Accelerate Clinical Trial Innovation

Meet the challenges of today and the opportunities of tomorrow with a secure, validated statistical computing environment

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Introduction

Getting a new therapy to market is a huge endeavor, often involving dozens of stakeholders from pharmaceutical companies, clinical research organizations (CROs), health care providers and regulators. Clinical trials are one of the most complex parts of the process, and that complexity is increasing due to:

- New types of trials (such as decentralized and adaptive design trials) that open new avenues for innovation.

- The adoption of real-world evidence, which is driving the demand to integrate new sources of information, from electronic medical records and genomics to data from smartwatches and wearables.

- Companies combining new analytical techniques – such as machine learning and deep learning – with increasingly sophisticated statistical programming to unlock new insights.

Central to a life sciences organization's ability to succeed and compete amid increasingly complex clinical trials is the strength, security and flexibility of its statistical computing environment (SCE). The right SCE is critical in accelerating scientific discoveries by enabling researchers to manage, process and analyze data efficiently and compliantly, all while maintaining the utmost regulatory integrity.

The decentralization, diversification and acceleration of clinical trials is putting greater pressure on all participants in the health care ecosystem to collaborate efficiently. A lack of standardization at the foundational level makes it difficult for teams to work together, share data in a safe and controlled environment, and provide robust tools to ensure that analyses are sound and reproducible. This is particularly challenging for startups and small to midsize companies that may lack much of the bandwidth and funding needed.
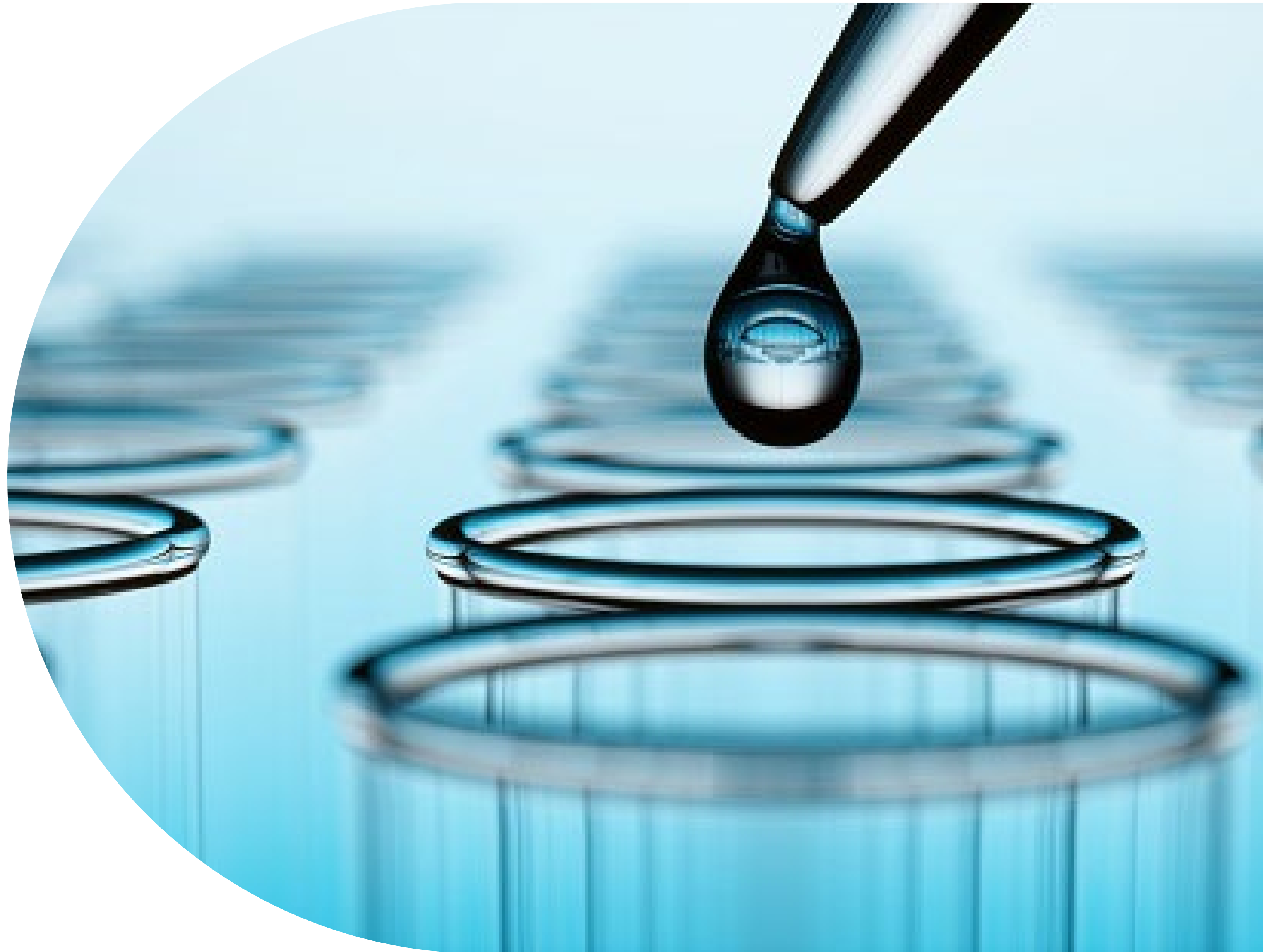
At the same time, regulatory scrutiny has never been greater. Legislation such as the Food and Drug Administration's Code of Federal Regulations Title 21, Part 11, and the European Union's Annex 11 set out rigorous compliance requirements for information systems used in clinical trials. And on top of these larger legislative frameworks, individual markets often have their own regulatory regimes that specify when, how often and in what format organizations must submit clinical trial information for regulatory review.

