



SAS® Drug Development

Manage and share relevant, accurate research information to make more informed business decisions



Overview

The life sciences industry is at a crossroads. In many ways, the industry's future looks bright. The technological and scientific advances gained in the last several years enable the pursuit of innovative drug treatments and breakthrough medical discoveries that can save lives and enhance quality of life.

But while the potential rewards are great, so are the accompanying challenges. As a result, there is increased pressure on life sciences organizations to:

- Develop a robust pipeline while controlling costs.
- Quickly deliver therapies to market, while complying with ever-tightening regulations.
- Ensure patient safety while meeting shareholder expectations.
- Optimize efficiency and productivity, and document research integrity across the life sciences value chain.

The key to accomplishing all this lies in your ability to access relevant, accurate information that you can use to make informed business decisions with confidence. SAS® Drug Development is the answer.

Challenges

- **Growing volumes of data.** Research studies and emerging areas such as proteomics and genomics produce massive amounts of data that threaten to overwhelm systems and processes, raise costs and slow down drug development cycles.
- **High-profile drug recalls and product liability lawsuits.** What once was an industry revered for its stellar contributions to society has now become an industry in danger of losing public trust due to negative publicity that erodes consumer and shareholder confidence.
- **Increased regulatory scrutiny.** Regulatory agencies – facing increased scrutiny themselves – are upping the ante on compliance in direct response to the public's concerns.



Challenge? Opportunity? Meet both head-on.

■ The solution

SAS Drug Development provides the intelligence and confidence you need to make more knowledgeable clinical and business decisions regarding your research programs.

Based on a centralized, controlled and compliance-enabling platform, SAS Drug Development gives you the power to:

- Efficiently manage the transformation, analysis and reporting of clinical research data.
- Rapidly assess the safety and efficacy of research compounds.
- Drive organizational knowledge and skills more effectively across trials and research programs.
- Get better, more profitable therapies to market faster.

Benefits

Go? No-go? Get the answer earlier.

If organizations could harvest the business insight hidden in scattered data repositories early on, trends would be spotted more quickly, allowing for better – and more timely – business decisions about whether to pursue or abandon particular research paths.

Challenge

Making key product development decisions is often difficult, due to:

- The inability to get adequate information early enough in the process to have a positive impact.
- Clinician reliance on the biostatistics department to perform even the most basic queries and analyses.

Our approach

A centralized repository integrates data from multiple, disparate sources across trials, phases and therapeutic areas. Scientists and other industry professionals can access, explore and investigate research data from any source with ease.

This enables them to identify trends and make key decisions as early as possible in the research process. The result is a deeper understanding of research programs and less time spent searching for and aggregating data for analysis.

With SAS Drug Development, you can:

- Load structured and unstructured data from disparate systems or external sources into a single repository that is easily accessible by researchers.
- View data from multiple sources via a user-friendly, point-and-click interface.
- Execute standard, scientific analyses against the repository data.
- Leverage existing and emerging industry standards, such as CDISC.
- Easily export data and analytic results to Microsoft Office products or other user-productivity applications.

Access data more quickly and easily

Accurate tactical and strategic decisions regarding research programs are critical.

Challenge

Researchers spend too much time searching for, gathering and aggregating data for analysis and reporting. Multiple barriers to data integration and information sharing are to blame:

- Limited interoperability across software applications.
- Restricted access to disparate data sources.
- Lack of technical skills among researchers needing access to multiple clinical software applications.

Our approach

The solution puts controlled power in the hands of the researchers who need it. Information from multiple clinical research programs – including data, documents and images – is integrated and stored in a controlled, validated environment. Using an interface that matches their skill level, scientists can:

- Explore and analyze data from a variety of sources.
- Efficiently manage research information that resides in a centralized repository.
- Perform sorting, filtering, data derivation, basic statistics and data visualization using embedded point-and-click tools that don't require programming knowledge.

This easily accessible, comprehensive view of all information pertaining to your research studies gives you the intelligence you need to make confident, timely decisions about go/no-go actions, new indications, marketing claims and product-line extensions.

