

Enhancing Data Sciences with Multilingual Capabilities

A Comprehensive GxP-Compliant Solution\

PHUSE US Connect 2025

Eli Miller and Casey Higgins



Ageirein – Integrated Data Platform

Fast GxP Deployment

Reduce time and effort to deploy a compliant R and multilingual environment

Automated User & Security

Streamline user management and data security

Accelerated Implementation

Leverage Shiny templates and OpenVal™

Integrated Solutions

System integrations leveraging APIs and data storage options

Ageirein: Integrated Data Platform

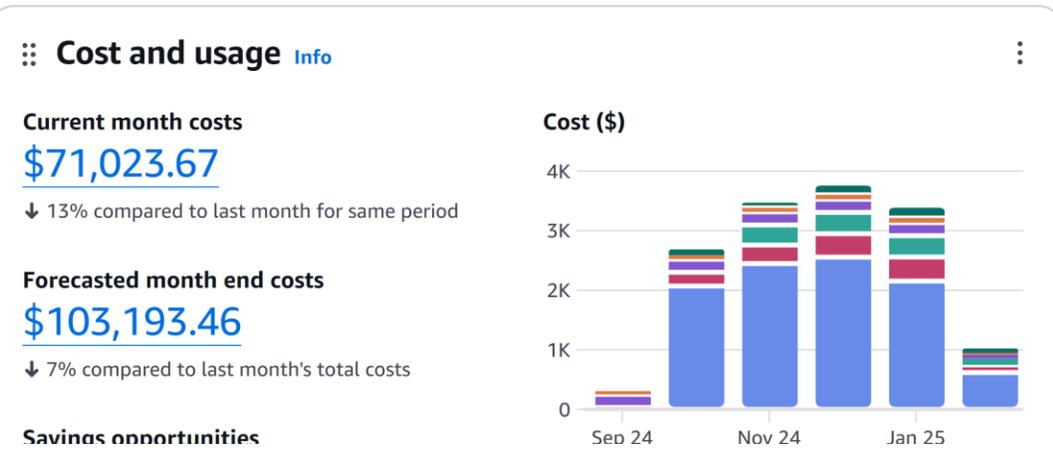
- **Configured Modules:** Easily add new functionalities and scale as your business needs evolve
 - **Application:** End user access to applications developed by Atorus
 - **Exploratory:** R / Posit Environment for non-GxP intended usage
 - **GxP:** Fully validated R / Posit or SAS core environment with SCE toolkit
 - **Multilingual:** Fully validated environment with centralized data storage for collaborative R / Posit and SAS usage
- **GxP Compliance Built-In:** Core platform fully validated
 - **Validated R Packages with OpenVal®:** Streamline statistical programming with pre-validated R packages designed for regulatory compliance
 - **Secure Workflow and File Management:** Centralized and compliant storage ensures data integrity and traceability
 - **Batch Execution and Automation:** Efficiently manage and execute large-scale computations with traceable, automated workflows
 - **Advanced Permission Management:** Granular user roles and access policies provide robust security and control over sensitive data
- **Integrated System Support and Monitoring:** Real-time system health monitoring ensures seamless operations with minimal downtime.
- **Partnered Ecosystem:** Integrated with leading cloud providers and storage solutions for comprehensive support and interoperability.
- **Pre-Configured Operational Accelerators:** Includes ready-to-use templates, SAS macros, and Shiny applications to reduce implementation time.

Empowering data sciences with compliant, scalable, and extendible solutions



Challenges in Data Sciences

- Managing diverse datasets
- Ensuring compliance
- Scaling operations efficiently
- Change Control and updates