In this e-book, we'll explore how life sciences companies of all sizes can drive speed to market with more efficient clinical trials using the SAS Life Science Analytics Framework – a comprehensive platform that fulfills all the requirements of an SCE.

Building a platform fit for industry needs

Each organization in the life sciences ecosystem has its own specific and unique needs from clinical trials and its own strategies for innovation. But underneath those custom requirements, there's a foundational level of common practice that is often overlooked. And these foundational practices are long overdue for standardization and automation.

Moreover, by creating standards for data integration, management and analytics, it becomes much easier and more efficient for pharmaceutical companies, CROs, health care providers and regulators to collaborate.

SAS solutions aim to give customers in the highly regulated life sciences industry the perfect balance of control to securely manage, scale and maintain data governance while providing the flexibility to incorporate different programming languages, data sources and analytics techniques. That's more important now than ever before.

There is a tremendous opportunity for life sciences companies of all sizes to reduce time to market and lessen regulatory query response time. SAS provides a fully validated environment that helps companies comply with CFR Title 21 Part 11.

With SAS as the FDA de facto standard for clinical data submissions, scalable from one or two users to hundreds, we aim to to provide you with everything in one environment, enabling seamless collaboration across departments to deliver success. And you get to mitigate risk and eliminate burdens on IT.

Key technical areas for clinical trial management

The SAS Life Science Analytics Framework delivers everything your organization needs to cover the five main technical areas that are fundamental for clinical trials management.

1

Clinical data repository

A central store with a rigorous governance framework built in allows users to provide complete auditability. This ensures full version control for data assets and role-based access management. All data and metadata for each clinical trial is held in one secure, tamper-proof environment, and data lineage is traceable from end to end.

2

Statistical computing environment

A powerful open analytics engine lets statisticians, data scientists and programmers write code and run analyses in SAS, R and other programming languages. Users can also connect seamlessly to external analytics environments such as SAS® Viya® to run - [machine-learning models] and integrate the results back into the clinical data repository.

3

Collaborative workflows

A cloud-based, GxP-compliant environment allows teams and partners to access data securely anywhere and from any device. Teams can integrate seamlessly with internal and third-party workflow management tools, simplifying handoffs between stakeholders and making it easy to adapt to new clinical trial methodologies.

4

Regulatory reporting

A fully governed environment with rigorous controls ensures that both data and analyses are documented and reproducible. This includes tools to create and manage regulatory submissions that comply with all relevant data standards and formats.

