

Developing Standardized Clinical Review Tools Using Shiny In R

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OBJECTIVES

Develop standardized, interactive tools for FDA reviewers by implementing routine analyses and programming tasks in the R Shiny framework:

- 1 Identify processes in statistical reviews that could be streamlined
- 2 Develop programming solutions in R to automate such processes
- 3 Design a homepage to host information for the tools and the instructions
- 4 Provide archival documentation of all relevant R code for future modifications

INTRODUCTION

At FDA/CDER's Office of Biostatistics, the development of Shiny apps to serve as standardized clinical review tools has begun. Routine analyses and programming tasks are continuing to be identified and implemented in the Shiny framework for streamlining. A homepage has been created to host documentation and instruction pages for the available tools.

Shiny is an R library that allows statistical programmers to develop web applications within the realm of R. Shiny applications are inherently interactive with field boxes, slider bars, etc. for users to specify. Outputs, such as visualizations and tables, can be returned based on user inputs to display the end results.

METHODS

1 Identify processes in statistical reviews that could be streamlined:

- Reviewers described analyses and tasks, which were either routine or tedious, that could be employed into GUI tools for efficiency and workload reduction
- The programmer and reviewers continuously exchanged communication to ensure a clear understanding of the inputs and outputs of each app

2 Develop programming solutions in R to automate such processes:

- Shiny scripts were started off from scratch, in which some included base code from previous research
- A variety of R libraries were utilized: *ggplot2* and *gridExtra* for visualizations, *dplyr* and *reshape2* for data manipulation, *boot* for bootstrap calculations, etc.
- Additional R libraries existed to support the functions of a Shiny app: *shinyBS*, *shinyjs*, *colorspace*, *DT*, *shinythemes*, etc.

3 Design a homepage to host information for the tools and the instructions:

- An existing CDERWiki website, focusing on sharing knowledge and information among CDER staff, based on MediaWiki was available for use
- An R Shiny Wiki page was created to showcase the available tools along with brief descriptions and instructions on how to use each one

4 Provide archival documentation of all relevant R code for future modifications:

- Documentations of relevant R code was generated using R Markdown and then converted to MediaWiki format
- Using the converted files, contents were uploaded onto the R Shiny wiki page
- Chunks of code can be obtained from the documentation and modified as needed

CONCLUSION

Using the Shiny library in R, standardized clinical review tools are being developed at the FDA to address the needs of reviewers. These tools are interactive in nature by receiving commands from users and outputting the requested results. This approach supports the office goals of increasing efficiency in clinical reviews and lightening the workload of reviewers, who are required to perform such routine work.

REFERENCES

- R Core Team (2016). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria.
- Winston Chang, Joe Cheng, JJ Allaire, Yihui Xie and Jonathan McPherson (2016). shiny: Web Application Framework for R. R package version 0.14.2.

