Paper SD12

Clinical Programming in the Fast Lane: Accelerating with SAS

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ABSTRACT

The demand for faster, more reliable clinical trial data analysis continues to grow as organizations face pressure to accelerate regulatory submissions without compromising compliance. SAS Clinical Acceleration® provides an integrated statistical compute environment designed specifically for clinical research, combining automation, traceability, and scalability. This session will highlight how SAS Clinical Acceleration enables teams to streamline workflows, automate statistical programming jobs, and ensure reproducibility across studies. With built-in auditability and seamless integration of both SAS and open-source tools, the platform empowers clinical programmers to manage complex analyses while maintaining full regulatory compliance. By unifying data, code, and results in a controlled environment, SAS Clinical Acceleration reduces operational risk, shortens development cycles, and supports sustainable, future-ready clinical programming practices.

INTRODUCTION

While the fundamentals of statistical programming, data cleaning, core statistical methods, and reproducibility have remained relatively unchanged over the last 50 years, computing environments, the size and complexity of data, and demands for integration with modern technologies have completely transformed the analytics lifecycle. Statistical programming today is less about writing isolated procedures and more about orchestrating multi-platform pipelines from early data cleaning through submission-ready outputs.

SAS Clinical Acceleration[1] builds on this evolution by shifting the focus from routine compliance and governance tasks to high-value analytical work. The platform automates many of the checks and controls to ensure datasets, analyses, and outputs meet regulatory standards, freeing programmers from time-consuming manual oversight. This allows them to spend more time on interpreting results, exploring complex study data, and supporting faster, more informed decision-making. By standardizing processes across studies and providing built-in auditability, the solution not only reduces the risk of errors but also helps teams accelerate study timelines enabling clinical insights to reach stakeholders faster and ultimately advancing the development of new therapies more efficiently.

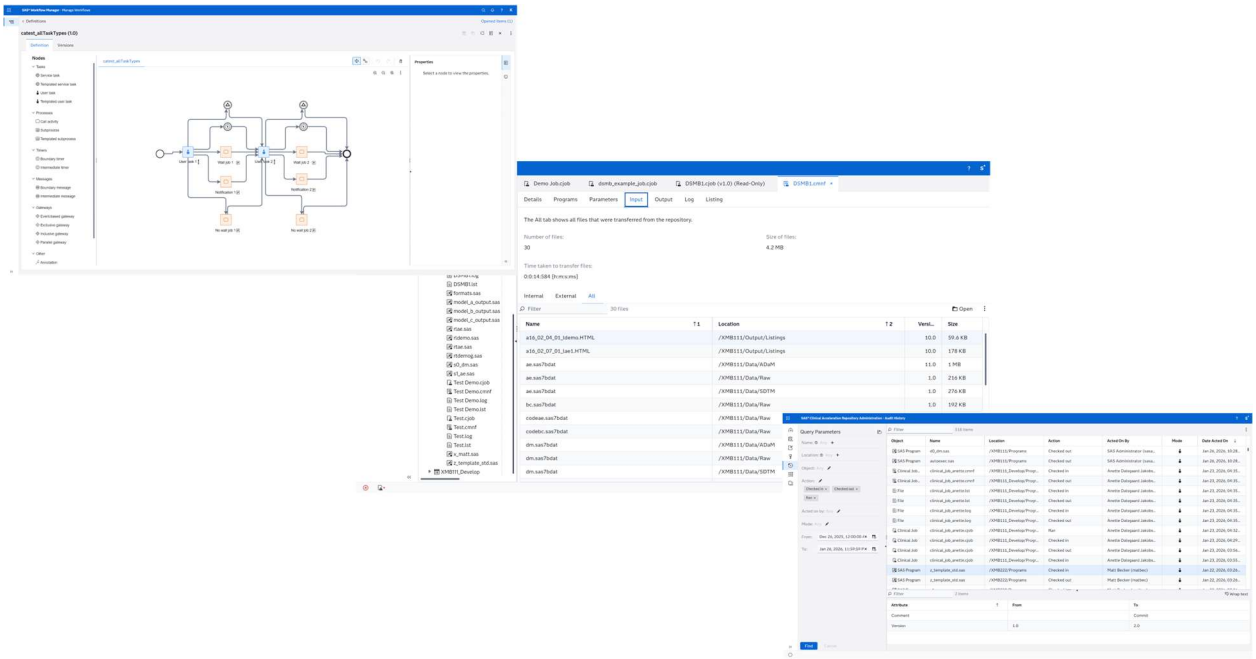

Figure 1: SAS Clinical Acceleration
From BPMN workflow to automated clinical jobs and a regulatory compliant audit trail.

