White Paper

The Next Frontier of Drug Safety Innovation: AI-Supported Signal Management

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Introduction

Safety signal management is the process of detecting and assessing adverse event data and relevant supporting pharmacologic, clinical, and epidemiologic evidence to determine if there is a new risk associated with a medicinal product or if an existing risk has evolved. For over 20 years, companies have utilized quantitative and qualitative methods to detect potential signals that require further investigation. Manual selection of relevant data and its subsequent review have underpinned the signal analysis process and been a resource-intensive exercise performed by a Team of Pharmacovigilance (PV) experts.

The rapid growth of data volume and source complexity, coupled with advances in technology has led pharma companies, regulators, technology providers, and industry bodies to explore opportunities for AI to strengthen signal detection and analysis, enabling faster identification of patterns across treatment categories and patient populations.

Agentic AI offers a promising approach for assisting signal management. These systems can autonomously adapt to new data, prioritize tasks, and proactively identify emerging risks while maintaining traceability and alerting for human oversight as needed. This capability aligns perfectly with the dynamic nature of PV, where timely and context-aware decisions are critical.

Opportunities for innovation in the signal management space

Technological advances and the desire to reduce the operational burden of signal management have strengthened the drive to improve signal-related processes. Over the past few years, the following trends have been driving the need and opportunity for change:

1. A growing regulatory emphasis on improving signal and risk management
2. Increased interest in utilizing supplementary data sources for evidence
3. Increased industry adoption of AI
4. A desire to move toward widespread use of predictive analytics

Data mining algorithms and manual data review have long been the accepted approach of regulators to detect and validate signals. Regulators and Marketing Authorization Holders (MAHs) have researched and refined disproportionality algorithms over the years, but traditional frequentist and Bayesian methods have not significantly improved the false positive rate for many MAHs, resulting in a time-consuming analysis step. There is a desire and mindset shift across industry to identify how technology can be best utilized to support PV experts in signal management.

Over the past ten years, regulatory-led and -backed initiatives including IMI PROTECT, DARWIN EU, and FDA Sentinel have paved the way for continued research and improvements in this area. In 2025, a new initiative from the Innovative Health Initiative (IHI) consortium outlined its focus on AI-powered signal detection in PV and will bring regulators, industry, and researchers together to improve the speed and accuracy of signal detection, which should in turn reduce the burden of the subsequent analysis.

The availability of data has increased exponentially and will continue to grow alongside the expectation to utilize all relevant evidence in signal management. While Spontaneous Reporting Systems (SRS) have long been the standard data sources, regulators and industry have demonstrated successful use of Real-World Data (RWD) in specific scenarios, including in retrospective observational studies utilizing electronic health records as a supplementary source. With advances in AI, it is now more achievable to harness RWD for routine signal management by utilizing Natural Language Processing (NLP) and Generative AI (GenAI) for the extraction of relevant data and to address identified challenges with standardization and quality. This stands to benefit small companies working in therapeutic areas with lower spontaneous reporting rates and more specialized data, e.g., rare diseases and precision medicine.

Across the industry and all stages of the drug development and manufacturing lifecycle, AI tools are being implemented to increase efficiency and reduce resource overload. In June 2025, the FDA launched Elsa, a GenAI tool to help FDA employees work more efficiently; thus far, Elsa has been used to speed up clinical protocol reviews and evaluations.[1] From a drug company perspective, GSK has implemented PVLens, an automated system that extracts labeled safety information from FDA Structured Product Labels (SPLs) to enhance PV with improved accuracy and insight.[2] These advancements indicate a changing tide as the industry realizes the benefits of how these AI solutions can augment product lifecycle management.

In an IQVIA-commissioned survey and study conducted by IDC, real-time signal detection is forecasted to become the primary focus area for automation initiatives in the next two years.[3] We have already started to implement AI solutions to support signal management, but within the near future we can see the potential to revolutionize how we manage patient safety as a whole. Predictive AI analytics can be used to identify long-term patterns in the data to help companies predict signal trends for their drugs and answer questions that have yet to be asked. Agentic AI can be used to seek out patterns, contextualize findings using multiple sources, and recommend next steps. As a result, they can take more proactive approaches to safety, replacing the retrospective routine activities that are adopted today and accelerating overall decision-making.

Where could AI implementation benefit safety signal management?

