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Interactive Safety Data Visualization Platform: Transforming Adverse Event Analysis Through Dynamic Dashboards in Clinical Trials

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ABSTRACT

Traditional safety data presentations in clinical study reports rely heavily on static tables, requiring manual review of extensive tabulations to identify adverse events (AEs) and serious adverse events (SAEs) of special interest. This process is time-intensive, tedious, and prone to oversight, particularly given the regulatory guidance requiring comprehensive safety endpoint presentations including confidence intervals, Kaplan-Meier estimates, and treatment comparisons at System Organ Class (SOC) and Preferred Term (PT) levels. We developed an R Shiny web application featuring interactive adverse event safety tables with advanced filtering, searching, and collapsible hierarchical display capabilities. The platform was built using pre-analyzed datasets from statistical computing environments without performing in-app derivations, thus avoiding the need for additional validation. The interface prioritizes minimalism and usability to reduce cognitive load, with dynamic filtering, drill-down, and search that streamline exploration of lengthy outputs. Users can efficiently explore AE data by SOC and PT levels, apply multiple filters simultaneously, and focus on key safety signals without manual table navigation. The interactive safety data visualization platform represents a significant advancement in clinical trial safety analysis, addressing regulatory guidance requirements while dramatically improving reviewer efficiency. The minimal viable product establishes a foundation for future enhancements, including Kaplan-Meier curve visualization and expansion to additional safety datasets. This approach demonstrates the transformative potential of interactive data visualization in regulatory science and clinical decision-making.

INTRODUCTION

The evaluation of safety data represents a critical component of clinical trial analysis and regulatory review. As emphasized in the ICH E9 guidance, "Late phase - controlled trials represent an important means of exploring in an unbiased manner any new potential adverse effects" (ICH E9, 1998). However, the traditional approach to safety data presentation has remained largely unchanged for decades, relying on static tables that present frequency counts, percentages, and basic statistical summaries across treatment groups.

The recent FDA 2022 guidance on safety data presentation has elevated expectations for safety analyses, leading to additional analysis including - Confidence intervals for treatment comparisons, Kaplan-Meier risk estimates at specified timepoints, both absolute (risk differences) and relative (hazard ratios) treatment comparisons, for safety data points. These requirements have resulted in analytical outputs that often span hundreds of pages. While comprehensive, such voluminous presentations create significant challenges for reviewers attempting to identify clinically meaningful safety signals efficiently.

The challenge lies in the review of this safety analysis. A typical late-phase clinical trial generates extensive safety data across multiple domains (adverse events, laboratory values, vital signs, ECG parameters). When presented in traditional table formats following new requirements, the resulting documentation can exceed hundreds or even thousands of pages for a single study. Reviewers must manually scroll through lengthy tables to locate specific SOCs or PTs of interest, compare treatment groups, and assess statistical significance - a process that is both time-consuming and prone to oversight.

The R shiny dashboard offers a minimalistic, easy to build solution, yet provides efficient means to review and interact with in identifying the potential safety signals.

SAFETY ANALYSIS SETUP AND REPORTING STRUCTURE

Late-phase randomized controlled trials routinely produce large and difficult-to-review safety outputs because follow-up duration varies across subjects (for example due to event-driven designs, discontinuations, withdrawal of consent, or administrative end of observation) while the safety review

must still cover a very large set of possible adverse events. In this setting, simple tabulations of crude percentages (n (%)) in the traditional setup are hard to interpret because the underlying “time at risk” is not comparable across subjects or necessarily balanced between treatment arms. Display 1 shows this traditional layout of adverse event analysis by SOC and PT. This creates a strong incentive to define safety targets in a way that explicitly accounts for time and intercurrent events, and to report treatment comparisons with uncertainty rather than only arm-specific summaries.

Template

Table 14.3.2.2

Adverse events by system organ class and preferred term - on-study period (Full analysis set)

System Organ Class Preferred Term	Drug A N=446 n (%)	Drug B N=441 n (%)	Drug C N=454 n (%)	Total N=1341 n (%)
Any AE	249 (55.8)	252 (57.1)	255 (56.2)	756 (56.4)
Infections and infestations	82 (18.4)	81 (18.4)	61 (13.4)	224 (16.7)
Appendicitis	1 (0.2)	0	0	1 (0.1)
Arthritis bacterial	0	0	1 (0.2)	1 (0.1)
Bacterial disease carrier	0	1 (0.2)	0	1 (0.1)
Bacteriuria	0	0	1 (0.2)	1 (0.1)
Bronchitis	4 (0.9)	8 (1.8)	7 (1.5)	19 (1.4)
COVID-19	4 (0.9)	6 (1.4)	2 (0.4)	12 (0.9)
Cellulitis	2 (0.4)	4 (0.9)	3 (0.7)	9 (0.7)
Cholangitis infective	0	1 (0.2)	0	1 (0.1)
Chronic sinusitis	0	0	1 (0.2)	1 (0.1)
Clostridium difficile colitis	0	1 (0.2)	0	1 (0.1)
Conjunctivitis	0	1 (0.2)	0	1 (0.1)
Cystitis	4 (0.9)	1 (0.2)	3 (0.7)	8 (0.6)
Dermatophytosis of nail	1 (0.2)	0	0	1 (0.1)

