



SAS® Drug Development

A dynamic solution for managing and sharing accurate research information to drive informed business decisions with confidence

What does SAS® Drug Development do?

It enables the efficient development, execution and management of clinical research data analysis and reporting. With the solution, organizations can make informed clinical and business decisions; streamline and optimize analysis and reporting processes; assess safety and efficacy more effectively; and improve collaboration with business partners and regulatory authorities. In addition to easing analysis and reporting for single trials, it also simplifies the derivation of insight from aggregated clinical data assets across multiple trials or therapies.

Why is SAS® Drug Development important?

The solution is the only clinical repository that provides seamless integration with the SAS program development and execution environment, along with workflow capabilities that streamline processes and ease project management for analysis and reporting. It supports the globalization of clinical research via a secure Web interface. The clinical repository enables rapid, efficient sharing of resources, data and knowledge across trials, phases and therapeutic areas at all stages of the clinical R&D process.

For whom is SAS® Drug Development designed?

The solution is designed for clinical research professionals (e.g., clinical programmers, biostatisticians, clinicians, medical experts, etc.) involved in the management, analysis, reporting and assessment of clinical trials data and information. It facilitates exploratory analysis by research scientists and medical experts.

SAS Drug Development is the only secure, globally accessible clinical repository that provides seamless development and execution of SAS programs. As a centralized, controlled and compliance-enabling solution for efficiently managing the transformation, analysis and reporting of clinical research data, SAS Drug Development provides the intelligence and confidence needed to accelerate informed clinical and business decisions.

While other solutions require extensive customization, excessive consulting expenses, and implementations measured in years, SAS Drug Development has a proven reputation for swift implementation at organizations of all sizes.

Key Benefits

Global Access to a Single Version of the Truth

SAS Drug Development provides a single version of the truth accessible via a scientist-friendly, point-and-click application. With the solution, you get:

- Global access to a centralized clinical information repository for all authorized development team members, so they no longer waste time and resources working on different systems across multiple organizations and geographies.
- Direct access to research content, plus seamless integration with the SAS programming environment.
- The ability to load data from all relevant sources, store all information related to a clinical research program (e.g., source data, derived data, analyses, reports, programs, logs, templates, documents, etc.), and consolidate this information in a standardized, centralized repository.

Full Compliance and Control

SAS Drug Development was designed to meet existing and emerging government regulations, including 21 CFR Part 11, as well as good industry practices and sound business methodologies. In addition, the solution provides:

- Automated versioning, security, audit trails and related controls for all programs, data, logs and results.
- Automated bundling of related analysis components (programs, data, logs and results), which ensures the accuracy and integrity of these activities.
- A complete, hyperlinked documentation package — provided for each study — that details where the data came from, the transformations performed and the structure of the resulting analysis data sets.
- The ability to apply electronic signatures to all research content as needed.

Streamlined Processes

Workflow capabilities aid project management oversight and support process enablement for analysis and reporting activities. The workflow system can:

- Support multiple analyses, including interim and final analyses. Each analysis can have different team members and different access rights and privileges, as required by each project.
- Assign tasks and track progress for each analysis activity and deliverable, which gives an overall project view that provides instant insight into the status of analysis and reporting activities.
- Serve as an ideal forum for communication between development and testing, or for broader issue communications to the entire project team.

More Confidence in Clinical Research Program Decisions

With SAS Drug Development, clinical researchers can:

- Easily make critical research program decisions earlier in the process with increased visibility and confidence.
- Have early visibility into trial results to enable adaptive trial designs.

Automated Integrity, Traceability and Transparency

The solution provides automated integrity, traceability and transparency documentation for all data analysis activities, which:

- Ensures ongoing quality control and assurance, so you can easily and confidently address regulatory inquiries.
- Lets you trace data back to the original source and easily reproduce your results to rapidly answer regulatory inquiries on how results were obtained.

Shorter Development Cycles

SAS Drug Development streamlines processes, reduces costs and speeds time-to-market by:

- Bringing together disparate information sources into a globally accessible central repository.
- Providing workflow functionality and seamless integration with the tools used to transform, analyze and report this information.
- Facilitating your ability to extract insights from all clinical data assets across trials, phases and therapeutic areas. These cross-trial insights can be used to improve future trial designs, better understand safety and efficacy and ultimately bring better therapies to market faster.

