Paper SD07

Developing a Compliant and Scalable Statistical Computing Environment Based on Phuse SCE Guidelines

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ABSTRACT

The Phuse SCE White Paper has become a critical industry guide for building compliant, scalable, and auditable Statistical Computing Environments. In alignment with these standards, Atorus developed Ageirein, a deployment framework that operationalizes the paper's recommendations into a modular, cloud-enabled solution. Ageirein embeds GxP compliance, validation, reproducibility, traceability, and role-based access control directly into its architecture, enabling rapid deployment without sacrificing regulatory rigor. By incorporating compliance controls from the start, Ageirein reduces the overall validation burden, simplifies ongoing maintenance, and streamlines audit readiness. Designed to support both exploratory and production statistical workflows, it provides a standardized, scalable foundation that helps life sciences organizations modernize data science environments while maintaining alignment with Phuse best practices.

INTRODUCTION

The Phuse SCE white paper outlines a set of requirements for a Statistical Computing Environment (SCE) that supports clinical trial reporting. The paper emphasizes the need for a unified platform that integrates various tools and languages, including R, SAS, Python, and more. Ageirein, a data analytics platform, integrating a variety of open-source and commercial components, has been designed to meet these needs. This paper provides a detailed analysis of how Ageirein aligns with the requirements outlined in the Phuse SCE white paper.

PHUSE SCE WHITEPAPER OVERVIEW

The Phuse SCE whitepaper outlines the requirements and recommendations for an optimal Statistical Computing Environment (SCE) that can support clinical trial reporting.

The following is a summary of some of the key points:

User Experience

- The SCE should have a user-centric design, creating personas to understand user needs.
- Rapid prototyping and usability testing are crucial for ensuring a great user experience.
- A well-designed UI and UX can make or break the adoption of an SCE.

Technical Infrastructure

- The SCE should be cloud-native, allowing for scalability, flexibility, and reduced costs.
- Cloud computing enables cost savings, security, flexibility, mobility, insight, increased collaboration, quality control, disaster recovery, loss prevention, automatic software updates, competitive edge, sustainability.
- Containerization (e.g., Docker) is essential for portability and ease of deployment.
- Infrastructure as Code (IaC) automates provisioning and management, improving consistency and reducing costs.

Programming Workflow and Processes

- A structured workflow should be implemented, with clear planning, development, validation, and finalization stages.
- Version control is crucial for managing changes and tracking updates.
- The SCE should support risk-based quality review to identify areas of greatest risk and implement targeted measures.
- An audit trail provides documented evidence of access and operations performed.

Regulatory Compliance

- The SCE must be GxP-compliant, with a robust audit trail, access controls, traceability, version control, and end-to-end documentation.
- Computer system validation is essential for ensuring the SCE meets regulatory requirements.

Automation

- Automation can improve productivity, efficiency, and reduce costs by minimizing human resources and shortening validation timeframes.
- Standards-based approaches enable code reusability, process repeatability, and increased efficiency.

The white paper itself naturally goes into much more detail and has become something of a touchstone in the industry. Many of the things that it highlights, for example, “user-centric design” or “version control”, can seem obvious, but so many tools, products and services available to the industry fail to offer a good experience in all areas. As a result, the industry is underserved for modern tooling that reflects these ideas and principles.

ATORUS AGEIREIN OVERVIEW

In clinical data analytics, speed, security, and reproducibility are essential. However, many pharmaceutical and biotech teams still use unconnected tools and environments with unique validation processes, which can slow decision-making and hamper consistency.

That’s why Atorus created Ageirein, a multilingual, GxP-compliant, data analytics platform with open source at its core. Designed as a unified statistical computing environment (SCE), Ageirein empowers modern, integrated workflows, from exploratory analysis to submission-ready outputs. Think of it as a launch-ready clinical analytics platform where languages coexist, regulatory requirements are seamlessly embedded throughout, and teams can code, validate, visualize, and deploy from a single shared space.

Whether you’re running open-source analytics in R or SAS, Ageirein eliminates tool-switching friction.

THE CHALLENGE: SILOED TOOLS AND DELAYED TIMELINES

Despite advancements, clinical teams often work in siloed systems. Developers write code in one platform, test it in another, visualize outcomes elsewhere, and manually transfer results. This fragmented workflow leads to inefficiencies, redundant efforts, and inconsistent documentation.

Open-source data analytics, using tools like R, can help address these challenges, though achieving complete data interoperability, especially within a GxP framework, continues to be difficult. Compliance is frequently considered later in the process and added onto existing systems rather than integrated from the beginning. Ageirein was developed to address this issue.