Display 1. Traditional Adverse Event summary output by SOC and PT

To improve interpretability, the safety objective can be translated into an ICH E9(R1) estimand-aligned question of the form: what is the magnitude of the increase in risk of experiencing an adverse event if treatment is taken, as prescribed, for a specific period of time? When framed this way, the relevant patient-level endpoint naturally becomes a time-to-first-event variable (time from randomization to first occurrence of the event of interest) paired with an event indicator. The corresponding population-level summaries move from crude incidence proportions to probabilities of experiencing the event by a fixed timepoint, estimated using survival analysis methods.

A key driver of both methodological and operational complexity is the handling of intercurrent events (ICEs), particularly premature treatment discontinuation and death, which truncate AE data collection and can be causally affected by treatment. An “on-treatment” approach (censoring at treatment discontinuation, commonly with a small follow-up window) focuses on events occurring during exposure and is often useful for assessing plausibly exposure-related risk. However, discontinuation is frequently informative, and some safety events may have longer latency or may still be relevant after stopping treatment. For this reason, complementary analyses are often needed, including an analysis that uses all available follow-up irrespective of treatment discontinuation, alongside the on-treatment analysis. This dual-view approach aligns with the practical need for both signal sensitivity and clinically meaningful interpretation, but it multiplies the volume of outputs that must be reviewed.

Consistent with modern expectations for safety reporting, outputs are produced at hierarchical medical coding levels, typically System Organ Class (SOC) and Preferred Term (PT), and they include explicit between-arm comparisons. For each SOC/PT category, reporting commonly includes the number of subjects with at least one event, Kaplan–Meier risk estimates at a pre-specified clinically relevant timepoint (often aligned with the primary efficacy timepoint), an absolute risk difference between treatment groups with a 95% confidence interval, and a relative comparison via a hazard ratio (for example from a Cox model with treatment as the covariate) with a 95% confidence interval. In addition, many implementations use “first event per subject per category” logic to avoid double counting within PT/SOC summaries and apply consistent censoring rules depending on the chosen analysis period definition. For rare events, estimates may be unstable or not computable, further increasing the interpretive burden.

Taken together, the combination of hierarchical SOC/PT structure, multiple analysis periods (on-treatment and all-observed), and multiple statistics per row (counts, KM risks, risk differences, hazard ratios, confidence intervals) yields outputs that can easily span hundreds of pages for a single study. This is the primary motivation for presenting the results in an interactive environment: in our approach, the Shiny application ingests pre-analyzed, analysis-ready TFL datasets (with no derivations performed inside the app) and provides dynamic navigation, search, and drill-down to make a complex but standard safety reporting structure practically reviewable.

Template

Table 14.3.2.5
Adverse events by system organ class and preferred term - on-treatment period (Full analysis set)

