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Unlocking Insights: Comparative Analysis of CRF Changes with R Shiny

Mayank Singh, J&J MedTech

ABSTRACT

In the clinical research industry, Case Report Forms (CRFs) undergo multiple updates throughout the course of study execution. It is the responsibility of the Biostatistics and Programming group to ensure that the downstream programs remain synchronized with any modifications to the CRFs, including the addition of forms, updates to fields, and changes to code lists. However, identifying these CRF updates is a manual and labor-intensive process, often prone to errors that can result in overlooking critical changes.

This paper presents an R Shiny application designed to facilitate the comparison of various versions of CRF metadata, whether within a single study or across studies. The application generates a comprehensive comparison report that is accessible via an R Shiny dashboard or available for download in Excel format. Additionally, it allows the team to utilize programming codes from similar studies, enhancing efficiency in their current research.

INTRODUCTION

As studies progress through various phases or years of its execution, the Case Report Form (CRF) undergoes multiple updates to accommodate new CRFs, modified or removed questions, and adjusted codelists. This iterative process presents significant challenges for Biostatistics and programming teams, particularly when the changes are both extensive and subtle. The teams often invest hours in manually comparing the new CRF with its predecessor to identify alterations, while still facing the risk of inadvertently overlooking some changes.

Moreover, programming team leadership often faces the challenge of allocating resources, managing deliverable timelines, and estimating programming costs without a clear understanding of how closely a new study aligns with previous studies or whether it adheres to established data standards and structures.

In this regard, R Shiny has emerged as an invaluable tool in the clinical research industry, facilitating the development of user-friendly dashboards that generate and disseminate meaningful insights across the organization. This paper introduces an interactive R Shiny application specifically designed for comparing different versions of CRF metadata, whether within a single study or across studies. The application produces a comprehensive comparison report that is accessible via an R Shiny dashboard or available for download in Excel format.

CRF COMPARISON R SHINY APP

PREREQUISITES

The Shiny app is developed using the RStudio. To successfully deploy this application, the following packages must be installed from CRAN ,as well as studies developed in Medidata Rave.

Packages:

- shiny
- haven
- tidyverse

- shinythemes
- tidyr
- dplyr
- openxlsx
- readxl

To install these packages, utilize the install.packages() function in R , followed by the package name enclosed in quotation marks. Below is the syntax for installing any package in R:

```
install.packages("shiny")
```

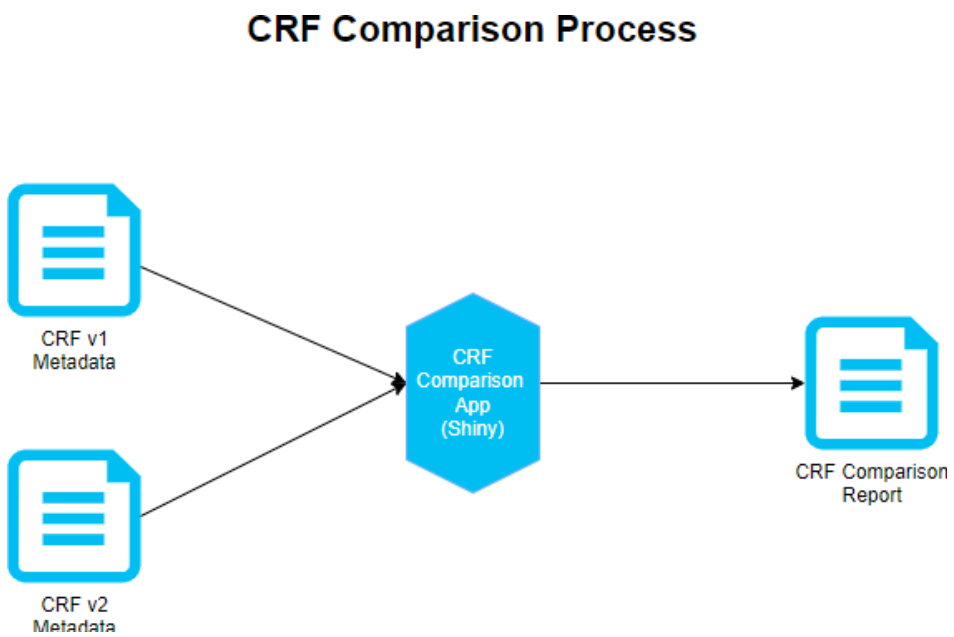

Figure 1. Overview of the application

Application Feature

Built on RStudio, this graphical user interface (GUI) enables users to:

- Upload two CRF metadata files.
- Identify newly added CRFs.
- Detect updated CRF fields.
- Identify fields that have been removed fromCRFs.
- Highlight updated or newly added code listvalues.
- Detect changes to variable attributes.
- Provide the current CRF version in a listing format.

