What does SAS® Clinical Data Integration do?
SAS® Clinical Data Integration helps you organize, standardize and manage clinical research data and metadata. It brings repeatability and automation to the process of transforming, managing and verifying the creation of industry-mandated data standards, such as CDISC.

Why is SAS® Clinical Data Integration important?
It facilitates operational efficiencies that enable rapid business insight from strategic clinical information. You can define analysis data sets and deliver cleaner, more-standard data for analysis. It provides the foundation needed to effectively deliver strategic analyses, such as safety and efficacy analysis and cross-study analysis.

For whom is SAS® Clinical Data Integration designed?
It 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.

SAS® Clinical Data Integration
Bringing repeatability and automation to analytical data preparation

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 will 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. In addition, SAS Clinical Data Integration provides built-in integration with Medidata Rave to support rapid clinical insights.

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 (and 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 or ADaM.
- Standardize data to CDISC SDTM, SEND or ADaM using prebuilt data models and processes.
- Manage version proliferation for data standards.

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.

Overview

Combines Clinical Data From Multiple Sources for Analysis
Clinical study data – EDC, IVRS, patient diary, pre-clinical, safety, 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, operational and safety data, no matter the location or source, which enables you to improve time to market and contain clinical research costs.

Prepares Uniform, Consistent Data for Analysis
Clinical data is rarely collected in the form needed for analysis, and many organizations write unique code for each project. Preparing clinical data for analysis may include transforming the data to a standard such as CDISC SDTM, transforming data to ADaM 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.
**Key Features**

**Combines clinical, operational and safety data from multiple sources for analysis**
- Protects your investment in legacy operational systems and data.
- Provides access to all data regardless of the source or format.
- Integrates data from disparate sources.
- Automates data loads for clinical data on a more frequent schedule.
- Integrates with Medidata Rave and other leading EDC systems.

**Prepares uniform, consistent data for analysis**
- Provides flow control, integrated error reporting, job performance monitoring and statistics, and reporting.
- Provides tools to support aggregation of data across clinical trials.
- Provides a full mapping of data source, data manipulations and the final destination for data.
- Conducts impact analysis, which 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.

**Ensures data quality**
- Automates data quality activities so you spend less time validating incoming clinical data.
- Limits the risk of overwriting the work of others through change management.

**Supports data standardization and performs adherence checks**
- Performs standards adherence checks.
- Provides prebuilt support for CDISC models, including SDTM, SEND, ADaM and Define 1.0 and 2.0, and is extensible for custom models.
- Enables specialized transformations for mapping clinical data to a standard model.
- Provides standards management capabilities to:
  - Match the application of standards to study requirements.
  - Oversee standards as they evolve.

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**Automates 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 affect your study. Your organization can get drugs to market more quickly by automating data quality checks to more efficiently validate clinical data.

**Supports Data Standards**

The use of data standards in clinical research 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 Define-XML.

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, ADaM 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.

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Process flow for running SDTM adherence checks with reports and Define 1.0 and 2.0 generation.
To learn more about SAS® Clinical Data Integration, please visit sas.com/clinical-di.

Transformation property showing graphical selection of Medidata Rave form data to update.

Easily manage and customize the compliance checks for a specific data standard version.