Open-Source Drug Development: ADAM, TLGs & Interactivity with R".

Presenters: Phil Bowsher and Rich Iannone, RStudio

Posit/RStudio will be presenting an overview of Pharmaverse, GT, Quarto and WebAssembly for the R user community at MBSW. This is a great opportunity to learn and get inspired about new capabilities for working with clinical trials data and generating TLGs (Tables, Listings and Graphs) for inclusion in Clinical Study Reports. The usage of R in pharma, especially in clinical trials, has increased rapidly over the last 3 years. This talk will review various public new drug applications and discuss the usage of open source within various areas of the submissions.

This is a great opportunity to learn about current trends of using open-source languages in submissions. This hands-on workshop will provide an introduction to the current landscape of prepping ADAM data and using GT, Quarto and Shinylive TLGs. In this talk, we will review and reproduce a subset of common table outputs used in clinical reporting containing descriptive statistics, counts and or percentages.

The talk will provide an introduction to TFL-producing R programs and include an overview of the GT R package with applications in drug development such as safety analysis and Adverse Events. Pharmas have been using Shiny for Exploratory Data Analysis for many years. Now there is much interest in creating interactive reports with Shiny and WebAssembly to help with efficiency gains when delivering results and to save reviewers time and streamline the review process.

The Shiny apps would support data review and exploration for clinical outputs. There has also been a public pilot to include Shiny in an FDA clinical trial submission as an opportunity to be more effective at processing the kinds of data and analyses that appear in clinical trial submissions. Moreover, the apps can help the regulatory bodies more quickly and accurately assess the safety and efficacy of new medical products.

This talk will discuss the new horizon for new drug submissions with tools like WebR, Quarto and Shinylive. Rich and Phil will also feature ways that you and your pharma can get involved in this exciting new effort that is bringing pharma together!

Please also plan to attend the special session on "Making an Interactive Shiny App with GenAI…Five Ways" during the conference.