5

Management insight

Powerful dashboards and reporting enable users in different roles – from data scientists to trial managers and executives – to view the data that's relevant to them in real time. This helps to identify and resolve issues quickly and maintain momentum in clinical trials to get new therapies to market faster.

Why SAS?

SAS has been working with life sciences companies to develop and refine solutions for clinical trial management for more than 20 years. SAS Life Science Analytics Framework incorporates the insights we've learned from working with pharmaceutical companies, CROs and health care providers during that period.

The framework is a modern platform built on cloud-native technology and open API integration, with full support for open source statistical programming languages and data science frameworks. Customers can trust in a secure, validated solution designed for flexibility and scalability to support long-term use, created by the leader in clinical research analytics.

Unique differentiators for the SAS Life Science Analytics Framework include:

1. Regulatory competence.
2. Openness.
3. Collaborative development.
4. Flexibility to modernize and evolve.
5. Speed of execution.

Unique differentiators

1. **Regulatory competence.** Avoid submission delays and reduce the risk of noncompliance.

   o The framework provides a controlled environment for clinical trials data, analyses and outputs – a secure, auditable and tamper-proof store that you and your regulators can trust.

   o Every analysis you run automatically generates a manifest file that specifies the exact data used as input, the code used to perform the analysis, and the versions of all the software tools and dependencies used to process that data.

   o The manifest ensures that all analyses are fully reproducible. Users can rerun any analysis with one click, even months or years after the code was written, and get the same results.

   o Users can also run the same code against a more recent data set (e.g., to perform month-on-month or year-on-year comparisons) and be completely confident that the methodology is consistent.

2. **Openness.** Integrate APIs with full support for open source statistical programming languages and data science frameworks.

   o The framework provides an open statistical programming environment with state-of-the-art execution engines for both R and SAS code, empowering data scientists, statisticians and programmers to write code in the languages they know best.

o In addition to a powerful web-based user interface, the framework also provides programmatic access to all analytical tools and functions via APIs – empowering experts to build their own automated scripts and workflows.

o The API architecture makes it easy to build workflows that support the use of external development and coding environments. This allows users to develop and validate code externally using a PC, server or on-demand environment, then automatically register it with the framework environment for secure management and submission.

3. **Collaborative development.** Improve efficiency, productivity and collaboration through automation, ease of use, and seamless integration and data management.

o As a cloud-native platform, users can access the framework from anywhere via a secure internet connection, making it easy to support remote working for internal stakeholders and dramatically simplifying collaboration between multiple organizations on large-scale trials.

o SAS delivers the framework as a managed service running in the SAS cloud. This means you don't have to burden your internal IT team with system maintenance, and you automatically get access to the latest features from SAS without having to manage complex upgrades.

o By automating the foundational, routine aspects of clinical trials management, analytics and regulatory submissions, the framework frees up your expert resources to focus on the truly innovative and value-adding aspects of their role: exploring the potential of new types of trials, investigating new sources of data and performing novel analyses.

4. **Flexibility to modernize and evolve.** Take advantage of a scalable, software-agnostic platform that supports the latest technology and advanced analytics, including AI and machine learning.

o Extend your team's skills from regulatory to exploratory with simple API-based integrations that work with analytics platforms such as SAS Viya. This allows data scientists to take advantage of the latest machine-learning frameworks from the R and Python ecosystems, perform exploratory analysis, and bring useful data and results back into a controlled environment.

o APIs can also be used to integrate large data sets stored on low-cost object storage platforms such as Amazon S3. As companies increase their use of real-world evidence and new data sources (such as genomics) to augment their clinical trial processes, this provides a cost-effective way to manage the rising tide of data.

o The API architecture of the framework makes it easy to build workflows that integrate best-of-breed third-party services, such as CDISC CORE and CDISC OpenStudyBuilder or Pinnacle 21, for data-quality management.

o APIs also enable rapid integration with your existing in-house applications and workflow management tools so you can protect the value of your existing investments with no need to rip and replace.

o Using SAS Life Science Analytics Framework and Viya together gives your teams the opportunity to stand up validated and nonvalidated environments to support innovation, then seamlessly scale from pilot to enterprisewide implementation.

