CASE STUDY

Case Study: Improving Clinical Trial Performance Through Central eSource

How a Top 5 Pharmaceutical Company Leveraged CRIO's eSource Platform to Enhance Site Performance, Improve Data Consistency, and Enable Remote Monitoring

70% Site Adoption

59% Fewer On-Site CRA Visits

30-day Faster Start-Up

BACKGROUND

A major pharmaceutical company undertook an initiative to improve site performance across their global studies. The company conducts numerous large trials with sites spread across multiple countries and therapeutic areas and sought solutions that could reduce burden on clinical sites leading to more efficient and effective clinical trial execution.

Following a large-scale global Alzheimer's disease trial, the sponsor observed that 43% of sites on the trial were using CRIO eSource to collect source data. Not only did this represent a significant portion of their sites, but many of the best performing sites on the study were part of this group. The sponsor reached out to CRIO to investigate whether there were ways to leverage the benefits of CRIO eSource across an entire trial.

CHALLENGE

To determine whether CRIO eSource would indeed provide expanded benefits if used at more sites, the sponsor deployed CRIO in an opt-in model for a global phase 3 Alzheimer's disease trial with **2000+ patients** and **150+ sites** worldwide. Sites were given in seven countries the option of using CRIO eSource for data collection.

The sponsor identified two primary objectives for this proof of concept:

1. **Improved Site Performance:** Enhance operational efficiency and data integrity by reducing manual processes and potential errors.
2. **Consistency in Data Collection & Quality:** Achieve standardized data collection across all participating sites through the implementation of uniform templates and processes.

Sites that opted-in received training and access to CRIO. The sponsor and CRIO worked in close collaboration to produce a standardized source template that was deployed across sites. CRIO then worked directly with sites to configure the template to meet their needs and preferences while maintaining the consistency that was key to improved data quality. This process was intended to increase voluntary adoption by sites, avoiding the pushback that often comes with mandatory system implementations of sponsor provided technology. Additionally, by providing the core template upfront, it decreased the effort normally required by sites to translate the protocol into a site specific source template.

RESULTS

While still early in the execution of the study, the sponsor has already reported significant benefits at sites that opted in to Central eSource.

Key Success Measures

70% site adoption

The site adoption rate for this initial study was substantially better than the sponsor anticipated.

59% fewer on-site monitoring visits at eSource sites

Remote monitoring visits cost 30% less per visit for this study. Central eSource CRAs can review data from anywhere there is an internet connection.

30-day faster start-up

Sites received protocol-driven source immediately after selection and were ready to begin without needing to create their own source documents.

24% improvement in monitoring effectiveness

All source is in one place and edit checks flag issues at the time of patient visit reducing downstream clean up. Monitoring effectiveness was measured as the number of patient visits a monitor reviewed per day.

Although this study is only partially complete, the sponsor believes the results will continue to improve over time. Additional results will be shared as the study progresses.

FUTURE PLANS

Following the clear successes demonstrated in the early stages of the pilot, the sponsor is already planning for expansion to new studies. Seven additional studies where CRIO will be deployed have already been identified.

Moving forward, the sponsor and CRIO are examining the lessons learned to optimize the system and processes moving forward to maximize benefits for sites and the sponsor alike.

EDC Integration Expansion

Early on, the sponsor and CRIO identified the substantial additional benefits that could be realized through a full integration with their existing EDC system. Work began on this integration during the pilot and user acceptance testing is currently underway. Future studies will feature EDC integration from the outset.

Additional benefits to EDC integration include:

- Eliminating source data verification (SDV) for all data transferred through the integration.
- Reducing site coordinator time required to re-enter data from source into EDC.
- Improving data quality by eliminating errors associated with data transcription.

Study Design Improvements

For the pilot study, the core source template was developed by CRIO in collaboration with the sponsor. One observation was that many of the site level configuration changes that were made were common across multiple sites. For future studies, several experienced CRIO sites will also participate in the development of the core template to reduce the number of common local configuration changes that need to be made.

Translations

Work is underway to translate the core platform in additional languages and to allow for automated upload of translated source documents to allow deployment of CRIO in additional countries. CRIO already offers multilingual user support through LiveChat and translated documentation and training materials in numerous languages.

This partnership demonstrates how strategic site technology adoption, when combined with a user-centric approach and voluntary implementation strategy, can deliver significant operational improvements while maintaining high levels of site satisfaction and engagement.