System Organ Class Preferred Term	Drug A N=718 n (%)	Drug A N=718 KM% (95% CI) at 6, 12, 24 and 36 months	Drug B N=698 n (%)	Drug B N=698 KM% (95% CI) at 6, 12, 24 and 36 months	Drug C N=706 n (%)	Drug C N=706 KM% (95% CI) at 6, 12, 24 and 36 months	Drug A vs Drug C Drug B vs Drug C Difference in KM% (95% CI) at 6, 12, 24 and 36 months	Drug A vs Drug C Drug B vs Drug C Hazard ratio (95% CI)
Any AE	423 (58.9)	63.1 (59.1, 67.1) 73.8 (68.4, 79.0) 73.8 (68.4, 79.0) 73.8 (68.4, 79.0)	410 (58.7)	62.7 (58.6, 66.8) 71.9 (67.2, 76.4) 73.4 (68.1, 78.4) 73.4 (68.1, 78.4)	418 (59.2)	65.1 (61.0, 69.2) 74.6 (69.3, 79.7) 89.4 (69.3, 98.6) 89.4 (69.3, 98.6)	-2.0 (-7.8, 3.8); -0.8 (-8.3, 6.6); -15.6 (-31.8, 0.6); -15.6 (-31.8, 0.6) -2.4 (-8.2, 3.4); -2.7 (-9.7, 4.2); -16.1 (-32.2, 0.1); -16.1 (-32.2, 0.1)	1.03 (0.90, 1.18) 1.01 (0.88, 1.15)
Infections and infestations	129 (18.0)	21.2 (17.9, 25.1) 27.1 (22.7, 32.2) 27.1 (22.7, 32.2) 27.1 (22.7, 32.2)	126 (18.1)	20.3 (17.1, 24.1) 27.1 (22.6, 32.3) 27.1 (22.6, 32.3) 27.1 (22.6, 32.3)	120 (17.0)	19.1 (15.9, 22.8) 24.9 (20.9, 29.6) 24.9 (20.9, 29.6) 24.9 (20.9, 29.6)	2.1 (-2.8, 7.1); 2.2 (-4.2, 8.6); 2.2 (-4.2, 8.6); 2.2 (-4.2, 8.6) 1.2 (-3.7, 6.1); 2.2 (-4.4, 8.7); 2.2 (-4.4, 8.7); 2.2 (-4.4, 8.7)	1.10 (0.86, 1.42) 1.12 (0.87, 1.44)
Abdominal abscess	1 (0.1)	0.2 (0.0, 1.5) 0.2 (0.0, 1.5) 0.2 (0.0, 1.5) 0.2 (0.0, 1.5)	0	0 (NC) 0 (NC) 0 (NC) 0 (NC)	0	0 (NC) 0 (NC) 0 (NC) 0 (NC)	0.2 (NC); 0.2 (NC); 0.2 (NC); 0.2 (NC) 0 (NC); 0 (NC); 0 (NC); 0 (NC)	Inf (NC) 1 (NC)

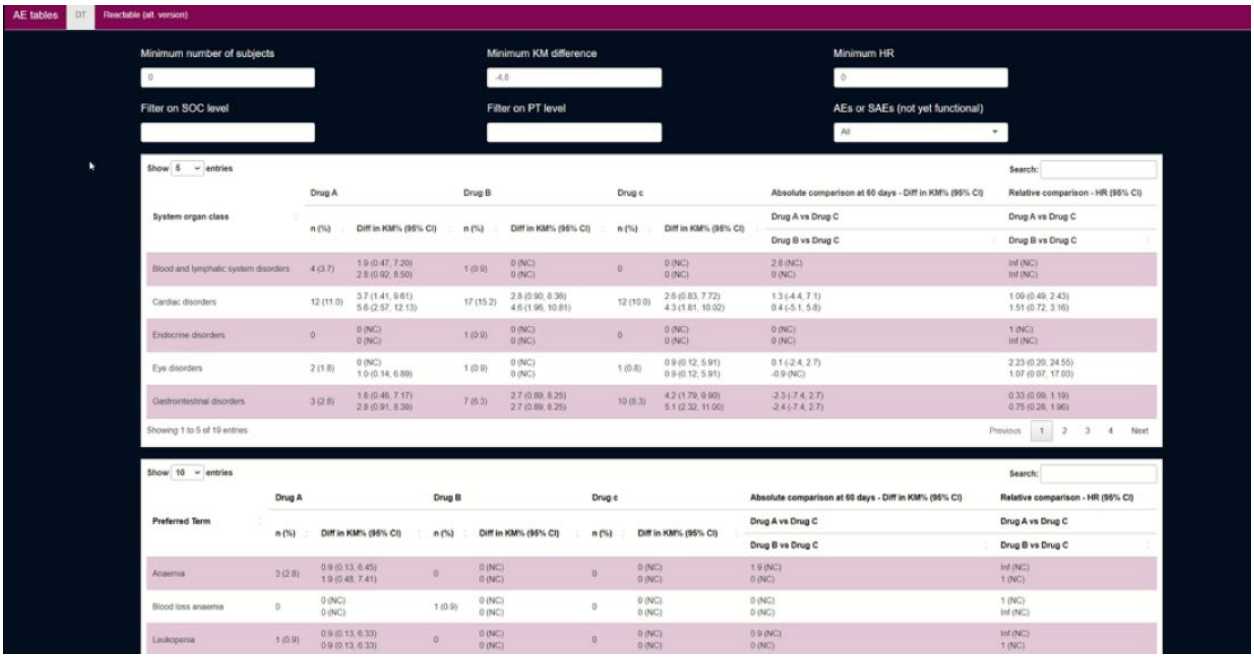
Display 2. Adverse Event summary output by SOC and PT with KM estimates and Hazard Ratios.

