PharmaSUG 2026: TT-393

From SAS Servers to AI Agentic SCEs: Integrating Agentic AI into GxP-Compliant Biometrics Workflows

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ABSTRACT

Biometrics teams in clinical trials are currently navigating a significant transition as traditional Statistical Computing Environments (SCE) move from local SAS servers toward the integration of Agentic AI within modern, multi-lingual ecosystems in SAS®, R and Python. The paper demonstrates how Agentic AI could be integrated into SCE environment and how SCE could be built and validated in GxP and 21 CRF Part 11 compliance.

First, the paper introduces the concepts of Agentic AI in AI agents and Agentic workflow, and its use cases such as SDTM/ADaM/TFL development and validation, clinical artifacts development, and synthetic data creation. Then, the paper provides a detailed look at the implementation and validation of a cloud-based SCE that is fully GxP and 21 CFR Part 11 compliant. It also illustrates the paradigm shift offered by Agentic AI, where autonomous agents use programming languages as tools to plan, reason, and execute statistical tasks within SCE.

Key insights provided in this paper include:

- **A Validated Multi-Lingual SCE:** A robust architecture supporting SAS, R and Python, ensuring compliance through IQ/OQ/PQ and risk-based validation.
- **The integration of Agentic AI:** how Agentic AI automates the process in SCE
- **Future-Proofing Compliance:** Strategies for maintaining "audit-ready" status in SCE

Ultimately, this paper provides biometrics leaders with a roadmap to transform their SCE from a passive storage and execution environment into an intelligent Agentic AI platform that not only manages data but actively drives clinical insights.

Introduction of SCE

A Statistical Computing Environment (SCE) is the foundation for biometrics programming in clinical development. Historically, many organizations relied on local or centralized SAS servers that provided a controlled place to run code and generate deliverables. While this model supported secure statistical production work, it often created limitations around flexibility, language support, automation, and integration with newer AI-enabled tools. As clinical development becomes more data-intensive and cross-functional, the role of SCE is expanding from a simple execution environment into a strategic platform for analysis, documentation, and workflow orchestration.

The SCE is not only a secure environment for programming, but also a controlled platform that can support clinical programming workflows with built-in compliance and validation. In this framework, AI is not treated as a separate experimental tool. Instead, it becomes part of the SCE ecosystem, operating inside governance boundaries with traceability, audit trails, and human review. This shift is especially important for biometrics teams, where reproducibility and inspection readiness are essential.

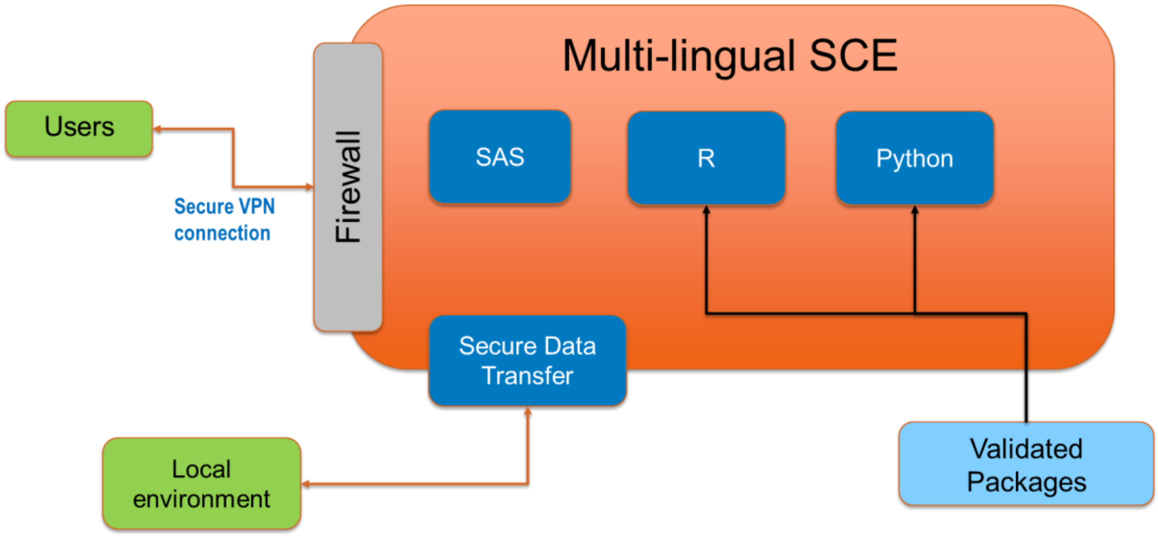
A modern SCE should therefore support the entire lifecycle of statistical work: coding, testing, review, output generation, validation, and archival. When designed properly, it becomes the operational backbone not only for the submission works like SDTM, ADaM, TFLs, but also for associated documentation and any other Biometrics works. The key question is no longer whether an SCE can run code, but whether it can do so in a secure, scalable, and compliant way while helping teams work faster and more consistently.

