



SAS® Clinical Data Integration

Bringing repeatability and automation to the data integration process

What does SAS® Clinical Data Integration do?

SAS Clinical Data Integration brings repeatability and automation to the industry need for transforming, managing and verifying the creation of data standards, such as those from CDISC. SAS provides the foundation you need to ensure standard, trusted clinical data that can be used to support strategic analysis, such as advanced safety analysis. With SAS, you can gain both speed and efficiency by automating repeatable clinical data integration tasks.

Why is SAS® Clinical Data Integration important?

SAS Clinical Data Integration facilitates the implementation of operational data management efficiencies that foster the delivery of rapid business insight from clinical information. Using SAS, companies are taking control of their clinical data to deliver cleaner, more standard data for analysis. SAS Clinical Data Integration provides the foundation organizations need to effectively deliver safety, efficacy and strategic cross-study analyses.

For whom is SAS® Clinical Data Integration designed?

SAS Clinical Data Integration is designed for clinical research professionals who need to improve efficiency, quality and speed during the collection, management, analysis, reporting and assessment of clinical trials data and information. It is also designed to meet and support an organization's corporate IT standards and initiatives.

Many pharmaceutical companies treat each requirement to prepare clinical study data for analysis as a unique project that requires expensive manual coding and processes that are neither standard nor repeatable. This approach is not repeatable across studies, requires expensive headcount to scale to support additional studies, and carries the increased risk of data corruption from coding errors and inconsistencies.

SAS Clinical Data Integration answers the need to transform, manage and verify the creation of standard data by bringing repeatability and automation to the creation of analysis-ready clinical data.

Inefficiencies in the collection and preparation of clinical data for analysis can slow the pace of drug development and can dramatically increase the cost of bringing a new drug to market. SAS helps you decrease time to submission by streamlining data integration and transformation processes with an easy-to-use solution that reduces the delays and high costs associated with custom-coding each clinical study. With SAS, you can gain both speed and efficiency by automating repeatable clinical data integration tasks.

SAS provides the foundation you need to ensure standard, trusted clinical data that can support all your clinical analyses. Only SAS offers a completely integrated solution that encompasses not only clinical data integration, but is also a part of the SAS Business Analytics Framework, which includes industry-leading data integration, analytics and reporting technologies.

Key benefits

Increase operational efficiency while lowering costs:

- Automate repeatable tasks to free up resources for more value-added tasks.
- Increase your capacity to handle additional trials, as well as more complex global trials.
- Write and validate less code, as well as potentially reuse code for future trials.
- Scale clinical studies without adding expensive, hard-to-find headcount.
- Support adaptive trials through rapid access to clinical data for interim analysis.
- Reuse the work of others via a common repository that enables the management and reuse of information, thereby reducing both development and maintenance time.

Ensure the proper use of standards:

- Validate both the structure and content of data for conformance to CDISC SDTM.
- Visually convert legacy data to standard data.

Deliver consistent, trusted and verifiable clinical information:

- Aggregate information from virtually any hardware platform or operating system.
- Address potential issues *before* they impact your study by automating data quality and data transformation routines.



Improve productivity:

- Build and document work with a user-friendly GUI interface.
- Reduce the need to write unique code for each study.
- Get new team members up to speed quickly on work done by others.

Reduce risk:

- Standard processes and GUI tools enable other resources to finish tasks for improved continuity of business.
- Less hand-written code means less code to validate and maintain.

Solution Overview

Speed and Efficiency

Improving speed to market while limiting costs are key metrics for drug development organizations. But custom coding is expensive and can introduce risk to accurate clinical data.

Only SAS helps you decrease time to submission by streamlining the process of preparing clinical data for analysis with an easy-to-use solution that reduces the delays and high costs associated with custom-coding each clinical study.

Breadth of Standards Support

Many companies have existing data standards that are integral to their operations. That's why SAS not only supports CDISC standards, but also gives you the flexibility to incorporate your own organizational data standards to support your business goals.

Embedded Data Quality

In clinical research, clean data is mandatory, not optional. Drug development firms must be able to consistently get accurate data when and where it is needed. SAS eliminates the problem of inaccurate, contradictory and inconsistent data by embedding data quality within data integration processes.

Business Analytics

Extracting business value from information requires advanced analysis. Only SAS offers a completely integrated solution that encompasses not only clinical data integration, but the industry's most comprehensive suite of business analytics software.

Data Aggregation

Data aggregation is the process of bringing scattered information together to support more accurate and timely business analysis. Clinical study data

is typically scattered among multiple clinical systems and stored in multiple formats across multiple operating environments and organizations. Typical disparate data sources include laboratory data, EDC data, IVRS data, patient diary data, pre-clinical data, CDMS data and CTMS data – among others. And to further complicate matters, key information may be scattered across the globe at external organizations such as CROs or development partners.

Today, many organizations use manual, resource-intensive approaches to aggregate scattered, disparate clinical information for strategic analyses. The ability to provide fast, efficient access to clinical data, regardless of the location or source, is becoming a critical capability for organizations to improve time to market and contain clinical research costs.

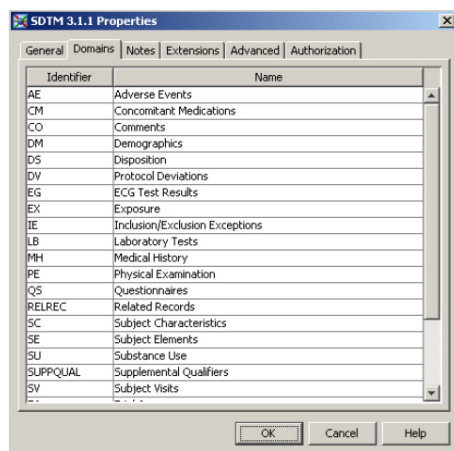
Data Mapping

Data mapping is the process of transforming clinical data to standard data (e.g., CDISC SDTM), transforming operational data to analysis data sets, or combining data from multiple studies to support cross-study data analysis. Today, many organizations use manual coding for each data mapping effort. In addition, clinical data is rarely collected in the form needed for analysis, so data summarization and transformation tasks must be efficient and cost-effective.

