Interactive Safety Review Using R Shiny Dashboard

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Abstract

Regular review of patient safety data during ongoing clinical trials is an important part of the drug development process. The review process contains different kinds of summary tables and listings. These lengthy reports make challenge reviewers to identify all signals and it is time consuming to go deeper into patient level data. To address these issues an R Shiny Dashboard was developed to review safety data interactively. The embedded summary table is dynamic and allows users to search, sort, and filter the displayed table. Moreover, users can drill down the summary table to access patient level records such as adverse events, laboratory findings, exposure, and disposition records easily.

Introduction of R and R-shiny

- R is a language and environment for statistical computing and graphics
- R is open-source and free
- The capabilities of R can be easily extended through user-created packages
- Shiny is an R package that provides an elegant and powerful web framework for building web applications using R

Domains Included

The R shiny Dashboard includes summary tables from four domains: Disposition, Medical History, Adverse Event, and Laboratory.

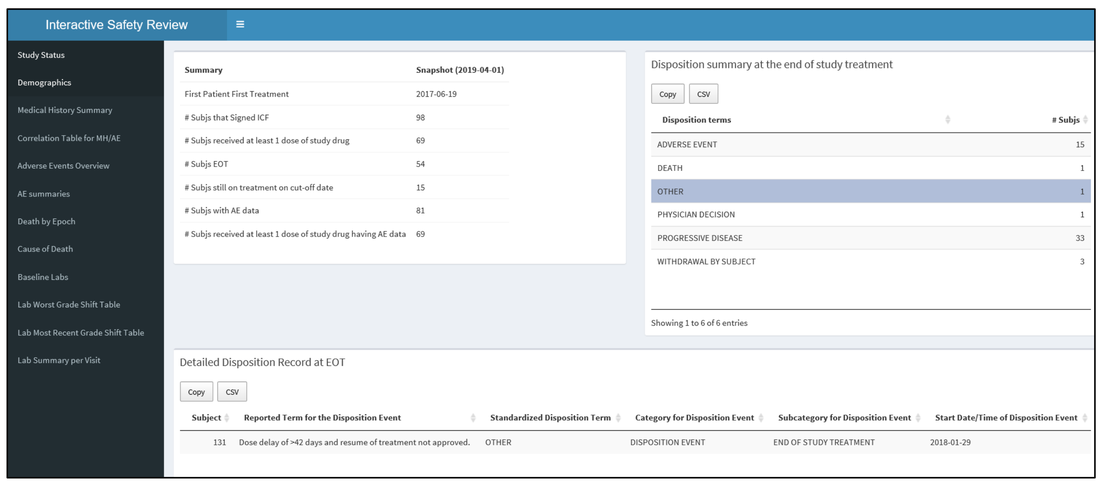

Figure 1. User interface of interactive safety review dashboard.

Dynamic Summary Tables

Dynamic summary tables allow users to search, sort, and filter on the table.

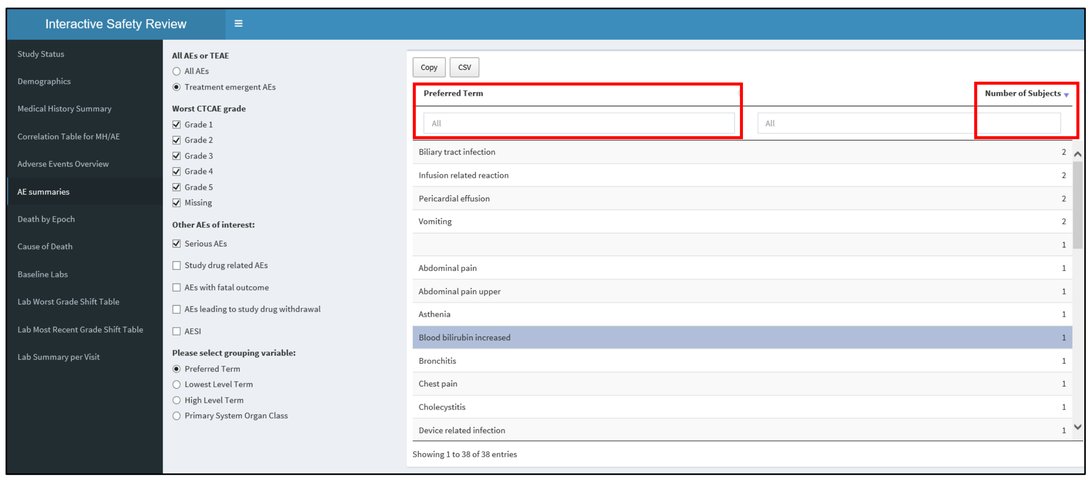

Figure 2. Serious treatment emergent AE summary table by preferred terms – order by decreasing frequency

Drill down to patient level records

Users can drill down the summary table to access patient level records such as adverse events, laboratory findings, exposure, and disposition records easily.

