Clinical Visual Analytics for Review and Submission (CVARS)



Project Scope
Development of an open-source tool and package to enable generation of 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.

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Objectives & Deliverables	Timelines
An open-source R Shiny tool for generating the plots and associated outputs and an accompanying paper for the tool	Q3 2022
Complete manuscript	Q4 2024

Resources
CVARS GitHub Page
CVARS

CURRENT STATUS **Q1 2024**

- Participation at the CSS
- Presentation at the FDA