Remote Clinical Trial Monitoring: CRA Success in an Era of Autonomy

By **Danielle Starke,** inSeption Group

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Remote work became a staple of clinical trials during the COVID-19 pandemic, prompting pharmaceutical sponsors, CROs, and other service providers to refine how they conduct such trials. This shift has been most prevalent in the use of traveling HCPs (who provide care off-site), as well as more widespread use of technologies and tools supporting those individuals' remote work.

However, remote work also has emerged as a viable option for clinical research associates (CRAs) — a position typically associated with frequent travel to be onsite. As organizations have become more skillful in training and monitoring CRAs, the latter can be empowered to enjoy greater flexibility and freedom in terms of scheduling and travel while remaining accountable (ensuring remote work options do not compromise data quality or project timelines).

CHALLENGES TO CRA REMOTE WORK

High-quality data that shows the sponsor/CRO has complete control of a trial, in addition to supporting regulatory filings, is difficult enough to produce when everyone is on-site. When CRAs work remotely, trial sites must provide those individuals with data to review, and problems can occur at either end.

Sites, for example, may provide a CRA with inappropriate EMR access (e.g., data for too many patients, or data for the wrong study). That said, CRAs utilizing a full-access EMR in situations where that is common can work remotely much more efficiently. Other sites, forced into remote monitoring because they had no other options to commence or continue research during the pandemic, may have turned to digital repository systems, (e.g., Veeva Vault, SharePoint, or Dropbox) or stuck with paper records. In the former scenario, a CRA can only work from what has been placed in the repository. If it is inaccurate or out of date, the CRA is only seeing a fraction of what the EMR would look like — a recipe for errors and delays, particularly when compared to a CRA with full EMR access.

PROLIFERATE THE POSITIVE, NIX THE NEGATIVE

The biggest indicator of effective remote work is the amount of work an employee can complete in a given time span. As the pandemic revealed, some remote workers function well, needing no

oversight to finish tasks in a timely fashion, while others do not handle the associated distractions well or simply do not have a home situation conducive to productivity. Ideally, individuals are self-aware and honest with their employer about their work habits and factors that may influence their productivity. However, it remains prudent to monitor those workers, encouraging good habits and correcting unproductive ones.

Remote CRA performance can be tracked via several metrics: for example, the number of queries added into the system or the number of pages submitted for source data verification (SDV) during an eight-hour workday. Organizations also can track time stamps in the EDC system, created when a CRA ticks an SDV box in that system. Depending on the person, gaps in such activities sometimes are explainable – perhaps they were referencing regulatory documents or working with the site. Other times, it is hard to reconcile tracked activities against what a person actually was doing. Everyone works a little differently, so queries should be entered into the EDC system — creating that trail is the point. Some people prefer to handle queries via email, which can be efficient, depending on the site, but it also is more difficult to track that productivity.

Consider that the industry standard for SDV is about 50 pages per day, but that count changes based on whether the pages are considered dynamic. For example, an adverse event (AE) pulled from the system only appears to be one page, but it contains numerous log lines that must be analyzed.

Thus, it can be difficult to determine what occurs during any given CRA monitoring visit. Looking at trends generally is helpful: maybe one site visit looks like the example described above, but then the CRA's activity returns to normal. Flexibility is intentionally built into this monitoring philosophy, and that is critical. CRAs' work can be stressful and the travel unforgiving, so taking mental health moments during the day is encouraged.

But that must be balanced against fulfilling our promise to clients by working through trial data quickly and efficiently.

Typically, a clinical trial manager (CTM) would be tasked with reviewing performance metrics, but CTMs in charge of specific protocols sometimes don't have time to micromanage. There is significant benefit in having a second set of eyes whose role might be to oversee a few studies and to maintain a relationship focused on sponsor and CRA needs.

My role at inSeption Group (ISG) fills this void, promoting additional conversations, oversight, quality check-ins, and resourcing reviews, supported by one-to-ones with every person on the clinical team once a month. Not only do these consistent touchpoints build rapport, they give everyone a chance to vent about issues, feeding into continuing improvement.

