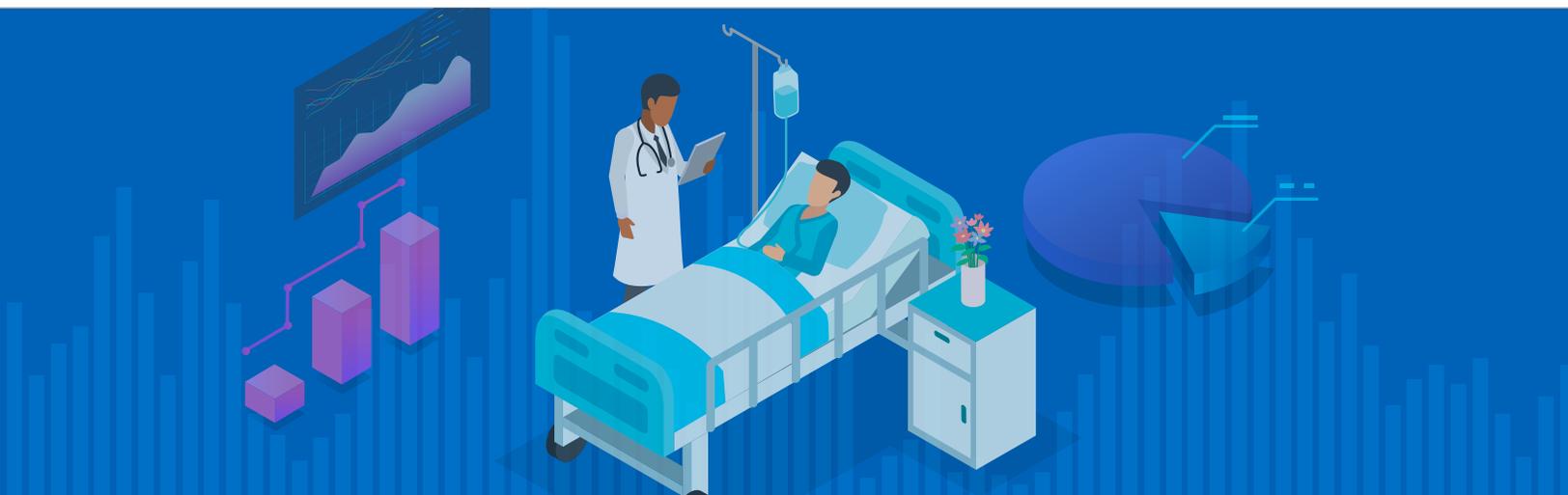§sas.

Clinical trial data analysis and submission

Get superior therapies to patients faster with more efficient analysis
and submission of clinical trial data

A single, open and
cloud-native platform

A secure, centralized
repository for data
and analytics

Seamless integration
for all stakeholders
across geographies

The Issue

To get the best return from R&D investments, clinical development teams must strive for rapid regulatory submission and approval of new products. To achieve this, they need to modernize clinical trials while maintaining data standards and regulatory compliance, integrate novel data sources and investigate emerging issues.

Speed to market requires an analytical ecosystem that outperforms legacy tools and methods – one that maximizes efficiency in the collection, analysis and submission of clinical trial data to regulators. Clinical development teams need validation, versioning, audit trails and documentation to avoid delays and rework. To streamline the path to submission, they also require automated workflows, integration support and data standards management. Assured analytical rigor and compliance is necessary as they evolve to address new complexities such as a growing patient-centricity and the explosion of real-world data.

The Challenge

Accelerate submission and time to market while ensuring regulatory compliance. Study start-up and clinical development timelines must be compressed to get therapies to market faster. At the same time, clinical development teams must uphold data standards and regulatory guidelines to avoid rework and reduce the risk of non compliance.

Manage and analyze new data sources. Modern trial designs, decentralized trial methodologies and greater use of real-world data bring an influx of new complexities and data.

Improve patient-centricity. Clinical trials must be accessible and convenient to the representative and diverse patient populations.

Balance collaboration and governance. Clinical trial stakeholders must collaborate across global clinical trials and among sponsors and clinical research organizations, without compromising traceability and data governance.

Our Approach

As a market leader in clinical research analytics, SAS provides a secure analytics foundation and scalable framework for clinical trial data analysis and submission. We approach the problem by providing software and services to help you:

- **Drive speed to market.** Deliver new therapies to submission faster and more efficiently.
- **Reduce the risk of non compliance.** Avoid delays and reduce risk on regulatory submissions.
- **Increase operational efficiency.** Improve processes and performance with insights to make informed operational decisions.
- **Modernize clinical research.** Increase the organization's analytical maturity and foster innovation in clinical development.

Robust analytic tools and techniques, including AI and analytics for IoT, accelerate R&D innovation in a heavily regulated world. Customers gain efficiencies in getting trials up and running, modernizing trial designs and delivering life-changing therapies to patients.

The SAS® Difference

The proven SAS statistical computing environment provides a universal approach to collecting raw data from clinical trials, managing and analyzing it and presenting it in easy-to-understand visuals for regulatory submissions. SAS has a long history of providing these capabilities in life sciences organizations of all sizes.

SAS **delivers faster insights** through:

- A single, open and integrated end-to-end platform.
- Seamless, secure integration across users, geographies and external partners.
- Near-real-time access to all data.
- Rapid GxP-qualified deployment by SAS managed services.

SAS **reduces risk** with:

- A secure, centralized repository that meets regulatory requirements.
- Auditable actions, data tracing and repeatable analysis.
- More than 20 years of standards-compliant implementations.

SAS **improves operational efficiency** by:

- Accelerating study start-up and optimizing study enrollment.
- Running simulations to keep studies on track and inform site supply.
- Using real-world data to guide operational decisions.

SAS helps **modernize clinical trials** by:

- Looking beyond compliance to collaboration and new data insights.
- Supporting modern, decentralized clinical trial designs with AI and IoT capabilities.
- Fully integrating with open source software.
- Scaling seamlessly from pilot to enterprisewide implementation.

CUSTOMER CASE STUDY:

Ferring Pharmaceuticals needed to optimize their clinical development processes to drive innovation and reduce time to market, while ensuring compliance to regulatory requirements. SAS Life Science Analytics Framework, hosted and managed by SAS in a fully regulatory-compliant cloud environment, provides process automation and real-time access to clinical data across the business, ensuring high data quality and ultimately driving speed to insights and business decisions.

Increase efficiency with process automation and collaboration

Ensure data governance, reproducibility of analysis and reduce risk

Evolve through a flexible modern framework with many integration capabilities

Speed to insights, more time focusing on actual results

"SAS provides a global proven industry solution for international teams at Ferring and Clinical Research Organizations to access clinical data in the same way and optimize working procedures. The extensive integration and workflow capabilities combined with real-time access to clinical data enables efficient processes, supporting centralized monitoring and rapid reporting of trial results."

Bjarke Klein, Vice President of Global Biometrics at Ferring Pharmaceuticals

For more information, please visit **SAS Life Sciences Analytics**.

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