R SHINY APPLICATION

Interactive review of clinical safety data is not new, and existing tools illustrate both the direction of travel and the practical gaps our platform aims to address. There are many open-source applications developed by various industry workstreams and is a useful indicator of emerging expectations around interactive review. However, the design methodologies, underlying derivations and validation needs may complicate the implementation of the applications.

A central design choice in our platform is therefore to minimize validation burden by separating analysis from visualization: the R Shiny app consumes pre-analyzed, analysis-ready datasets produced by standard statistical programming (for example macro-generated TFL datasets) and performs no in-app derivations. This approach avoids duplicating complex statistical logic in the application layer and keeps the app's validation focus on data integrity, traceability, access control, and rendering correctness, rather than re-validating the safety analysis itself.

We developed this R Shiny web application featuring interactive adverse event safety tables with advanced filtering, searching, and collapsible hierarchical display capabilities. The platform was built using pre-analyzed datasets from statistical computing environments without performing in-app derivations. The application utilizes SAS Macro-generated standard TFL (Tables, Figures, and Listings) AE table datasets as input, ensuring validation and compliance with analysis requirements. Display 3 shows the web application interface with filtering capabilities on multiple data points and criteria to review the relevant events of interest.



Display 3. Dynamic Output web application interface

RESULTS

The developed R Shiny application successfully converts conventionally static adverse event outputs into an interactive, review-oriented dashboard while preserving the underlying analysis as produced by standard statistical programming. In the pilot implementation, the app ingests pre-analysed AE table datasets (for example, SAS macro–generated TFL datasets) and presents them through a minimal interface optimised for rapid safety signal exploration. A key result of this architecture is that the application performs no in-app statistical derivations, thereby avoiding duplication of validated analysis logic and keeping the Shiny layer focused on presentation, navigation, and controlled access rather than re-computation of endpoints.

From a safety reporting perspective, the platform is designed to handle the increasingly complex structure expected in late-stage safety outputs, where reviewer needs extend beyond counts and crude percentages. In line with modern expectations for treatment comparisons and the time-at-risk challenges seen when subject follow-up varies, the reviewed outputs can include, at System Organ Class (SOC) and Preferred Term (PT) levels, the number of subjects with events, Kaplan-Meier (KM) risk estimates at prespecified timepoints, and explicit between-arm comparisons on both absolute and relative scales (for example, KM risk differences with confidence intervals and hazard ratios with confidence intervals). This directly addresses a central operational burden highlighted by estimand-aligned safety thinking: once safety is framed around risk by a fixed timepoint (rather than crude incidence over variable observation), the volume of statistics per AE category increases markedly, and static table review becomes progressively less feasible.

The interface provides interactive capabilities specifically intended to reduce the cognitive and operational load of reviewing these high-dimensional outputs. Users can search across SOC/PT terms, collapse and expand the SOC-to-PT hierarchy and apply multiple filters simultaneously to focus on medically relevant subsets (for example, narrowing to selected SOCs, to PTs exceeding a chosen incidence threshold, or to rows where treatment comparisons warrant closer review). In practical use, this consolidates outputs that would typically span hundreds of pages of static tables into a single navigable view, enabling faster location of topics of interest and more consistent cross-row comparison of treatment effects.

The platform also supports review needs that arise from the presence of intercurrent events and differing analysis periods. Late-stage safety evaluation often benefits from complementary perspectives. While these perspectives are clinically and methodologically informative, they substantially multiply the number

of required tables and increase the risk of oversight when reviewed as static documentation. In the dashboard, switching between such pre-generated outputs and aligning SOC/PT exploration across them becomes materially easier, allowing reviewers to examine whether apparent signals are robust to analysis-period definitions without manually cross-referencing lengthy appendices. Finally, relative to existing interactive tools assessed during solution exploration, the results demonstrate a practical balance between capability and validation burden.

CONCLUSION

This project successfully developed and validated an interactive safety data visualization platform that transforms how adverse event data from clinical trials is reviewed and interpreted. By converting lengthy static tables into dynamic, filterable dashboards, the platform addresses fundamental limitations of traditional approaches. Ultimately, by making safety data more accessible and interpretable, the platform supports better-informed decisions about drug development, regulatory approval, and clinical use - decisions that impact patient health and public health. As regulatory agencies increasingly embrace innovative approaches to data presentation, and as the volume and complexity of clinical trial data continue to grow, interactive visualization will become not just advantageous but essential. The planned enhancements - Kaplan-Meier curves, additional safety domains, benefit-risk integration will further increase the platform's value. Beyond these specific features, the platform establishes a paradigm that can be extended to other clinical trial domains, supporting a broader transformation in how clinical trial data is analyzed, presented, and interpreted.

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