5. Speed of execution. Get everything you need for an out-of-the-box statistical computing environment that can be deployed quickly.

o With the SAS Life Science Analytics Framework, organizations no longer need to build and maintain their own clinical trials management platforms in-house. The framework covers all the key requirements for an SCE specified by PHUSE, together with robust data management and regulatory reporting features.

o The framework is modular and flexible enough to meet any requirement and fit into any existing software ecosystem while providing a backbone of standardized capabilities. Integration is quick and seamless, making it easy to interact with other companies throughout the ecosystem.

o SAS can typically deploy the framework in three to four months for a midsize pharmaceutical company, and four to six months for large companies. In-house platforms may require years of development work and cost much more.
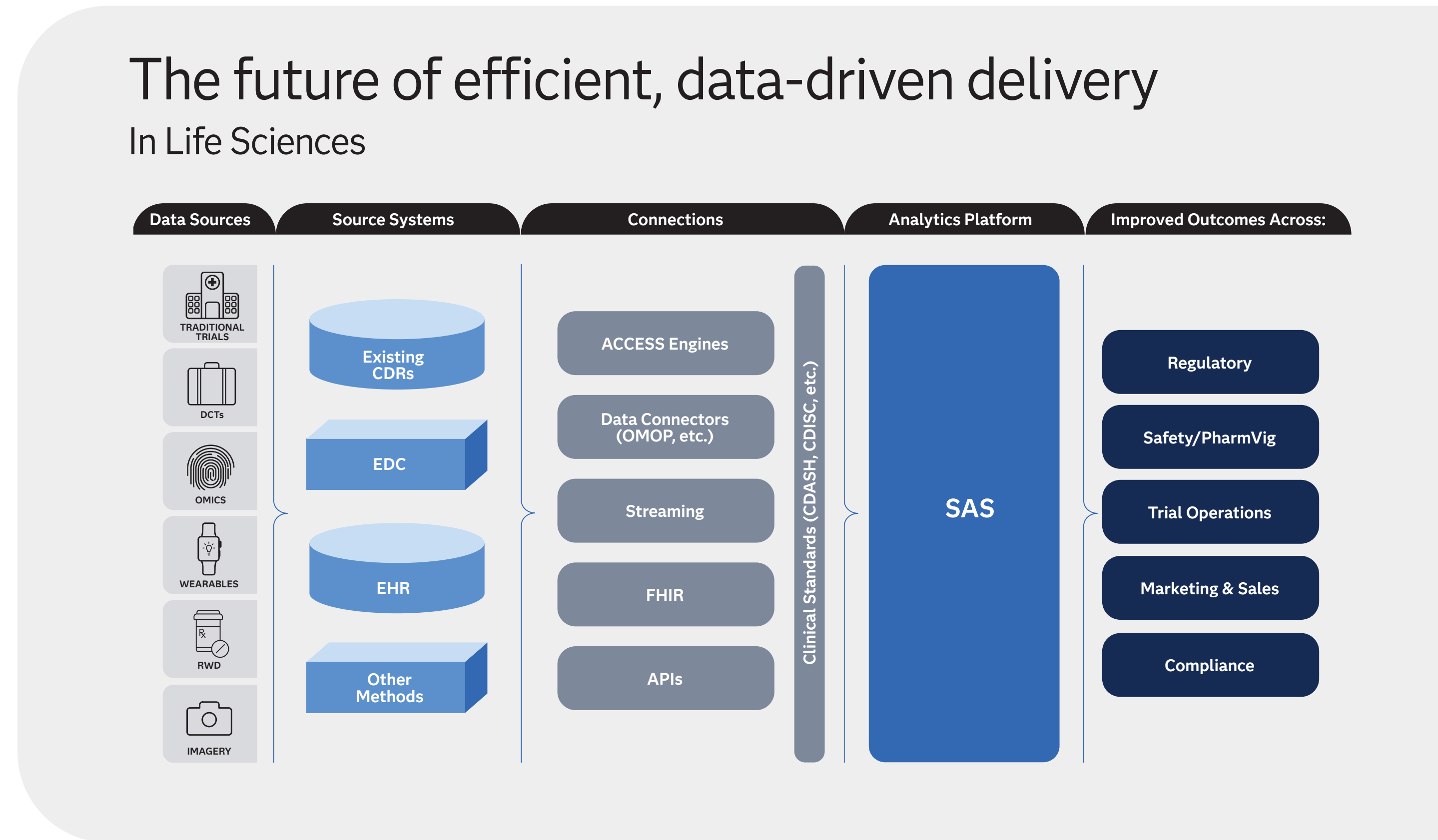
Delivering real-world value

