Data Visualisation & Open Source Technology

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Clinical Visual Analytics for Review and Submission (CVARS)

Scope

The Data Visualisation and Open Source Technology Working Group aims to support, address and answer pertinent questions around data visualisation and open-source technology. The combination of these two subjects is natural in today's environment, given the powerful data visualisation tools within the open-source languages available today.

Proposed End Date

Q1 2026

Deliverable Type

An open-source R Shiny tool

Leads

Melvin Munsaka, Neetu Sangari & Jiang Hu

Key Achievements This Quarter:

Completed the additional r code snippets for specific functionality including severity and relatedness sub-setting, event onset, duration, time-to-resolve, AE outcome, recurrence, and other key safety review questions and code for tables and graphs for several other safety data domains (lab data, vital signs, ECG). Also created code for quantitative safety analyses and identified the requirements for incorporating AI/LLMs (needs discussion).

Deliverables & Targets Planned for the Next Quarter:

Implement the additional functionality in CVARS (possibly in modular fashion) as above and update the vignette in early Q1 2026.

Project Status

Project Status: Green
Accepting New Members

- On track

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Communication of Version Metadata for Open-Source Languages

Scope

This project aims to develop a new template or enhance an existing one, such as the Study Data Standardization Plan (SDSP) or the Analysis Data Reviewer's Guide (ADRG), to ensure metadata pertaining to the versions of statistical packages and procedures is consistently documented in alignment with health authority expectations. This standardised template will streamline the submission of clinical study metadata to health authorities as part of the regulatory review process.

Q1/Q2 of 2026 (TBD)

Proposed End Date

White paper

Deliverable Type

Joel Laxamana & Lovemore Gakava

Leads

Two functions have been drafted for the adrgOS package. In review by other members.

Key Achievements This Quarter:

- Continue working on drafting new functions per the open list of issues in our adrgOS package.
- Draft the R submission completion guide.
- Hoping to hear back from the PHUSE DRG standards group on when the new version of the ADRG template will be available. This new template will give us the metadata to finalise our documentation and R package with tools/functions to help studies populate the ADRG for R submissions with automation.

Deliverables & Targets Planned for the Next Quarter:

Project Status: Green
Accepting New Members

- Making progress where we can, because we are dependent on the PHUSE ADRG standards group.

Project Status

Comparing Analysis Method Implementations in Software (CAMIS)

Scope

Several discrepancies have been discovered in statistical analysis results between programming languages, even in fully qualified statistical computing environments. CAMIS seeks to clearly define this problem and provide a framework for assessing the fundamental differences for a particular statistical analysis across languages. In this context, the risk of interpreting numerical differences in analysis results due solely to differences in programming language can be mitigated, instilling confidence in both the sponsor company and the agency during the review period.

Ongoing

Proposed End Date

White paper & open-source collaboration repository

Deliverable Type

Lyn Taylor, Christina Fillmore & Chi Zhang

Leads

New content into the repository to include:

- R vs East vs SAS for group sequential designs for survival endpoints
- Updated Cochran-Mantel-Haenszel pages
- First draft of GEE pages (R, SAS & COMP) submitted

Key Achievements This Quarter:

- Finalise sample size comparison pages
- Update CI for props to include cicalc package
- Improve MMRM SAS page
- Finalise the GEE pages

Deliverables & Targets Planned for the Next Quarter:

Project Status: Green
Accepting New Members

- CAMIS yearly awards will be announced 8 December. This is where we recognise our biggest yearly contributors and thank them for their work on our project. We plan to continue to write periodic blog posts and distribute these via PHUSE, to keep our project at the forefront of people's minds and advertise the good work our contributors are doing.

Project Status

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Demonstrating Real-World Impact of Modernization of Statistical Analytics (MSA) Framework

Scope

The PHUSE project team will extend the MSA framework by creating a reference architecture that takes into account real-world scenarios and design solutions to remediate them, ultimately providing a practical guide to building an end-to-end validated environment for regulated work. Companies seeking to build an open-source programming environment for regulatory reporting can leverage the MSA framework for guidance. However, since the framework is designed to be both flexible and extensible, implementing it may prove challenging for companies, resulting in situations where risks are not sufficiently mitigated. While the original MSA paper provided conceptual guidance, the PHUSE handover of the project will seek to provide an overview of practical implementations of the framework being applied.

Q1 2026

Proposed End Date

White paper

Deliverable Type

Benjamin Chiang

Leads

Key Achievements This Quarter:

- Assessed visual documentation tools for the white paper
- Completed details and analysis of technical/business use cases with common markdown documentation in GitHub
- Unified (Amgen/UCB) mapping of use cases and MSA accuracy tenet

Deliverables & Targets Planned for the Next Quarter:

17/12/2025

- Unified mapping of MSA reproducibility and traceability tenets
- Identify representative technical components and process components for the MSA framework
- Diagram and document within the context of the full data pipeline (white paper)

15/02/2026

- Implement proposed open-source options - based on available resources - actual implementation of pipeline (altogether or as individual modules)

-Use any available infrastructure resources - corporate/personal AWS , laptop, etc.

- Test and document results

-If sample test data or synthetic data available, create tests and document results

Project Status: Green
Accepting New Members

- Moving ahead steadily but need more time based on everyone's schedules. Need to extend timeline to 15/02/2026 (vs. end of year). https://github.com/phuse-org/phuse-moa/blob/main/timeline.md

Project Status

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Teal Enhancements for Cross-Industry Adoption

Scope

The teal framework has provided significant value to the pharma community via its power of interactive data exploration in clinical trials and beyond, together with its pre-built modules in teal.modules.clinical which analyse standardised clinical data and generate outputs that meet general industry standards. However, the industry's varied standards and analysis needs may pose a limitation to wider company adoption of teal. This has led to companies developing ad hoc clinical modules from scratch to meet their requirements, which can be resource-intensive and inefficient. The proposed project seeks to address this challenge by enhancing features and flexibilities of the teal framework. With these enhancements, users can tailor the output formatting and presentation without modifying the core modules, ensuring the framework remains widely usable across companies while reducing the overhead of custom module development.

Proposed End Date

Q1 2026

Deliverable Type

Presentations, training & deployment of proposed enhancements of the teal framework

Key Achievements This Quarter:

- Webinar on 10 October - AI integration with teal
- Prepared workshop materials for the PHUSE EU Connect
- Developed the experimental {uteals} package to address industry needs

Deliverables & Targets Planned for the Next Quarter:

- Enhancing {uteals} package to maturity and submitting to CRAN
- Publishing a comprehensive teal tutorial and adoption guide

Leads

Peyman Eshghi & Nina Qi

Project Status

Project Status: Green
Accepting New Members