

## Using Virtual Study Coordinators for EDC Entry and Query Resolution to Speed Up Data Access and Cleaning



### OVERVIEW

With CRIO's site facing technology, clinical research sites can globally outsource services such as EDC entry, query resolution, quality control, financial management and regulatory management. Some sites now use global coordinators to achieve overnight EDC data entry and same-day query resolution.



### CHALLENGE

Elevate Clinical, a Texas-based network of multi-therapeutic sites has set up their network implementing CRIO from the outset. The founders of Elevate also used CRIO at their last two previous site networks.

Like all site executives, Elevate founders need to protect their coordinators time, ensuring they can focus on patient recruitment and retention, while at the same time fulfilling their contractual obligations to enter the site data into the EDC and resolve data queries in a timely manner.



### SOLUTION

CRIO eSource enables new operating models. With eSource, sites can free clinical research coordinators from many of the administrative tasks they historically have performed and centralize them with more cost-effective on- or off-shore teams. In Elevate Clinical's case, they set up their own in-house, global EDC team to manage EDC entry and query resolution - a service Elevate Clinical provides to other sites utilizing CRIO.

"By offloading EDC entry to global resources, we can greatly increase the productivity of our higher-paid coordinators, resulting in more recruiting and retention," said Elevate's management team. "At the same time, our networks deliver unbelievable data entry and query resolution timelines to sponsors - critical KPIs that make our sites stand out."

While Elevate Clinical Research and other networks are creating in-house teams, other sites are using third party vendors such as Koncord Clinical Services ("KCS"). KCS has over 40 full-time resources who act as virtual study coordinators, serving on the delegation log. Their staff is cross-trained on a wide variety of clinical research competencies, from regulatory management to EDC entry.

# Using Virtual Study Coordinators for EDC Entry and Query Resolution to Speed Up Data Access and Cleaning

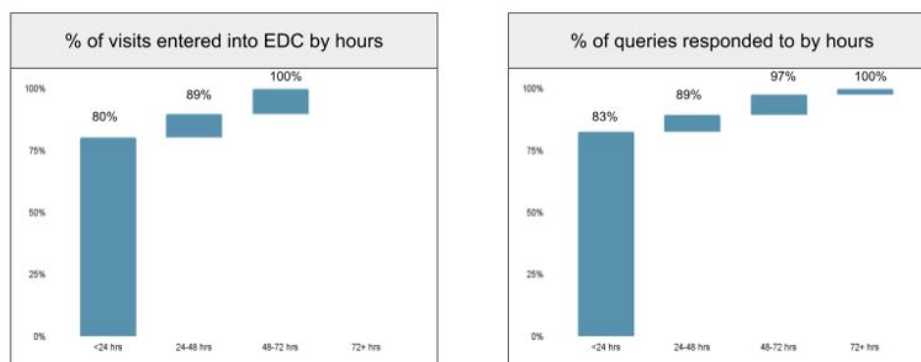
For EDC services, KCS coordinators review the site's completed source every day and enter all new and modified entries into the EDC on a same-day basis. Given that KCS is based out of India, that means the majority of time, the site's visits are entered into the EDC on an overnight basis. The KCS coordinators also review all outstanding queries in the EDC and resolve 60 to 90% of the queries themselves on a same-day basis. If site staff clarification or response is required, the KCS coordinators will inquire with the site staff using CRIO's internal querying feature, ensuring the coordinators don't have to log into the EDC to retrieve the queries.

KCS provides site directors with weekly metrics, providing transparency they usually do not have. As a complementary service, KCS can also perform source QC review and corrective action and re-training to coordinators, for complete source data oversight.

## OUTCOMES

On a recent global endocrinology study, where KCS is providing EDC services to three separate sites, the sites achieved overnight EDC entry at an 80% rate, and a 3-day EDC entry turnaround at a 100% rate, as well as a same-day data query response rate of 83% and a 3-day query response rate of 97%.

### EDC and query resolution KPIs: Site network client, major endocrinology study



Source: Service provider data for a multi-site trial with 3 sites; data is for Feb 24 through Jun 24; 312 visits total  
Note: EDC entry time based on business hour count

The average EDC entry time for these sites comes to 0.8 day post-visit, vs. 7.7 days for the industry average<sup>1</sup> - 10x faster performance.

<sup>1</sup> Harper, B., Smith, Z., Snowdon, J. et al. Characterizing Pain Points in Clinical Data Management and Assessing the Impact of Mid-Study Updates. Ther Innov Regul Sci 55, 1006–1012 (2021). <https://doi.org/10.1007/s43441-021-00301-z>

## Using Virtual Study Coordinators for EDC Entry and Query Resolution to Speed Up Data Access and Cleaning



### Conclusion

To be sure, these KPIs rely on site staff performing thorough source data collection and responding to internal queries in a timely manner. But when CRIO is used appropriately, a centralized tech-enabled service function can drastically improve site KPIs while freeing up coordinator and investigator time, creating significant value for sites, sponsors and CROs alike. As sponsors struggle to achieve recruiting and diversity targets, tech-enabled staff augmentation could be a powerful tool for site enablement and expansion of patient reach.