SAS Life Science Analytics Framework is used by a number of life sciences companies, from small to top 10 pharmaceutical companies around the world. It has also been used by specialist firms such as Santen Pharmaceutical and Ferring Pharmaceuticals.

"Working in a global, cross-functional team environment on critical projects, it was important to ensure consistency, seamless access and version control across all the various groups at Santen. ... With the SAS Life Science Analytics Framework, everyone is viewing the same snapshot of the data. Global access to consistent data is the dream, and we've achieved it."

Nina Worden, Director of Statistical Programming, Santen

> Read the Santen case study.

The future of efficient, data-driven delivery
In Life Sciences

Data Sources	Source Systems	Connections	Analytics Platform	Improved Outcomes Across:

Data Sources: TRADITIONAL TRIALS, DCTs, OMICS, WEARABLES, RWD, IMAGERY

Source Systems: Existing CDRs, EDC, EHR, Other Methods

Connections: ACCESS Engines, Data Connectors (OMOP, etc.), Streaming, FHIR, APIs

Clinical Standards (CDASH, CDISC, etc.)

Analytics Platform: SAS

Improved Outcomes Across: Regulatory, Safety/PharmVig, Trial Operations, Marketing & Sales, Compliance

The SCE of the future gives users the flexibility to ingest multiple data types and sources and integrate third-party APIs all in one platform. This approach drives innovation and efficiency throughout the clinical development and delivery continuum.

