



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?

SAS Drug Development provides a centralized, integrated system for managing, analyzing, reporting and reviewing clinical research information. The solution enables life sciences organizations to make informed business decisions with confidence; assess the safety and efficacy of research compounds more effectively; collaborate across trials, phases and therapeutic areas successfully; and ultimately get better products to market faster.

Why is SAS® Drug Development important?

SAS Drug Development leverages the strength of the SAS®9 Enterprise Intelligence Platform to enable the collection and sharing of clinical research data throughout the entire organization via a well-managed, controlled, centralized repository. This single version of the truth enables rapid, efficient sharing of resources, data and knowledge across trials, phases and therapeutic areas at all stages of the clinical R&D process.

Who is SAS® Drug Development designed for?

SAS Drug Development is designed for research professionals (e.g. clinicians, biostatisticians, clinical programmers, medical experts, etc.) involved in the management, analysis, reporting and assessment of clinical trials data and information. It is also designed to meet and support an organization's corporate IT/IS standards and initiatives.



Last year, life sciences organizations spent nearly \$90 billion on R&D globally — a 56 percent increase since 2001. Unfortunately, this increase in spending has not been matched by an increase in the number of new drug applications being submitted to the FDA for approval. In fact, that number has fallen by almost 50 percent since the mid-1990s.

There are many reasons for this. Researchers lack adequate, reliable information early enough in the process to make informed research program decisions. And inefficient data transformation, analysis and reporting, along with a cumbersome submission process, stretch the time-to-market for potential new drugs.

As a result, life sciences organizations are looking for ways to improve R&D efficiency and productivity while simultaneously enabling themselves to make better go/no-go decisions on research programs earlier in the research process.

SAS Drug Development was designed to provide the intelligence and confidence that life sciences professionals need to accelerate making informed business decisions regarding their research programs. Using the open, extensible SAS®9 Enterprise Intelligence Platform, SAS Drug Development provides a centralized, controlled and compliance-enabling platform for efficiently developing, executing and managing the transformation, analysis and submission of clinical research data.

Key benefits

- **A single version of the truth.** SAS Drug Development delivers full data integration and standardization via a centralized information repository that gives researchers throughout the organization direct access to both the research content and embedded intelligence tools at all stages of the clinical R&D process.
- **Full compliance with industry standards.** SAS Drug Development provides the ability to meet industry expectations for managing research information content in accordance with government regulations, including 21 CFR Part 11, good industry practices (GxP) and sound business practices.
- **More confidence in research decisions.** Researchers can easily review multiple data sources to analyze research across trials, phases and therapeutic areas. This comprehensive view makes it easier to make go/no-go research program decisions earlier in the process.
- **Shorter development cycles.** With the ability to make more confident decisions and analyze data from a single repository, researchers can reduce the time spent searching for, gathering and aggregating data for analysis. The solution also helps streamline and automate research and analysis tasks.

Solution overview

SAS Drug Development is a fully integrated solution that facilitates the data integration and standardization that life sciences research organizations need to bring better therapies to market faster.

The solution provides the means for building and maintaining a central information repository (including data, programs, reports, documents and images) along with the applications necessary to take full advantage of the repository. These applications include metadata management, data transformation, and analysis and exploration tools, all operating within a secure server architecture.

By bringing together disparate information sources both within and external to the research organization, along with providing the value-added tools to manage this information, SAS Drug Development streamlines research operations, reduces costs and time-to-market, and helps identify new revenue opportunities.

In addition, SAS Drug Development directly addresses the complex regulatory requirements mandated for organizations that are involved with electronic information related to life sciences research.



SAS Drug Development provides the ability to fully trace the development of all analyses and derivations.