The application is built from several key modules that work together to streamline clinical programming and analytics. The heart of the application is SAS Clinical Acceleration Repository, a clinical data repository that serves as a centralized, secure location for all study data, programs, and outputs, ensuring version control, auditability, and regulatory compliance. Integration with SAS Studio provides programmers with a modern, browser-based IDE,

enabling interactive development, debugging, and execution of traditional SAS9 and open-source R and Python code in a controlled environment. SAS Clinical Job Management® automates and schedules program execution across studies, helping complex pipelines to run efficiently and reliably. Finally, Clinical Workflows provide a flexible, repeatable framework that supports your organization's BPMN-driven processes and standards maintaining consistency while allowing teams room to adapt to the specific needs of each study.

The foundation of Clinical Acceleration is SAS Viya®, a cloud-native analytics platform that provides the scalability, flexibility, and integration capabilities required for modern clinical programming and statistical analyses. Viya builds on SAS's trusted reputation in the life sciences industry, modernizing the traditional SAS9 architecture to support scalable, collaborative, and innovative approaches to complex clinical and statistical challenges. By handling large, complex datasets across multiple studies, distributed processing, and enabling secure collaboration, Viya lets teams run analyses faster, access data from anywhere, and scale resources dynamically. Clinical Acceleration on Viya provides the foundation teams need in their daily programming work and the new challenges presented in this industry.

WHY REPOSITORIES STILL MATTER IN CLINICAL PROGRAMMING

Despite the widespread adoption of data lakes, data lakes don't meet the requirements of a clinical data repository. Data lakes store massive amounts of information, but they don't enforce structure, versioning, or compliance. A repository provides a single source of truth, guaranteeing data, programs, and outputs are secure, auditable, and standardized. A repository supports reproducibility, collaboration, and regulatory requirements giving teams confidence that analyses are reliable and compliant, even as they integrate with broader cloud or lake-based environments.

The SAS Clinical Acceleration Repository serves as the central system of record for submission assets across the application. It provides fine-grained permissions and role-based privileges to ensure users can only see and modify what they are authorized to, enabling protection for sensitive data and easy access to collaborative assets.

Within the repository, simple version control allows for multiple versions of datasets, programs, specifications, and output without losing traceability. Version numbers can be determined according to your processes and comments can be added on the versions to easily track what changed, when it changed, who changed it, and why, thus maintaining a comprehensive history of assets.

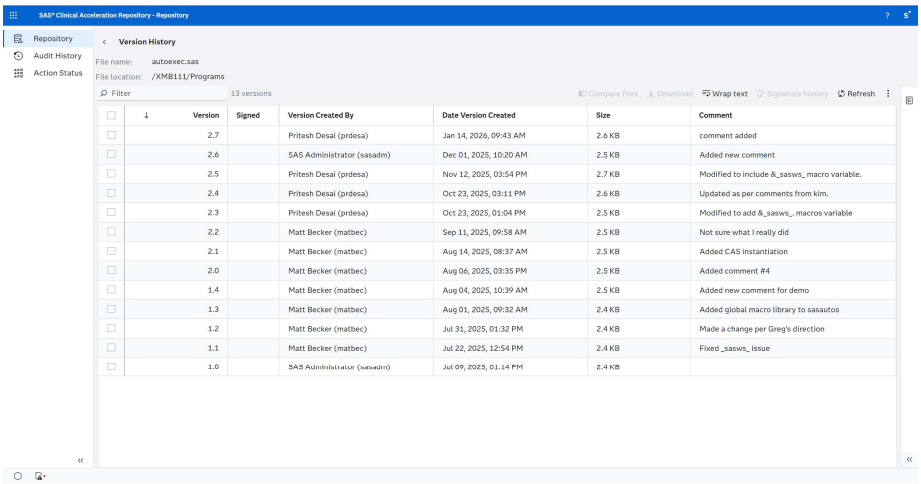

Figure 2: Repository Version History

Electronic signatures can also be captured directly within the repository to standardize formal review and approval workflows, making sure signatures are completed and captured at the appropriate times. These esignatures are securely bound to specific versions of assets recording the signer's identity, date, time and intent while previous esignatures remain intact as newer versions are loaded.

