eClinical
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Case Study

Next Generation Data Management Strategies for Clinical Trials

Lessons Learned Using an Agile Approach



Challenges In Data Management

Karyopharm had multiple trials in their pipeline, all in various phases of development, and all on tight timelines. Each of these trials produced large amounts of complex data reported from multiple sites and in varying formats. Rather than devote the majority of their time to data aggregation, cleaning, metric generation, and the manual development of SAE and external data reconciliation, Karyopharm's clinical operations team decided to outsource these tasks.

> "We wanted to work with a subject matter expert—someone who knew the technology we wanted to use and could deliver on the use of that technology."
>
> **Lilia Fenelon**
> Associate Director of Clinical Data Management, Karyopharm

Solutions:

Outsourcing Data Acquisition and Aggregation

To help gather and analyze data — mostly in their hematologic malignancies trials — Karyopharm turned to Biometrics Services team and their Clinical Data Cloud, elluminate®.

Biometrics Services include services in data acquisition, clinical data management, data conversion and standardizations, as well as biostatistics and statistical programming. The company's elluminate platform enables end-to-end data management, allowing users to import clinical trial data as well as map, visualize, and export that data for submission.

Managing Tight Timelines

Karyopharm had multiple trials in their pipeline competing for resources. These trials were on an extremely ambitious timeline, with multiple protocol amendments and deliverables expected yearly.

Karyopharm® Therapeutics

- Founded in 2008
- Headquartered in Newton, MA
- Focused on commercializing novel drugs to treat patients with cancer and other major diseases

elluminate®

Products Utilized

→ Biometrics Services
→ elluminate Clinical Data Cloud

Success highlights

1. Five database locks that provided data for FDA Approval
2. Four Phase II studies deployed in four months
3. Accelerated database build for SARS-COV2 research

To address the needs of these competing trials, the eClinical and Karyopharm teams communicated cross-functionally. eClinical's team attended calls with Karyopharm CRAs, and Karyopharm's medical directors were able to discuss coding issues with eClinical's coding team. This efficient communication allowed Karyopharm to allocate resources when and where they were needed in order to achieve timeline milestones.

Using an Agile Data Management Approach

When eClinical and Karyopharm began working together, Karyopharm's Phase I studies were already underway and needed to be updated to incorporate a more flexible design of the Medidata Rave EDC system which was initially not designed to support the type of protocol amendments that were expected. The company also needed a series of Phase II studies built, and these builds required a complex study design and implementation of the Rave Clinical Cloud.

To address these varying needs within a tight timeline, eClinical and Karyopharm instituted an Agile approach. "This means using principals of Agile software development methodology and applying them to data management," Fenelon explained.

One of the key principals of an Agile Approach: Build on efficiencies you've already designed and build on lessons learned from previous studies. The teams created a system that incorporated adaptive planning, early delivery, continual improvement, and a rapid, flexible response to change.

Top Three Lessons Learned

Anticipate Protocol Amendments

The more complex protocols are, the more difficult they will be to amend. "You don't want to build complex database dynamics," said Diane Lacroix, VP Clinical Data Management at eClinical Solutions. "They're difficult to modify." Lacroix recommends that companies consider the downstream impacts of their trial and anticipate changes they might have to make. They can then rapidly build amendments into their database and minimize database timelines.

Use Available Technology

Utilizing technology across both teams allowed Karyopharm and eClinical to reduce the manual and administrative work these assignments previously required. Incorporating lessons learned from each study into the technology process allowed for continual improvements to each subsequent study.

Be Strategic When Cleaning Data

With trials competing for resources and completion of key deliverables on a tight timeline, the Karyopharm and eClinical teams found it efficient to stratify their database subjects into different groups, rather than attempting to tackle whole databases. elluminate's data aggregation and analytics capabilities were key in allowing the teams to clean data in a timely, effectual manner.

Results

Working with eClinical Solutions Biometrics Services and the elluminate Clinical Data Cloud, Karyopharm achieved greater efficiency and agility across their portfolio of trials, by simplifying their data flow. Source data from the Medidata Rave Clinical Cloud along with data from numerous Lab providers and other sources all flowed into elluminate and allowed Karyopharm to expedite their data collection, cleaning, and analysis processes. These process enhancements alongside a productive partnership with eClinical Solutions enable Karyopharm to accelerate development and maximize the value of their clinical data moving forward.

The Results:

- Four Phase II studies deployed in four months
- Five additional studies and 25 protocol amendments delivered
- Five database locks that provided the data for an FDA Approval in 2019 for Xpovio
- Established a strong foundation of technology, people, and process to underpin ongoing agile research, including Karyopharm's response to the SARS-COV2 pandemic

> "The [eClinical Solutions'] team's knowledge of Karyopharm data standards and processes combined with their expertise in data collection platforms and clinical data management practices helped us meet our accelerated timelines for this important new research."
>
> **Kristan Gallitano**
> SVP Development Operations at Karyopharm Therapeutics

Positioning Karyopharm for efficiency in a new era of clinical development, and supporting time-critical SARS-COV2 research

This overarching data approach enabled Karyopharm, with eClinical Solutions' support, to respond decisively during the SARS-COV2 pandemic. With high unmet clinical need and a global crisis, accelerated research and streamlined workflows became more important than ever. When Karyopharm initiated randomized clinical trials in hospitalized patients with severe Covid-19, the team built a fully validated database for physicians and patients in a 15-day compressed timeline to meet the first patient milestone.

In addition to the technology and process benefits, Karyopharm has reaped the rewards of a long-term partnership with the eClinical Solutions' team, dedicated to data stewardship and delivering successful outcomes over the long term in a new era of digital trials.

For more information: **eclinicalsol.com**
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