Solution Overview

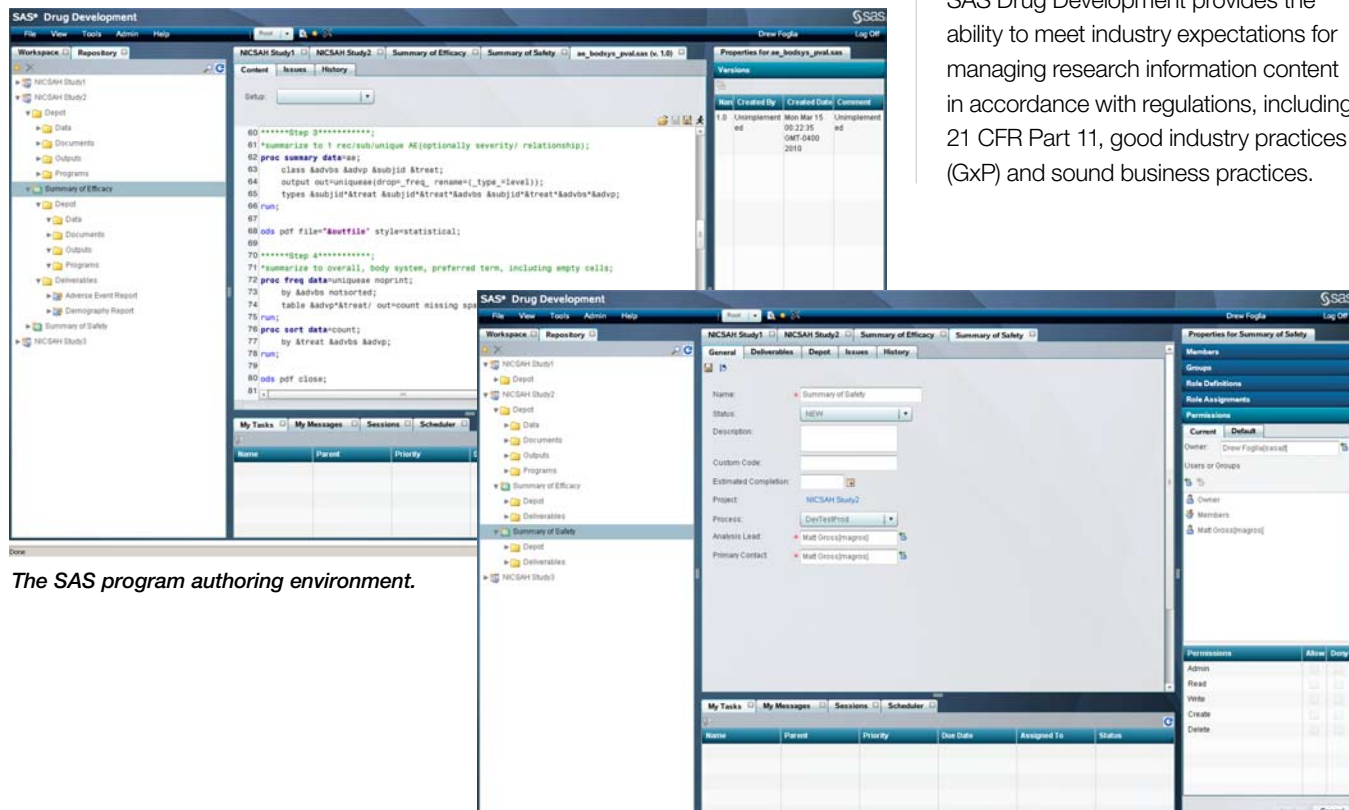
Information Management

SAS Drug Development provides a centralized information repository that facilitates secure global collaboration across organizational boundaries, both internally and with external business partners. With SAS Drug Development, researchers spend less time searching for and aggregating data for analysis and reporting.

SAS Drug Development enables rapid response to regulatory inquiries concerning data, transformations or analytical results. Once a program has been executed, a manifest 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.

Compliance and Control

SAS Drug Development provides the ability to meet industry expectations for managing research information content in accordance with regulations, including 21 CFR Part 11, good industry practices (GxP) and sound business practices.