While much of the data review for signal management has historically been manual, with an agentic AI approach, these processes could be automated to increase efficiency and reduce manual work. When and where it makes sense to introduce AI into a signal workflow may differ based on the needs of a pharma company and their existing processes. Let's consider a few scenarios where AI could streamline signal management.

Scenario 1: Detection algorithm improvement

AI is being applied to develop better algorithms that can uncover potential signals and consolidate information from various sources. Both *k*-means and random forest algorithms have been explored in signal detection, and the IHI consortium is now exploring algorithms to enable faster, more accurate signal detection, marking a drastic shift from the disproportionality algorithms — Empirical Bayes Geometric Mean (EBGM), Information Component (IC), Proportional Reporting Ratio (PRR), and Reporting Odds Ratio (ROR) — that have been widely used in signal detection over the last twenty years.

While signal detection has traditionally been performed on a monthly or quarterly basis, AI workflows are driving a shift toward real time detection that refreshes as new data comes in. Predictive analysis is another possible advantage, thanks to AI's ability to detect trends across compounds and adverse events that can help forecast a product's safety profile. With this added color, companies could gain greater insight into not only what is happening with their current drugs but also how they want to focus their development efforts.

Scenario 2: Data contextualization

When data volumes are high and coming in a variety of different formats — including company data, literature, labelling documents, the FDA Adverse Event Reporting System (FAERS), the EudraVigilance Data Analysis System (EVDAS), or other health authority documentation — relying solely on key words for qualitative signal detection may be less effective. This is due to differences in the way information is reported across these diverse sources.

AI can be used in signal management to uncover potential trends in specific populations or through related terms while including supporting evidence in its response. It can also be used to reduce false positives and identify connections in multi-source data. AI will augment the previously manual signal analysis step and ensure that traceability is maintained, so that users can rapidly uncover insights within their data to form their evaluation of a signal.

Scenario 3: Data summarization

AI can be leveraged to conduct data extraction from health authority documentation, competitor labels, and literature to build a comprehensive picture of a product. GenAI can assist in creating data summaries for critical analysis of a signal. Teams can then review AI output to gain insight and aid decision making. As new data is received, agentic AI can not only summarize the data, but dynamically update the analyses as new evidence emerges, creating a 'living' signal assessment. Pharmacovigilance teams can receive actionable insights faster, while still retaining full control through human-in-the-loop validation.

How is IQVIA approaching AI in safety signal management?

IQVIA's existing signal management solution, Vigilance Signal, will be enhanced with AI capabilities to deliver next-generation pharmacovigilance functionality. This evolution is being shaped in close collaboration with our customers. The objective is to create a unified data lake of information across multiple sources, including structured sources (e.g., regulatory databases) and unstructured sources (e.g., electronic health records and social media) to pool data for the comprehensive and efficient analysis of signals. To ensure reliability and compliance, IQVIA will use a step-based approach to implementation to ensure the system functions as intended and can be validated effectively.

Because the platform can assess both structured and unstructured data sources, it will be adaptable to different types of companies, from emerging biotechs to large pharma dependent on the sources they wish to review for their portfolio.

Thanks to our broad experience with AI solutions, IQVIA has an established and auditable approach to AI validation and governance, which we have built in from the earliest stages of product and process development. AI governance is used to determine whether AI would be feasible in specific use cases. For instance, AI will be turned on only in situations where we retain control over and can validate that the right information is being gathered. When summarizing data for a signal, AI must correctly assess the context and information across various sources. To achieve this, IQVIA is designing and testing precise prompt engineering approaches to ensure that AI responses are relevant and correct.

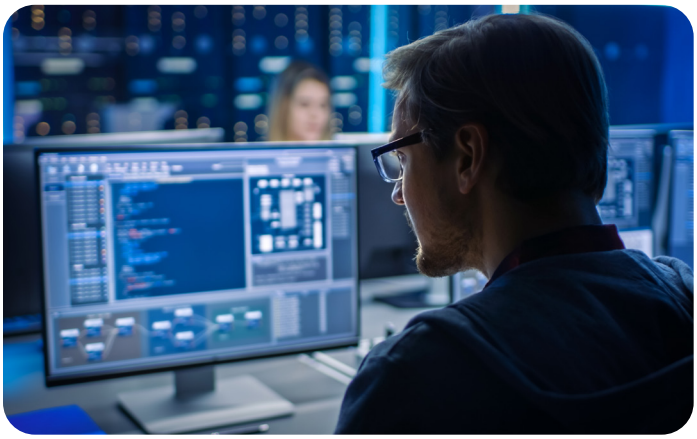
To further protect these workflows, the tool will require a human in the loop throughout the process. In safety signal management, a human will create the initial command to compile the necessary analysis and then review the AI's output. The AI must be traceable, providing a step-by-step explanation of how it reached its conclusions. This allows humans to verify the information and maintain confidence in the results.

