White Paper

The Answer To Your Pharmacovigilance Challenges: AI-Powered Adverse Event Detection

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Introduction

As AI and Machine Learning (ML) technologies expand their reach across a wide range of industries, the Pharmacovigilance (PV) and device safety space is no exception. Due to the growing number of sources for Adverse Events (AE), pharma companies are navigating previously unprecedented volumes of data from which they must identify AEs and extract Individual Case Safety Reports (ICSRs) to protect patient safety and ensure regulatory compliance. As a result, many companies are turning to AI-powered solutions to help safety professionals process these large data volumes more efficiently and accurately.

But, to embrace the power of AI-enabled safety solutions, pharma companies must be confident in their chosen system's ability to produce reliable results and maintain alignment with the latest regulatory guidelines. The solution? Activating a proven, AI-supported PV platform that is backed by rigorous AI governance and expert-in-the-loop support to improve the accuracy and precision of AE detection.

What concerns accompany AI implementation in drug and device safety?

Despite the efficiencies demonstrated by AI, pharma companies may be hesitant to use it in a safety-regulated environment due to three primary concerns:

1

Lack of reliability

Inaccuracies in AE identification, case narratives, and/or signal detection can have direct consequences for patient safety. Generative AI models can "hallucinate" — producing factually inaccurate or misleading outputs — which can present a major risk to patient safety and regulatory compliance.

2

Data privacy and security risks

Drug and device safety teams deal in highly sensitive patient data that companies have a duty to protect. Patient data must be kept secure to remain compliant with General Data Protection Regulation (GDPR) and HIPAA laws, amongst others. Activating Generative AI (GenAI) to process and interact with this data inherently raises concerns around how to sufficiently maintain data privacy and protection and mitigate potential security risks.

3

Regulatory challenges

The speed of AI's evolution and integration has outpaced concrete and prescriptive regulation. As a result, the industry is navigating an evolving regulatory landscape. To protect their patients, their products, and their businesses, stakeholders must implement AI in a way that is compliant with current regulations and flexible to adapt as new guidance emerges.

Though concerns about AI in patient safety are valid, they are not insurmountable. Global policy initiatives and regulatory frameworks are rapidly coming online to guide AI compliance in safety workflows. The U.S. Food and Drug Administration (FDA) and U.K. Medicine and Healthcare products Regulatory Agency (MHRA) have released draft frameworks on AI usage, and the Council for International Organizations of Medical Sciences (CIOMS) XIV Working Group is currently developing a framework that focuses on the use of AI in PV and safety. Companies do not have to navigate AI implementation and compliance in a silo. With the right multi-disciplinary technology partner, they can use AI to improve AE detection. This type of partner can provide essential support through embedded AI governance, experienced experts-in-the-loop, and strategic selection of appropriate, fit-for-purpose use cases.

What is Vigilance Detect and how does it improve AE detection?

IQVIA's Vigilance Detect data safety platform is a CFR Part 11 validated Software as a Service (SaaS) safety solution that leverages validated proprietary safety ontologies to perform a first layer of review to surface safety risks in large and diverse data sets. GenAI is used to further refine for accuracy and context. Easily integrated with any downstream intake software, this system supports and accelerates global safety process timelines, reduces cost and complexity, and futureproofs AI use cases. With AI and ML support, Vigilance Detect provides more accurate AE detection, false positive reduction, proactive safety risk identification, and efficient ICSR data extraction. In concert, these capabilities significantly enhance and accelerate safety workflows.

Vigilance Detect was originally purpose-built for safety surveillance by safety professionals to accurately identify and classify AEs, special scenarios, and product risks within a wide variety of data sources, including CRM, social media, Chatbot, audio, and PDF data. It does so across millions of records annually and over the past decade in production, it has yielded results in 60-90% efficiencies over human review. Now, powered by GenAI, Vigilance Detect demonstrates dramatically enhanced precision and accuracy.

By the numbers, Vigilance Detect powered by GenAI has exhibited the ability to reduce false positive rates by nearly 80%. In one case study of 2500 audio files, a Vigilance Detect process supported by GenAI resulted in 94% precision, 99% accuracy, and an 81% reduction in manual review for the client. The platform streamlines safety activities and accelerates processing by reducing redundant data and manual review.

With automatic narrative generation, Vigilance Detect generates report snapshots for human-in-the-loop oversight to save valuable time for safety professionals. The embedded scoring mechanism assigns confidence levels based on GenAI's certainty in accurate data extraction so that a reviewer can determine whether further review is necessary. The platform can be activated for both prospective and retrospective reviews of any source type. While many clients prefer that data is monitored on an ongoing basis (prospective review), others use Vigilance Detect to assess past data to support audit and inspection prep (retrospective review).

What is IQVIA's approach to AI governance?