The SAS program authoring environment.

The content repository view shows the navigation of the content repository on the left and a view of an analysis in the center section.

The solution provides a secure repository for analyzing and reporting on clinical research information and gives organizations confidence and peace of mind by incorporating industry-driven compliance and control with the development and execution of SAS programs.

Statistical Analysis

SAS Drug Development facilitates the statistical analysis of clinical research information with integrated compliance and control. The solution includes full support for a robust SAS statistical programming environment. An embedded program development, testing and execution environment enables easy development, testing, validation and execution of SAS programs. The solution not only eases statistical analysis and reporting for single trials, but also simplifies the derivation of insight from all clinical data assets across trials.

Workflow

SAS Drug Development provides workflow capabilities that aid organization and oversight for analysis and reporting activities. Workflow capabilities help provide immediate and ongoing insight to project progress, thus enabling better control and deployment of resources as well as the streamlining of clinical R&D processes and tasks. Together these lead to more efficient and better organized analysis and reporting processes.

Data Exploration and Visualization

Scientists and other industry professionals can access, explore, visualize and investigate clinical data with ease. This enables more rapid insight into early trial results and facilitates their ability to make key decisions as early as possible in the research process. The result is a deeper understanding of the research program earlier in the process.

Key Features

Information Management

- Consolidate clinical information into a single global repository.
- Easily review specific data set versions used, log files created, SAS programs executed and/or results generated.
- Reproduce results rapidly.
- Trace data pedigree back to the source data and rapidly answer regulatory inquiries.
- Audit changes – readily determine what changes were made, when and by whom, for all content stored in the repository.

Compliance and Control

- Control all information within the repository via secure logins, audit trails, versioning and role-based privileges and policies.
- Quickly document the integrity of research content.
- Easily apply e-signatures when required.

Statistical Analysis

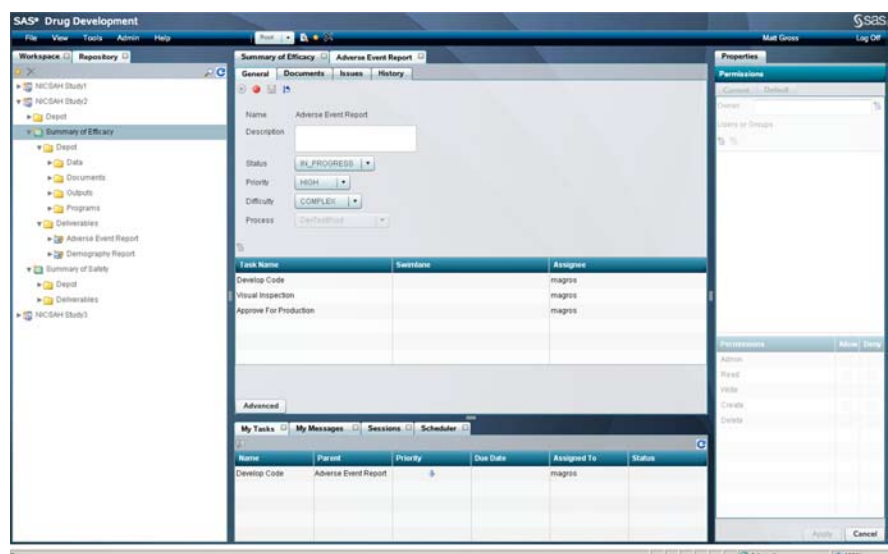
- Seamless integration with SAS programming and execution within a well-controlled and managed repository.
- Full control over SAS job execution.
- Easily load and utilize standard analytic programs.
- Check in/out new programs under development.

Workflow

- Assign tasks and track progress for each analysis activity and each deliverable.
- Supports workflow for multiple analyses, including interim and final analyses.
- Flexible access rights and privileges by project.
- Issue management system facilitates communication between the project team members.

Data Exploration and Visualization

- Examine study data using an intuitive point-and-click interface.
- Subset data and perform exploratory statistical analyses without a detailed understanding of underlying data structures.



The workflow environment shows an overview of a deliverable plus all current user tasks.



SAS Institute Inc. World Headquarters +1 919 677 8000

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