

Data Visualisation & Open Source Technology

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Clinical Visual Analytics for Review and Submission (CVARS)

Description

The Clinical Visual Analytics for Review and Submission project aims to support the community by addressing key questions and challenges related to data visualisation and open-source tools.

These areas naturally align in the current landscape, where open-source programming languages offer powerful and flexible data visualisation capabilities. By exploring this intersection, the Working Group seeks to promote effective use of modern tools, share best practices, and improve understanding of how open-source technologies can enhance data visualisation in a regulatory and clinical context.

Q1 2027

**Proposed
End Date**

**An open-source
R Shiny tool**

Deliverable

**Melvin Munsaka,
Neetu Sangari
& Jiang Hu**

Leads

- Engaged a broad set of stakeholders: pharma statisticians, development teams and patient safety, as well as FDA clinical and statistical reviewers. Feedback confirmed that reviewers need to interrogate the data and follow the story behind it (big picture → key findings → AESI/patient-level drill-down), not just receive static outputs.
- Benchmarked existing open-source forest plot implementations (HH package, Merck, Bayer) and began incorporating the best features of each.
- Responded to FDA oncology division feedback on gaps in oncology-specific content by integrating functionality from two additional packages.
- Added AI features to the latest version of the tool, in collaboration with Marvin and others.
- Arranged with Posit to host and share code on the Posit platform, enabling contributors to run and view work in progress.

**Key Achievements
This Quarter:**

- Hold a detailed two-hour project review with the team to consolidate recent developments.
- Update project progress through GitHub issues.
- Decide on long-term code hosting (Posit platform and/or the PHUSE GitHub).
- Address performance when working with pooled data across multiple studies.

**Deliverables &
Targets Planned for
the Next Quarter:**



**Project Status: Green
Accepting New Members**

- Development is active, and scope is growing in response to stakeholder and regulator feedback. Key risks are scope creep, performance with pooled studies, and the passed end date.

Project Status

Communication of Version Metadata for Open-Source Languages

Description

This project aims to develop or enhance a standard template (such as the Study Data Standardization Plan [SDSP] or the Analysis Data Reviewer’s Guide [ADRG]) to ensure consistent documentation of metadata related to statistical package versions and procedures. The goal is to align with health authority expectations and streamline the submission of clinical study metadata as part of the regulatory review process.

Historically, with proprietary statistical programming languages, version information has typically been captured at a high level within the SAP, often as a general statement of the software and version used. However, with the increasing adoption of open-source technologies, more detailed and transparent metadata is now required. This project will address this gap by enabling structured, standardised capture of package-level metadata, supporting improved traceability, clarity and regulatory confidence.

Q4 2026

Proposed
End Date

White paper

Deliverable

Joel Laxamana &
Lovemore Gakava

Leads

- Delivered the completion guideline for R submissions and handed it over to the ADRG working group.
- Progressed R-based approaches for capturing package-level version metadata.
- Maintained a GitHub repository of reusable R scripts for the different ADRG sections, open to community contributions.
- Engaged regulatory agency members (including FDA participants on the team) for feedback, drawing on members’ experience from the R Consortium pilot submissions.

Key Achievements
This Quarter:

- Finalise the complete ADRG example for an R submission and hand it over to the ADRG working group to combine with their SAS examples.
- Deliver guidance for the ADRG appendix on recreating the R environment, consolidating the varied approaches companies use.
- Support integration of the open-source components into the broader ADRG package.

Deliverables &
Targets Planned for
the Next Quarter:



Project Status: Green
Accepting New Members

- On track in substance, with the core guidance already handed over. Focus is now on the R ADRG example and the environment-recreation appendix - both high-demand items the industry is waiting on.

Project Status

Comparing Analysis Method Implementations in Software (CAMIS)

Description

The CAMIS (Comparing Analysis Method Implementations in Software) project builds on the earlier Clinical Statistical Reporting in a Multilingual World initiative, addressing differences observed in statistical results across programming languages. Even within validated environments, variations in underlying computational approaches can produce results that differ but remain statistically valid. These discrepancies create uncertainty for sponsor companies when submitting to regulatory agencies, particularly regarding how such differences will be interpreted.

