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

Q2 2026

Deliverable Type

An open-source R Shiny tool

Leads

Melvin Munsaka, Neetu Sangari & Jiang Hu

Key Achievements This Quarter:

No update

Deliverables & Targets Planned for the Next Quarter:

No update

Project Status

Project Status: Green
Accepting New Members

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 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.

Q3 2026 (TBD)

Proposed End Date

White paper

Deliverable Type

Joel Laxamana & Lovemore Gakava

Leads

Key Achievements This Quarter:

1. We have provided input to the sections of the ADRG template where open-source tools have been used, in particular R. The ADRG template is meant to be tool agnostic
2. We have provided the completion guideline for R submissions
3. Development of the R package for deriving version metadata across ADRG sections is ongoing

Deliverables & Targets Planned for the Next Quarter:

1. Provide a complete example of an ADRG for an R submission
2. Provide guidance for the appendix detailing how to recreate the R environment used in the submission

Project Status: Green
Accepting New Members

1. Completion Guideline under final review by the PHUSE ADRG Working Group
2. Preparation of a complete R submission example underway

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.

Proposed End Date

Ongoing

Deliverable Type

White paper & open-source collaboration repository

Leads

Lyn Taylor, Christina Fillmore & Yannick Vandendijck

Key Achievements This Quarter:

- GEE pages finalised.
- Improved binomial test section.
- Random effects model page improvements
- First 2/5 sections of CIs for proportions completed (single proportion and two independent proportions)
- Standard slides and poster created for 2026 conferences.
- Improved SAS code rendering process
- PHUSE US Connect - Becca Krouse represented CAMIS project.
- Christina Fillmore presented to PSI statistician apprentices
- Lyn Taylor presented at the AstraZeneca R conference
- Blog released in January: CAMIS Blog

Deliverables & Targets Planned for the Next Quarter:

- Improve MMRM SAS page - September 2026
- Remaining 3/5 sections of CIs for proportions (paired 2 proportions, rates (Poisson EAIR), stratified design proportions - End 2026)
- Accerated failure time models - End 2026
- Continual activity to update and improve content on repo
- Poster presentation at PSI conference

Project Status

Project Status: Green
Accepting New Members

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.

Q3 2026

Proposed End Date

White paper

Deliverable Type

Benjamin Chiang, Lu Yao & Neil Ward

Leads

Key Achievements This Quarter:

- Completed unified MSA use case mapping and analysis among member companies
- Completed initial draft of MSA architecture diagram based on unified MSA use cases

Deliverables & Targets Planned for the Next Quarter:

- Architecture diagram – visual revisions
- Architecture diagram – architectural approach revisions
- Architecture testing – stand up physical testing where appropriate/possible

Project Status

Project Status: Green

- Initial draft of reference architecture completed
- Further architecture revisions and refinement in progress
- Potential for physical testing to be decided once reference architecture is finalised

Open Source Technology Adoption in Japan

Scope

This project promotes practical adoption of OST in clinical development in Japan through knowledge-sharing and community resources. Activities include case studies, practical guidance, training materials and small-scale tools such as R-based utilities. The project focuses on practitioner support rather than regulatory policy.

Q4 2026

Proposed End Date

Presentation at a PHUSE Single Day Event

Deliverable Type

Conducted initial planning for OST adoption activities in Japan for this year

Key Achievements This Quarter:

Start preparation for the next PHUSE SDE presentation

Deliverables & Targets Planned for the Next Quarter:

Tomoki Nishikawa & Yuichi Nakajima

Leads

Project Status: Green

- The project is in its initial phase, with early-stage planning and exploratory activities underway

Project Status

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PharmaForest: collaborative repository of SAS packages for pharmaceutical industry

Scope

To promote the adoption of reusable SAS packages and best practices across the pharmaceutical industry, addressing inefficiencies, lack of standardisation and limited community collaboration. The focus is on creating an open, sustainable ecosystem that improves productivity, compliance and knowledge sharing.

Objectives:

- Create educational materials and presentations: Tips for implementing PharmaForest packages and the SAS Packages Framework (SPF). Share at webinars, industry events (e.g. PHUSE Connect) and internal training sessions.
- Build and maintain an open-source repository: Curate high-quality SAS packages for common pharma use cases. Enable easy installation and version control through the SPF.
- Foster community engagement: Encourage contributions, peer reviews and discussions. Provide onboarding resources for new SAS programmers.

Proposed End Date

TBD

Deliverable Type

Workshop & guidance materials

Key Achievements This Quarter:

- Joined PHUSE DVOST
- Kick-off for volunteers held in March
- Presented at the PHUSE US Connect

Deliverables & Targets Planned for the Next Quarter:

- Have meeting with project members (volunteers) in May
- Present at the Kagoshima Data Science Symposium in June

Leads

Hiroki Yamanobe, Ryo Nakaya & Yutaka Morioka

Project Status

Project Status: Green
Accepting New Members

- Preparing for interaction with new project members (e.g. member list, guidelines, task allocation)

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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 adoption of teal across companies. 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

Q4 2026

Deliverable Type

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

Leads

Peyman Eshghi, Nicholas Masel & Nina Qi

Key Achievements This Quarter:

- Delivered a teal presentation and led an Advanced Session at the PHUSE US Connect 2026
- Published uteals to CRAN

Deliverables & Targets Planned for the Next Quarter:

- Development of teal.picks, a new teal R package for the teal framework - Q2 2026
- Collaborate with the gtsummary maintainer to address performance issues when generating teal modules using gtsummary as the engine - Q2 2026

Project Status

Project Status: Green
Accepting New Members

- Project progressing