THE SOLUTION: AN INTEGRATED, COMPLIANT ENVIRONMENT

Ageirein combines the core components of a validated statistical computing environment and enhances them with seamless, open-source functionality, empowering modern analytics engineering across the life sciences. It stands apart with its modular platform that comes pre-configured with practical defaults while remaining flexible for custom use cases.

Whether you are exploring dashboards in Shiny, validating packages across environments, or generating reproducible clinical outputs, Ageirein enables these workflows through full GxP alignment with OpenVal®, Atorus’ trusted platform for package validation. This provides the advantages of open-source tools along with confidence of compliance. Core capabilities include:

- Multilingual support for R, SAS, and Python
- End-to-end GxP-compliant workflows, documentation, and access controls
- Native integration with Git, storage solutions, and review systems
- First-class support for Shiny dashboards and open-source visualization tools
- Modular, scalable architecture that evolves with your needs

Unlike generic SCEs or ad hoc open-source setups, Ageirein is purpose-built for regulated life sciences environments. That means:

- Built-in GxP support from day one, with no workarounds
- Real-time collaboration across functions and file types
- Proven implementation support from Atorus' domain experts
- Secure, modular deployment via Docker, Kubernetes, or cloud-native architecture
- Validated using OpenVal, with 500+ pre-validated R packages included

With Ageirein, you're solving today's challenges, while future-proofing your workflows.
Ageirein's architecture follows FDA-backed standards for computerized systems. It entails audit trails, versioning, traceability, and the integrity of electronic records regulated by 21 CFR Part 11 and ICH GCP E6 (R3) requirements.[1,2,3] As a result, your statistical programming workflows come fully documented, easily reproducible, and ready for regulatory review straight out of the box. It's compliance that accelerates, not obstructs.

HOW IT WORKS

Ageirein unifies your end-to-end clinical analytics workflows in four key stages:

1. Develop
Statisticians, programmers, and data scientists operate within a secure environment equipped with R and optionally SAS, ensuring all code is validated and subject to version control. Centralized libraries facilitate collaboration and enable efficient code reuse across teams.

2. Validate
The platform standardizes and documents validation workflows, maintaining rigorous processes through enforced protocols such as programming validation and audit trails. Ageirein upholds the compliance standards required by life science regulators.

3. Visualize
Teams can generate both submission-ready tables and interactive dashboards using preferred open-source tools. These open-source visualizations have supported regulatory-reviewed trials, providing real-time insights into adverse events, enrolment metrics, and safety trends. Within Ageirein's secure, compliant framework, data managers and clinical reviewers can access and interact with insights in real time with shared tools.

4. Deploy
Final outputs are published to designated repositories that incorporate versioning controls, role-based access management, and metadata tagging. Instead of multiple disconnected systems, deliverables are efficiently prepared for review by internal stakeholders or external regulators.

WHO IT'S FOR

Ageirein is a powerful, compliant solution for growing life sciences organizations, without the overhead of erecting their own system from scratch:

- Small and midsize biotechs looking to scale analytics with speed and compliance
- Statistical programmers and IT directors seeking a single environment for cross-team collaboration
- Clinical reviewers and QA directors needing traceable, audit-ready outputs
- Data managers' and statisticians' requirements are consistent and clear across studies

With Ageirein, teams get all of that, plus the flexibility of open-source.

WHY IT MATTERS

The inefficiencies caused by fragmented analytics can pose a serious business risk. Redundant work, unreliable outputs, and disconnected tools lead to delays in submissions, compromised data quality, and clouded decision-making. By streamlining development, validation, visualization, and deployment into one environment, Ageirein delivers:

- Faster timelines from data cleaning to submission
- Higher confidence in reproducibility and compliance
- Reduced tech debt from shadow systems and redundant infrastructures
- Stronger collaboration across technical and non-technical users

It's analytics engineering with speed, clarity, and control.

HOW AGEIREIN MEETS THE REQUIRMENTS FROM THE PHUSE SCE WHITEPAPER

User Experience:
Ageirein's user-centric design is a key feature that meets the need for a user-friendly and intuitive interface. The platform supports multilingual languages, including R, and SAS, allowing users to code and analyze data in their preferred language. This feature aligns with the requirement for a language-agnostic environment, ensuring that users can access and utilize the platform without modification.
Ageirein's user interface is designed to be intuitive and easy to use, providing a seamless experience for users. Several of the tools included in the platform are already familiar to potential users, such as the Posit suite of tools. The platform features a modular architecture that enables flexibility and customization, catering to diverse user needs. This feature aligns with the requirement for a flexible and adaptable SCE.

