

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