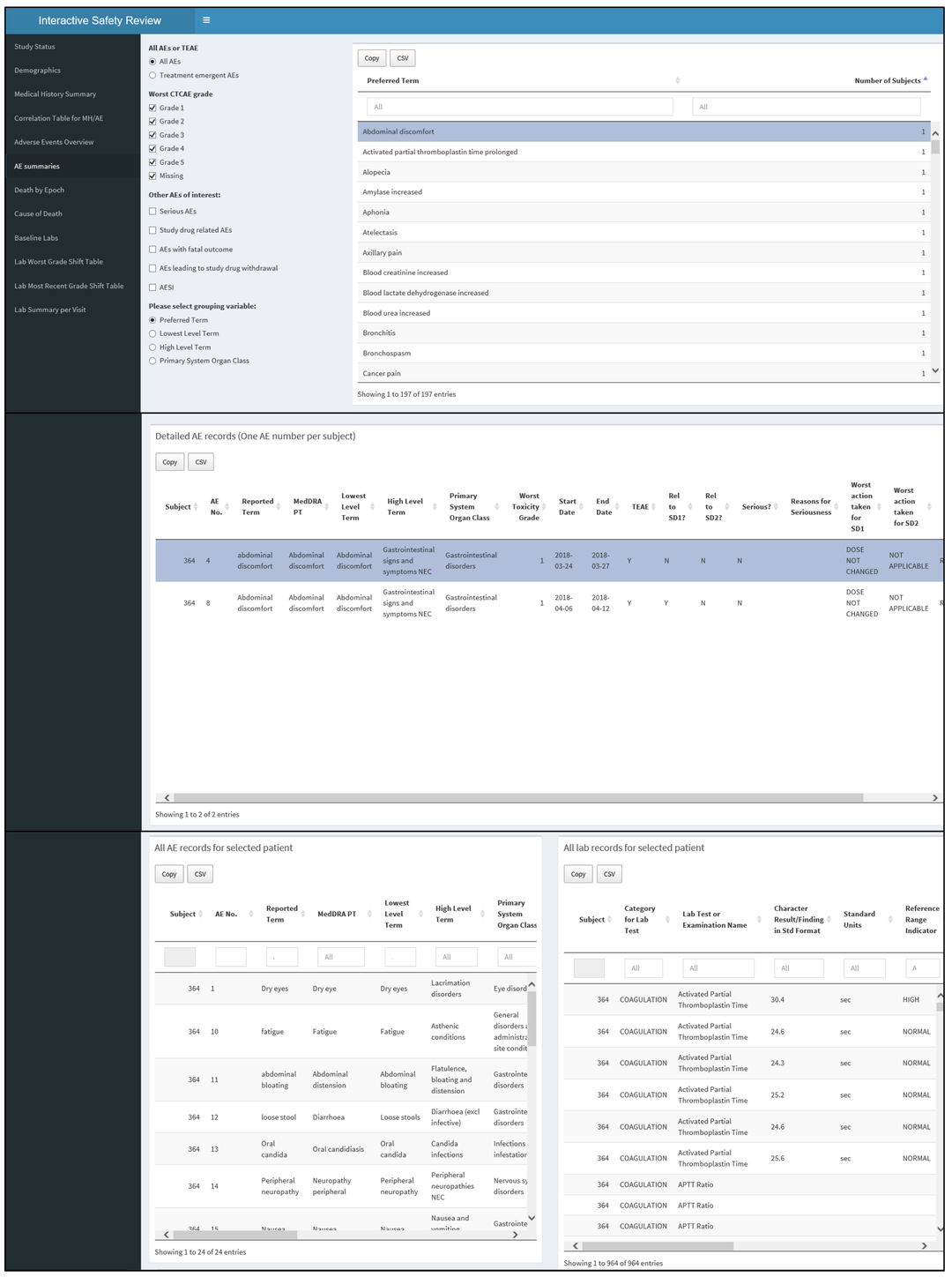

Figure 3. Example of drilling down the AE summary table to patient level AE and Lab records

Conclusion

An interactive R Shiny Dashboard was developed to assist in trial monitoring by the core study team.

References

The R Project for Statistical Computing: https://www.r-project.org/
Shiny from R Studio: https://shiny.rstudio.com/

Acknowledgement and Contact Information

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