R SHINY APPLICATION INTERFACE

Users can access the application without any prior knowledge of R or the need to install any packages. They simply need to open the published URL link, upload the required inputs listed below, and then run the app.

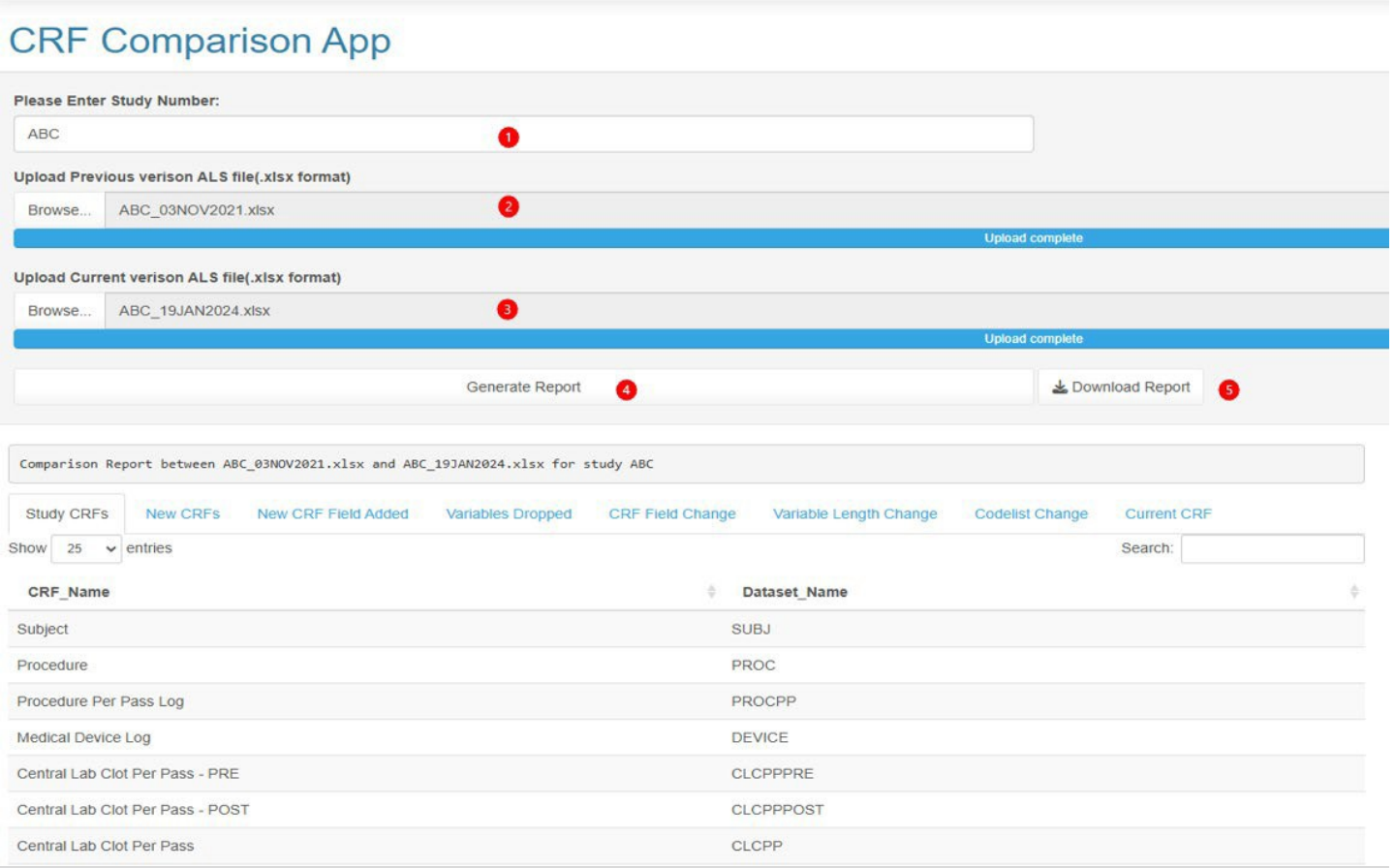

Figure 2 Application User Interface

Components in Figure 2 are numbered to facilitate clarity.

1. **Text Field**: A field to enter the study name or number.
2. **Upload Previous/Base CRF Metadata**: Upload the previous or base CRF metadata file in xlsx format. ALS short for 'Architect Loader Spreadsheet' is system generated and contains key configuration components for the study in Rave.
3. **Upload Current CRF Metadata**: Upload the current CRF metadata file in xlsx format.
4. **Generate Report**: Click this button to initiate the comparative analysis and generate the report.
5. **Download Report**: This option allows the user to download the report (in excel) generated on the dashboard.

