In-Stream Safety Review: Vital Challenges

With the staggering complexity and volume of clinical trial data, the risk of missing a safety signal for medical monitors and safety review teams is growing exponentially. In a recent informal survey, 37% of respondents cited the risk of missing a safety signal as their single greatest challenge in medical review, followed by slow decision making and the high cost of supporting analytics infrastructure. This risk can place organizations in danger of a delayed or rejected submission or even a market withdrawal, while compromising the safety of trial subjects.

Faster Review, Decreased Risk, Lower Cost

The key to getting submission ready faster is speeding the time to review, collaborate, and make decisions on data. Signals Medical Review allows you to cut through the noise to go straight to the subjects of interest, and analyze data for those subjects with exactly the visual analytics you need:

Tailor-built Workflow

AT A GLANCE

PerkinElmer Signals Medical Review empowers medical monitors to detect safety signals faster and reduce time to submission by combining innovative workflow and advanced analytics.

- Powered by TIBCO Spotfire® visual analytics
- 360 degree visibility across CDISC domains with built-in patient profiles
- Single unified data analytics solution – from source to visualization to action
- Curated analytics experience with configurable alerts on cohorts of interest
- Medical Review status reporting and tracking
- Secure, regulatory compliant cloud solution

Quickly find what you need with workflows built specifically for the medical monitor. And, explore data with curated analytics based on therapeutic area and study design.
Missing a safety signal is the #1 concern of medical monitors. With Signals Medical Review, you can reduce the risk of missing a safety signal, and simultaneously reduce the risk of a market withdrawal or rejected submission, by increasing data visibility. Signals Medical Review is:

Configurable Alerts

Configure and track cohorts of interest throughout the study and quickly identify and investigate potential safety signals.

Track Line Listing Review

Configure which domains of data require review and track review progress and audit trail.

Secure Cloud

The Signals Medical Review SaaS application meets the demanding requirements for performance, security, and compliance with your clinical data.

- The PerkinElmer Cloud allows for automatic application updates without complex upgrade projects
- Allows for lower total cost of ownership (you don’t have to manage IT and servers)

Signals Data Factory

Store all your vast and disparate clinical data and access it when you need it.

- Expedites the process of setting up new studies
- Allows for the persistence of data (perfect for cross-study and historical data analysis)
- Expedites data unification and SDTM standardization

Configure which domains of data require review and track review progress and audit trail.

For more information on PerkinElmer Signals Medical Review visit www.perkinelmer.com/smr