

Lessons Learned from Implementing an Enterprise Clinical Data Hub

Business Challenges

Clinical data is not only driven by complex protocols and medicine, but it also stems from multiple sources (Labs, EDC, CTMS, wearables, among others). Agios needed a way to collect, compare, and extract meaning from their clinical data.



“The question is how do we utilize technology advantages to manage our clinical data more efficiently?”

Bob O'Connor

Associate Director, Clinical Data Systems, Agios Pharmaceuticals

Agios required a system that would streamline and centralize data acquisition, one that would allow them not only to intake, but to output data for review and analysis. They also wanted a platform that possessed the ability to map that data in a standard structure, SDTM, and enabled the review of data-sets with user friendly visualization. Their ultimate goal was to implement a data hub that would allow them to analyze their data in-house, saving both time and money.

Solution

SELECTING AND EVALUATING A CLINICAL DATA HUB

Agios employed a cross-functional team of members from IT, clinical operations, safety, data managements, and biostats. To evaluate the various providers, they created a list of testing criteria that they used like a report card. While the cross-functional team tested the product, a quality team audited the vendor for proper practices.

The first product that Agios piloted took the team four months to fully test. “We learned a lot from that process” said O'Connor. Though the functionality of the product was adequate, the team agreed that it needed a few enhancements and, overall, the product wasn't as user friendly as they wanted it to be. Luckily, the company had better luck piloting a second clinical data hub: illuminate.

USE OF THE ELLUMINATE® CLINICAL DATA HUB

For its second pilot product, Agios used eClinical Solutions' cloud-based Clinical Data Hub, illuminate. The illuminate platform allows for end-to-end data management by

CLIENT BACKGROUND



Founded in 2008 and headquartered in Cambridge, Massachusetts, Agios Pharmaceuticals is a company of over 500 employees that focuses on cellular metabolism and precision medicine. Their three focus areas are cancer metabolism, rare genetic disease, and metabolic immuno-oncology.

Among their molecules in various stages of clinical development are IDHIFA (co-developed with Celgene), TIBSOVO, Vorasidenib, and Mitapivat.

not only enabling the import of clinical trial data, but by also allowing users to map, visualize, and export that data for submission.

illuminate can ingest data from multiple sources and in almost any format. While the platform retains the data in its original format, it also enables standardization of that data into a powerful relational database engine and groups it into user-defined staging areas. Agios not only made use of illuminate’s data repository capabilities, but also illuminate’s Mapper application. Mapper employs an intuitive drag and drop interface that allows users to produce customized data sets as well as map those sets to SDTM. Once uploaded, both raw and mapped data sets are available for visualization, enabling users to easily review and analyze their data.

KEY PRACTICES & LESSONS LEARNED

a) Establish Testing Criteria

Know what qualities you wish to evaluate in a product, “especially if you don’t know what kind of functionality is available in the market,” said O’Connor. Having the criteria and the score card made the ultimate selection of illuminate’s Clinical Data Hub easy.

b) Involve QA

Make sure Quality Assurance is engaged early in the process. “Involving QA in the selection process enabled us to perform our evaluation of illuminate faster,” said O’Connor, speaking about Agios’ pilot program.

c) Check Resources

“Make sure you have appropriate resources lined up for when you’re doing your testing,” O’Connor advises. Agios had multiple GXP systems going live for other projects, and the Data Systems group was competing for necessary resources.

Results

By implementing data loading, reporting, mapping, and extraction through illuminate, Agios was able to simplify its data flow. As part of the implementation, Agios validated illuminate’s data loading module, including importing data from its Medidata Rave URL and from individual vendors (through the use of Aspera).

To date, Agios has completed SDTM mapping for numerous studies. “We achieved excellent Pinnacle 21 scores as well, demonstrating illuminate’s ability to produce compliant, submission-worthy SDTM data sets,” said O’Connor.

Moving forward with illuminate

Agios is in the process of expanding their use of illuminate, including rolling out the Clinical Trial Operations Analytics product for use by Clinical Operations. illuminate Data Central is also being considered. “We see Data Central as something that could play a central role in our data review process... That’s something we’re very excited about.”

ENTERPRISE CLINICAL DATA HUB – TESTING CRITERIA SCORE CARD

Is 21 CFR Part 11 Compliant.	Includes an efficient mapping interface.	Is able to demonstrate data integrity by creating a true copy of data sets.
Is Able to configure the System Administration to both user accts and system metadata.	Contains SDTM metadata built into the system.	Contains role-based reporting permissions to access reports.
Possesses automated data loading capabilities.	Is able to import and export mapping programs for reuse.	Allows for access to canned and programmable reports.
Accepts multiple data formats from multiple sources (EDC, FTP, network drives).	Contains automated mapping execution.	Is able to export reports and visualizations in multiple formats.
Is Able to identify changes in source data format.	Contains a folder system to store loaded and exported datasets, study documents, e tc.	Possesses interactive filtering and drill-down capability.
Contains an alert system for load failures.	Is able to extract data in multiple formats.	
Is able to map data sets in SDTM.	Is able to automate extracts.	
Is programmable from any source.		

For more information or to request a demonstration, visit us at www.eclinicalsol.com or email us at info@eclinicalsol.com.