The audit trail provides a clear, comprehensive record of all activity, capturing who made changes, when changes were made, and the specific actions taken. The audit history is presented in a human-readable format that makes it easy for reviewers to filter, search, and navigate through contexts, dates, actions, and edits without needing to dig through multiple systems or logs. The comprehensive audit trail and human-readable presentation make it easy for teams to demonstrate compliance, track asset history, and remain prepared for regulatory inspections, while minimizing the administrative burden typically associated with maintaining detailed audit documentation.

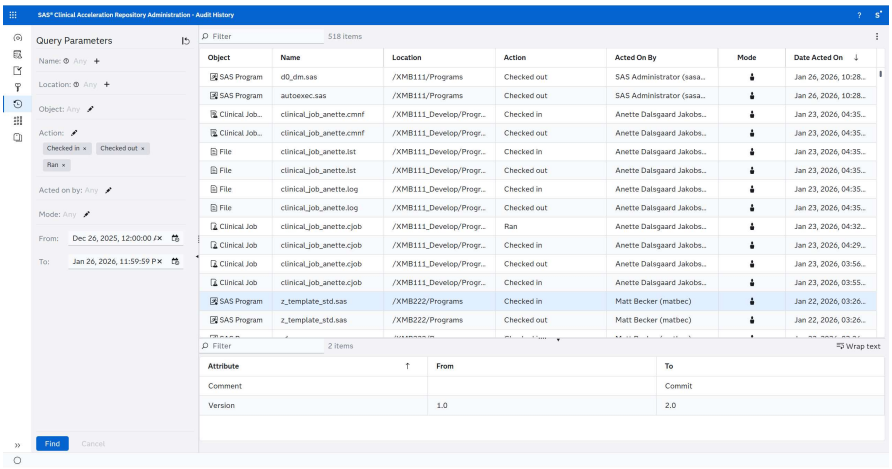

Figure 3: Audit History

END TO END INTEGRATION WITH SAS STUDIO

The tight integration between the repository and SAS Studio enables programmers' easy movement between a shared, governed repository into a focused development space without leaving the same controlled environment. Studies created in the repository are immediately available in SAS Studio and respect all permissions and privileges applied so users can bring assets into their workspace to begin modifications leveraging all the tools and functionality that SAS Studio offers.

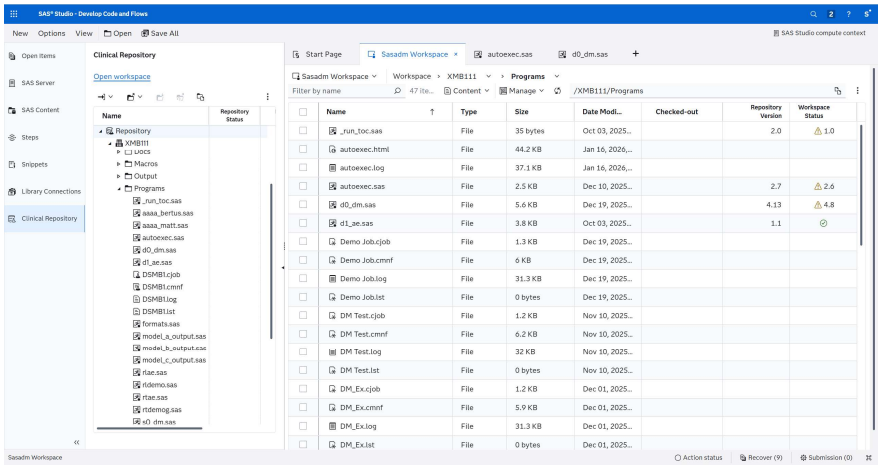

Figure 4: Repository and SAS Studio Integration

As development progresses, SAS Studio displays the status of all assets, so all users know who has an asset checked out and is actively working on it. Checking out an asset prevents a second user from being able to check in any changes until the first user is done with their work and has released the asset back to the repository. Changes can be made locally and tested while maintaining clear lineage in the repository, ensuring only relevant modifications are captured within the audit history.

When the version of an asset in a user's workspace does not match that of the repository, the application notifies the user via status icons in both the workspace and repository. Built-in comparison capabilities allow programmers to quickly understand what has changed between their workspace and the repository, eliminating uncertainty and reducing the risk of missed updates. Assets can be synched back to the repository on demand to give users confidence that they are always working from the appropriate versions.

