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Case Study

Wave Life Sciences Increases Data Review Quality and Efficiency



The Business Challenge

Wave Life Sciences had a stringent list of requirements for a data management solution. They needed a single solution that could import and ingest all of their data, from EDC to external vendors, into a centralized platform. They also needed the ability to conduct structured and efficient cross-functional data reviews, with the ability to access their most recent data quickly. They were looking for a solution that could integrate easily into their existing infrastructure, while allowing them effective oversight of data and all activities performed. Wave had a strenuous evaluation process to make sure that all team members were satisfied with the finala decision.

The Solution

As an eClinical Biometrics Services client, Wave Life Sciences was already benefiting from the team's clinical trial expertise. When presented with the possibility of expanding their relationship to draw on eClinical's other services and software expertise, Wave was eager to learn more. The team at Wave quickly discovered that elluminate® Data Central met all of their requirements for a data management workbench solution.

Since the solution was customized to Wave's specifications, deployment was a collaborative process between the medical monitor, all stakeholders and eClinical. Role based configurations were set up within elluminate Data Central, where all users have access to data, but each role has specific data that they are expected to formally review. This allowed for cross-functional data analysis for all team members. Data Central also addressed the issue of determining which data was reviewed by each user to ensure that there was efficient follow-through on all data review processes. Enabling the ability for team members to work collaboratively through the data management process helped gain stakeholders' agreement on the platform, as they knew what was expected of them in advance.

WAVE™
LIFE SCIENCES

- Genetic medicines company committed to delivering life-changing treatments for people battling devastating diseases
- Founded in 2012
- Headquarters in Cambridge, Massachusetts

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Success Highlights

- One centralized issue log in elluminate speeds time to resolution
- Clear roles and responsibilities for discrete data points decreases data review cycle time
- On-demand SDTM data provides data access in real time to data management customers

> "Since implementing elluminate Data Central, there is no backlog in data, data review or queries in the studies that use the platform. Everything is addressed in a timely manner, both internally and from the eClinical team."
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> **Jelly Dominic Maratt**
> Director, Data Management, Wave Life Sciences

Although the initial collaboration took time, as Wave was looking for cross-funtional assessment and agreement on the platform, it took just over three months to get Data Central set up on their first study. The training was provided by eClinical, and Wave was able to leverage the expertise of the lead data manager and the elluminate implementation expert whenever needed.

Increased Data Visibility

With almost half of all data coming from external sources, the most important requirement for Wave Life Sciences was that all their data sets were integrated into a single source. elluminate Data Central, a data management workbench, can integrate with any data source and streamline it into a single, centralized system for management, review and analysis. It can support any number of studies within the platform and all data are available on the dashboard. Although data review is assigned to specific roles, users can access and review all data, either for acceptance or for reference, allowing for a holistic data review process.

Within the platform, EDC data are refreshed every night to ensure that users can view the most recent data when they log in. They are also able to configure an agile refresh with seamless real-time integration, which Wave has found to be beneficial when the team is working towards a milestone or deliverable, such as database lock. To ease the review process, SDTM generation is part of the clinical data import process into elluminate. This takes place within 10 minutes of a database refresh. Because data are visible at all times and updated frequently, trends and issues can be quickly identified and addressed. This enables data to be delivered in a timely manner to meet deadlines for specific tasks.

Results: Timely Review of Data and Queries

The data review process is a role-based, collaborative exercise between all users and stakeholders. Because this was all predetermined and required agreement by all users, Wave Life Sciences has noticed that all data review are accomplished almost instantly. There is no longer any backlog for data review.

In addition, they've noted that all queries are addressed promptly. As there is transparency across all users, the Data Central dashboard has a summary of all open and resolved queries, along with who it is assigned to and who created the query. Issues can either be assigned to an eClinical data manager or to an internal Wave user. All issues are resolved and tracked within the Data Central module, which improves visibility. Prior to using Data Central, issues were created in a log and tracked by users through email. Now, each item can be easily tracked in the platform through each round of review. Every three months, a report of all issues is created within the platform. This can be reviewed by all users to see if there are any trends or larger problems that need to be addressed.

Conclusions

Finding new treatments for rare disease is a complicated process and the goal of the Wave/eClinical collaboration is to streamline the data review and management process to help researchers monitor patient safety and determine therapy efficacy as quickly as possible. "Since implementing elluminate Data Central, there is no backlog in data, data review or queries in the studies that use the platform. Everything is addressed in a timely manner, both internally and from the eClinical team," said Jelly Dominic Maratt, Director, Data Management, Wave Life Sciences.

eClinical clients accelerate their trials and power their most important initiatives with the elluminate Clinical Data Cloud® and Biometrics Services.

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