

Case Study

Modernizing SRC Workflows Through Integrated Safety Visualizations

Traditional Safety Review Committee and Data Monitoring Committee workflows often depend on static tables, listings, and PDF review packs. Answering one safety question may require reviewers to cross-check separate adverse events, laboratory, concomitant medication, dosing, and patient listings. This creates preparation and reconciliation work, while meeting time can be spent locating information rather than interpreting findings and agreeing next steps. Questions raised during review may also require additional programming and follow-up outputs before they can be resolved.

A clinical-stage biotech partnered with MMS to support recurring SRC review for a Phase 2a study. MMS brought data from multiple external sources into Datacise® Explore and provided standard and study-specific visualizations, statistical support, SRC preparation, project management, and safety reporting. This gave the sponsor and committee a shared review environment where they could examine study-level findings and move into relevant patient-level detail without relying solely on disconnected reports and listings.

The Challenge

The study required frequent SRC review across two study parts with safety-relevant information generated through eCRF, and several third-party vendor data sources including participant diaries. The sponsor needed a practical way to bring this data together for committee review while preserving the clinical context needed to investigate emerging questions.

The solution also needed to be straightforward for both the sponsor and SRC members to adopt. Rather than adding a complex standalone platform, the goal was to strengthen the existing review workflow and support committee preparation, discussion, recommendations, and reporting, while maintaining a regulatory ready audit trail of Safety Review Visualization contents.



The Solution

MMS implemented Datacise® visualizations specifically for the sponsor's SRC workflow with delivery phased so that the most important safety views were available from the first meetings, and additional views were introduced as needs developed.

The solution combined standard dashboards covering adverse events, concomitant medications, laboratory results, and data management with study-specific views for dosing, protocol deviations, and study specific safety signal summaries. These were supported by regular data refreshes, validation, and preparation for each SRC meeting.

This was implemented as part of a broader engagement including statistical input, SRC preparation, project coordination, meeting support, and interim safety reporting.

The Impact

The sponsor and SRC gained a shared, interactive view of the study data needed for recurring safety review. Committee members could move from summaries and trends into relevant subject-level information, helping them explore questions with greater context during the review process.

The approach reduced dependence on separate static listings and created a more connected workflow across data review, committee preparation, statistical support, recommendations, and safety reporting. It also provided a practical foundation that the sponsor could extend as its oversight needs evolved.

MMS gave the sponsor a practical way to modernize safety review without implementing and managing a heavy standalone platform. By connecting study data, interactive review, statistical expertise, and committee support, the model enabled the SRC to spend less time navigating fragmented outputs and more time evaluating findings and supporting timely study decisions.

Success Factors

- Proactive project management kept delivery aligned with the SRC schedule, prioritized the most valuable safety views, and adapted the solution as review needs evolved.
- The Datacise® foundation unified access to data from multiple study systems, giving reviewers a connected path from study-level trends to relevant patient-level detail.
- MMS' statistical and operational experience supporting safety review committees shaped a practical workflow around committee preparation, discussion, recommendations, and reporting.



Let's Talk!

If you'd like to discuss this case study further or learn more on how our technology-enabled services can support your next clinical trial please visit mmsholdings.com or get in touch info@mmsholdings.com