Paper PP18

R Shiny Application to Optimize Review of Multiple Myeloma Efficacy Data Listings

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ABSTRACT

This paper explores the challenges encountered by clinical teams in Multiple Myeloma studies during manual reviews of SAS-generated listings. Emphasizing the importance of data like biochemical test results, BMA, BMB, bone lesion, and plasmacytomas data, crucial for the adjudication process, we delve into the labor-intensive nature of existing review processes, particularly in larger studies. The paper introduces a transformative solution – an intuitive web application developed using R Shiny. This innovation empowers clinical teams through personalized data scrutiny, comparative analysis, and seamless collaboration, promising heightened efficiency, data integrity, and improved team collaboration.

INTRODUCTION

In the landscape of Multiple Myeloma studies, the reliance on SAS-generated listings is paramount for the adjudication process. These listings, housing indispensable data, are fundamental for critical efficacy evaluations. However, the manual review process becomes increasingly challenging, particularly in larger studies, involving intricate data quality checks and efficacy assessments.

KEY CHALLENGES

- **Labor Intensive Process:** The manual annotation and review of extensive datasets hinder the timely assessment of data quality and efficacy. The complexity of handling diverse data types presents a significant challenge for comprehensive assessments.
- **Timeliness:** The manual processes result in delays, impacting the timely evaluation of data quality and efficacy in larger studies.
- **Complexity:** The diversity of data types poses challenges in handling and conducting comprehensive assessments.

INNOVATIVE SOLUTION

As a transformative solution, BMS has pioneered an intuitive web application using R Shiny. This innovative approach empowers clinical teams through personalized data scrutiny, comparative analysis, and seamless collaboration. By enabling tailored filtering based on subjects and visits, supporting side-by-side or stacked report comparisons, and integrating notetaking, this solution addresses the challenges posed by the labor-intensive manual review process.

OVERVIEW OF THE APPLICATION

The R Shiny app aims to utilize SAS-generated listing datasets for Multiple Myeloma efficacy data review, offering visualization and adjudication capabilities to the clinical team.

Analysis Dataset generation

Specific lab tests to support IMWG evaluation like Serum M-Protein, Serum Immunofixation, Urine M-Protein, Urine Immunofixation, Serum Free Light Chain, Plasma Cell (%), CD138+/Plasma Cell (%), Conclusion, Bone Marrow Aspirate, Bone Marrow Biopsy are required to generate Lab analysis dataset (ADLBEFF). Plasmacytoma data points like Measurable, New lesion (to calculate total area) and non-measurable along with bone lesion information are also required for Plasmacytoma analysis dataset (ADTREFF). Change from baseline, percent change from baseline, nadir, change from nadir and percent change from nadir are derived to support the analysis for required parameters. The units for the parameters are ensured to align with IMWG 2016.

Relevant lab/imaging data are:

- Serum M-protein (SPEP)
- Urine M-protein (UPEP)
- Serum Free Light Chains (sFLC), κ, λ, κ/λ ratio, |κ-λ|
- Serum immunofixation
- Urine immunofixation
- Plasmacytoma
- Bone Marrow: Number of PlasmaCells, %PlasmaCells, biopsy/aspirates
- Bone Lesion: Location Laterality, size of bone lesion increased- if present at baseline

Listings Generation

3 listings are generated from the ADaM datasets:

- Listing 1: Comprehensive Adjudication data
- Listing 2: Plasmacytomas data
- Listing 3: Bone Lesion data

Listing 1

The source for this listing is ADLBEFF and ADTREFF. This listing contains comprehensive adjudication efficacy data which includes the results for biochemical tests, bone marrow aspirate, bone marrow biopsy, measurable plasmacytomas, non-measurable plasmacytomas and bone lesions. The structure of the listing is one record per subject per visit per date per lab name (local or central).

Listing 2

The source for this listing is ADTREFF. The listing contains comprehensive plasmacytoma data. The structure of this listing is one record per subject per visit per date per test category per assessment method per lesion type per lesion location.

Listing 3

The source for this listing is ADTREFF. This listing contains comprehensive bone lesion data. The structure of this listing is one record per subject per visit per date per assessment method per lesion location.

Specifications for R-Shiny Application

The specifications for the R-Shiny application need to be created to include all the variables that need to be visualized for data review and adjudication by the clinical team.

Deployment

The data visualization developer uses the specifications and the location of the listing datasets to deploy interactive clinical data visualizations to user acceptance test (UAT) environment.

BENEFITS

The implementation of our innovative approach results in a range of benefits:

- **Efficiency Boost:** The accelerated data review process ensures timely and insightful conclusions.
- **Data Integrity:** Thorough data quality checks are conducted, ensuring the reliability of findings.
- **Enhanced Collaboration:** Improved communication among clinical teams fosters a more collaborative working environment.

CASE STUDY

To exemplify the effectiveness of our solution, we present a case study where the web application could potentially expedite the data review process in a Multiple Myeloma study.

FUTURE WORK

Further exploration could involve real-world implementation, gathering user feedback, and continuous refinement of the web application based on the evolving needs of clinical teams.

CONCLUSION

BMS's innovative approach significantly enhances the clinical efficacy data review process. This web application promises streamlined, efficient, and comprehensive evaluations for Multiple Myeloma studies. The integration of R Shiny's web application transforms the landscape of data assessment, driving towards more efficient and insightful conclusions.

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