Multi-lingual SCE

The next evolution of the SCE is multilingual support. In the traditional model, SAS dominated statistical programming. Today, many Biometrics teams also rely on R and Python for data manipulation, automation, visualization, and advanced analytics. A multilingual SCE allows these languages to coexist in one controlled environment rather than forcing users into separate disconnected systems. The secure SCE environment includes SAS, R, and Python, connected through a protected local or VPC-based architecture with secure transfer, firewall protection, validated packages, and controlled access.

A multilingual design offers several practical advantages. SAS remains central for many regulated deliverables, especially in legacy processes and submission outputs. R supports statistical methods, graphics, and modern package ecosystems. Python provides flexibility for automation, orchestration, and AI-related utilities. When these languages are managed within one validated computing environment, users can move more efficiently between tasks without compromising control.

From a governance perspective, the multilingual SCE must still behave like a single controlled system. Package management, version control, access permissions, and execution logs need to be monitored consistently across languages. That means the validation strategy cannot focus only on the SAS layer. Instead, it must address the whole stack, including user interfaces, package installation, compute access, AI agent integration, and output generation. In this way, multilingual support becomes not just a technical feature, but a strategic enabler of biometrics modernization.



What does it mean by GxP compliance?

In a regulated clinical environment, GxP compliance is more than a policy statement. It means the system must support data security, disaster recovery, access control, and audit trail requirements in a way that is consistent with regulated operations. The GxP compliance will function as the foundation that makes an SCE suitable for clinical work. Without these controls, an environment may be useful for research, but not acceptable for validated production use.

For an Agentic AI-enabled SCE, GxP compliance must extend beyond infrastructure to include the behavior of the AI workflow itself. For example, prompts, generated code, execution logs, human approvals, and output summaries should all be retained so that the process is explainable and inspectable. The environment should also enforce controlled access, separation of duties, and documented change management. In other words, compliance is not an afterthought; it must be built into the architecture from the beginning.

This is particularly important because AI systems can introduce new risks such as nondeterministic outputs, hallucinations, and model updates that change behavior over time. In a GxP setting, such risks must be understood and controlled through validation, monitoring, and governance. We should emphasize the audit-ready status which reflects the need for continued compliance even as systems become more intelligent and automated.

Introduction of Agentic AI – AI Agents

Agentic AI refers to autonomous systems where AI agents, driven by LLMs, pursue goals through planning, reasoning, and action. Core components include:

- LLM Core — Provides reasoning and natural language understanding.
- Prompts — Guide agent behavior and task decomposition.
  For example, we set the role of AI Agent by providing below instruction in the prompt.
  'You are stat programmer.
  Use the input and generate SAS output.
  Follow below steps:
  1. Generate SAS codes based on input
  2. Execute generated SAS codes using SAS Studio.
  3. If there are error messages, debug SAS codes.
  4. Rerun SAS codes to create the output.
  Do Step 2 to 4 until there are no error message. '

- Tools — External functions and application (e.g., R, SAS, Python) for real-world interactions.
- Memory — Short-term (context) and long-term (vector stores) for retaining knowledge and audit trails.

In clinical trials, agentic AI is gaining traction for automating data analysis, protocol optimization, and anomaly detection. Within SCEs, agents can do the followings:

- Draft and validate statistical code in SAS/R/Python.
- Automate SDTM/ADaM mappings and TLF generation.
- Perform exploratory analyses with reproducibility guarantees.
- Collaborate in multi-agent workflows (e.g., one agent plans, another executes code).