CAMIS aims to define this challenge and provide a structured framework for assessing cross-language differences in statistical analyses. The project focuses on key analyses commonly used in submissions (e.g. summaries, models, bioequivalence testing), documents where equivalence can be achieved and known differences evaluated through practical use cases. It also provides sample code via a public repository and promotes statistically sound implementation choices over software-specific defaults, supporting greater confidence in multi-language regulatory submissions.

The [CAMIS repository](#) to document known differences is now live and open for community contributions.

Ongoing

Proposed End Date

White paper & open-source collaboration repository

Deliverable

- Substantial new GLM/GLMM content added in July - a large PR with around 10 SAS/R comparison examples.
- Completed accelerated failure time models and survival weighted log-rank content.
- Poster presentation at the PSI conference.
- CAMIS blog cross-posted on PHUSE. A simplified PHUSE blog submission process is now in place, and the team is targeting a blog post every two months.
- A fix for the renv issue that had been blocking incoming PRs has been developed and tested, and is pending final merge.
- CAMIS attendance at the PHUSE US Connect 2027 confirmed; an abstract was submitted and a hackathon proposed for the Open Source & Data Visualization Pavilion.

Key Achievements This Quarter:

- Merge the renv fix and clear the backlog of pending PRs.
- Improve the MMRM SAS page.
- Complete the remaining 3/5 sections of CIs for proportions (paired 2 proportions, rates (Poisson)).
- Continue to improve sample size content.
- Complete the strategic review of all open/assigned issues.
- Present at R/Pharma (20-21 October).
- Prepare for the PHUSE US Connect 2027 presentation and workshop, including a demonstration of an AI bot that answers questions using the repository's QMD files.

Deliverables & Targets Planned for the Next Quarter:

Lyn Taylor,
Christina Fillmore &
Yannick Vandendijck

Leads



Project Status: Green
Accepting New Members

- Community contributions continue at a strong pace. Most Q3 activity has moved to Q4 because of the renv blocker, which now has a working fix, so the backlog of PRs can be brought in.

Project Status

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

Description

The PHUSE project team will extend the MSA framework by developing a reference architecture grounded in real-world use cases. This work will identify common implementation challenges and propose practical design solutions to address associated risks, providing clear guidance for building a validated, end-to-end environment for regulated activities. While the MSA framework offers flexible, open-source guidance for regulatory reporting, its adaptability can create implementation complexity and gaps in risk mitigation.

Building on the original 2021 TransCelerate framework, which established the conceptual foundation but did not include demonstrable solutions, the PHUSE handover will focus on practical application. This includes showcasing how the framework can be implemented using real tools and workflows, helping organisations move from theory to operational adoption with greater confidence and consistency.

Q4 2026

**Proposed
End Date**

White paper

Deliverable

- Finalised the content and structure of the reference architecture diagrams, with data organised so it can be consumed by multiple audiences.
- Built on the in-depth end-to-end analysis of all data flows of the framework (Rave to submission) completed in Q2.
- Submitted an abstract for the PHUSE US Connect 2027.
- Secured organisational recognition at BMS for the project lead's participation.

**Key Achievements
This Quarter:**

- Complete visual improvements to the architecture diagrams.
- Complete architectural approach revisions.
- Assemble the output package (white paper, presentations, diagrams and guidance) in the existing project repository.
- Explore participation in the US Connect Open Source & Data Visualization Pavilion.
- Note: physical architecture testing has been deprioritised as a nice-to-have, as the architecture reflects tools and practices already in use at UCB, Amgen, BMS and Sanofi.

**Deliverables &
Targets Planned for
the Next Quarter:**

**Benjamin Chiang,
Lu Yao &
Neil Ward**

Leads



Project Status: Green

- Architecture work is substantively complete; the team is now in the refinement and packaging phase.

Project Status

Open Source Technology Adoption in Japan

Description

This project aims to promote the practical adoption of open-source technology (OST) in clinical development in Japan by strengthening knowledge-sharing and providing community-driven resources. It focuses on supporting practitioners through case studies, practical guidance, training materials and small-scale tools such as R-based utilities, rather than addressing regulatory policy.

Despite increasing global adoption, OST use in Japan remains cautious and inconsistent, limiting the industry’s ability to fully realise its benefits. This project seeks to address these challenges by improving access to shared knowledge and real-world examples, particularly in clinical development and real-world data (RWD) analytics.

