eClinical
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Case Study

Simplifying external data management for complex rare disease trials with people, process, and technology

BACKGROUND

Our client is a biotechnology company headquartered in the USA creating novel therapeutics for rare diseases.

They have a portfolio of early phase studies investigating their innovative product for an area of high unmet patient need. In rare diseases, every data point counts, so the biotechnology client approached eClinical Solutions to support their biometrics services and execute an end-to-end data strategy from EDC (Electronic Data Capture) implementation to statistical analysis and reporting. While these projects have many unique challenges across the data life cycle, for this case study we focus on the specific challenges the client faced in handling the external data volume and variety characteristic of increasingly complex trials. We will explore the solutions that eClinical Solutions put in place through its Biometrics Services, Center of Excellence for External Data, and the elluminate Clinical Data Cloud®, and highlight efficiencies achieved working across several studies.



THE CHALLENGE OF EXTERNAL DATA

With ongoing technology advances and an increase in overall research complexity, trials are now incorporating an ever-increasing variety of data types and sources collected outside of traditional electronic data capture (EDC) systems. This volume and variety, combined with growing data velocity, brings transformational opportunities for richer patient insights, and more efficient clinical development. However, a proliferation of external data brings accompanying challenges of standardization, reconciliation, and more complex vendor collaborations. In the face of this continual change, it is important to take a strategic approach to collecting, processing, and managing external data, and avoid bottlenecks that risk delays to Last Patient Last Visit (LPLV) to database lock cycle times.

Key challenges and risks include:

- Handling data transfers and data transfer agreements with multiple vendors and ensuring that any risks are identified and addressed swiftly.
- The integration and standardization of diverse data types including biomarker and genetic data.
- Overcoming variability in how external data sources are collected, managed, and curated.

SOLUTIONS

eClinical Solutions delivered full end-to-end biometrics services to the biotechnology client, with the capabilities of the elluminate Clinical Data Cloud embedded throughout the data life cycle. As part of the Biometrics Services group's continual transformation towards clinical data science framework, it has established a Center of Excellence for External Data. As a crucial pillar of biometrics services delivery for complex trials, the Center of Excellence develops and disseminates best practices cross-functionally, leverages elluminate® adoption to enable more effective external data management, and oversees external data workflows. The solution incorporated:

An external data management lead was assigned as part of the overall biometrics team, working closely with the portfolio lead, data managers, and biostatisticians. The external data management specialist identified that the risks inherent with multiple vendors, required meticulous oversight and a comprehensive system of tracking to ensure positive outcomes.

The solution implemented to streamline the external data process flow included:

- The team conducted a specific external vendor kick-off meeting with the sponsor to discuss workflows and expectations, and identify any key risks.
- A full tracker was established at the outset of the engagement documenting all vendors, Data Transfer Agreements (DTAs), milestones, timelines, and status of deliverables.
- All members of the internal delivery team and the sponsor were provided with full visibility over the tracker, and it was discussed during regular calls with the client to monitor the project's progress.



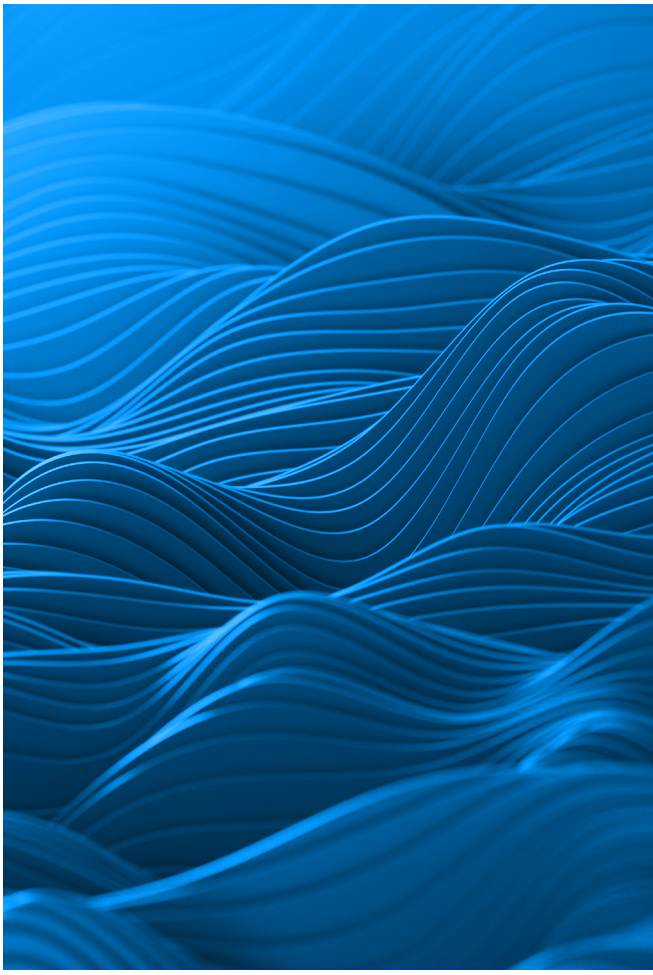
To streamline data standardization the eClinical Solutions team developed and shared DTA templates with vendors by specific data type, including guidance to facilitate CDISC compliance.

The portfolio of complex trials involved multiple parts and interim locks, where the provision of external data was essential to the interim analysis. With a birds-eye view of the external data vendors and the required deliverables, the team could easily identify and target the highest priority vendors critical for the completion of the respective study parts. The oversight also enabled risk profiling of vendors to mitigate issues or escalate to the trial sponsor as required.

For some of the external data types, standard exception listings were unusable for reconciliation checks. To handle this additional complexity, the team put in place a hybrid solution whereby the reconciliations were programmed in SAS before ingestion into the elluminate Clinical Data Cloud.

Lessons learned were conducted for each study within the portfolio to ensure external data insights were carried from one study to the next.

With studies using the same data types and often the same vendors, the team was able to reuse DTA components to the next to streamline the process flow.



OUTCOMES

The proactive approach to external data handling supported the timely delivery of interim analyses across several studies.

For one of the most complex studies in the portfolio, incorporating over 16 vendors, the team was able to accomplish LPLV to database lock 30% faster than the industry average.

Time and cost efficiencies were created for external data handling across DTA agreements, templates, reconciliation specifications and communication flows.

To streamline future studies, the Center of Excellence for External Data continues to enhance its roadmap for tracking and KPIs.