

Designing a modular and interactive visualization tool for DMC

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ABSTRACT

During Data Monitoring Committee (DMC) meetings, it is important to cross-check both aggregated data and individual records from areas such as adverse events, laboratory results, baseline conditions, concomitant medications, and other domains to better understand safety concerns. Traditional static reports make this process time-consuming, often requiring extensive manual searches or additional listings. To address this, we developed a modular R Shiny application that integrates summary tables, listings, figures, and patient profiles into a unified interactive environment. Modules are interconnected through participant identifiers, enabling seamless drill down from aggregate results to subject level detail. The modular structure accommodates both internal and open-source R packages, while allowing expansion with customized features. Key development challenges include coordinating between multiple packages, establishing cross-module communication, and debugging nested functions. By thoroughly reviewing the source code and resolving the compatibility issues, we delivered a functional prototype that received positive feedback from statisticians and programmers. A pilot deployment is now planned to further evaluate performance and usability.

INTRODUCTION

Across therapeutic areas, DMC members consistently request the ability to quickly access subject-level details for participants associated with specific safety findings. For example, clinicians often wish to move directly from an adverse event summary table to the corresponding participant's profile containing laboratory trends, medical history, and concomitant medication. Motivated by these needs, we designed an interactive Shiny application structured around linked modules that support rapid navigation from aggregated analyses to detailed clinical information.

The application includes dedicated modules for introductory content, summary statistics, hierarchical frequency tables, exemplary listings, eDISH plots, laboratory line plots, AE forest plots, and a comprehensive patient profile. Each aggregated display supports drill-down to participant identifiers, which can then be passed to the patient profile module for a customizable participant-level safety review.

DEVELOPMENT

DATA SOURCE

The application accepts standard ADaM datasets, which support reliable and consistent analysis across studies. Certain SDTM domains, such as concomitant medication (CM) or medical history (MH), may alternatively be provided as input datasets. Before data ingestion, users are advised to validate date formats and factor levels to ensure compatibility and accuracy.

MODULAR ARCHITECTURE

To develop the app, we evaluated modules available internally and from open-source packages. Many required functions were already available, enabling us to focus on integration and user-centric enhancements. The final implementation incorporates:

- DaVinci Modules: hierarchical frequency tables, Tplyr summary statistics, eDISH plots, laboratory line plots, exemplary listings, and patient profiles (<https://boehringer-ingelheim.github.io/davinci/>)
- Custom AE Explorer Module: developed on top of the forestly package with additional filtering and data processing using the metalite framework

The core feature of the application is cross-module communication. Aggregated modules extract relevant subject identifiers and pass them to the patient profile module using paired parameters (sender_ids and receiver_ids). Several DaVinci modules include this communication capability natively.

The custom AE Explorer module currently lacks this integration, so a temporary pop-up window is used to display selected participant identifier until cross-module communication is fully implemented.

CHALLENGES

Modularized R development introduces complexity, particularly when working with deeply nested functions and diverse package ecosystems. Error logs often provide limited guidance, necessitating targeted debugging and strategic breakpoint selection. Although AI-assisted solutions can offer useful suggestions, hands-on troubleshooting remains essential due to the app's interdependencies and custom logic.

DOCUMENTATION

To facilitate adoption, we created detailed documentation outlining required datasets, expected variable formats, and module-specific preprocessing needs. Future enhancements will include practical examples and case demonstrations to further support users.

CONCLUSION

This paragraph uses the PaperBody style. We developed an interactive R Shiny application that enhances the efficiency of DMC meetings by integrating aggregated safety summaries with subject level clinical information in real time. The application streamlines data review, supports informed decision making, and directly addresses common DMC feedback.

CONTACT INFORMATION

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