With SAS Drug Development, you can:

- Facilitate global collaboration among internal stakeholders as well as effective communication with external partners via controlled access to research content.
- Comply with 21 CFR Part 11 and other regulatory requirements and industry guidelines.
- Have confidence in the integrity of the data and your ability to address external or internal audits successfully.

Streamline processes for greater efficiency

Collaboration among research teams and full utilization of available scientific knowledge, data and resources across all departments will improve overall productivity and efficiency.

Challenge

Lack of immediate access to research information across disciplines and an inability to monitor the progress of ongoing research projects hamper efficiency and delay time to market for new products. There are several contributing factors:

- Lack of standardization among departments and disciplines.
- Security concerns over access to information.
- Lack of control over the use and deployment of resources.
- Duplication of effort among researchers and teams.

Our approach

SAS delivers knowledge and insight by providing a 360-degree view of all your clinical research information. As a result, SAS Drug Development lets you:

- Make use of all the knowledge your operational systems have to offer.
- Tap into data from partners, CROs and other sources, while generating new intelligence.

The SAS® Difference

SAS Drug Development delivers the intelligence and confidence you need to make more knowledgeable decisions about your research programs. Through a centralized, controlled platform, SAS Drug Development provides:

- **Integration.** Integrate and manage data from a multitude of sources while leveraging investments in legacy systems and resources.
- **Analysis and reporting.** Give users the power and flexibility to assess data and generate study reports. Readily produce presentation-ready statistical summaries of clinical trials data and share the results rapidly with researchers or reviewers, as required.
- **Discovery.** Investigate critical drug safety issues, pursue new marketing claims and explore potential product-line extensions.
- **Regulatory compliance.** Comply with regulations – including 21CFR Part 11 – using integrated processes that document research content thoroughly by providing versioning, audit trails and electronic signatures, as well as fully describing the relationships between all process inputs, transformations, analyses and results.

- Make quick, confident decisions, uncover risk/benefit issues and develop a better understanding of the overall safety and efficacy of your products.
- Save programs, derived data and statistical reports in a common, validated repository for sharing across research studies.
- Create data transformation and analysis programs that generate user interfaces automatically, enabling users to select parameters and execute validated routines – and reuse them as needed.
- Build the submission structure at the beginning of a research program and populate it directly throughout the project's duration.
- Standardize data in accordance with organizational and emerging CDISC data standards.
- Easily create required SAS transport files and the associated data document for regulatory submission.
- Use automated versioning, security, audit trails and related controls for all data management and analysis activities.
- Seamlessly bundle related analysis components (programs, data, logs and results) so there's no doubt about their accuracy and integrity.
- Authorize and control access at all levels to all content in the repository.

Compliance, with confidence

Your organization must be certain that it's meeting all regulatory requirements and industry guidelines. You also must guarantee your ability to address internal and external audits.

Efficiently demonstrating regulatory compliance will bring about additional confidence and increase the efficiency of your clinical development programs.

Challenges

Compliance missteps can be costly, with disciplinary actions ranging from fines and citations to a full shutdown of operations, not to mention the loss of consumer and shareholder confidence. But compliance can be tricky, due to:

- Research information spread across multiple platforms and systems.
- Lack of standardized data management processes.
- Changing regulatory requirements.

Our approach

SAS Drug Development uses advanced technologies and methodologies to meet today's stringent regulatory demands, including 21 CFR Part 11, as well as good industry practices (GxP). The ability to meet these goals is not an "add-in" to existing technology, as the solution was carefully and specifically designed to address compliance.

The solution integrates audit trails; versioning; electronic signatures; and time, date and user stamps into the research itself, so compliance is automated with no extra cost or work required.

With SAS Drug Development, you can:

- Store data in a controlled, validated environment.
- Access research content via a single, centralized repository.
- Use a single solution, rather than multiple applications, to conduct day-to-day business activities.
- Comply with current and future regulatory requirements and guidelines.

About SAS

SAS is the leader in business analytics software and services, and the largest independent vendor in the business intelligence market. Through innovative solutions delivered within an integrated framework, SAS helps customers at more than 45,000 sites improve performance and deliver value by making better decisions faster. Since 1976 SAS has been giving customers around the world THE POWER TO KNOW®.

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