As regulatory guidance evolves, agentic AI stands out as a practical and future-ready solution. By combining autonomy with robust governance, it enables pharmacovigilance teams to move from reactive to proactive safety management where they can anticipate risks before they materialize.

What's on the horizon?

Though there is some hesitation about adopting AI for safety, recent regulatory guidance from both the FDA and EMA is providing further insight and education to pharma companies looking to reap its rewards and enhance patient safety offerings. Ideally, the industry will continue to identify pathways to share AI insights and discoveries, which will foster collaboration across stakeholders, ultimately saving time and money.

Opting to work with a partner that has extensive experience with AI and an established commitment to AI governance will help your team benefit from AI-enabled signal management while securing the safety of your data and processes along the way. We are committed to engaging with industry to share learnings and to enhance safety signal management with AI. By collaborating across different segments, we, as an industry, will be well positioned toward ensuring better patient safety for all.



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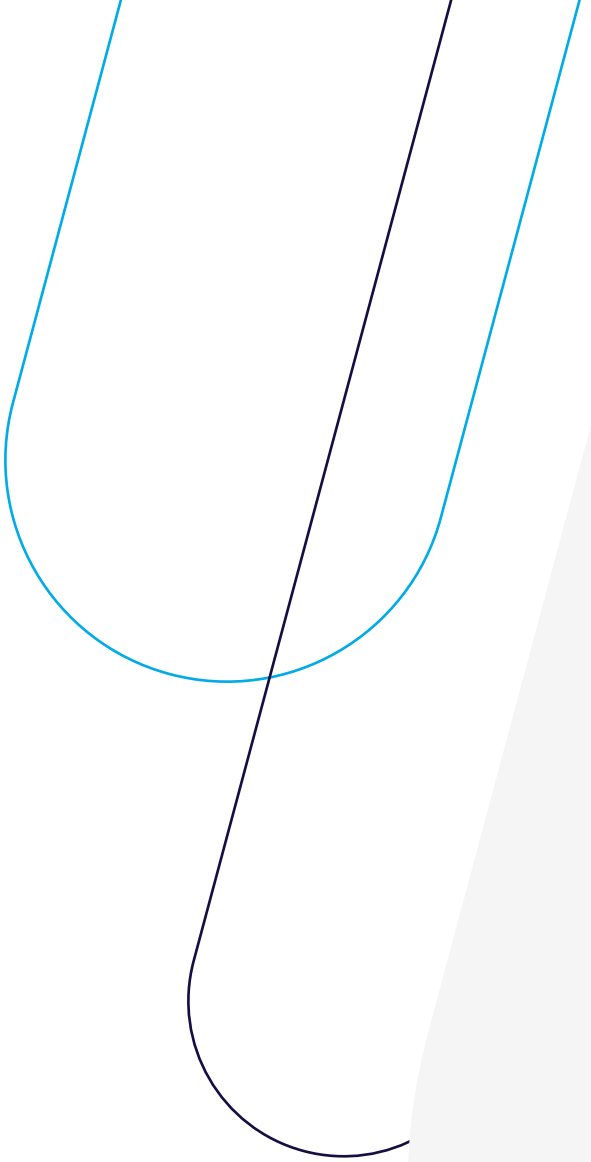
She is responsible for driving the overall strategy for IQVIA's signal detection and management solution. She is focused on identifying innovative opportunities to continuously improve the solution and support evolving requirements. Senn has fourteen years of experience within safety and pharmacovigilance, and worked within the industry before joining IQVIA in 2018. She utilizes her knowledge and first-hand experience in signal management to guide and support clients in the adoption of optimized, compliant signal processes. Senn obtained her bachelor's degree in Neuroscience from the University of Manchester and passed her master's degree in Drug Development Science with Distinction at King's College London.



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