

# SAS® Life Science Analytics Framework

A singular analytics foundation for clinical research to increase efficiency



## What does the SAS® Life Science Analytics Framework do?

The SAS Life Science Analytics Framework provides a singular analytics foundation for clinical research – paving the way for the efficient development, execution and management of the analysis and reporting of clinical studies through a hosted environment.

## Why is the SAS® Life Science Analytics Framework important?

The SAS Life Science Analytics Framework brings clinical research groups the ability to integrate any analytic applications into the framework to deliver the power of analytics to more roles within the organization. These analytic applications help to improve clinical research and speed the development of new therapies through optimized operational activities.

## For whom is SAS® Life Science Analytics Framework designed?

The SAS Life Science Analytics Framework is designed for clinical researchers, making it possible for anyone involved in data management, data standards management, biostats, clinical operations – from programmers to executives – to efficiently manage the transformation, analysis and reporting of clinical trials data.

Small biotech companies just getting started in clinical development, nutrition companies, large pharmaceutical and medical device enterprises with thousands of users, all rely on SAS.

This cloud-based product enables clinical researchers – internally and externally – to manage and analyze trial information in a collaborative platform as well as deliver trial results to regulatory authorities.

SAS Life Science Analytics Framework provides a single, integrated environment that delivers centralized and auditable clinical information repository optimized for data standardization, improves project management through workflow enablement and streamlines the management of compliance, transparency and traceability.

While other vendors require extensive customization and consulting over years of implementations, SAS has established a proven reputation for swift, out-of-the-box implementation at organizations of all sizes.

As a trusted business partner in life sciences clinical research, SAS has delivered good-practice validated environment and software in the cloud since 2002 for both leading and

emerging life sciences companies, with on average 10 yearly audits.

Our framework has strong integration capabilities, allowing users to connect with different applications including SAS and other analytic applications.

## Benefits

- **Expand information management.** The fully integrated environment spans from operational data systems (such as eCRF), electronic health records, sensors and wearables“-omics,” biomarker data, etc., through standardization, analysis and reporting and post-approval meta-analysis. This end-to-end management of clinical data translates to less time spent on operational data management activities, and more time spent on exploring, monitoring data quality and executing advanced analytics and statistics.
- **Empower multiple roles with approachable analytics.** Opens analytic applications to knowledge workers in areas such as pre-clinical, clinical operations and medical affairs to drive global collaboration between internal team members, consultants, contractors and development partners.
- **Global standards and study metadata management.** The model-driven approach for CDISC standards governance and enhanced study metadata management drive efficiency from study setup to submission.
- **Streamline and automate processes.** Lowering cost and increasing speed and efficiency in clinical research are critical to delivering future high-value treatments. The SAS Life Science Analytics Framework delivers workflow capabilities that aid project management oversight, and support process enablement to:
  - **Support multiple analysis**, including interim, data and safety monitoring board, and final analyses, with different team members, access rights and context-specific privileges.
  - **Assign tasks and track progress** for each analysis activity and deliverable to improve overall project performance and provide instant insight into the status of analysis and reporting activities for a single study or your entire portfolio.
  - **Automate activities** in your clinical process using process orchestration capabilities, such as scheduled job initiation and completion notifications.

## Overview

SAS is the de facto standard for clinical trials data analysis and reporting for new product submissions to regulatory authorities, such as the US Federal Drug Administration.

With this product, SAS delivers a foundation for building one integrated source of clinical data and metadata from various data sources and departments where clinical researchers can instantly query or analyze data.

The SAS Life Science Analytics Framework integrates both information management and analytics in a single solution while seamlessly integrating with the SAS program development and execution environment, complete with CDISC global standards, study metadata management and workflow capabilities.

It is by far the most comprehensive framework available that provides the proper balance between user efficiency and regulatory compliance. To support the total data movement, analysis and reporting process – including CDISC standards, information management and analytics – it offers proven scalability.

This complexity is delivered through a user-friendly interface, so that all stakeholders in the organization can delve into analytics and reporting with ease and expedience – increasing the value and return on your investment.

### **Analytic applications to solve your business challenges**

SAS is widely recognized as the gold standard for determining safety and efficacy for clinical trials. SAS is also the primary mechanism for preparing analysis-ready data for traditional clinical research safety and efficacy analysis activities.

Because the SAS Life Science Analytics Framework includes a SAS program development and execution environment, your analytical applications based in SAS can be integrated into the system without significant rework. Integrating the right analytic applications helps improve clinical research and speed the development of new therapies by optimizing operational activities.

Cross-functional teams can visualize and explore the data available in the repository using SAS Visual Analytics and SAS Visual Statistics or tools not from SAS. New data mining and machine learning approaches on clinical trial data can be applied using SAS Visual Data Mining and Machine Learning.

Images are also becoming more important as data sources, and therefore image analytics can be performed on images stored and managed in the SAS Life Science Analytics Framework repository.

Finally, real-world data patient cohorts can be generated using SAS Real World Evidence and pulled into the repository for further analysis and submission to regulatory authorities together with your clinical trial data.

