



BIOMAPAS

The use of AI/Automation in Pharmacovigilance

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Introduction

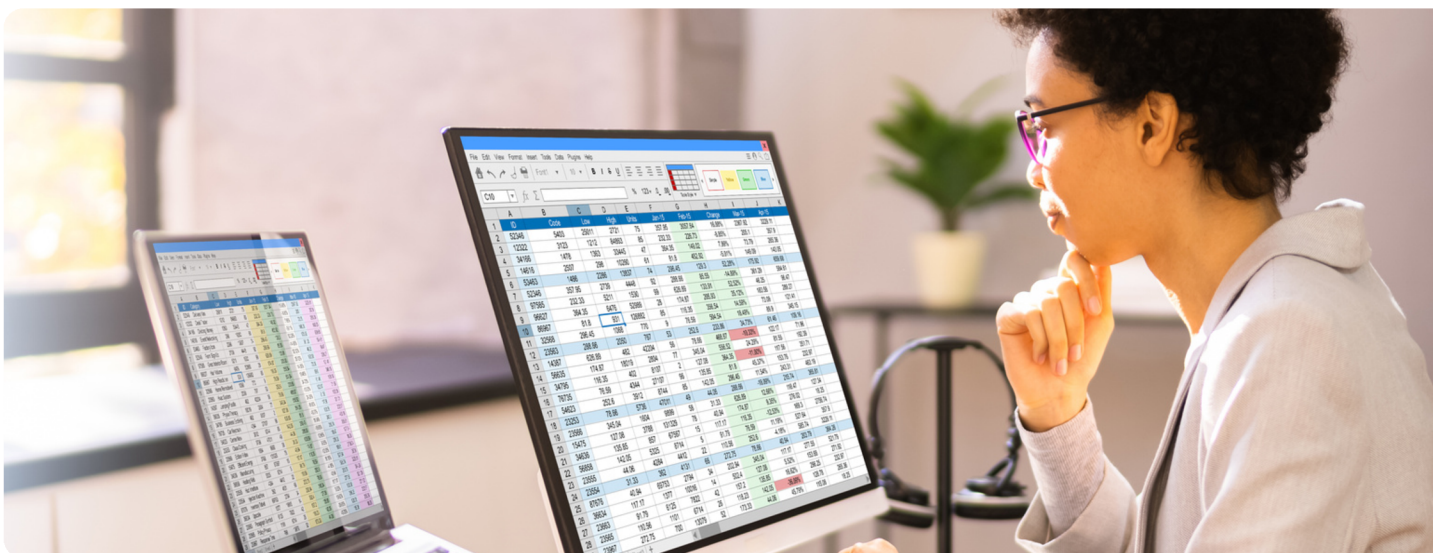
As pharmacovigilance (PV) evolves into a more data-intensive and globally distributed discipline, artificial intelligence (AI) and automation are no longer futuristic concepts – they are becoming operational necessities.

From accelerating signal detection to improving risk-benefit assessments, automation and AI-enabled tools offer unmatched speed, scalability, and analytical depth. But technology alone is not enough.

Usual signal detection methods, such as disproportionality analysis and aggregate reporting, are increasingly strained by rising data volumes and fragmented systems.

With AI, machine learning, and rule-based automation, there is faster and more accurate processing of safety data from reports, studies, and real-world sources.

This article provides a focused review of current technologies, highlights emerging solutions such as Veeva's upcoming AI capabilities, and outlines key considerations for the future of AI in PV.



The use of AI/Automation in PV signalling process: current and future

Artificial intelligence (AI) and automation are rapidly transforming pharmacovigilance, particularly in signal detection and risk-benefit assessment. This article reviews current AI applications in safety monitoring, highlights efficiency gains through automation, and examines emerging tools shaping the future of PV.

Recent innovations from **Veeva Systems** illustrate how AI can support data-driven decision-making in regulatory contexts. While these advances enable earlier signal detection and streamlined processes, they also raise challenges around validation, transparency, and compliance. Drawing on Biomapas' expertise in global PV, we outline key considerations for integrating AI ethically and effectively into safety systems – ensuring both innovation and patient protection remain central.

1. The Role of Signal Detection in Modern Pharmacovigilance

Signal detection remains a core function in PV, enabling the timely identification of new or evolving safety concerns. Traditionally, this process relied on reporting systems (e.g., EudraVigilance, FAERS) and statistical methods to uncover potential safety signals. However, with ever-increasing data volumes, multiple data types (structured and unstructured), and growing regulatory expectations, these approaches are under pressure.

