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Is CRA Turnover a Significant Cause of Clinical Trial Delays?

By Craig Morgan

Demand for Clinical Research Associates (CRAs), professionals whose main function is to monitor clinical trials, is expected to grow 1.52% annually by 2018, which results in many sponsors and CROs finding themselves in a never-ending recruitment cycle for qualified CRAs.

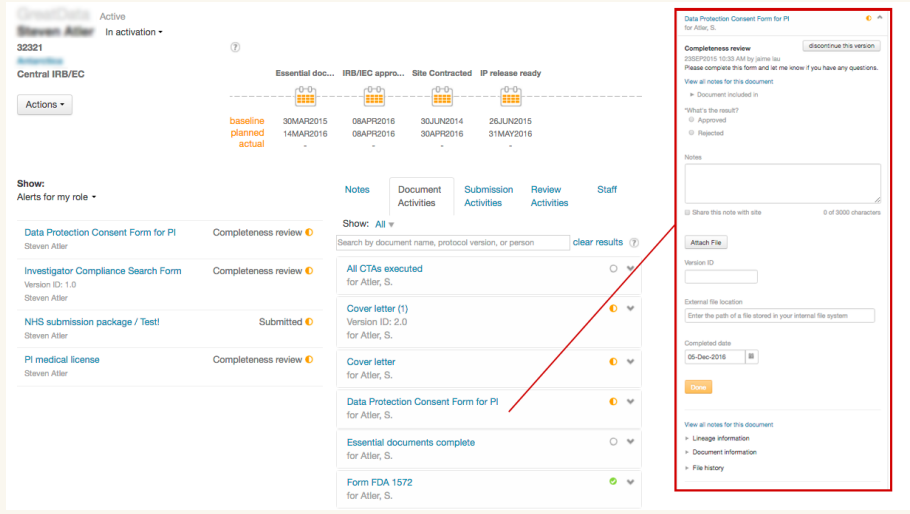
One of the biggest factors contributing to the global shortage of experienced CRAs is the lack of training opportunities for clinical professionals to begin their careers as CRAs. Many pharmaceutical companies have tabled their new CRA training programs, requiring instead that CROs have experienced CRAs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

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 CRAs assigned to their studies, typically requiring a minimum of two to four years of monitoring experience, often with expertise in specific therapeutic areas.

"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 that sites report negative impact on study operations, timelines and even quality. Collectively, this reality ultimately impacts all stakeholders."

In an industry plagued by rising development costs and increasing complexities, to what extent is the CRA shortage to blame for 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, IRB approvals and contract and budget negotiations contribute to significant trial delays, and these are not the primary responsibility of the CRA.

Figure 1: Central repository ensures permissioned accessibility and safe, reliable retrieval of documents in the case of CRA turnover



According to research conducted by the Tufts Center for the Study of Drug Development (CSDD), most protocols (57%) still require substantial amendments, which leads to significantly longer clinical trial cycle times and higher costs.

Additionally, many researchers have complained that the use of different local IRBs to review each research site for a multicenter trial is extremely inefficient and leads to additional cost burdens and trial delays. In a survey conducted by the Federal Demonstration Partnership (FDP) in 2012, principal investigators on federal grants reported that they spend about 42% of their time on "administrative burden," with IRB-related burdens ranking highest. Despite this, many U.S. research sites have been hesitant to use a single, central IRB.

Furthermore, a recent study by KMR Group that analyzed 20,000 contracts found that, over a four year period, contract cycle times have doubled.

CRA inexperience and turnover can be mitigated using purpose-built Study Startup (SSU) technology, which provides an intelligent workflow management system to guide clinical operations teams through the clinical trials process with alerts to ensure compliance with country-specific regulations and organizational SOPs. Role management ensures workflow continuity during staff turnover and analytics

based on operational metrics empowers risk mitigation efforts via the identification of process bottlenecks, which teams can proactively address. (See figure 1.)

Though sponsors have largely outsourced the CRA role to CROs (by 2020 over 70% of trials will be outsourced), the challenge is ultimately a shared responsibility. It's critical 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. However, at a time when protocols are increasing in complexity, competition for patients is on the rise, and regulatory mandates continue to proliferate across the globe. These issues make the CRA shortage feel even more acute.

Craig Morgan is a technology and life sciences management professional with more than 15 years experience in the application of informatics to drug discovery. He leads the marketing and brand development functions at goBalto, working with sponsors, CROs and sites to reduce cycle times, improve collaboration and oversight in clinical trials. Email cmorgan@gobalto.com or tweet @goBalto.