



## SAS® Clinical Data Integration

Bringing repeatability and automation to analytical data preparation

### What does SAS® Clinical Data Integration do?

SAS Clinical Data Integration helps you organize, standardize and manage clinical research data and metadata. The solution brings repeatability and automation to the process of transforming, managing and verifying the creation of industry-mandated data standards, such as CDISC. 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 derive rapid business insight from strategic clinical information. This solution lets you take control of your clinical data in order to deliver cleaner, more-standard data for analysis. SAS Clinical Data Integration provides the foundation organizations need to effectively deliver strategic analyses, such as safety and efficacy analysis and cross-study analysis.

### 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 clinical data integration effort as a unique project that requires expensive manual coding and processes that are neither standard nor repeatable. This approach cannot be duplicated across studies, requires expensive headcount in order to support additional studies, and carries an increased risk of data corruption from coding errors and inconsistencies. Such 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 Clinical Data Integration provides the foundation you need to ensure standard, trusted clinical data that can be used to support strategic analyses, such as cross-study and advanced safety analysis. SAS Clinical Data Integration is an easy-to-use solution that streamlines data integration and transformation processes, thereby reducing the delays and high costs associated with custom-coding each clinical data integration project, and enabling you to decrease your time to submission. With SAS, you can gain both speed and efficiency by automating repeatable clinical data integration tasks.

Only SAS offers a solution that encompasses not only clinical data integration, but also the industry's most comprehensive suite of business analytics software, including data mining.

### 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, as well as more complex, global trials.
  - Write and validate less code, and potentially reuse code in 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.
- **Drive top-line growth.**
  - Use existing clinical data to make new marketing claims or discoveries.
  - Speed data preparation for medical publications.
  - Automate migration of acquired data assets through data standards.
  - Support and automate data aggregation and standardization for ongoing clinical trials.
- **Ensure the proper use of standards.**
  - Validate both the structure and content of data for conformance to CDISC SDTM.
  - Standardize data to CDISC SDTM using prebuilt data models and processes.
  - Visually convert legacy data to standard data.



- **Deliver consistent, trusted and verifiable clinical information:**
  - Aggregate data from virtually any hardware platform or operating system.
  - Address issues *before* they affect your study by automating data quality and data transformation routines.
- **Improve productivity:**
  - Build and document work with a user-friendly GUI.
  - Reduce the need to write unique code for each study.
  - Get new team members up to speed quickly on work done by others.

## Solution Overview

### Combine clinical data from multiple sources for analysis

Clinical study data – e.g., EDC, IVRS, patient diary, pre-clinical, CDMS and CTMS data, etc. – is typically scattered among multiple systems in multiple formats across various operating environments and organizations. Key information may also be scattered across the globe at external organizations, such as CROs or development partners. Many

organizations use manual, resource-intensive approaches to aggregate this scattered, disparate clinical information for strategic analyses. SAS Clinical Data Integration provides rapid and efficient access to clinical data, no matter the location or source, which enables you to improve time to market and contain clinical research costs.

### Prepare uniform, consistent data for analysis

Clinical data is rarely collected in the form needed for analysis, and many organizations use manual coding for each project. Preparing clinical data for analysis may include transforming the data to a data standard, such as CDISC SDTM, transforming operational data to analysis data sets or combining data from multiple studies to support cross-study data analysis.

SAS Clinical Data Integration uses standard SAS Data Integration Studio functionality to visually design data transformations. SAS is an industry leader in providing an easy-to-use data integration solution that has the ability to work in diverse environments, making data summarization and transformation tasks more efficient and cost-effective.

### Automate data quality routines to ensure trustworthy analytical conclusions

A critical part of any clinical development program is ensuring that the data you analyze is trusted, high-quality clinical data. Inefficiencies in the 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. Data cleansing is key to facilitating the delivery of consistent, trusted and verifiable clinical information.

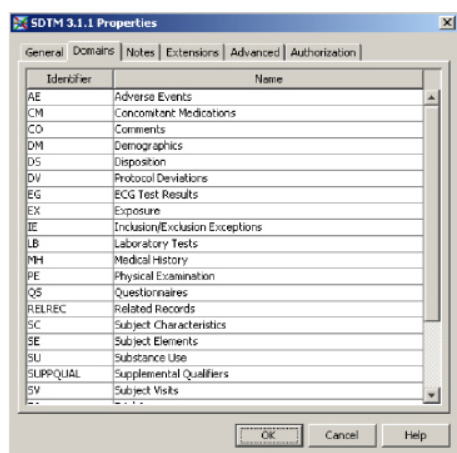
SAS Clinical Data Integration provides an accurate, real-time view of clinical information using automated data quality and data transformation routines that enable you to address potential issues before they impact your study. Your organization can get drugs to market more quickly by automating data quality checks to more efficiently validate clinical data.

### Support data standards

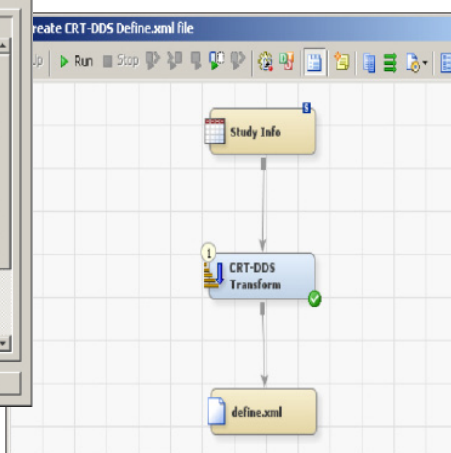
The use of data standards aimed at clinical research data and metadata is gaining momentum. Clinical Data Interchange Standards Consortium (CDISC) standards are used increasingly for submitting study metadata and data to regulatory agencies. In the US, the FDA has adopted CDISC standards for submission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

SAS realizes that data standardization involves more than just mapping to CDISC standards. That's why SAS Clinical Data Integration gives you the flexibility to apply different standards – even different versions of SDTM or custom data standards – as required by your organization (by therapeutic area, development program, etc.).

In addition, SAS understands the importance of supporting health care data standards in the future.



Data standard component properties showing installed domains.



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





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