Efficient signal detection now demands not only scientific expertise but also agile systems capable of processing diverse data streams – from individual case safety reports (ICSRs) to real-world evidence, literature, and digital health data.

2. How AI and Automation Are Reshaping Signal Management

AI and automation are unlocking new dimensions in safety monitoring, offering speed, scalability, and enhanced pattern recognition that human review alone cannot match. Key innovations include:

- ◆ Natural Language Processing (NLP): For extracting adverse event information from unstructured case narratives and literature.
- ◆ Machine Learning (ML): For predicting which signals are likely to be validated based on historical data.
- ◆ Automated Prioritization: AI models help triage large volumes of ICSRs by seriousness, completeness, and novelty.
- ◆ Continuous Surveillance: AI systems can monitor global datasets in near real-time, reducing signal detection lag.

Automation also supports case processing workflows, helping reduce manual burden and standardize outputs, thereby freeing pharmacovigilance teams to focus on expert review and strategic decisions.



3. Veeva and Other Key Technologies: AI in Action

Among the technology providers enabling AI in PV, Veeva Systems has made notable advances. The integration of Veeva Safety Signal and Veeva Safety supports:

- ◆ Automated signal detection, tracking, and documentation workflows
- ◆ Seamless traceability of signal back to case series
- ◆ Benefit-risk frameworks with integrated visualization and decision support
- ◆ Seamless data flow across safety, clinical data, clinical operations, regulatory, and quality functions

In 2025, Veeva announced **Veeva AI** – a platform-wide initiative that brings agentic AI into the Vault Platform and deep industry-specific AI agents for all Veeva applications, including safety. Key highlights:

- ◆ Vault Platform provides a single platform for data, content, and agents
- ◆ Veeva AI Agents have direct, secure access to Vault data and content
- ◆ Context-aware Veeva AI Agents work seamlessly in Veeva applications to automate specific tasks within workflows (e.g., unstructured case intake and narrative generation with Veeva AI for safety)
- ◆ LLM agnostic supporting most major LLMs, or use the Veeva-supplied LLM

Together, these tools enhance productivity, accelerate decision-making, and maintain compliance – all within the secure and validated Veeva environment. As noted in Regulatory Affairs News (2025), these capabilities operate within pre-existing workflows and systems, allowing companies to adopt intelligent automation without compromising regulatory expectations. Embedded AI not only increases efficiency but also ensures traceability and governance – critical for safety systems handling sensitive data.

4. Challenges in Implementation: Validation, Compliance & Trust

While the promise of AI is strong, its application in PV must overcome several practical and regulatory difficulties:

- ◆ **Model Validation:** AI systems require validation under GxP and Good Pharmacovigilance Practices (GVP) standards.
- ◆ **Regulatory Alignment:** Agencies such as the EMA and FDA have begun issuing guidance on AI, but standards are still evolving.
- ◆ **Transparency:** Black-box algorithms pose a risk if their outputs cannot be explained or audited.
- ◆ **Bias and Data Quality:** Poor-quality input data can compromise model performance and introduce bias, especially for underrepresented populations.

Ultimately, human oversight remains essential. AI should complement, not replace, medical judgment in PV.



5. The Future of AI-Driven PV: What's Next?

Emerging trends that will shape the next wave of AI-enabled pharmacovigilance include:

- ◆ Federated Learning: Allowing collaboration between pharma companies or CROs without sharing sensitive raw data.
- ◆ Explainable AI: Increasing transparency and trust in model outputs.
- ◆ Real-time Safety Intelligence Dashboards: Combining multiple data streams into a unified, AI-filtered view.
- ◆ Personalized PV: Using AI to identify patient subgroups at higher risk based on genomics, comorbidities, or treatment pathways.

Why Choose Us?

At Biomapas, we see AI and automation not as standalone tools, but as integral components of an efficient, scalable, and compliant PV system.

Our teams apply innovation and automation to enhance signal detection, optimize safety workflows, and align with evolving regulatory requirements across diverse markets. With regional insight, scientific precision, and operational flexibility, we provide efficient, compliant, and future-ready safety solutions.



We keep promises. **Always.**

Biomapas serves as a comprehensive outsourcing solution provider to the global life sciences sector.

Our offerings encompass end-to-end clinical research services in countries known for their high recruitment rates.

We excel in delivering regulatory and pharmacovigilance services throughout Europe, the CIS, EAEU, and MENA regions, spanning the entire product lifecycle.



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