



■ Business impact

Using SAS, a top-10 pharmaceutical company has reduced a 45-day processing and reporting cycle to two days.

■ Challenges

- **Reduced “time on patent.”** Costly delays reduce “time on patent” before generic production begins.
- **Changing regulatory demands.** Compliance with current guidelines and CDISC standards (ODM, SDTM) is difficult.
- **Data discrepancies.** Inconsistencies that need to be reconciled with source data cause time delays.
- **Multiple data formats and sources.** Study data submitted in different formats from multiple global clinical sites is hard to integrate and standardize.
- **Unpredictable end-of-study demands.** Last-minute issues and unforeseen problems necessitate the support of unscheduled data management resources.



**THE
POWER
TO KNOW®**

How can we streamline late-stage clinical development processes to speed regulatory submissions and approvals?

YOUR GOAL: Get new drugs to market faster

In the competitive race to market, pharmaceutical companies are continually looking for better ways to reduce the time between end-of-study and FDA submission. Accomplishing this requires that you address the issues that cause delays in collecting, verifying and auditing the accuracy of your data and in converting that data into the right format for statistical analysis.

Combining disparate data from multiple sources and systems can result in errors, discrepancies and a backlog of queries that require unplanned time and resources to resolve. In addition, as pharmas and CROs manage increasing amounts of clinical information, ensuring data integrity and complying with industry standards are more important than ever.

Minimizing the time from database lock to an analysis-ready data set is crucial to getting drugs to the FDA—and ultimately to market—faster.

OUR APPROACH

The ability to move, transform and standardize clinical data quickly is critical to getting new drugs to market faster. SAS approaches the problem by helping you:

- **Build a data integration framework** that incorporates repeatable processes based on a common platform to reduce manual activities and improve decision making.
- **Ensure the proper use of standards** by analyzing both the structure and the content of the data.
- **Provide an accurate, real-time view** of the information by applying reliable data quality measures.

About three-quarters of any data integration process is repeatable. The trick is finding out *which* 75 percent. SAS can help you identify and automate repeatable tasks—which reduces manual intervention and speeds up the process—while standardizing your data set using CDISC standards such as ODM and SDTM.

By using SAS to manage and automate data integration, data quality and compliance with industry standards, you can free up valuable resources to work on more complex and strategic projects.

THE SAS® SOLUTION: Save time in clinical data integration

SAS helps you decrease time to FDA submission by streamlining data integration and analysis processes. Our end-to-end data integration framework helps eliminate the time, rework, costs and potential for errors that can occur in aggregating information from different systems and locations.

SAS' data integration framework is unique, offering:

- CDISC standards, such as ODM and SDTM, imbedded directly into the data management process.
- Solutions that support standards and FDA requirements for electronic submissions.
- Support for both existing and emerging methodologies, as well as providing the technology for moving between them.

The SAS data integration framework is configured as a continuous improvement loop. When a correction is made in one area, the change is propagated across all instances of the data throughout the system. This helps you perform impact analysis by accessing a relevant data point, changing it and evaluating the impact of the change across all studies.

CASE STUDY: A top-10 pharmaceutical company

■ Situation

The company needed to decrease time from clinical trial completion to FDA submission. SAS analytics were already in place; the next step was to reduce the time it took to get data from disparate source systems ready for analysis.

■ Solution

SAS provided a complete data processing and data integrity solution that saved time by:

- Improving the process of getting data ready for statistical analysis.
- Increasing accuracy through electronic data quality control.
- Embedding industry-standard data models (CDISC) into the analysis system.
- Optimizing auditability and traceability.
- Accelerating data access.
- Integrating and leveraging powerful SAS statistical and reporting tools.

■ Result

- Reduced a 45-day processing and reporting cycle to two days.

■ DISCUSSION POINTS

A single, integrated platform

What if you could use a common platform to aggregate the many sources of research information across the entire drug life cycle – from discovery through submission – so that strategic decisions were based on complete, current information and handoffs occurred seamlessly with no corruption or loss of data?

Repeatable processes

What if you could automate up to 80% of repeatable data processing tasks, freeing your resources to concentrate on the 20% that require special attention and expertise to reconcile?

Embedded standards

What if compliance with CDISC and SDTM standards was built into the system, so that as data was processed, you could immediately submit it to the FDA, freeing your resources for use on more profitable tasks?

Shared metadata, impact analysis

What if you could analyze the structure and content of your data so that you could address inconsistencies, compliance with standards and data quality issues proactively, before potential problems impact your study?



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