Actions								New	Loader
	Name /	Size	Type	Modified	Modified by	Signed	Versioned	Checked out	
	AE_Listing_Report.pdf	26 KB	document	2/25/05 3:46:27 PM GMT	dahand1	<input checked="" type="checkbox"/>			
	AE_Listing_Report.rtf	194 KB	document	2/25/05 3:24:27 PM GMT	dahand1	<input type="checkbox"/>			
	AE_Listing_Report.sas	12 KB	process	2/25/05 3:25:32 PM GMT	dahand1	<input type="checkbox"/>			
	AE_Summary.pdf	86 KB	document	2/25/05 3:46:28 PM GMT	dahand1	<input checked="" type="checkbox"/>			
	AE_Summary.rtf	675 KB	document	2/25/05 3:24:26 PM GMT	dahand1	<input type="checkbox"/>			
	AE_Summary.sas	5 KB	process	2/25/05 3:25:33 PM GMT	dahand1	<input type="checkbox"/>			
	Demography.pdf	4 KB	document	2/25/05 3:46:29 PM GMT	dahand1	<input checked="" type="checkbox"/>			
	Demography.rtf	10 KB	document	2/25/05 3:24:27 PM GMT	dahand1	<input type="checkbox"/>			
	Demography.sas	6 KB	process	2/25/05 3:25:33 PM GMT	dahand1	<input type="checkbox"/>		<input checked="" type="checkbox"/>	
	Traceability	0 KB	folder	2/25/05 3:26:48 PM GMT	dahand1	<input type="checkbox"/>			

SAS Drug Development provides a controlled information management environment that has been designed to meet government regulations, documented good industry practices (GxP) and sound business practices.

A standardized, centralized repository

SAS Drug Development integrates data from all relevant sources, stores all information related to a clinical research program (including source data, derived data, analyses, reports, programs, logs, templates, documents, etc.), and brings this information together in a standardized, centralized repository. The result is a single version of the truth — a 360-degree view of all the factors pertaining to your research studies, accessible via a scientist-friendly, point-and-click application.

Both structured and unstructured data from disparate systems and external partners can be loaded into the repository and viewed as a single, intuitively organized table — allowing standard, scientist-driven analyses to be executed against the merged data and then easily exported to other applications or end-user productivity tools, such as Microsoft Office products.

Streamlined processes

SAS Drug Development provides clinical researchers with confidence in the integrity of their clinical research information content, as well as the ability to explore that content directly — freeing biostatisticians to tackle more complex analytic questions. By providing immediate access and ongoing insight into project progress, SAS Drug Development gives organizations better control over the deployment of resources, as well as the streamlining of clinical R&D processes and tasks.

The solution enables the creation of validated data transformation and analysis programs that automatically generate user interfaces where users can select the appropriate data and analysis parameters that will enable a single program to work across multiple studies. Programs, derived data and statistical reports can be saved in a common, validated repository for easy sharing across research studies.

Integrated SAS® program development and execution

SAS Drug Development includes all of the tools that the SAS core user community has come to expect. An embedded program development environment provides the ability to easily develop SAS programs and macro libraries, review log files and test program functionality.

Alternatively, users can load programs from local SAS implementations directly into SAS Drug Development; these programs then immediately become executable in the controlled repository environment. Batch production and scheduling capabilities support producing a single result or hundreds, on a one-time or continuous basis.

Once executed, automatically generated manifests document all inputs, programs and results that are associated with an execution run, ensuring the retention and availability of all the data and metadata necessary to understand the results — or recreate them.

A truly collaborative environment

With the solution's collaborative environment, all research content is readily available for distribution and review. Research scientists and less technical users have direct access to research data, statistical results and all other relevant clinical research content via a secure, user-friendly interface.

The solution's Data Explorer enables users to examine data across protocols with easy filtering and summarization features, without requiring knowledge of the underlying database schemas and related technical information. And the Results Viewer enables easy examination of clinical trial analyses and results alongside all associated supporting information.

Full compliance

SAS Drug Development was carefully designed to meet existing and emerging government regulations, including 21 CFR Part 11, as well as good industry practices and sound business methodologies. The solution integrates audit trails, versioning, and time, date and user stamps into the research itself, so that compliance is automated with no extra cost or work required.

