Technology Networks

How AI Is Moving From Promise to Practice in Pharmacovigilance

Pharmacovigilance is entering an AI-driven era—see how adoption is evolving and what comes next.

Blog Published: April 7, 2026

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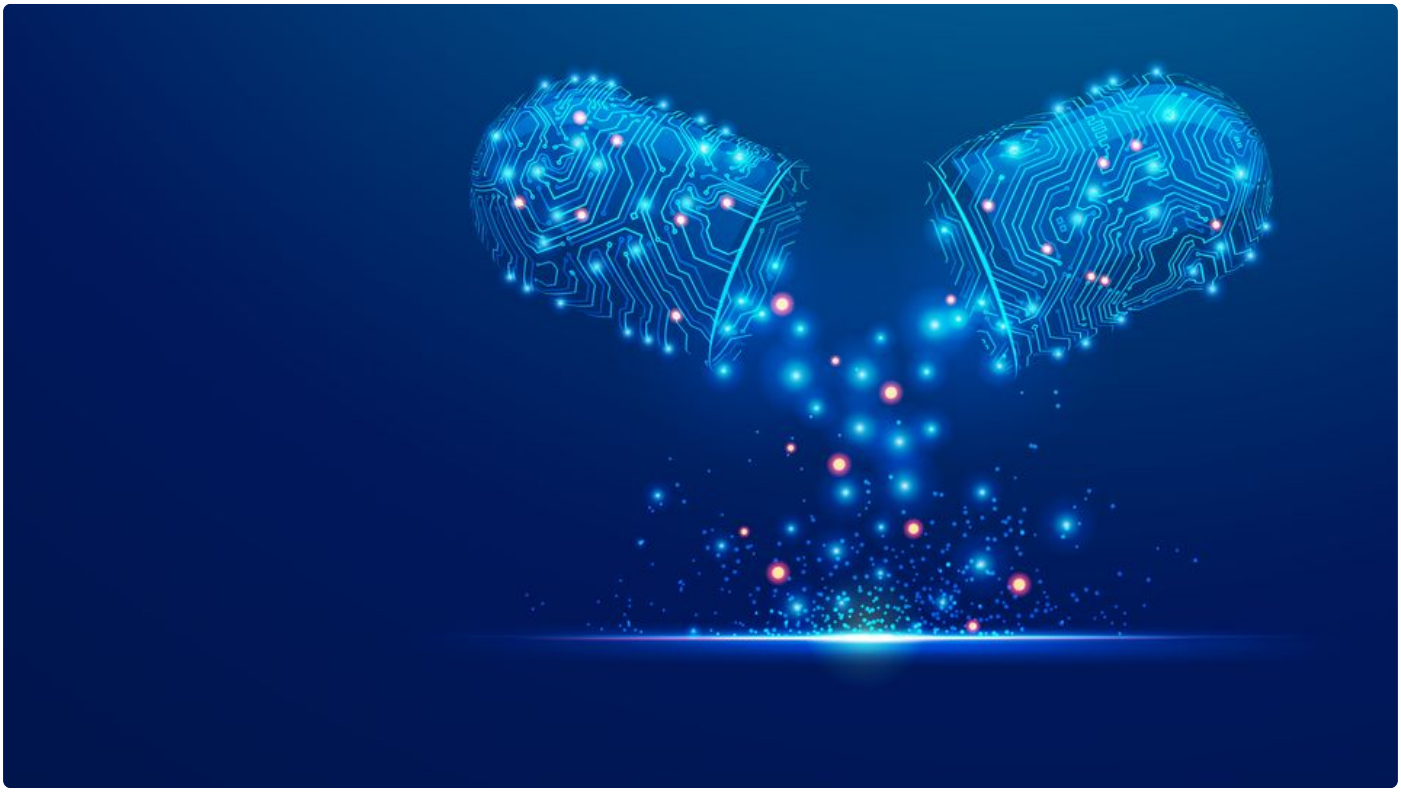

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Artificial intelligence has been seen as a promising tool for pharmacovigilance (PV) for some time, but only recently has it begun to make a tangible impact. As life sciences organizations face rising case volumes, growing regulatory demands, and

pressure to increase efficiency without compromising patient safety, advances in large language models (LLMs), automation platforms, and scalable cloud technologies are rapidly expanding what AI can realistically deliver.

AI-enabled tools are now moving from pilot projects into real PV workflows. Yet questions around auditability, data quality, and the risks of introducing such technologies into a highly regulated environment continue to slow widespread adoption.

To explore where AI is proving its value, the challenges that remain, and how global organizations can scale these technologies responsibly, we spoke with Gary Barker, executive director of pharmacovigilance, PPD™ FSP Solutions, Clinical Research, Thermo Fisher Scientific.

In this interview, Gary shares how AI is being applied in PV today, the role of functional service partnerships (FSPs) in ensuring safe and compliant implementation, and the innovations likely to shape the future of PV over the next three to five years.