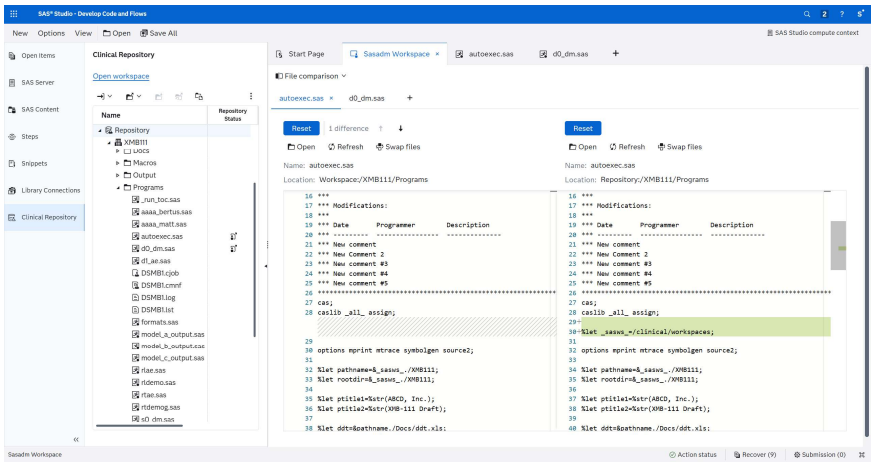

Figure 5: Clinical Acceleration Compare Function

In addition to SAS9 programming, Viya provides native support for open-source languages such as R and Python. Programmers can access these languages directly within SAS Studio or via connected IDEs like Microsoft VS Code, leveraging the same governed repository and workspace environment. This empowers teams to select the right tool for the job, combining the flexibility and rich libraries of open-source tools with the compliance, versioning, and audit capabilities of the application. Users can work entirely within SAS Studio in their browser or, for those who prefer a different development environment, leverage the SAS Viya VS Code extension, a comprehensive set of Viya REST APIs[2], or the SAS GitHub repository with macro API wrappers[3] providing the user with SAS Clinical Acceleration capabilities from virtually any IDE.

AUTOMATING AND TRACKING CLINICAL JOBS

Clinical Job Management in Clinical Acceleration provides a centralized environment for creating, executing, and monitoring clinical batch runs. Users can define new clinical job definitions by selecting the programs, datasets, and specific versions they wish to utilize, establishing clear inputs and outputs while maintaining links to the governed repository. This structured approach ensures that all jobs are reproducible, traceable, and aligned with study-specific workflows.

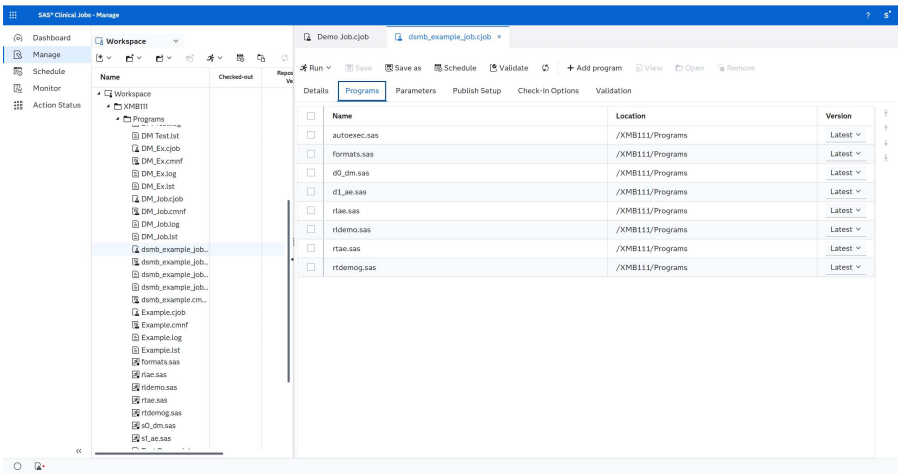

Figure 6: Clinical Job Definition

Once a job is created, the user has multiple opportunities to be sure that it will run as expected before checking it into the repository. It can be executed immediately within the workspace for testing, or the job definition can be validated against the repository so programmers can be confident all required datasets, programs, and permissions are in place for the job to execute successfully. Alternatively, users can leverage the 'run and populate' functionality to help the user identify what inputs, folders, or files a job definition will need to run successfully in the repository. Once a job run is initiated/triggered in the repository or the workspace, the system handles the orchestration of multiple programs and manages the sharing of data between them while providing real-time feedback and logs as the job runs. This provides users the visibility to monitor progress, quickly identify any issues, and resolve them promptly, ensuring an uninterrupted workflow.

