Dialog Solutions

An End-to-End Approach to Drug Safety Literature Monitoring

Among the many complex and time consuming tasks pharmacovigilance (PV) teams sweat over every day is accurately identifying adverse drug events from biomedical literature to help determine the benefit-risk profile of a drug. PV teams have to sift through a vast and growing library of biomedical literature and cross-disciplinary reports to review, document, and report the efficacy and safety of a drug. The sheer volume of data available is overwhelming and growing each year; even in the most precisely constructed searches, less than five percent of references retrieved are said to be relevant. Specifically, just 4.12 percent of references are ICSR reportable, and Safety Signals account for only 0.12 percent of the literature. Add to this the increasingly stringent global regulations and compliance requirements, and pharma companies are faced with inefficient, siloed, and time-consuming processes that lead to additional operating costs and overheads. The need of the hour is a novel, extensive, cost-effective, and efficient literature monitoring solution that aligns with continuously evolving regulatory and strategic requirements.

Enter Dialog Solutions' end-to-end biomedical literature monitoring solution that offers a modular approach to literature surveillance for PV. The software gives any organisation tasked with drug safety reporting a streamlined, efficient, and compliant path to the entire literature triage process. With Dialog Solution's biomedical literature monitoring system, PV teams can efficiently and cost-effectively manage an increasing workload while remaining compliant with regulatory best practices. Michael Rai, general manager of Dialog Solutions, says, "We provide our clients with the right tools needed to review literature articles in the quickest time possible. At every stage of the biomedical literature monitoring process, we help pharmaceutical companies save time and money."

Without the right review team in place, even the best PV workflow can miss articles for ICSRs, aggregate reports, and safety signals or struggle with peaks in review volumes. Dialog Solutions delivers the necessary platform that pharmaceutical companies, contract research organisations, medical device manufacturers, biotech and biopharma companies need for performing a more streamlined and compliant monitoring process.


Michael Rai

Dialog Solution's end-to-end pharmacovigilance literature monitoring workflow includes the Dialog content platform, Dialog Alerts Manager, Drug Safety Triager, and Dialog Solution's literature review services team. Using the Dialog search platform, PV teams can precisely access and search biomedical literature databases, and identify all relevant drug safety results. "We standardise all our medical literature database content to provide a consistent and comprehensive search experience, eliminating the need for complex post processing," adds Rai. Dialog Alerts Manager simplifies the process of automating and managing multiple drug safety searches in the platform. The literature triage solution's automated workflow ensures that all articles are methodically ingested, processed, and outputted for drug safety issues. The system streamlines the literature monitoring workflow

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by eliminating duplicated content, reducing the volume of articles to be reviewed, and automatically outputs literature references relevant to patient safety issues.

But what's truly unique about the Drug Safety Triager solution is it seamlessly ingests relevant alert results and then deduplicates and ranks ICSRs for relevancy. This helps reviewers to improve the quality, speed, and efficiency of the literature review process. The Drug Safety Triager is also fully validated and compliant with the reporting requirements of the regulators, including the FDA, EMA, and PMDA. "There are a lot of vendors out in the marketplace today that offer different aspects of biomedical literature monitoring as outsourced services. We do all of it under one roof, providing us a strong understanding of the areas of the process to continually improve," informs Rai.

The firm also has literature review services teams that work as an extension of the client's business and adapts to their specific needs. They utilise the different solutions offered by Dialog Solutions to more accurately and efficiently ensure that ICSRs aren't missed and relevant non-ICSR articles are processed appropriately. "Everything our team does is set against strict quality measures, forming part of the validated literature workflow," affirms Rai. "In short, we offer more than just software and services for PV. We provide businesses with the consultancy and support they need to ensure their drug safety reporting processes are compliant, validated, and efficient. We work together with our clients to put in place the processes, technology, and teams needed to meet pharmacovigilance obligations."

Over the years, the firm has helped several leading biopharmaceutical companies decrease the time spent on monitoring literature for aggregate reports and safety signals by around 70 percent, minimise the time it takes for literature reviewers to monitor literature for ICSRs by 50 percent, and shorten drug alert set up time by 80 percent. For the road ahead, the company has several plans. Predominantly, Dialog Solutions will continue to develop and iterate its current platform to improve functionality. The firm is also working on launching its enhanced relevancy ranking for ICSR and reducing ICSR review time. Alongside this, Dialog Solutions continues to embrace process automation and work on the case processing component of PV to improve overall process efficiency. ph