UNDERSTANDING STAKEHOLDER SUPPORT, TECHNOLOGY, AND CRAS PROFICIENT IN REMOTE WORK

Typically, ISG seeks only senior CRAs that have previously worked remotely, understand their own work habits, and can complete their work with minimal (if any) oversight. That said, those attributes generally are inherent in this industry: oncology trials usually are more complex, detailed, and high volume, entailing numerous queries and emails. Accordingly, by the time people are working in oncology, they usually have years of experience, some level of proficiency, and the maturity to handle autonomy. Newer CRAs are not incapable of high-quality remote work, but they should be at a company where the check-ins described are firmly in place.

For example, ISG performs QC reports annually for each CRA, wherein I meet with them remotely before, during, and after a site visit to review process-

es, as well as to learn and reinforce efficiencies that create success. We also evaluate the effectiveness of the remote CRA's methods. Have they thought about sending the site information in a different way? How responsive has the site been to the way our CRA presents data? Have we confirmed with both the site and the CRA the best way to maintain contact? These seemingly minor insights into each site's day-to-day work — and how to best adapt to their needs — are vital to a pragmatic and functional collaboration. The clinical research team is supposed to be malleable, not the site.

Additionally, as noted above, the technologies to which CRAs have access can make a big difference in their remote performance. However, the trial sponsor ultimately decides which technologies it will invest in, based largely on the information it most values. Some have their own clinical trial management software (CTMS) versions. Others have Excel trackers that are rarely, if ever, updated properly, so oversight can be very difficult because the CRA lead or CTM only knows what the CRAs have shared.

Typically, large CROs have a multitude of trackers serving thousands of employees. These generally are well-engineered systems that collect and distribute information to appropriate parties automatically. Smaller companies can be more of a mixed bag. Something that appears to be delinquent or "in the red" — data metrics-wise — could be a mistyped equation in Excel. However, sometimes smaller organizations possess the infrastructure to provide the oversight described.

In any case, the sponsor has a say in CRA remote work, because that comprises both a financial decision and a data quality decision. Every person who must be flown to a site, and put up in a hotel while there, is a major expense, so a hybrid approach (splitting on-site and remote work) has immediate cost benefits. The choice of how to make that split is based on data, on enrollment, and on the availability of remote co-monitors — all while complying with ever-changing site policies.

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Ideally, on-site visits would be based on data. At a minimum, for instance, someone would need to go on-site twice a year, or more frequently if the data quality warrants it. Other scenarios justifying more on-site time might include a site being heavily backlogged or otherwise struggling (e.g., lots of deviations, issues, and/or retraining). A site that is high-enrolling, with critical information always prepared and accessible, that is responsive to queries in advance of site visits, is showing the ability to run smoothly with minimal oversight. The established trust between a CRA or sponsor and that site also informs the amount of oversight necessary.

FINAL THOUGHTS

It is clear that full-time, on-site work is burdensome for CRAs and expensive/inefficient for sites, while full-time remote work by CRAs is likely unsustainable because it could create a disconnect between the CRA and colleagues, or some people just don't work well remotely. Thus, a hybrid approach to remote work is best to keep both sites and CRAs productive and happy, even as oversight and trial complexity increase.

Currently, many CRA contracts stipulate up to 75 percent travel will be required. Talk to any CRA who has worked in the industry for a while about the toll heavy travel has taken on them, their families, their relationships, and even their passion for the work. Moving forward, that number should go down closer to 25 percent if organizations want to minimize the "burnout" they see among CRAs, who may leave or seek to be promoted out of the position. To support this shift, triggers indicating when an on-site visit is necessary likely will need to be implemented. For example, once a year the CRA must go on-site, or perhaps they have to visit if backlogged EDC queries exceed 100.

In sum, providing remote work options for CRAs and establishing structures to guide and monitor that work are essential to the survivability, profitability, and sustainability of an organization conducting clinical trials. Maintaining talent is a key industry challenge and a company reputed to offer lots of flexibility and autonomy, while keeping its clients happy, is an attractive place to work. That concept is rare, but incoming generations of workers have come to expect some level of work/life balance accommodations. They will not be doing less work or have diminished quality expectations placed on them, but they will be freer to perform tasks on their own time and in their own way.

To learn more, call:
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