

R Shiny to Drive Automation in Clinical Analysis & Reporting

Jocelyn Wang, Statistical Programmer, jocelyn.wang1@astrazeneca.com

Abstract

R is becoming increasingly popular in the pharma industry, with collaboration on “PharmaVerse” developments where R Shiny is central. R shiny is used to share content with an interface enhancing the end-user experience.

The intent with this poster is to show one application of R to inspire automation in the regulatory environment. All clinical drug projects are required to create periodic safety update according to a specific standard, which is a repetitive activity that can be highly automated and simplified. Below is an example of how R Shiny can be used to automate and simplify generation of Development Safety Update Report (DSUR). This implementation supports data import, metadata review and generation of the DSUR output automatically in a standardized way. It is assumed that data are highly standardized using the CDISC SDTM format.

Method

Process: File info about the uploaded data – View to check the uploaded data – Output to check the chosen output - Report to check all outputs using below sequential steps

- i. Load the needed datasets of all studies using same compound with the DSUR report period
- ii. Check the info of the uploaded files including name, type and size of each file as shown in the right picture, default choice is preview and see all datasets can be seen by clicking View
- iii. Choose summary to see the total number of the subjects and deaths
- iv. Click output, specific output will then be displayed as shown in below picture
- v. Download the report in PDF / Word format

R ShinyDSUR Genertor

Upload files

Browse...

8 files

Upload complete

Display

☒ preview

☐ summary

Choose an output:

exposure by age and sex

Download Report

Document format

☒ PDF

☐ Word

Files info

View

Output

Report

Appendix 4 Table 1 Estimated cumulative subject exposure to AZD0001 from completed or ongoing clinical trials by age and sex

Age range (years)	Male	Female	Total
< 18	0	0	0
18 - 65	21	10	31
66 - 75	0	0	0
> 75	0	0	0
Total	21	10	31

Conclusion

- It is possible to build an R application supporting business workflows in an easy way compared to other software
- Using R Shiny applications can successfully drive automation in clinical analysis & reporting with user friendly interface.

Challenge

- However, validation of the applications needs lifecycle management which is different from standard SAS
- The source data are stored in the cloud and cannot be fetched easily.

Next up

- Build up connection between this website and the source data from the cloud to obtain the data automatically.
- Explore more uses of R Shiny such as reporting, decision making, raw data cleaning, validation and visualization.

References

- pharmaverse, <https://pharmaverse.org/>
- Development Safety Update Report (DSUR), <https://publicsafetyandvigilance.com/development-safety-update-report-dsur/>
- R Shiny, <https://shiny.rstudio.com/>