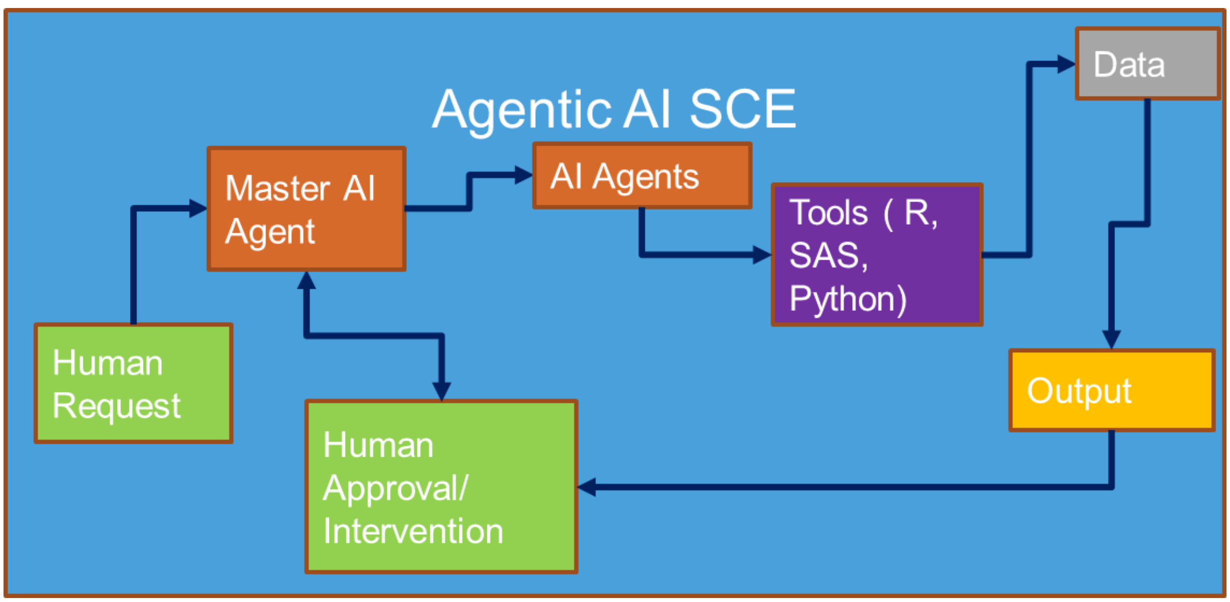
Agentic AI will play a pivotal role in SCEs because Biometrics workflows are tool-intensive: agents equipped with R/SAS/Python can execute complex statistical tasks autonomously, reducing manual effort while logging actions for compliance.

Agentic AI Mult-lingual SCE

An Agentic AI multilingual SCE combines the strengths of a controlled SCE with autonomous AI-driven workflow support. In this model, the AI agent can interact with SAS, R, and Python tools inside the same governed ecosystem. The human user provides a request, the master agent plans the steps, the necessary tools are invoked, and the output is returned with traceability.

This Agentic AI architecture is especially relevant for Biometrics because many tasks require cross-language support. A study may begin with data preparation in Python, move into analysis in R, and finish with regulated output generation in SAS. The AI agent can help coordinate these transitions by selecting tools, generating code, executing commands, and summarizing results. Because the process occurs within a controlled, secure environment, the output remains within the organization's compliance boundary.

The Agentic AI SCE environment will function as a secure, local multi-agent system powered by agentic workflow, but adapted for clinical programming and compliance. Its value lies in combining ease of use with data security, traceability, and inspection readiness. Instead of forcing programmers to manually manage every step, the AI layer can assist with code generation, debugging, documentation, and workflow orchestration while still requiring human approval or intervention where appropriate.



Validation Process of Agentic AI SCE

Validation is the critical bridge between innovation and regulated use. A structured validation approach can include risk assessment, validation planning, user requirements specification, installation qualification(IQ), operation qualification(OQ), performance qualification(PQ), traceability matrix, and validation summary report. This lifecycle aligns well with a risk-based GxP validation mindset.

The process begins with risk assessment. Here, the system is reviewed for compliance risk, data security risk, and 21 CFR Part 11 implications. Based on the outcome, the validation plan defines the scope and depth of testing. This is important because not every component of the system carries the same level of risk. AI-related functionality, for example, may require stronger controls and more detailed documentation than standard execution features.

User Requirement Specification documents what the users need the system to do. For an Agentic AI SCE, those requirements include secure access, role-based permissions, the ability to write and execute SAS, R, and Python code, and the ability to use AI agents for code creation. IQ then verifies the installation of infrastructure and applications, including SAS Studio, RStudio, Jupyter, and the AI agent components. OQ confirms that the system operates as intended under normal conditions, including access controls and basic functionality. PQ demonstrates that the system can perform in real use cases, such as producing code outputs, logs, and deliverables correctly and consistently.

The traceability matrix connects requirements to test evidence, ensuring that each expectation is verified. Finally, the validation summary report brings together the risk assessment, validation results, and conclusion that the system is fit for intended use. For an Agentic AI-enabled platform, this documentation is especially valuable because it shows that the intelligence layer has been introduced in a controlled and reviewable manner rather than as an unmanaged experimental capability.

Why Agentic AI in SCE

The main reason to introduce Agentic AI into the SCE is to improve productivity without sacrificing compliance. Agentic AI in secure SCE means data security, access control, audit trail, and productivity increase. These are not competing goals. In a well-designed solution, AI can help achieve them together.