R SHINY APPLICATION COMPARATIVE ANALYSIS

The comparative report generated on the dashboard features multiple tabs, each representing different aspects of the application:

- **Study CRFs**: Displays the CRFs currently utilized in the study along with the associated dataset.
- **New CRF(s)**: Highlights any new CRFs that have been added to the study.
- **Variables Dropped**: Lists questions/fields (dataset variables) that have been removed in the current update.
- **CRF Field Change**: Details any modifications made to questions/fields in the current CRF update compared to the previous version.
- **Variable Length Change**: Specifies any changes to the attributes of the raw dataset variables.
- **Codelist Change**: Identifies modifications to dropdown values in the current CRF.
- **Current CRF**: Presents the current CRF in a list format, making it easily searchable.

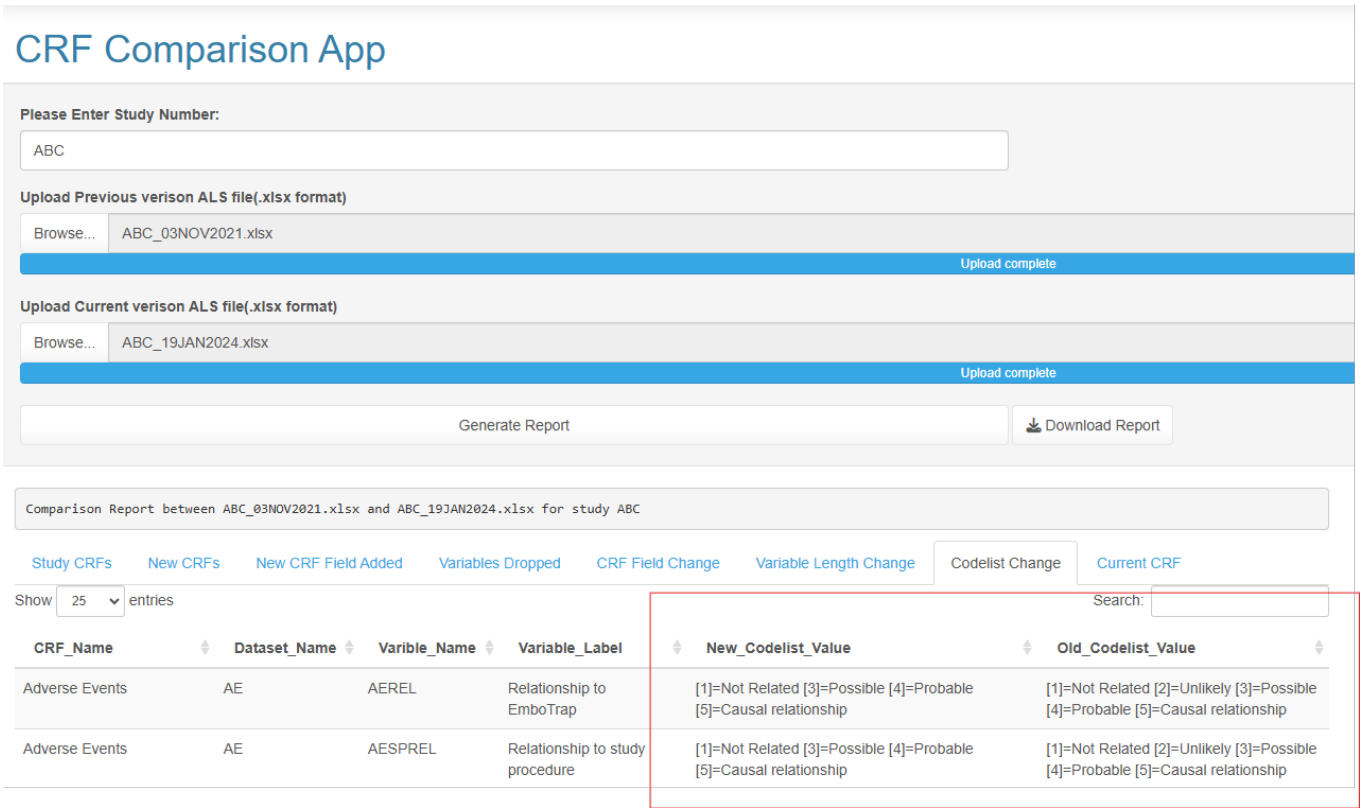

Figure 3 Illustrates changes in Codelist values

CONCLUSION

The "CRF Comparison" app discussed in this paper is a solution developed using the R programming language. This application enables teams to efficiently compare CRFs within minutes and implement necessary changes downstream. Additionally, it assists programming team leadership in resource allocation, managing deliverable timelines, and estimating programming costs.

The app's features are continuously being enhanced to include additional comparative analyses that cater to the needs of various functional teams.

REFERENCES

https://shiny.rstudio.com/

https://cran.rstudio.com/

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the authors at:

Mayank Singh
Johnson & Johnson's Cardiovascular & Specialty Solutions Group
Msing133@its.jnj.com