Rapid Prototyping:
Ageirein's rapid prototyping capabilities also align with the Phuse SCE white paper's emphasis on usability testing and rapid iteration. The platform allows users to create and deploy interactive dashboards using Shiny, a popular open-source visualization tool. This feature enables real-time collaboration across functions and file types, meeting the requirement for seamless interaction between different stakeholders.
Ageirein's rapid prototyping capabilities are facilitated by its modular architecture, which allows users to quickly build and test new features. The platform also supports version control capabilities, including Git and fully integrated storage, ensuring that changes are tracked and audited.

Shiny Dashboards:
Ageirein's Shiny dashboard functionality, leveraging Posit Connect, aligns with the Phuse SCE white paper's emphasis on interactive dashboards and real-time collaboration. The platform allows users to create and deploy interactive dashboards, providing a seamless experience for stakeholders.
Ageirein's Shiny dashboard feature allows users to quickly build and test new dashboards and apps

Collaboration:
Ageirein's collaboration features align with the Phuse SCE white paper's emphasis on seamless interaction between different stakeholders. The platform allows users to share files and data across functions and file types.
These collaboration features are facilitated by its modular architecture, which allows users to quickly build and test new features.

Technical Infrastructure:
Ageirein's technical infrastructure is built on cloud-native technologies, including containerization (Docker) and IaC (Kubernetes). These features provide a scalable and secure infrastructure for the SCE, aligning with the Phuse SCE white paper's emphasis on cloud-native architecture.
The platform is built and managed using infrastructure as code (IaC), enabling us to provision and manage infrastructure resources programmatically. This feature meets the requirement for automated infrastructure deployment and management, reducing manual effort and increasing efficiency.

Docker:
Ageirein's use of Docker as an underlying technology aligns with the Phuse SCE white paper's emphasis on containerization. The platform uses Docker to provide a scalable and secure environment for the SCE, ensuring that changes are tracked and audited.
The use of Docker also enables users to quickly build and test new features, meeting the requirement for rapid prototyping and iteration.

Kubernetes:
Another component of the Ageirein technology stack is Kubernetes which aligns with the Phuse SCE white paper's emphasis on IaC. The platform uses Kubernetes to provide a scalable and secure environment for the SCE, ensuring that changes are tracked and audited.

Programming Workflow and Processes:
Ageirein's modular architecture provides a standardized workflow that meets the requirement for reproducibility and traceability

The SCE also features an audit trail mechanism, which provides documented evidence of access and operations performed on data and code.

Audit Trails:
Ageirein's audit trail mechanism aligns with the Phuse SCE white paper's emphasis on maintaining rigorous processes through enforced protocols. The platform provides documented evidence of access and operations performed on data and code, ensuring that changes are tracked and audited.

Regulatory Compliance:
Ageirein is built to meet FDA-backed standards for computerized systems. The platform supports GxP compliance, validation, and verification, ensuring that data and code are audited and validated according to regulatory requirements.
The SCE also features a validated platform that contains pre-validated R packages, using Atorus Research's OpenVal product, meeting the requirement for reliable and compliant analytics solutions.

CONCLUSIONS:

Ageirein effectively addresses the critical aspects outlined in the Phuse SCE white paper. The platform's user-centric design, technical infrastructure, programming workflow and processes, regulatory compliance, and automation features all align with the requirements laid out in the document.
Our analysis shows that Ageirein provides a comprehensive statistical computing environment for clinical trial reporting as well as general analysis work, meeting the needs of pharmaceutical and biotech companies seeking to streamline their analytics workflows.

RECOMMENDED READING

- Phuse SCE whitepaper, Bynans, M, et al. https://www.lexjansen.com/phuse-us/2021/hw/PAP_HoW04.pdf
- 21 CFR Part 11 – Electronic Records; Electronic Signatures. U.S. Food & Drug Administration. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11
- U.S. Food & Drug Administration. Guidance for Industry: Computerized Systems Used in Clinical Trials (2007). https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/fda-bioresearch-monitoring-information/guidance-industry-computerized-systems-used-clinical-trials
- International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use. Guideline for Good Clinical Practice E6(R3). *ICH.org*. Published 2025 January.
- Cougnaud, L., Faes, M., Van Krunckelsven, D., et al. Interactive medical and safety monitoring in clinical trials with clinDataReview: a validated and open-source reporting tool. *Frontiers in Medicine*. Published 2024 July.

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