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Safety 360 – A Holistic Approach to Pharmacovigilance

By Bruce Palsulich

Safety is paramount in the development of new therapies and treatments. As such, pharmacovigilance requirements and methodologies continue to evolve to reflect new technologies and current best practices. Increasingly, life sciences enterprises seek a holistic approach to pharmacovigilance that enables 360-degree visibility and a new level of insight and efficiency.

One of the greatest changes in recent years has been the desire and need to capture and analyze safety information from a growing number of channels. These new data types extend well beyond traditional sources, such as patient-reported data, clinical trials, and registries, to encompass electronic health records and usage and outcome information. Increasingly, organizations are looking to mine unstructured data, such as scientific literature and social media interaction, for safety information.

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At the same time, life sciences enterprises are facing a new level of surveillance complexity as governments, the world's largest healthcare payers, are expanding efforts to achieve the greatest benefit for their growing expenditures. Recently, this has manifested itself in regulations tying pharmaceutical pricing to relative benefits compared to existing treatments. To this end, global regulators are increasingly leveraging medical records to perform active surveillance on post-marketed products. To be as informed as the regulators in this new paradigm, pharmaceutical enterprises must incorporate observational studies into their standard pharmacovigilance protocol.

While working to navigate this new landscape, life sciences organizations also continue to battle perennial challenges: rising case volume, expanded reporting requirements, shorter turnaround timelines for responses, and decreasing safety team resources.

In response to these changing requirements, the industry is experiencing a paradigm shift from pharmacovigilance rooted in case processing and compliance reporting to a safety program built around benefit-risk management. Instead of tackling safety issues on a case-by-case basis, life sciences organizations seek a more complete understanding of trends in various adverse effects – including patient risk factors, medication errors, and more – to minimize the risk of safety issues moving forward.

A 360-degree approach to safety is the new gold standard in this rapidly changing environment. It enables a holistic view of safety by capturing information from traditional as well as emerging sources. Equally important, it gives enterprises the power to rapidly operationalize this information and automate its workflow.

Suppose a pharmaceutical enterprise sees that social media spiked during August with negative mentions of its new treatment for Hepatitis C. 360-degree safety capabilities would enable the firm to rapidly review sources

of social media as well as general news media and review similar data for competitive products in the same class, while creating a workflow for competitive benefit-risk review. Ideally, workflow would then promote a review of operational metrics for the potential increased number of serious adverse events and set a trigger for a review next month. Next, the workflow would initiate a review of signal detection analysis on the product and a search against existing scientific literature. The clinical team would then perform an analysis against medical records. The team would also record its observations for incorporation in the next Periodic Benefit-Risk Evaluation Report.

In their quest to achieve the new gold standard for pharmacovigilance, life sciences organizations are taking a hard look at their safety infrastructures. In many enterprises today, signals enter the pharmacovigilance process from diverse systems, and significant manual intervention is required to aggregate disparate signal data into a single location. The data must then be transferred to another environment for interrogation and analysis, often involving a combination of manual transfer and point integrations, which slow down processes and can compromise data quality. In short, the legacy environments in many organizations prohibit the multi-source visibility, end-to-end integration, and automated workflow from signal detection to aggregation to analysis and reporting that are required for a 360-degree approach to safety.

Enterprises require a platform that enables them to integrate, visualize, and operationalize data from diverse information sources to support evolving safety requirements (including benefit-risk profile evaluations and real-world effectiveness studies), improve overall accuracy, and support benefit-risk management – all while putting the power of data and analysis in the hands of safety teams, as opposed to IT professionals.

Adoption of a 360-degree approach to safety represents a significant paradigm shift for the industry – one that will require organizations to question and rethink long-standing processes and systems. Enterprises that remain steadfast on this journey will be in a position to reap several important benefits, including reduced risk, increased agility and insight, and improved efficiency, even as regulatory mandates continue to evolve and expand.

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