In practice, many Biometrics tasks are repetitive, rule-based, and time-consuming. Code generation, dataset checks, documentation drafting, and output QC often require significant manual effort. Agentic AI workflow can assist by generating first-pass code, finding errors, suggesting fixes, and summarizing actions. This reduces the burden on programmers while still leaving final decisions to humans.

A further advantage is process standardization. When AI agents are guided by SOPs, validated prompts, and controlled tools, they can help apply consistent coding patterns and documentation formats. That consistency can improve quality and reduce variation across studies and team members. At the same time, the environment remains auditable because every action of AI and humans can be logged and reviewed.

Benefits and Cons

The benefits of Agentic AI in SCE are substantial. There will be significant productivity gains, faster time-to-insight, improved data quality, consistency and standardization, enhanced compliance and traceability, scalability across studies, decision support, knowledge augmentation, 24/7 automation, and integration with modern tools. These advantages are compelling for organizations that are under pressure to deliver faster while maintaining quality.

At the same time, the limitations are real. There will be frequent change control with Agentic AI, validation challenges, trust and explainability issues, initial setup effort, data privacy and security risks, over-reliance on automation, model drift, integration complexity, skill gaps, cost considerations, and the possibility of hallucinations or errors. These risks underscore why Agentic AI must be implemented as a governed system rather than a casual productivity tool.

Agentic AI is most effective when used to support, not replace, statistical programmers and biostatisticians. The best operating model is human-centered AI: AI agents handle repetitive execution and reasoning support, while the humans retain responsibility for scientific judgment, regulatory accountability, and final approval. In a GxP environment, that balance is not optional; it is the basis for safe adoption.

Lessons Learned

One of the most important lessons is that compliance must be designed into the workflow from the start. It is much harder to implement traceability and validation after AI capabilities have already been embedded into day-to-day work. We should consistently emphasize guardrails, controlled access, prompts, logs, and documented validation as core design elements.

Another lesson is that human oversight remains essential. Agentic AI can accelerate our works like analysis and coding, but it should not operate as an unchecked authority in regulated clinical development. Human review is needed for interpretation, scientific appropriateness, and final sign-off.

A third lesson is that change management will be ongoing. AI agents, underlying models, and supporting tools will evolve quickly. That means the organization must be prepared for support for employees as well as controlled updates, periodic revalidation when needed, and continuous monitoring of system behavior. In this sense, Agentic AI not only changes the technology stack but also continue to empowering our teams.

Future of Biometrics

The future of biometrics will likely be shaped by environments that are both multilingual and AI-enabled. Instead of viewing SCE as a static runtime for SAS code, future organizations may treat it as an intelligent platform for statistical operations, workflow automation, and knowledge support.

In that future, Biometrics teams may increasingly use AI agents for dataset checks, code generation, validation support, documentation drafting, and exploratory analytics. The value will not come from replacing expertise, but from amplifying it. Programmers, statisticians, and data scientists will spend less time on repetitive execution and more time on interpretation, oversight, and decision support.

Ultimately, the transformation will depend on trust. If organizations can demonstrate that Agentic AI operates within a validated, secure, and auditable SCE, then the technology can become a practical asset in regulated clinical development. That is the central message of this paper: the future of Biometrics is not just automated, but governed automation inside a compliant intelligent SCE.

Conclusion

The transition from traditional SAS servers to an Agentic AI-enabled Multi-lingual SCE represents a significant step forward for Biometrics operations. The direction and future of SCE will combine SAS, R, and Python within a secure, GxP-compliant environment and add Agentic AI as a controlled productivity layer. With a risk-based validation strategy, documented workflows, and human oversight, this approach can support innovation without compromising compliance.

For Biometrics teams, the opportunity is clear: move from passive computing environments to intelligent, auditable platforms that improve efficiency, data security, access control, and traceability. Agentic AI does not eliminate the need for skilled statistical programmers nor biostatisticians. Instead, it equips them with a more powerful and adaptable environment for modern clinical development.

REFERENCES

- Wikipedia – AI Agents in https://en.wikipedia.org/wiki/AI_agent
- Agentic AI in https://blogs.nvidia.com/blog/what-is-agentic-ai/
- FDA – 21 CFR Part 11 in https://www.fda.gov/media/75414/download
- ICH E6(R2) Good Clinical Practice in https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/FDA/E6%28R2%29-Good-Clinical-Practice_-Integrated-Addendum-to-ICH-E6%28R1%29-_-Guidance-for-Industry.pdf
- ISPE GAMP 5 in https://ispe.org/sites/default/files/publications/guidance-documents/2026-TOC/ISPE_GAMP-GPG2-GPCS3_TOC.pdf
- FDA Electronic Systems / Part 11 in https://www.fda.gov/media/166215/download

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