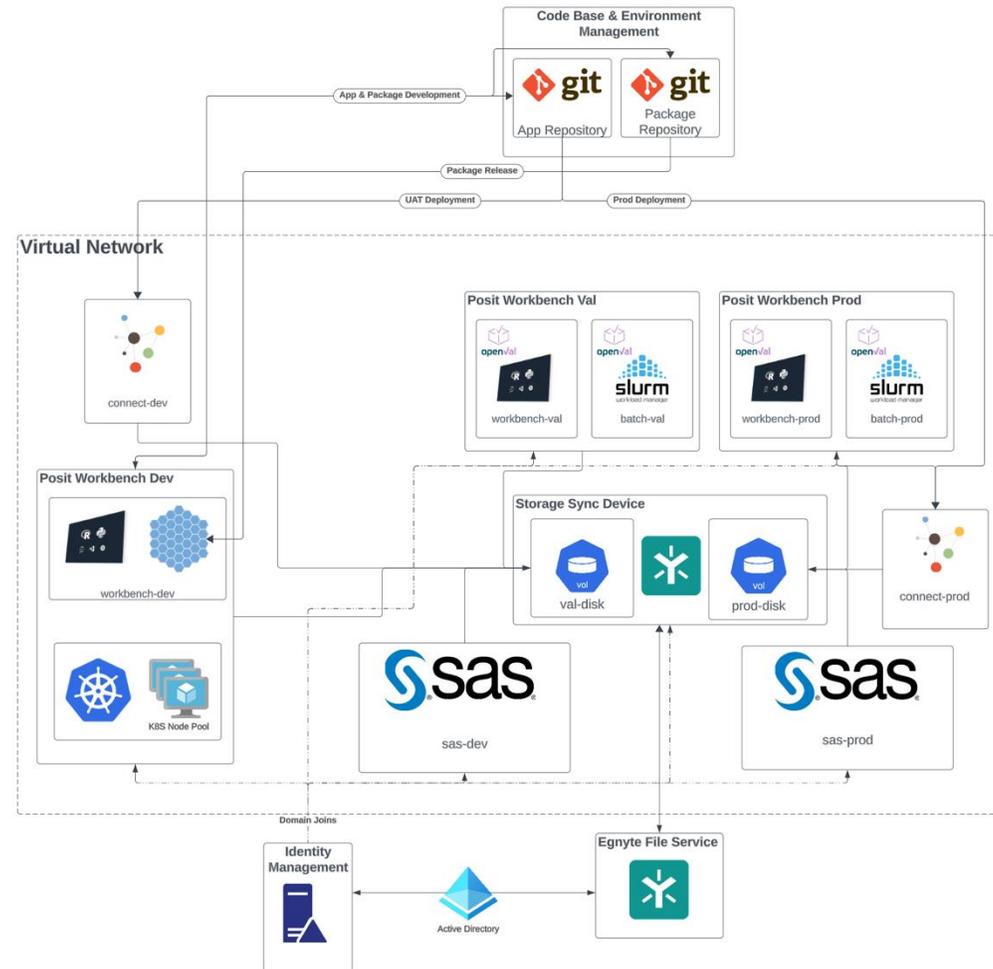


```
0[ | 1.3%] 4[ | 1.3%]
1[ | 1.3%] 5[ ||| 6.0%]
2[ | 3.3%] 6[ |||| 5.2%]
3[ | 2.0%] 7[ | 0.0%]
Mem[ | 1.27G/7.55G] Tasks: 76, 195 thr; 1 running
Swp[ | 0K/2.00G] Load average: 0.50 0.23 0.09
Uptime: 00:01:23
```

PID	USER	PRI	NI	VRT	RES	SHR	S	CPU%	MEM%	TIME+	Command
2599	_apt	20	0	22320	15072	10824	S	4.0	0.2	0:00.43	/usr/lib/apt/methods/https
2600	_apt	20	0	19156	9120	8140	S	4.0	0.1	0:00.41	/usr/lib/apt/methods/http

Solution

- Multilingual platform for data sciences
- Centralized, GxP-compliant data storage
- Automated user and security policies
- Features OpenVal®, SAS macros, and Shiny templates
- Robust ecosystem for data storage, integrations, and cloud services



Modules

- R: Optimized for R, scalable performance
- Posit - Exploratory: Agile experimentation, no regulatory overhead
- Posit - GxP: Compliance-ready, secure and validated
- Multilingual: Supports multiple programming languages
- SAS SCE: Advanced analytics for large-scale clinical datasets



