CRIO

Case Study

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CRO uses CRIO eSource to double monitoring productivity

Achieving efficiency increases while improving data quality

PROBLEM

During COVID, a large CRO on a global Phase 3 trial faced a dilemma. Flights were getting canceled, CROs grounded CRAs, and sites decided that the last people they wanted to see were CRAs who had traveled through three major airports that week. How could the CRO stay productive, minimize the backlog of monitoring visits and ensure ongoing data quality in this environment?

SOLUTION

Takoda Roland, the global Clinical Team Manager (CTM) assigned to the study, realized that many of the sites on the trial were utilizing **CRIO eSource**. Sites that already had standardized on CRIO were able to continue recruiting patients and running trials with minimal to no disruption. This was not the case for sites that had not made the switch to eSource.

Takoda pulled in resources from data management, the sponsor, sites, and the clinical team to amend the study monitoring plan to allow for remote monitoring visits. As this was the CRO's first real use of remote monitoring, he kept metrics to ensure that the CRO could deliver on its targets. In addition, since remote monitoring meant that CRAs no longer needed to be assigned geographically, the study team cross-deployed monitors, meaning that the team's findings represented the collective experience of the CRAs - new and experienced, tech-savvy and not.

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OUTCOMES

The team was highly productive and accounted for 25% of the company's revenue in that quarter. Unlike the other study teams, they were able to work through the entire monitoring backlog for the CRIO sites, and could keep their team productively deployed. Their experience clearly showed that with remote monitoring thru CRIO eSource, the CRO can achieve 55% more monitoring days per month per CRA than with onsite monitoring - from 8-10 per month to 12-16. This increase is independent of the fact that other sites weren't enrolling or permitting onsite monitoring.

Where does the increase in efficiency come from?

- **Limited to no travel.** Not only do the CRAs save the scheduled travel time, but they don't have to deal with travel delays or the time managing travel logistics. CRAs frequently spend entire days traveling from site to site. All of this wasted time goes back to the CRAs for monitoring.
- **Scheduling remote visits is much easier than scheduling on-site visits.** Sites with eSource can accommodate many monitors with much shorter notice since they do not need to plan for physical space for the monitors. Thus, they were more flexible in accommodating monitoring visits on short notice, and could address study findings without the visit disrupting their schedules. They were also substantially less likely to cancel or reschedule planned visits.

The CRO learned that not only could they increase the number of days CRAs could devote to monitoring, but when they do monitor, they are ***20% more productive*** in terms of Pages monitored per day. CRAs were able to use multiple screens from their home offices rather than working solely from a laptop. It is easier to find information by scrolling through source data than flipping through paper charts. When there were errors, the audit logs and queries directly on the eSource page were considerably easier to close than the traditional pile of sticky notes monitors are accustomed to utilizing.

So with a 155% increase in monitoring days per month per CRA and a 120% increase in pages monitored per day, the CRO observed a ***1.9x increase*** in overall monitoring productivity (1.55 x 1.20).

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This doesn't capture the monitoring productivity from improved quality. Takoda's team noticed that the CRIO eSource sites had distinctly fewer errors than non-eSource sites. Combined with the ability of monitors to review source data closer to the date of collection, this means fewer downstream corrections and CAPAs. The team did not quantify this, so it's fair to say that ***the productivity gain is at least 2x***.

Moreover, this 2x productivity improvement ***understates*** the true potential of the CRIO model:

- This experience continued to utilize the concept of "days on site" where the monitors still have to schedule a remote monitoring visit with the site and devote the day's activity only to that site. In the CRIO model, where source is standardized across sites, monitors can simply review data as it comes in, regardless of which site the data originated from. This eliminates the need to work in 8-hour blocks, and having to assign CRAs to geographically grouped sites.
- This study had the monitors doing traditional SDV activities, which CRIO's **survey on how CRAs spend their time** shows is 30% of total monitoring time. If the CRO is using **CRIO Reviewer** as the EDC, this activity goes away entirely.
- The calculations do not factor in the negative impact of high churn with CRAs. Takoda noted that the CRAs on his team were much happier with remote monitoring and a reduced travel schedule; during the study, his team experienced 100% CRA retention. **Read more about why CRAs love CRIO.**

Conclusion

Altogether, Takoda's experience showed how powerful site eSource can be for improving quality, cost efficiency and time to market for sponsors. Now an Associate Director of Clinical Operations for a different CRO, Takoda Roland incorporates CRIO eSource in studies whenever he can. This approach aligns with his new employer, Sitero's, philosophy of using technology to empower sites and run more efficient trials.