to another for a variety of reasons only to find that change to be just as, or even more dissatisfying. I sense that CRAs don't feel appreciated in many respects and it is important that managers and leaders are intentional in showing appreciation more so since teams primarily function remotely. When a CRA leaves a project, there is usually a gap in time before the

CRA is replaced unless there was an adequate advance notice for providing a replacement. In most cases there is not and this may increase the work load of the remaining members of the team until a new person is on boarded. I have heard complaints from CRAs who have been assigned the additional work and their concerns regarding this issue have been unfavorable. What remains clear is that it takes time to identify and onboard a new CRA as this can take several weeks and, in some cases, months as the demand for quality CRAs is much higher than the supply. Since we don't want to further upset the applear and cause remaining members of the team to question their loyalty, much is dependent on the leadership of the team in maintaining a strong, steady, and satisfied workforce. In the meantime, it is most important that there be a concerted effort towards aggressively identifying and developing the CRA workforce.