IQVIA has a long-established track record as an industry leader in AI solutions across healthcare. Thanks to industry partnerships, including with NVIDIA, IQVIA already has several AI solutions on the market. Built on a foundation of experience, the company's commitment to responsible AI usage guided by human oversight is a core tenet of the Vigilance Detect platform. IQVIA ensures AI safety and reliability through a comprehensive approach that includes:

- **Human-in-the-loop safeguards:** Contest and redress mechanisms are deployed with defined feedback loops alongside continuous human oversight to guarantee responsible AI use. IQVIA always has a subject matter expert as the human-in-the-loop or on-the-loop. These methods assure transparency and explainability
- **Embedded governance:** AI governance is built into IQVIA's AI-powered safety systems by design. A reliable AI governance model considers the entirety of an AI implement to assess risk and establish regulatory adherence every step of the way. At IQVIA, the AI governance model considers all potential risks, evaluates their consequences, and determines where human interaction is necessary
- **Lifecycle and application specific controls:** Each model follows a defined development and deployment lifecycle, including CSV-based approaches tailored to GenAI and specific applications and supported by credibility assessment reports

With these procedures in place, companies can secure data, remain compliant, and deploy AI responsibly across workflows.

What's next?

Vigilance Detect has long supported companies in their detection of safety risks; now, a GenAI-powered version of Vigilance Detect is slated to go live in the winter of 2025. This innovative technology delivers rapid and accurate AE detection and safety data extraction in formats compatible with any upstream and downstream systems to enable efficiency and reliability while easing the burden on safety, quality and regulatory professionals. By working with a partner experienced in implementing AI-workflows, companies can ensure compliance and safety governance, protecting patients and future proofing safety workflows.

About the authors

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Anuradha Prabhakar (Annie) is an Associate Director of Product Management for IQVIA's Vigilance Detect (safety risk identification technology). With over 20 years of professional experience, including more than a decade in PV, Annie has a proven track record of managing large and complex projects for leading global pharmaceutical companies. Her expertise spans product release management, pharmacovigilance remediation, automation, and digital governance.

She holds a Master's degree in Computer Applications from the University of Mysore. Her commitment to driving innovation and digital transformation in manual pharmacovigilance workflows has been a cornerstone of her career.

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Sanmugam Aravinthan, Senior Director of Product Management for IQVIA's Vigilance Detect, leads the product management and delivery of a solution designed to optimize the detection of AEs, product quality complaints, and other safety risks across large-scale structured and unstructured data sources.

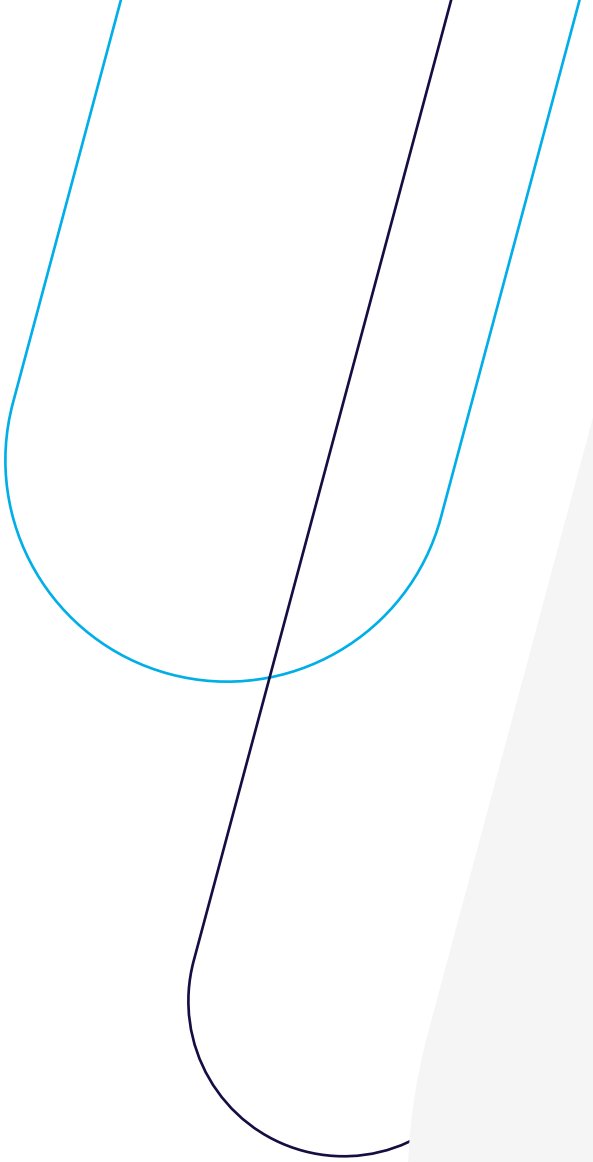
With over 20 years of industry experience in software engineering and systems development — including the past decade focused on the pharmaceutical and life sciences sectors, he has a proven track record in directing software product development, managing technology delivery for clients, and leading pharmacovigilance operations during client implementations.

He is also the holder of two U.S. patents titled "System and method for multi-dimensional profiling of healthcare professionals" and "System and method for detecting drug adverse effects in social media and mobile applications data."

Ready to transform your safety workflows with proven, GenAI-powered precision? Visit our website or email us at vigilancedetect@iqvia.com to learn more.

About IQVIA

With more than a decade of experience in AI, IQVIA is well positioned to lead the industry in ensuring governance is in place. We advocate for policies that prioritize patient benefits and manage risks, ensuring AI is developed and deployed in the most ethical and responsible way. IQVIA AI Governance works with industry partners globally, and as members of the World Economic Forum AI working group — help define AI global policy and regulations. We drive efficiency through standards and have an intellectually rigorous approach to the development of AI with over 200+ AI scientific publications, publish AI benchmarks and dedicated AI data scientists



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