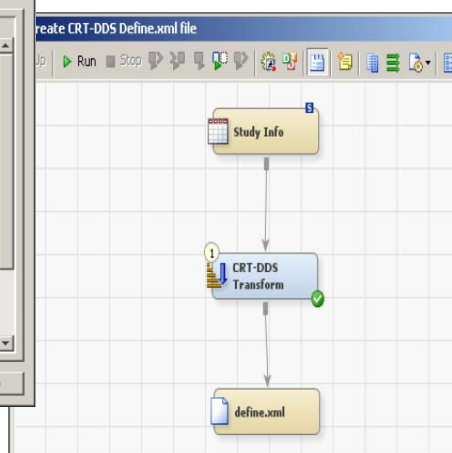
Using SAS Clinical Data Integration, the data transformation process is achieved using standard SAS Data Integration Studio functionality to visually design data transformations. SAS provides an easy-to-use data integration solution that has the ability to work in diverse environments.

Data Preparation

A critical part of your clinical development program is ensuring that your clinical data is trusted, high-quality data. Unfortunately, inefficiencies in the



Data standard component properties showing installed domains.



Process flow to create CRT-DDS define.xml file.

preparation of clinical data for analysis can slow the pace of drug development and dramatically increase the cost of bringing a new drug to market. One of the keys to providing accurate data for analysis is cleansing the data to facilitate the delivery of consistent, trusted and verifiable clinical information.

SAS Clinical Data Server provides an accurate real-time view of clinical information through the application of automated data quality and data transformation routines to allow you to address potential issues before they affect your study.

Your organization can increase speed to market by automating data quality checks to more efficiently validate clinical data. Plus, you can understand your compound faster through more frequent interim analysis of high-quality data.

Data Standardization and Validation

The use of data standards aimed at clinical research data and metadata is gaining momentum. CDISC standards are increasingly used for submitting study metadata and data to regulatory agencies. In the US, the FDA has adopted CDISC standards for submission of tabulation data (SDTM) and the main study metadata XML file (CRT-DDS).

Key Features

Data integration

- Investment protection for legacy operational systems and data.
- Access all data regardless of the source or format.
- Automated data loads for clinical data on a more frequent schedule.

Data mapping

- Flow control, integrated error reporting, job performance monitoring and statistics, and reporting.
- Full mapping of data source (where data came from), data manipulations (how the data has been manipulated) and the final destination for data.
- Impact analysis reports on (and helps you plan for) the impact of any change to the process, including:
 - Changes to incoming data formats.
 - Changes in data standards.
 - Additional data requirements for analysis data sets.

Data preparation

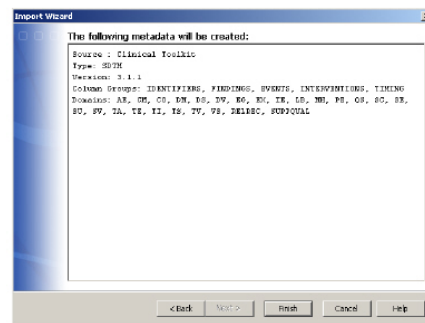
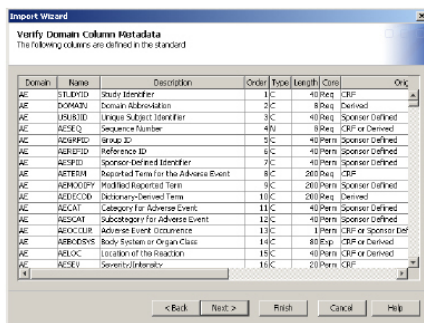
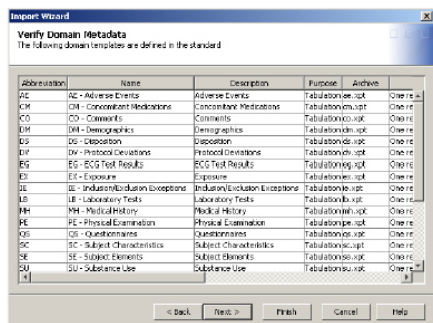
- Automated data quality activities let you spend less time validating incoming clinical data.
- Automatically incorporated data quality ensures consistent, trusted and verifiable clinical information.

Data standardization and validation

- Standards validation and conformance checking.
- Specialized transformations for mapping clinical data to a standard model.
- Standards management to:
 - Match the application of standards to study requirements.
 - Provide lifecycle management for standards as standards evolve.

SAS realizes data standardization involves more than just mapping to CDISC standards, so SAS Clinical Data Integration supports the implementation of an organization's internal data standards. SAS provides the flexibility to apply different standards, even different

versions of SDTM or custom standards, as required by your organization (by therapeutic area, development program, etc.). In addition, SAS understands the importance of supporting healthcare data standards in the future.



SAS Clinical Data Integration Server sample displays from the metadata importer.

Technical Requirements

Client

- Windows XP Professional, Windows Vista
- Internet Explorer 6+, Firefox 2+

Server

SAS servers can be installed on one or more hardware systems in a multitier configuration.

- HP-UX PA-RISC 11.23+
- HP-UX Itanium, Release 11.23+
- Solaris on SPARC, Version 9,10
- Solaris on x64, Version 10
- Windows XP Professional, Windows Vista



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