After a job runs, users can review the job manifest, a detailed record of all programs executed, inputs consumed, outputs generated, and any errors encountered. The manifest provides transparency into all steps of the job submission making it easy to trace lineage and support regulatory submissions. With this level of detail, both programmers and reviewers gain confidence that the outputs are accurate, complete, and fully traceable to their source assets. The resulting manifest is a versioned json file that can be stored in the repository for reference.

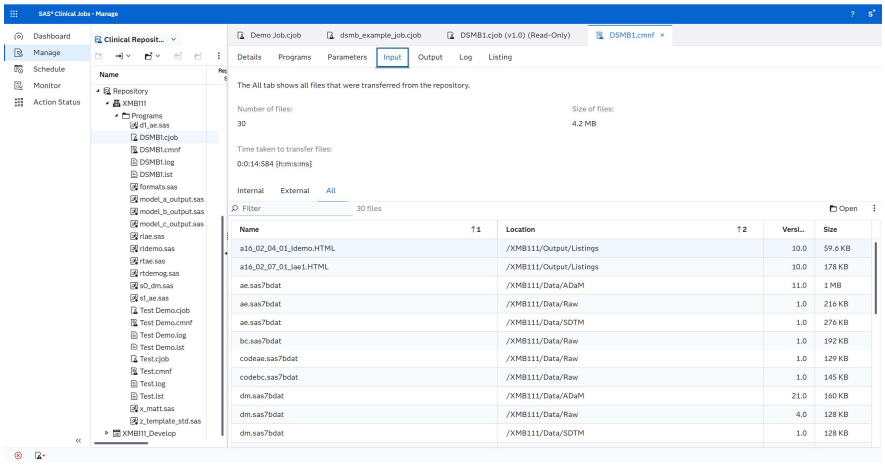

Figure 7: Clinical Job Manifest

In addition to immediate execution, Clinical Job Management provides the ability to schedule jobs to run later, enabling teams to optimize computing resources and align processing with operational needs. Jobs can be queued for off-peak hours, triggered by data availability, or set to repeat at a defined cadence. This scheduling flexibility allows teams to maintain productivity, reduce manual intervention, and know that large or complex workflows are completed efficiently and reliably.

STANDARDIZED AND GOVERNED CLINICAL WORKFLOWS

SAS Clinical Acceleration Clinical Workflows provide a unifying layer across the application, helping to make customer-defined clinical processes not only automated, but also standardized, traceable, and easy to maintain. With workflow embedded directly into the application, teams can move beyond emails and spreadsheets, replacing them with repeatable, well-defined workflows that guide work from data ingestion through analysis and delivery.

At the core of this capability is a built-in BPMN-based workflow designer that allows organizations to model clinical processes using industry-standard notation. Workflow definition authors can visually define steps, decisions, approvals, and dependencies, while seamlessly incorporating repository actions and job execution events. This approach enables documented workflows to reflect real-world work while remaining flexible enough to adapt to study-specific or organizational requirements without custom coding.