Key Features

Information management

- Easily review specific data set versions used, log files created, SAS programs executed and/or results generated. Results can be reproduced as necessary.
- Readily determine what changes were made, when and by whom for all content stored in the repository.
- Access content from SAS Drug Development through a variety of interfaces: a browser-based interface, a mapped drive interface, a WebDAV interface or published APIs that link SAS Drug Development to other applications as needed.
- Develop and test SAS code, including non-interactive as well as user-driven programs.

Compliance and controls

- Automatically construct SAS transport and *define.pdf* files for submission to regulatory agencies.
- Easily construct data sets that conform to the CDISC models.
- Quickly document the integrity of research content.

Metadata analysis

- Interactively review data structures and compare data models between research protocols.
- Compare data provided by external suppliers against established organizational data structures.

Data transformation, standardization and integration

- Examine all related components of completed transformations and reports.
- Create a validated library of standard transformations and reports.
- Build a series of sequentially executed transformations and reports.

Statistical analysis

- Easily load and utilize standard organizational analytic routines.
- Check in/out new routines under development.
- Take full advantage of all the statistical capabilities of SAS within a well-controlled and managed repository environment.

Data exploration

- Examine study data using an intuitive point-and-click interface.
- Subset data, create traffic light indicators and perform statistical analysis without a detailed understanding of underlying data structures.

Information interchange

- Control all information stored within the system via secure logins, audit trails, versioning, role-based security privileges and policies.
- Easily apply e-signatures when required.

A complete, hyperlinked documentation package — provided for each study — details where the data came from, the transformations performed and the structure of the resulting analysis data sets. Electronic signatures can be applied to all research content as needed.

SAS Drug Development is the only offering on the market that integrates industry-driven compliance and control with the development and execution of SAS programs. In addition, the solution

brings these same controls to other desktop analytics — not from SAS — used during the clinical research analysis process, giving organizations confidence and peace of mind.

Data standards

Data standards bring enormous value to life science industries, and SAS actively supports both organizational data standards as well as emerging Clinical Data Interchange Standards Consortium (CDISC) standards.

While the use of standards is highly encouraged, SAS Drug Development does not require their use in order to give customers more flexibility as standards are adopted.

With implemented standards, validated libraries of transformation and reporting programs are more readily created for use across each research protocol, which provides tremendous processing efficiencies.

Optional hosting available

SAS Drug Development can be deployed as either a hosted or customer-based solution. When hosted, SAS provides all of the necessary hardware and software, installation and validation (IQ/OQ/PQ), as well as ongoing maintenance and support. The hosted approach allows a quicker implementation without causing additional strain on an organization's internal IT infrastructure and resources.

Technical Requirements

Server

Operating systems

UNIX server(s)

- Solaris 10
- HP-UX 11.11 PA-RISC
- HP-UX 11.23 Itanium

PC server

- Microsoft Windows Server 2003

Required software

SAS Drug Development ships with all required SAS software components. Additional third-party, server-side software components are required, depending on platform. These include:

- BEA WebLogic Server 8.1 SP5 (Solaris, HP-UX)
- Oracle 9.2.0.6.0 (Solaris, HP-UX)
- Java Development Kit: JDK 1.4.2_13 (or higher) for WebLogic systems

Optional software

All core functionality for SAS Drug Development is readily available within the solution environment. This functionality can be extended, however, through integration with other components of the SAS Enterprise Intelligence Platform in the client or related server environments.

The SAS Drug Development Command Facility is available for SAS programmers who wish to execute API-based commands from within a SAS programming environment.

Some content within SAS Drug Development requires native client applications in order to view the information. For example, Microsoft Word must be installed for Word documents to be viewed. Some of the most common applications used in conjunction with SAS Drug Development are:

- Microsoft Office
- Adobe Reader
- SAS System Viewer
- WinZip

Client

The following browsers supporting JRE 1.4 or higher can be used with SAS Drug Development:

- Microsoft Internet Explorer 6.0 or higher
- Safari 2.0.4 is supported on the Apple Macintosh
- Firefox 2.0.0.2 is supported

Supported standards

SAS supports the CDISC standards for clinical data interchange.



**THE
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TO KNOW.**

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