Data Visualisation & Open Source Technology

Clinical Visual Analytics for Review and Submission (CVARS)

Project Leads:
Melvin Munsaka, Neetu Sangari & Jiang Hu

Proposed Project End Date:
Q1 2026

Project Scope:
Development of an open-source tool and package to generate identified interactive plots for clinical review and direct inclusion in submissions to regulatory agencies. The initial scope is to develop a package to generate interactive forest and volcano plots for adverse events and FDA Medical Queries (FMQs) analysis outputs for inclusion in submissions to the FDA. This work is a collaboration among the American Statistical Association (ASA), PHUSE and the FDA. Extended scope for E2E safety assessment.

Deliverable:
An open-source R Shiny tool for generating the plots and associated outputs and an accompanying paper for the tool.

Project Status:
Green

Project Accepting New Members:
Yes (both technical folks and other cross-functional stakeholders)

Key Achievements This Quarter:

- Draft code snippets for additional CVARS functionality
- Tarrytown SDE CVARS presentation

Deliverables & Targets Planned for the Next Quarter:

Updated CVARS tool and vignette

Communication of Version Metadata for Open-Source Languages

Project Leads:
Joel Laxamana & Lovemore Gakava

Proposed Project End Date:
Q3/Q4 of 2025 (TBD)

Project 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.

Deliverable:
White paper

Project Status:
Amber

Project Accepting New Members: Yes

Key Achievements This Quarter:
- Made a start on the R package
- Submitted our feedback to the PHUSE ADRG standard group. We are waiting for the final ADRG template from the PHUSE standard group
- Presented at the PHUSE CSS 2025 and collated feedback from sponsors and regulatory groups

Deliverables & Targets Planned for the Next Quarter:
- Draft of ADRG R completion guideline
- Draft of ADRG R example
- Draft of ADRG R package (ADRG quarto template and functions to complete sections of the ADRG)

Comparing Analysis Method Implementations in Software (CAMIS)

Project Leads:
Lyn Taylor, Christina Fillmore & Chi Zhang

Proposed Project End Date:
Ongoing

Project 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.

Deliverable:
- White paper providing a framework for addressing language discrepancies in statistical analysis implementations, including specific use cases as examples
- Creation and maintenance of an open-source collaboration repository

Project Status:
Green

Project Accepting New Members: Yes

Key Achievements This Quarter:
- Revamp of landing page & help pages
- Corrections to Wilcoxon rank sum & ANOVA/ANCOVA & Survival
- New pages for tipping point analysis
- New pages for propensity score matching
- New pages for recurrent events
- Attended PSI conference, with two presentations

Deliverables & Targets Planned for the Next Quarter:
- Finalise sample size comparison pages
- Update CI for props to include cicalc package
- Present at PHUSE EU Connect

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

Project Lead:
Benjamin Chiang

Proposed Project End Date:
Q4 2025

Deliverable:
White paper

Project Status:
Amber

Project Accepting New Members: Yes

Project 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.

Key Achievements This Quarter:

- Three technical/business use cases detailed and analysed
- Defined approach for describing/visualising MSA impact and reference architecture
- MSA to use case mapping analysis (business and technical) for one use case

Deliverables & Targets Planned for the Next Quarter:

- Finish data flow analysis for all use cases
- Open-source options for full pipeline
- Implement proposed open-source options based on available resources
- Test and document results

Project Leads:
Peyman Eshghi & Nina Qi

Proposed Project End Date:
Q1 2026

Project 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.

Deliverable:
Presentations, training and deployment of proposed enhancements of the teal framework

Teal Enhancements for Cross-Industry Adoption

Project Status:
Green

Project Accepting New Members: Yes

Key Achievements This Quarter:

- Organise a webinar focused on exploring the synergy between Generative AI and the teal framework in the pharmaceutical industry
- Facilitate cross-industry discussions on bookmarking within the teal framework
- Initiate the development of the **uteals** package to coordinate and streamline the development of utility functions for teal

Deliverables & Targets Planned for the Next Quarter:

- Webinar scheduled for 10 October
- Hands-on Workshop at the PHUSE EU Connect
- Development of the **uteals** package, with the aim of having a functional version ready to be announced at the PHUSE EU Connect