eClinical
Powered by elluminate®

Case Study

Executing Data Management Solutions for eSource-based Workflows in Phase 1 Trials



Project Background

Our client, a top 20 pharmaceutical company has a portfolio extending across rare diseases, oncology, and immunology indications. The client's longstanding partnership with eClinical Solutions encompasses both adoption of elluminate Clinical Data Cloud, and biometrics services outsourcing for over 15 Phase 1 trials.

The client planned a double-blind, placebo-controlled dose escalation Phase 1 study. Rather than deploying a traditional electronic data capture system, the clinical CRO (Contract Research Organization), working directly with its own network of Phase 1 units was using an eSource tool to collect data directly from the sites. The client approached eClinical Solutions for a solution combining elluminate and eClinical Biometrics Services to handle the data management for this study to tight timelines.

The advantages of adopting eSource include reduced cycle times, improved data quality, and greater potential for remote monitoring.

In the context of greater trial decentralization, workflows for effectively handling eSource approaches are increasingly vital.

Challenges

The central focus of Phase 1 dose escalation trials is assuring the safety of patients in determining the Maximum Tolerated Dose with investigators and sponsors reviewing all data at defined points and documenting the dose escalation decision.

This particular Phase 1 trial involved over 50 patients across several cohorts with more than 5 external data sources. The assertive timelines incorporated data review meetings every 3 weeks.

> "With the trend towards decentralized and hybrid trials, we would expect to see an increase in use of trials that use eSource."

Diane Lacroix
VP, Clinical Data Management, eClinical Solutions

Company Profile

- Top 20 Ranked Pharmaceutical Company in Revenue
- Headquartered in Europe
- 90,000+ Employees

eClinical

Products Utilized

→ elluminate Clinical Data Cloud
→ Biometrics Services

Solutions

The eClinical Solutions leadership and assigned biometrics services team designed a solution that allowed the data from the eSource capture tool and external data sources to be ingested into elluminate with data cleaning conducted on an ongoing basis within the elluminate platform.

The successful implementation relied on excellent communication and working relationships between eClinical Solutions, the sponsor and the clinical CRO. As a specialist provider of biometrics services, eClinical Solutions is adept at stakeholder management, and ensuring seamless collaboration with third parties to meet the needs of the sponsor.

There was significant complexity with multiple external data sources and variation between the eSource data structures across the sites which the eClinical team normalized by using the mapping and standardization functionality within elluminate.

Customized creation of workflows to support non-EDC model

The eClinical Solutions data management team devised a coding workflow whereby data was exported from elluminate, imported into a coding tool complemented by manual coding and then reintegrated into elluminate on an ongoing basis.

A customized data visualization package within elluminate informed the client's regular data review meetings.

The eClinical Solutions team designed a hybrid workflow combining tech-enabled and manual processes to generate and resolve queries using issue management functionality in elluminate.

Agile project management to meet needs of speed-driven trial

To meet the fast pace of the project, the eClinical Solutions team created micro timelines including expectations for review cycles, documentation, receipt of external data and other milestones to ensure that activities remained on track. The team assigned a dedicated portfolio lead to oversee the deliverables and implemented frequent stand-up meetings to report progress against the plan.

> "Achieving the speed of data cleaning to accommodate the client's cadence of data review meetings would have been impossible without our team's use of elluminate."
>
> **Diane Lacroix**
> VP, Clinical Data Management, eClinical Solutions

Success factors

- eClinical Solutions' track record of leveraging people, processes and technology to create and execute innovative solutions
- Strong, well-established collaboration with the sponsor provided a solid foundation for novel approaches to succeed
- Both the client and the clinical CRO partner had already adopted elluminate, facilitating the creation and use of decentralized workflows
- The project benefited from eClinical Solutions' deep experience in Phase 1 clinical trials and supporting real-time, fast-turnaround data cleaning and review to enable rapid decision-making

Results

The team was able to coordinate multiple activities and meet the assertive timelines for the project, which encompassed significant data volume and variety for over 50 patients.

By cleaning data for each cohort on an ongoing basis within elluminate, the team coordinated the data management activities for adverse event coding, SAE (Serious Adverse Event) reconciliation, external data, and client data review so that the data was continually analysis ready and to enable an expedited data lock.

This project resulted in an innovative, streamlined framework for working directly with eSource data in collaboration with sponsor, clinical CRO, eClinical Biometrics Services, and elluminate. Future projects will further extend automation to include query resolution.

The strategy realized both cost and time savings for the client.

For more information, please visit us at:
eclinicalsol.com

Or email us at:
info@eclinicalsol.com

©2023 eClinical Solutions LLC. All rights reserved. elluminate® is a registered service mark of eClinical Solutions LLC.