CRIO

Case Study

617-302-9845
sales@clinicalresearch.io
www.clinicalresearch.io

CRIO Provides Data 90% Faster Without Sacrificing Data Quality

Using CRIO to Run Trials Across a Large Network of Specialty Practices

OVERVIEW

Our client is a diversified health care service provider with thousands of specialists who treat well over 10 million patients.

This client operates a clinical research arm that runs large-scale observational studies on behalf of pharmaceutical clients. Through their real-world evidence database, they can run feasibility and recruit from 10+ million patients, then manage the studies across the practices.

They selected CRIO for their data platform and implemented it across three studies to date. CRIO's technology allows a small in-house staff to remotely manage multiple studies while delivering high-quality data at 90% faster speed than typical industry solutions.

CHALLENGE

From late 2022 through early 2023, our client started 2 large-scale studies for pharmaceutical sponsors: a multi-site, 18-month, 1000+ subject cancer study and a 25-site, 5-year, 500 subject oncology registry. In addition, they launched a third internal study designed to abstract and aggregate medical chart data for future registry use.

With these large scale study efforts and a monitoring team of just two, our client needed an efficient, scalable solution that would standardize data collection across their sites while enabling a centralized, remote monitoring process.

CRIO Provides Data 90% Faster Without Sacrificing Data Quality

SOLUTION

Their team was already familiar with CRIO's eSource solution from one of their active sites. When the team saw CRIO's integrated sponsor-facing EDC application (Reviewer), they quickly realized the CRIO system would allow them to scale rapidly.

With CRIO, our client builds study templates and publishes them to the research sites, which ensures accurate upfront data collection. Once the data is collected, CRIO surfaces the anonymized data in the Reviewer application within minutes. CRIO eliminates the need for double data entry, traditional onsite monitoring, and a significant amount of source data verification. Critically, the CRIO system ensures that the sites' Protected Health Information (PHI) remains within the site databases, thus preserving patient anonymity for the study team.

For sites, CRIO eSource provides an extremely intuitive and efficient interface for collecting data. Because the system's edit checks operate at point of capture, sites collect data in a protocol compliant manner, with minimal errors and without the resulting need for downstream data corrections. Because CRIO eSource was built and perfected over several years for direct site usage, even the new-to-CRIO research sites were self-sufficient after just a few days of training and usage.

Meanwhile, the Reviewer application is intuitive and easy to navigate, and organizes the workflow to enable the clinical team to clean and lock data quickly. "I appreciate how CRIO's Reviewer organizes tasks for us," said the Director of Clinical Operations. "It lets us know when visits are done and ready for review, what queries are outstanding vs. what queries we need to attend to, and what changes have been made to the source since our last review."

CRIO Provides Data 90% Faster Without Sacrificing Data Quality

OUTCOMES

CRIO accelerates sponsors' access to study data by 90%. Unlike a traditional approach with EDC being used as a secondary data system, CRIO's system surfaces source data immediately into Reviewer, letting the study team perform contemporaneous and continuous monitoring.

Besides facilitating rapid review by the monitoring team, the system, in parallel, obtains PI signature on the completed source visits. Once the visit has been reviewed, all queries resolved, and the PI signature obtained, Reviewer allows the clinical team to lock the visit.

The study team typically locks a visit within 2 weeks of the visit being completed. This is about 1/10th the time of the industry standard. In a typical trial, the local site may take 1-2 weeks just to enter the visit data into the EDC, and then an onsite monitoring visit needs to occur on a 6-8 week cadence for the purpose of source data review and source data verification. Sometimes two monitoring visits need to occur before the data is considered ready for Data Management to approve and lock. The entire cycle time can easily take 12-18 weeks.

Because of this lock-as-you-go cadence, our client provides their sponsors study data extracts that are much more accurate and up-to-date than in traditional EDC-based studies. They also leverage CRIO's flexible reporting system to create customized data views and study KPIs. Since these reports are querying actual source data, they are far more reliable and contemporaneous than traditional EDC-generated reports.

CRIO Provides Data 90% Faster Without Sacrificing Data Quality

Conclusion

With CRIO, our client has developed a powerful and unique value proposition: The ability to standardize, review and extract data at 90% faster speed than a normal trial. When combined with their analytics capability and access to 25+ million patients, the value proposition is extremely compelling. And thanks to a lean, remote monitoring model, our client can deliver all of this at a substantial cost savings to traditional CROs.

With CRIO, their Director of Clinical Operations foresees even more growth potential. For one, CRIO's site-facing tool can be used to operationalize research at research-naive physician practices, allowing them to go deeper into their physician bench. Beyond this, the client recently started utilizing CRIO's open API to send extracted EMR data into the CRIO Recruitment module that their sites use. From there, the site team can review, curate, and push the data into the study eSource, thus ensuring an end-to-end digital pipeline from the local practice's EMR into the site's own trial registry and ultimately the study registry.

CRIO enabled this client to become a fully integrated, tech-enabled CRO that can offer their Life Science clients extensive patient access combined with accurate, super-fast, and cost-efficient data delivery.