"The SAS Life Science Analytics Framework – hosted and managed by SAS in a GxP-qualified cloud environment – provides a proven global industry solution in which international virtual teams at Ferring and clinical research organizations access clinical data in the same way, and continuously aim at optimizing working procedures while ensuring compliance with regulatory requirements."
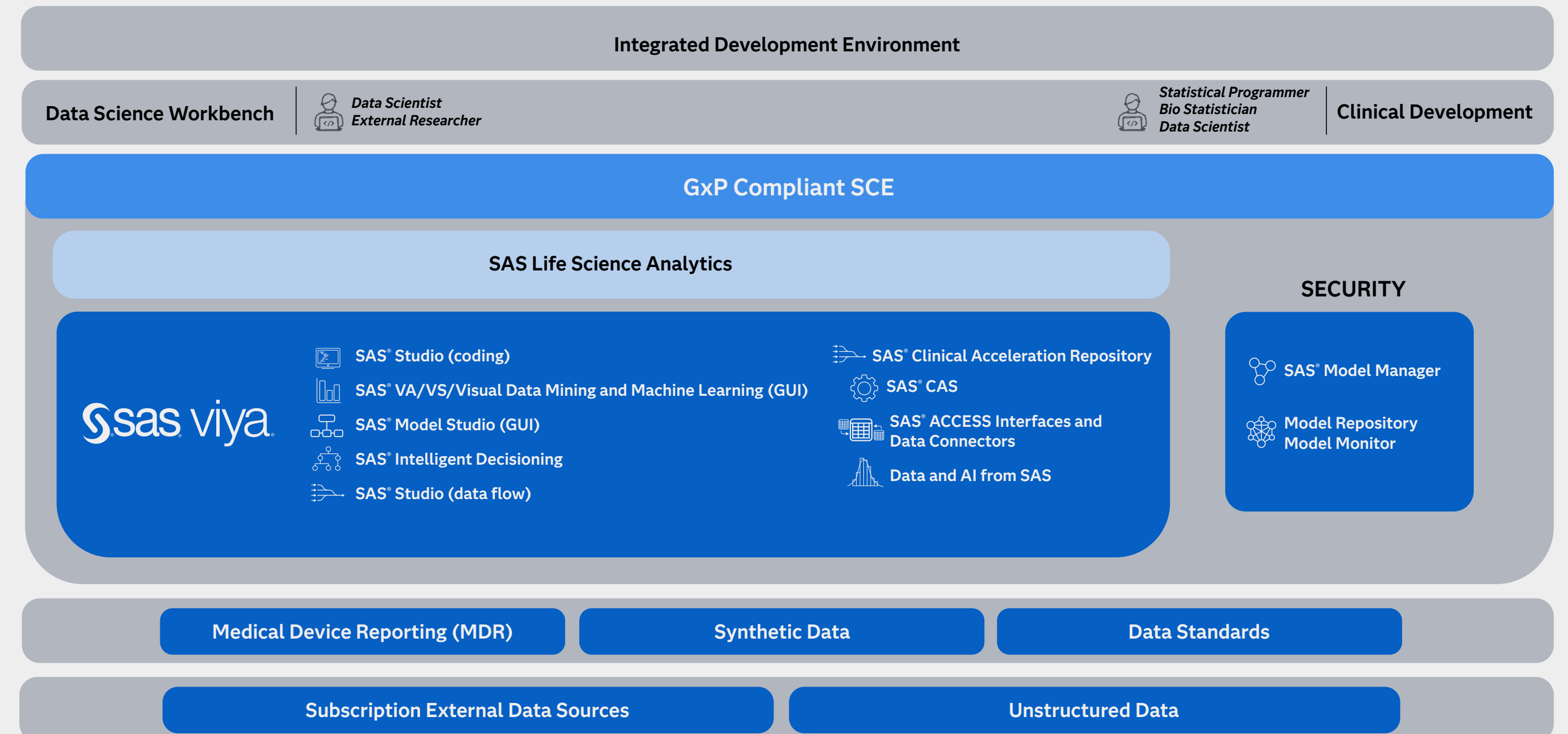
Bjarke Klein, Vice President of Global Biometrics, Ferring Pharmaceuticals

Unlocking key business benefits

With SAS Life Science Analytics Framework, your organization can:

- o Reduce time to market and lower costs by accelerating clinical trials management.

- o Automate foundational capabilities to support traditional and emerging clinical trial types.

- o Improve efficiency and reduce errors in data aggregation and preparation.

- o Ensure rigorous statistical analys is in an environment built for regulatory

- o reporting.

- o Extract maximum value from new and existing analytics applications and investments.

- o Broaden access to programming talent from the SAS, R and Python communities.

- o Expand access to clinical data and streamline collaboration across the ecosystem.

Building a modern SCE for life sciences

Integrated Development Environment

Data Science Workbench | Data Scientist, External Researcher | Statistical Programmer, Bio Statistician, Data Scientist | **Clinical Development**

GxP Compliant SCE

SAS Life Science Analytics

SECURITY

sas viya

- SAS® Studio (coding)
- SAS® VA/VS/Visual Data Mining and Machine Learning (GUI)
- SAS® Model Studio (GUI)
- SAS® Intelligent Decisioning
- SAS® Studio (data flow)
- SAS® Clinical Acceleration Repository
- SAS® CAS
- SAS® ACCESS Interfaces and Data Connectors
- Data and AI from SAS

- SAS® Model Manager
- Model Repository Model Monitor

Medical Device Reporting (MDR) | **Synthetic Data** | **Data Standards**

Subscription External Data Sources | **Unstructured Data**

SAS has extensive experience supporting customers' analytics environment. No matter where the data is coming from or how it's connected, SAS can support the entire analytics life cycle for pharmaceutical organizations and enable them to drive insights in a secure yet agile manner.

Next steps

To learn more about how SAS can help transform the way you plan and deliver clinical trials and get vital new medicines to market faster, visit SAS Life Science Analytics Framework.

To contact your local SAS office, please visit: **sas.com/offices**