By enhancing collaboration and providing practical resources, the initiative will support more informed adoption decisions, reduce duplicated effort, encourage consistent practices, and improve overall efficiency and reproducibility within the clinical research community in Japan.

Q4 2026

Proposed
End Date

Advanced planning
and content
development for the
PHUSE Single Day
Event presentation

Finalise presentation
materials and deliver
the PHUSE Single Day
Event presentation

Presentation at a
PHUSE Single
Day Event

Deliverable

Key Achievements
This Quarter:

Deliverables &
Targets Planned for
the Next Quarter:

Tomoki Nishikawa
& Yuichi Nakajima

Leads



Project Status: Green

- The project is progressing as planned

Project Status

PharmaForest: collaborative repository of SAS packages for pharmaceutical industry

Description

This project aims to drive adoption of reusable SAS packages and best practices across the pharmaceutical industry, addressing inefficiencies, fragmentation and limited collaboration. It focuses on establishing an open, sustainable ecosystem - PharmaForest - built on the SAS Packages Framework (SPF) to improve productivity, compliance and knowledge sharing.

Key activities include developing educational materials and presentations on implementing PharmaForest packages and SPF, and sharing these through webinars, industry events (e.g. PHUSE Connects) and training sessions. The project will also create and maintain an open-source repository of high-quality SAS packages for common pharmaceutical use cases, enabling consistent installation and version control.

By fostering community engagement through contributions, peer review and onboarding resources, PharmaForest will reduce duplicated coding, improve standardisation and enhance quality. This approach will accelerate development timelines, lower costs, strengthen compliance and support a more collaborative and innovative SAS programming community.

Ongoing

Proposed
End Date

Workshop &
guidance
materials

Deliverable

- Held a meeting with project members (volunteers) and onboarded new volunteers.
- Presented at the Kagoshima Data Science Symposium.
- Presented at SAS Innovate on Tour Tokyo.

Key Achievements
This Quarter:

- Present at the SAS User Group Conference Japan.
- Present at PharmaSUG 2026 Japan.
- Explore representation at the PHUSE US Connect 2027 - as the abstract deadline has passed, identify a US-based member who could attend and potentially introduce the project in the Open Source & Data Visualization Pavilion.

Deliverables &
Targets Planned for
the Next Quarter:

Hiroki Yamanobe,
Ryo Nakaya &
Yutaka Morioka

Leads



Project Status: Green
Accepting New Members

- Progressing well, with strong outreach in Japan and a growing volunteer base.

Project Status

Teal Enhancements for Cross-Industry Adoption

Description

This project aims to enhance the teal framework by increasing its flexibility for use across pharmaceutical companies. Through research, development, testing, documentation and training, it will introduce new functionality that allows users to reformat, post-process and decorate outputs from existing teal modules without changing the core code.

While teal and teal.modules.clinical already provide strong support for interactive exploration of standardised clinical data, differences in company standards and analysis requirements have limited broader adoption. As a result, organisations often build custom modules from scratch, creating unnecessary effort and inefficiency.

By enabling customisation of tables, graphs and listings through reusable enhancements, this project will reduce the need for bespoke development, improve scalability of existing modules, and support greater consistency across the industry. Overall, it will make teal more practical, adaptable and widely usable in pharmaceutical workflows.

Q2 2027

**Proposed
End Date**

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

Deliverable

- Published teal.picks to CRAN, giving users a streamlined way to specify inputs; dependent packages are being updated to use it.
- Brought gtsummary performance improvements to a good stopping point in collaboration with the package maintainer (roughly three-quarters improvement so far); performance is no longer blocking adoption.
- Roche added examples to their open-source packages showing how to use the improved gtsummary.
- Completed and released the CSV download feature for uteals reports.
- Began the refresh of the teal training materials with Working Group members.

**Key Achievements
This Quarter:**

- Finalise the gtsummary performance report.
- Progress integration of gtsummary into teal modules.
- Build out the comprehensive tutorial and adoption guide, and plan its publication.
- Complete the leadership transition to Nick Burkoff.

**Deliverables &
Targets Planned for
the Next Quarter:**

**Peyman Eshghi,
Nicholas Masel &
Nina Qi**

Leads



**Project Status: Green
Accepting New Members**

- On track. The key adoption blocker (gtsummary performance) has been addressed. The focus now shifts to training and adoption materials.

Project Status