

Embracing End-to-End Clinical Data Management

Top 20
Global Pharmaceutical

Companies are experiencing increased costs, greater risks, and trial delays due to cumbersome manual data management processes, reliance on vendors, and a time-consuming need to reconcile data across multiple systems. One pharmaceutical company examined their approach and discovered the value of advanced data management technology.

+ The Challenge

The study teams at this Top 20 global pharmaceutical company were finding it increasingly difficult to manage, trust, and share their clinical data throughout the life of a trial. Data flow was both linear and manual, and business processes were designed on a per-study level. This required complex workarounds to address the problem of key stakeholders lacking access to available data within appropriate timelines.

The data management team was relying on more than 100 ad-hoc reports that needed to be created for every study, due to lack of adherence to standards. Study Data Tabulation Model (SDTM) mapping was done before entering their existing data repository, so if data was needed before SDTM was available, it took an extraordinary effort to fulfill the request.

+ The Implications

Under even more pressure from growing data volumes coming from disparate sources, complex data management standards, and the FDA requirement of full data lineage, the company decided to look for a better way.



+ The Solution

Having standardized on Oracle Health Sciences InForm (EDC), the company decided to explore data management solutions with Oracle. After sharing their challenges, requirements, and vision for the future state, and learning more about Oracle Health Sciences Data Management Workbench (DMW), they decided DMW was the right solution. Some of their key requirements, which were met by DMW, were:

- Use of a library of global standards
- Implementation of parallel business processes
- Complete traceability from source to submission to meet FDA requirements
- Movement of SDTM mapping to after data review



The real-time access to new data was one of the biggest benefits we saw with DMW. To not only have the queries fire against external and InForm collective data, but then to feed that back without human intervention to the site was a win-win. We couldn't pass it up.

+ The Results

With Oracle Health Sciences DMW, the company was able to automate and streamline processes to eliminate the time and risk associated with their previously manual data collection and standardization processes. This ultimately led to a significant decrease in costs associated with data management. With DMW, the company now has:

- A highly scalable and secure clinical data warehouse
- Seamless integration with their InForm EDC system, as well as other external data sources
- Built-in data conformance and traceability, and robust and flexible binding features, to ensure data consistency and quality
- A metadata-driven mapping engine which enabled them to move the SDTM mapping out of the critical path, reducing trial lead time

With the help of Oracle Health Sciences, this Top 20 pharmaceutical company was able to re-tool their entire data collection, cleaning, transformation, analysis, and reporting structure to streamlines processes, improve quality and achieve the coveted "single source of truth".

FIND OUT MORE

Contact us about
Oracle Health Sciences
InForm (EDC) and Data
Management Workbench

+1 800 633 0643

www.oracle.com

[healthsciences_ww_@oracle.com](mailto:healthsciences_ww_grp@oracle.com)