These are only a few examples of how SAS Life Science Analytics Framework can be integrated with other analytical applications to help improve clinical research and speed the development of new therapies by optimizing operational activities.

### **Rigor of statistical analysis and regulatory controls**

Clinical programmers need a clinical data analytics framework that supports how they work in SAS, and this solution includes the tools that the SAS core user community has come to expect. We are the clear market leader in integrating regulatory compliance and control features with the seamless development and execution of SAS programs. In addition to statistical analysis and reporting of clinical research information,

SAS has a long-standing tradition of helping you foster adherence to regulatory guidelines and standard operating procedures. That means full support for robust data preparation and statistical programming environments. And an embedded program development, testing and execution environment provides the ability to easily develop and test program functionality, review results and log files, and validate and execute SAS programs and macro libraries – along with more advanced and specialized interfaces. Workflow capabilities help to streamline processes for data preparation, analysis and reporting.

### **Global standards and study metadata management**

CDISC standards are required for data submission to the FDA and PMDA (Japan). Ensuring standards adherence is a serious challenge that can influence your speed, efficiency and effectiveness. By affecting activities from study design, data collection, data preparation and analysis, through to cross-trial aggregation and comparative effectiveness, data standards have the potential to improve time to market and help to constrain clinical research costs.

That's why SAS integrated standards support into SAS Life Science Analytics Framework. We give you the flexibility to apply different standards – even different versions of SDTM, SEND, ADaM or custom data models – as required by your organization. SAS helps you ensure that all clinical studies adhere to both industry and internal standards – including data structures, metadata and terminology. The proper management of standards through SAS Life Science Analytics Framework simplifies the organizational implementation of data standards – and includes the ability to consume specifications provided via CDISC SHARE.

### **Efficient workflow management**

An efficient research program needs workflow capabilities that aid project management and facilitate process improvement efforts for analysis and reporting activities. SAS helps by providing immediate and ongoing insight into project progress for better control and deployment of resources and the streamlining of clinical R&D processes and tasks. Together these capabilities improve the efficiency of analysis and reporting processes, leading to reduced costs and faster time to market.

### **Superior information management**

With SAS, researchers spend less time searching for and aggregating data for analysis and reporting by harnessing a centralized clinical information repository where clinical researchers across the globe can gain a single version of the truth. With global access to a clinical analytics foundation for all authorized development team members, regardless of organization, they'll no longer waste time and resources working

on different systems across multiple geographies and organizations. In addition, SAS enables rapid response to regulatory inquiries concerning data pedigree, transformations or analytical results. Once a program has been executed, a manifest file is generated that documents all inputs, programs and results that are associated with an execution run – ensuring the retention of all the data and metadata necessary to understand how results were created.

## TO LEARN MORE »

To learn more about SAS Life Science Analytics Framework, download white papers, view screenshots and see other related material, please visit [sas.com/lifesciences](https://sas.com/lifesciences).

## Key Features

### Information management

- Consolidation of clinical information into a single global repository.
- Review of specific data set versions used, log files created, SAS programs executed and results generated.
- Rapid result reproduction.
- Tracing of data pedigree back to source data.
- Rapid answering of regulatory inquiries.
- Ability to readily determine what audit changes were made, when and by whom, for all content stored in the repository.

### Statistical analysis and regulatory controls

- Seamless integration with SAS programming and program execution environments.
- Full control over SAS job execution.
- Ability to easily load and utilize standard analytic programs.
- Check in/out, audit trails, electronic signatures, versioning and role-based privileges.
- Quick reproduction of results using a job manifest (complete hyperlinked documentation package for each job that includes programs, data, logs and results).
- Control of all information via secure logins, audit trails, versioning and role-based privileges and policies.
- Ability to integrate with CTMS and document management systems.

### Analytical data preparation

- Full mapping of data source, data manipulations and final destination for data.
- Impact analysis, reporting on (and helping to plan for) impact of any change to the process, including changes to incoming data formats and data standards or additional data requirements for analysis data sets.
- Automated data loads for clinical data on a more frequent schedule.
- Data extraction from Medidata Rave and other leading EDC systems.
- Connectable with EHRs and wearables and sensor data.
- Ability to integrate with third-party coding systems.

### CDISC data standards support (model-driven)

- Standards governance.
- Study metadata management.
- Cell-based editing for adding and modifying metadata.
- User interface provides validation against model.
- Integration with Pinnacle21 (community and enterprise versions).
- Import Define-XML 2.0.
- Create Define-XML 2.0 (complete with style sheet).
- Data standards comparison reports.

### Workflow optimization

- Assignment of tasks and progress tracking for each analysis activity and each deliverable.
- Support for workflow on multiple analyses, including interim and final analyses.
- Flexible access rights and privileges by project.

### Analytic applications

- Integration of analytic applications – either purchased from SAS, user-developed, third-party (e.g., R and Python) – for a variety of business needs.

To contact your local SAS office, please visit: [sas.com/offices](https://sas.com/offices)