Anna MacDonald (AM): How are AI and automation currently used in PV workflows?

Gary Barker (GB): AI-enabled automation is now most mature in PV case intake and early case processing, reducing the manual effort required for safety data triage, extraction, and transformation into draft individual case safety reports.

Current best-in-class technology uses a hybrid of rules-based logic for predictable, higher-volume structured formats, and LLMs for variable, lower-volume unstructured content. Together, these approaches extract key data elements from structured

sources (e.g., E2B XML), semi-structured sources (e.g., CIOMS-I forms), and unstructured sources (e.g., emails, literature articles, web screenshots).

In operational terms, these tools are being used to improve data capture consistency, shorten cycle times, and stabilize performance during volume surges, with human review rather than attempting full end-to-end automation. Benefits seen in practice include earlier duplicate detection, faster identification of problematic cases, and improved operational metrics with increasing scalability as product portfolios grow.

AM: What are the most persistent barriers to broader AI adoption in PV?

GB: What PPD™ FSP PV solutions experts often see from clients is that barriers today are less about whether PV teams see value and more about whether they can adopt AI without increasing compliance risk.

PV remains a conservative, highly regulated discipline, and organizations have been wary of introducing models that behave like "black boxes," particularly where audit and inspection readiness depend on being able to explain how an output was produced, show the chain of information, and demonstrate proof of quality control.

A second challenge is the operational reality of variable data formats and fragmented data ecosystems. Safety teams must handle a wide variation in source types, solicited program designs, and partner-specific formats, which can make automation unrealistic or inefficient if it requires extensive bespoke configuration for each new data channel.

Earlier generations of tools also demanded large training datasets and heavy configuration, which represent cost and time frictions that, while reduced in more modern systems, still influence "build vs buy" decisions.

AM: What progress is being made to overcome these barriers?

GB: The rapid evolution and adoption of AI platforms over the last few years have significantly accelerated the adoption trajectory, increasing the feasibility of using these tools for many organizations.

Firstly, unprecedented adverse event volumes during the COVID-19 vaccine rollout forced rapid operational deployment of automation due to insufficient availability of human PV case processors. This period enabled the involved parties to gain important practical implementation experience, which was later shared by both companies and regulators at industry conferences, decreasing anxieties around regulatory authority inspections.

Secondly, the broad availability of LLMs since late 2022 has reduced the historical burden of training data and bespoke configuration, especially for unstructured and low-frequency formats. At the same time, clear best-practice approaches for implementing AI in PV are emerging. This includes keeping automated steps human-readable and auditable, pairing automation with defined human oversight, engineering for variability, and institutionalizing change management through updates to procedures, training, governance, and escalation pathways.

AM: What role do FSPs play in helping organizations implement and scale AI technologies in PV?

GB: Our PPD FSP PV solutions experts typically see that FSPs increasingly serve as the way by which companies can rapidly operationalize AI at scale, particularly for clients that need enterprise-grade capability and specialized skillsets without building the entire technology and validation infrastructure internally.

In practice, strong FSP partners bring repeatable implementation experience from supporting multiple clients and apply that expertise to design end-to-end case processing flows tailored to each client's case mix, while establishing validation frameworks that support accuracy, compliance, and inspection readiness.

Beyond automation in case processing, FSPs play a central role in regulatory intelligence, including the monitoring, interpreting, and operationalization of regulatory changes globally using specialized platforms and multilingual expertise. This skillset is particularly relevant where regulatory changes trigger downstream system updates (e.g., safety database configuration, reporting process updates) and when having a single, centralized source of information reduces inconsistent interpretation across different vendors and geographies.

AM: Looking ahead, what innovations or regulatory developments do you anticipate will have the biggest impact on PV over the next three to five years, and how should companies prepare?

GB: So far, automation and AI have largely focused on labor-intensive data processing activities. Technologies are emerging with the potential to support other PV activities (e.g., unsupervised translation, automated surveillance [literature, websites], document authoring [aggregate safety reports, RMPs, PSMFs, PVAs], signal management, and medical evaluation); however, these platforms are not widely deployed and have yet to mature.

Taking into account the cost of technology platforms vs existing resources, whether automation of less labor-intensive activities can achieve a positive return on investment for most companies remains to be seen. Some currently available systems may only be viable for large pharmaceutical companies supporting many tens or hundreds of products through highly standardized PV processes.

There are already examples emerging among smaller companies where automation has resulted in a higher overall cost compared to previous compliant manual processes. Companies need to thoroughly understand their existing processes vs what can actually be achieved through automation, including any process or data source assumptions made by technology vendors.

Ultimately, future platforms that bundle together support for a wide variety of different PV activities or which can be used by other functions within the company (e.g., medical

writing, regulatory affairs) may be the key to unlocking a positive return on investment.

The introduction to this interview includes text that has been created with the assistance of generative AI and has undergone editorial review before publishing. Technology Networks' AI policy can be found here.