



What does SAS® Life Science Analytics Framework do?

SAS Life Science Analytics Framework affords 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 SAS® Life Science Analytics Framework important?

SAS Life Science Analytics Framework brings clinical research groups the ability to integrate analytic applications and other SAS solutions 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?

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

SAS® Life Science Analytics Framework

Democratize access to analytics. Deploy analytic applications. Increase efficiency.

The SAS® Life Science Analytics Framework renders a single, integrated program environment that delivers three key efficiencies: it provides a repository optimized for data standardization; eases the burden of project management through workflow enablement; and streamlines the management of compliance and transparency – all from the world leader in clinical data analysis and reporting.

The availability of analytic modules within the framework opens the power of analytics to a wider audience of knowledge workers within the organization – so that statistical expertise is no longer required for most clinical researchers to derive business benefits from analytics.

And while other vendors require extensive customization and consulting expenses over years of implementations, SAS has established a proven reputation for swift implementation at organizations of all sizes. As a trusted business partner in life sciences clinical research, SAS has hosted secure clinical analytics solutions in the cloud for over a decade for both leading and emerging life sciences companies.

Benefits

- **Empower multiple roles with approachable analytics.** Open 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.
- **Streamline and automate processes.** Lowering cost and increasing speed and efficiency in clinical research are critical to delivering future high-value treatments. SAS delivers workflow capabilities that aid project management oversight, and support process enablement to:
 - **Support multiple analyses**, including interim 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 automatic job initiation and event notifications.
- **Expand information management.** The fully integrated environment spans from operational data systems 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.

Overview

SAS is the de facto standard for clinical trials data analysis and reporting for new product submissions to regulatory authorities, such as the FDA. With this solution, 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.

It integrates both information management and analytics in a single solution while seamlessly integrating with the SAS program development and execution environment, complete with workflow capabilities and a data standards repository.

The SAS programming and program execution environment is by far the most comprehensive framework available that provides the proper balance between user efficiency and SOP compliance.

To support the total data movement, analysis and reporting process - including CDISC standards, information management and analytics - it offers both proven scalability and CDISC data standards support. This complexity is delivered through a user-friendly interface, so that data scientists, executives and other roles 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.

Beyond these capabilities, the SAS Life Science Analytics Framework lets you deploy a broad range of analytic

applications to solve the most challenging business problems of biopharmaceutical companies. These analytic modules and tools can allow you to:

- Implement risk-based scoring and monitoring.
- Select the best investigator sites and recruit clinical trial participants.
- Improve safety surveillance and post-marketing activities.
- Support medical monitoring programs.

Integrating the right analytic applications into the SAS Life Science Analytics Framework helps improve clinical research and speed the development of new therapies by optimizing operational activities. For example, applying an analytics module for risk-based monitoring in clinical trials can save time and money by allowing CRAs to focus on sites with the greatest risk, while providing less monitoring coverage for those areas of minimal risk.

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

With its unparalleled set of advanced analytics tools, SAS provides the right technologies and solutions to bring additional analytical applications to clinical research.

SAS has been widely accepted as the gold standard for providing statistical capabilities to determine the safety and efficacy of individual and integrated projects, and is frequently the tool of choice in clinical trial data quality and transformation activities. The proven experience of SAS builds confidence and invites you to join an active community of users, as well as access to proven technical support when you need it.

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.

Repository to keep pace with data standards

The importance of clinical data standards (such as CDISC) is rapidly increasing, and keeping pace to manage standards proliferation and ensure standards adherence is a serious challenge that can influence your speed, efficiency and effectiveness. By affecting activities from study design, data collection, data preparation, analysis, through to cross-trial aggregation and comparative effectiveness, data standards have the potential to improve time to market and help to contain clinical research costs.

Most companies utilize a hierarchy of standards that may include global, company-wide, therapeutic area, and project or study standards. When combined with the reality of frequent CDISC updates, the management of standards proliferation becomes a major business challenge. SAS realizes that data standardization involves more than just mapping to CDISC standards. That's why we've integrated standards support into the SAS Life Science Analytics Framework. We give you the flexibility to apply different standards – even different versions of CDASH, SDTM, SEND, ADaM or custom data standards – as required by your organization.

The SAS data standards repository is renowned for helping life sciences companies implement and properly manage all these data standards. 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 the SAS Life Science Analytics Framework simplifies the organizational implementation of data standards – and also includes the ability to connect to CDISC SHARE for updates.

Key Features

Analytic applications

- Integration of analytic applications – either user-developed or purchased from SAS – for a variety of business needs.

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.)
- Tracing of data pedigree back to source data.
- Control of all information via secure logins, audit trails, versioning and role-based privileges and policies.

Data standards support

- Matching of application of standards to study requirements.
- Ability to oversee standards as they evolve.
- Performance of standards adherence checks.
- Prebuilt support for CDISC models – including SDTM, SEND, ADaM and Define 1.0 and 2.0; extensible for custom models.
- Specialized transformations for mapping clinical data to a standard model.

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.
- Integration with Medidata Rave® and other leading EDC systems.

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.

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.

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 – as well as 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

Using 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 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 the results were created.

To learn more about SAS Life Science Analytics Framework, download white papers, view screenshots and see other related material, please visit sas.com/lifescience.