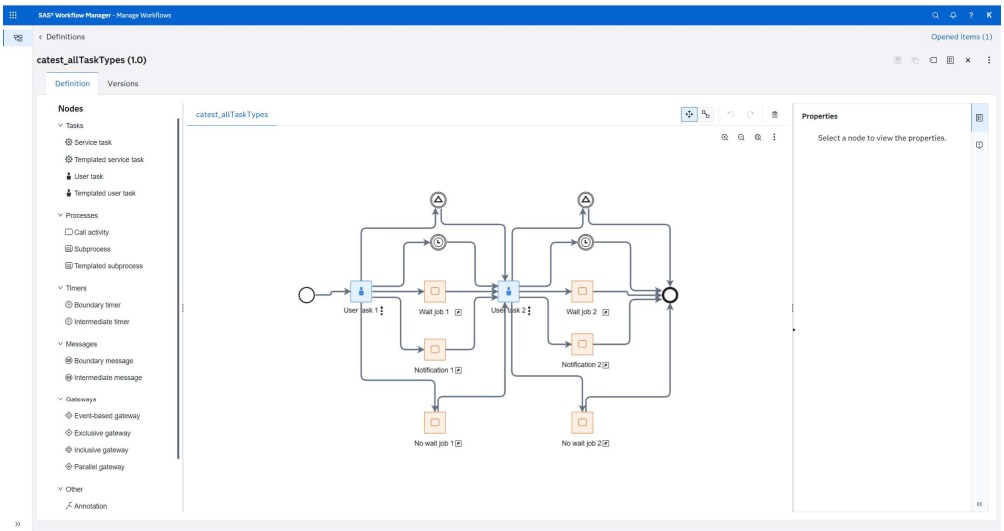

Figure 8: SAS Viya Workflow Manager

Once workflow definitions have been defined and activated, they can be leveraged in the repository as repeatable workflows that can be easily monitored and managed. Study managers can quickly see the status of in-flight workflows, identify bottlenecks, and understand where action is required, all from a centralized view. Individual users can utilize a narrower view to focus on the workflows that matter to them. Combining Clinical Workflows with repository functionality provides clear visibility into who ran what, when, and with which code and datasets.

Task management functionality is tightly integrated with the repository, keeping users appraised of what is due and when to help prioritize actions and ensure deliverables are met. Workflow steps automatically surface as actionable tasks that can be assigned to individuals or groups, with time spent and completion status tracked in real time. This provides teams with clear accountability and visibility into progress, making it easy to manage approvals, reviews, and handoffs without disrupting the overall workflow.

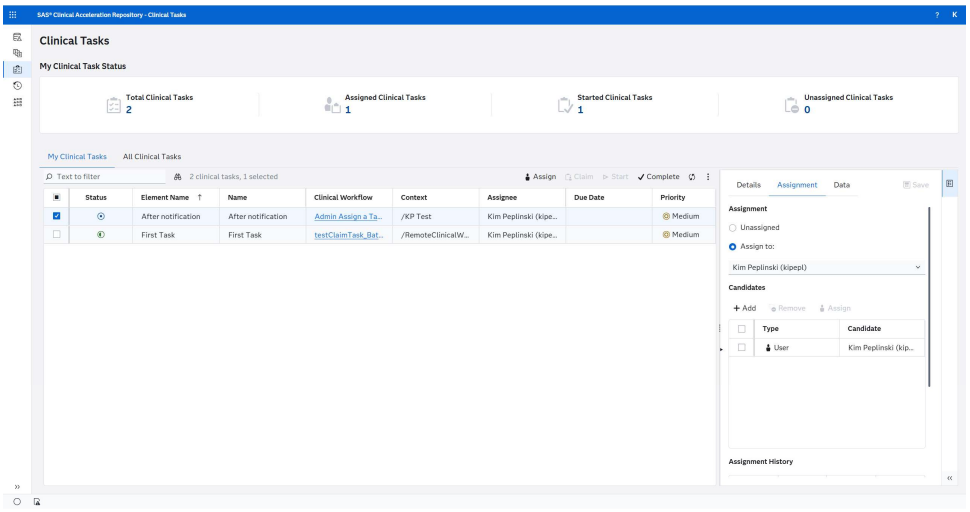

Figure 9: Clinical Acceleration Task List

CONCLUSION

SAS Clinical Acceleration extends SAS Viya to fulfill the unique requirements of a validated clinical trial environment while leveraging all the platform's innovations. By integrating the Clinical Acceleration Repository, SAS Studio, Clinical Job Management, and Workflow capabilities, the application streamlines complex processes while maintaining strict compliance and reproducibility. Built-in validation, version control, audit trails, and e-signature support gives users confidence that every dataset, program, and output meets regulatory requirements, giving teams confidence in the accuracy and integrity of their work.

At the same time, SAS Clinical Acceleration emphasizes ease of use and operational efficiency. Users can move seamlessly between development, execution, and monitoring tasks, leveraging workflows, task management, and automated job orchestration to focus on high-value analytical work rather than manual oversight. With scalable architecture and the integrated repository, teams can run more complex jobs, reuse standards more easily, and deliver analyses to study teams and regulators faster, ultimately enabling more informed decisions and advancing the development of new therapies.

REFERENCES

1. SAS Clinical Acceleration: https://www.sas.com/en_us/software/clinical-acceleration.html
2. SAS Clinical Acceleration Rest APIs: https://developer.sas.com/rest-apis?categories=health_and_life_sciences
3. SAS Clinical Acceleration Macro API Wrappers: https://github.com/sassoftware/sas-clinical-acceleration-repository-rest-api-call-examples

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