

Introduction

The clinical research landscape is rapidly evolving, driven by increasing complexity in trial designs, regulatory expectations, and the need for faster decision-making. Traditional static listings often fall short in providing timely insights, making it challenging to detect emerging safety signals proactively.

Objective

- Automate & Prioritize safety signal detection.
- Integrate SAS & Tableau for scalable, visual monitoring.
- Enable proactive Decisions through timely insights.

Methodology

- 01 Data Sources:** AE, CM, VS, Dose, ECG & LAB
- 02 SAS Framework:**
 - Rule-based scoring for Grade ≥ 3 AEs, SAEs, AESIs, lab shifts, dose interruptions Risk score assignment logic.
- 03 Tableau Dashboards:**
 - Visualize risk scores from rule-based scoring.
 - AE timelines, lab shift plots, boxplots.
 - Cross-domain signal views for comprehensive safety insights.

Results

- Interactive dashboards (Visual 1.1) display Total Risk Scores and cross-domain views.
- Dynamic visualizations (Visual 1.2) of AE timelines, box plots, and lab shift values.

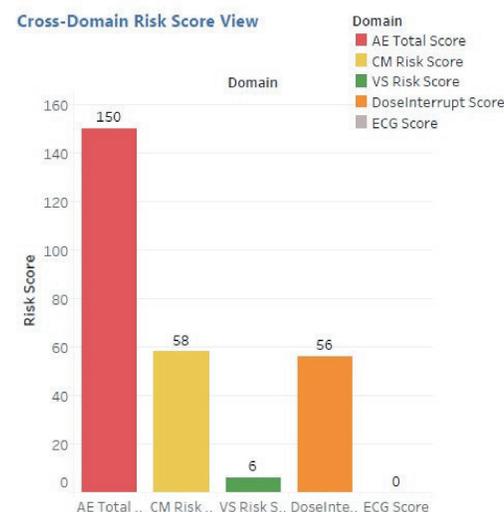
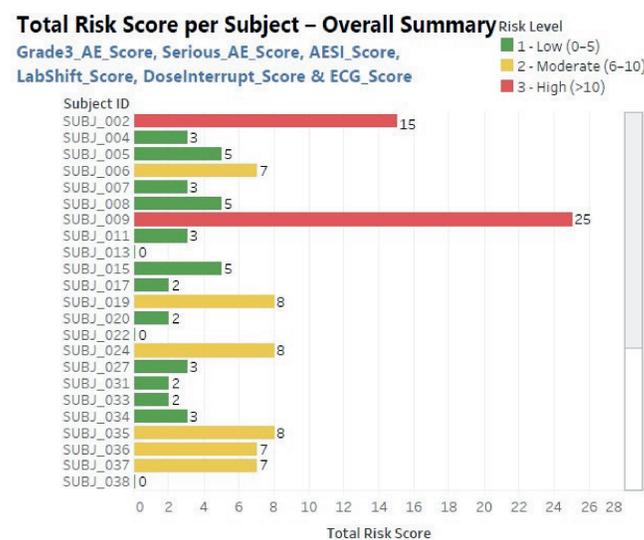
Discussion

- Identify high-risk subjects/timepoints via interactive analytics.
- Reviewer efficiency and signal traceability.

Conclusion

- Summary of impact: transforming static listings into dynamic safety oversight.
- Future directions: integrating ML models.

Visual 1.1



Visual 1.2