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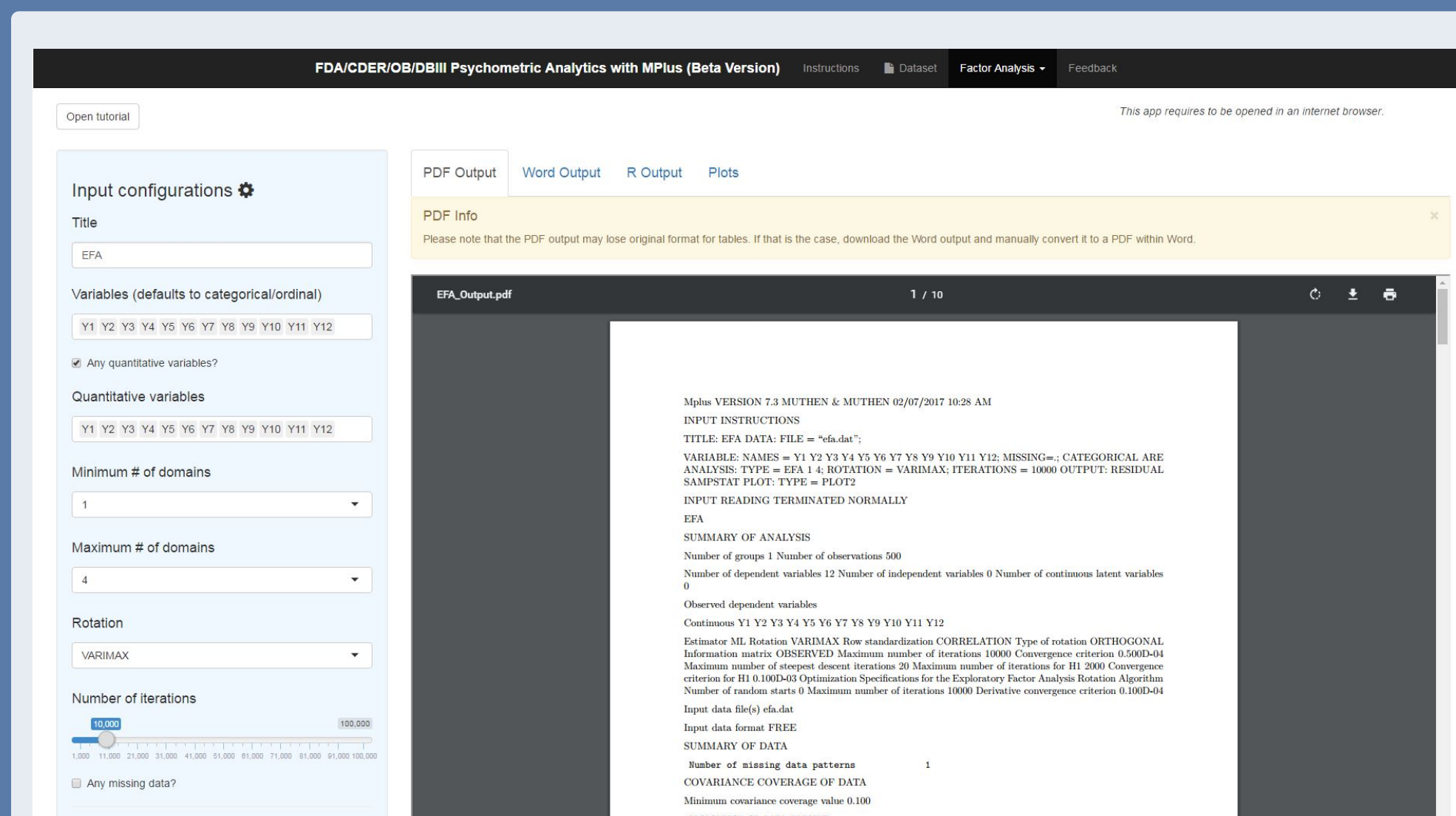
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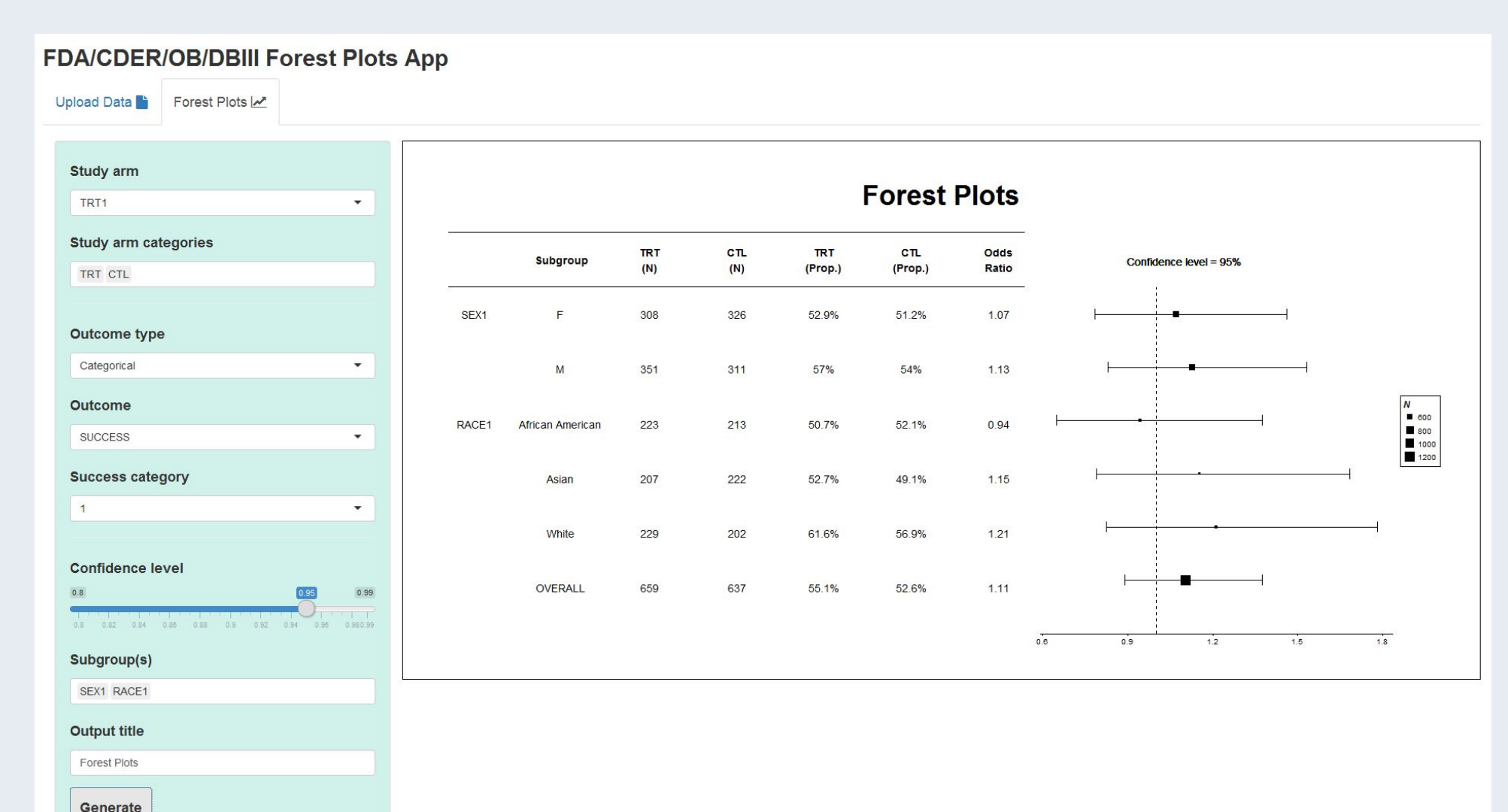
CURRENT R SHINY APPS



(a) MPlus Psychometric Analytics: This app utilizes MPlus to perform exploratory and confirmatory factor analysis on questionnaire items data.



(b) Patient-Reported Outcomes Visualization: This app generates a variety of visualizations to analyze patient-reported outcomes data over a study period.



(c) Forest Plots: This app produces forest plots with either continuous or categorical endpoints, supporting both imputed and multiple-imputed data.

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