Accelerator - OpenVal

OpenVal™ Packages

Future OpenVal™ Packages

OpenVal™ Release Calendar

OpenVal2024.09.01

OpenVal2024.09.00

OpenVal2024.03.01

OpenVal2024.03.00.01

OpenVal2024.03.00

OpenVal2023.09.02

OpenVal2023.09.01

OpenVal2023.09.00

Show

10

entries

Search:

Package Name	Version
--------------	---------

ARTool	0.11.1
--------	--------

askpass	1.1
---------	-----

assertive.types	0.0-3
-----------------	-------

assertthat	0.2.1
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backports	1.4.1
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Validation Report

Validation Release Details

Risk Assessment

Validation Assessment

Dependency Packages



OpenVal Sample Validation Report

Atorus Research

2024-02-06

N Tests	Tests Passed	Tests Failed
1735	1735	0

Validation Release Details

Resource	Detail
OS	Ubuntu 22.04.3 LTS
R	4.2.1
OpenVal Version	Sample
Package Snapshot Date	2023-07-31

Risk Assessment

The risk assessment is completed for each release of OpenVal and packages are categorized as "accepted", "low", "medium", or "high" risk. The term risk refers to the risk of an error in the code that, when used appropriately, could lead to an incorrect calculation. This incorrect calculation may lead to an incorrect decision during data analysis. Examining a package risk involves looking at the following metrics.

- Number of downloads as a proxy for community testing
 - The scoring function is a simplification of the classic logistic curve with a log scale for the number of downloads
 - $1/(1 + \exp(-k(x - x[0])))1/(1 + \exp(-k(x - x[0])))$
 - sigmoid midpoint is 1000 downloads
 - ie. $x[0] = \log(1,000)x[0] = \log(1,000)$
 - logistic growth rate of $k=0.5$. $1-1/(1+\exp(\log(x)-\log(1.5e5)))=1-150,000/(x+150,000)$
 - Does the package provide references for how the functions are derived?
 - Packages with peer reviewed references provide data for confirmation of correctness
 - Does the package have vignettes?
 - Vignettes or user instructions decrease risk of a package being used incorrectly and explain proper use

Accepted Packages

- Certain R packages may be accepted for validation and presented without any additional testing.
- They are accepted based on their low risk and high degree of reliability and prior testing within their software development life cycle.

Accelerator – Change Management

The screenshot displays a pipeline interface for 'Platform Deployment - Precept' under 'Release-256'. The pipeline is manually triggered by Eli Miller on 2/21/2025 at 9:35 AM. The pipeline consists of four stages:

- Deploy Infrastructure:** Not deployed.
- Workbench Dev:** Not deployed.
- Workbench Val:** Succeeded on 2/21/2025 at 9:39 AM.
- Workbench Prod:** Pending approval for 22 days, initiated by Eli Miller.

The interface includes a navigation bar with 'Pipeline', 'Variables', and 'History' tabs. Action buttons include '+ Deploy', 'Cancel', 'Approve multiple', 'Refresh', 'Edit', and a menu icon. The 'Workbench Prod' stage is highlighted with a blue border and a user icon, indicating it is the current focus.

Accelerator – Shiny Application

AE-SMT [User Guide](#) [AE Events/Incidence](#) [AE Frequency](#) [AE Timeline](#) [Tables and Listings](#) ▾



AE Incidence

graphs of AE incident rate and cumulative events count



Common AE

most frequent AEs



AE Timeline

AE overview by subject



Tables and Listings

AE summary tables and listings

Terms and Conditions

The user is requested to bear in mind that this application and its outputs are intended for **internal use only** and should not be used in external reports. If these explorations lead to any findings worthy of reporting externally, please consult with your study and program statistician. Formalized specifications and validated reports for external communication can then be developed as warranted.

Conclusion

- Multilingual, GxP-compliant integrated data platform
- Scalable and extendible architecture
- Configured modules and operational accelerators
- Empowering organizations to unlock data potential while ensuring compliance

Questions?

Get in Touch!

Eli.Miller@atorusresearch.com

