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Artificial Vigilance

Where AI Meets Drug Safety

essjay SOLUTIONS LTD

The Year of the AI Agent, and the Reckoning to Come

Every few years the technology industry falls in love with a single idea. In 2026, that idea is the **"agent":** AI that can act on your behalf, booking a meeting or steering a task from start to finish.

The appetite is enormous. Deloitte's early-2026 research found that **close to three-quarters of companies plan to deploy agentic AI within two years.** Yet only **21% of those companies** say they have a mature model for governing what those agents are allowed to do. That gap matters: an agent with system access can approve the wrong payment as quickly as the right one. Deloitte titled its companion analysis bluntly: agentic AI is **"scaling faster than guardrails".**

Not everyone is convinced the substance matches the noise. Gartner predicts that more than **40% of agentic AI projects will be cancelled by the end of 2027,** "due to escalating costs, unclear business value or inadequate risk controls". Its analyst Anushree Verma is blunter still, calling most current projects "early-stage experiments or proof of concepts that are mostly driven by hype and are often misapplied". Gartner even has a name for the marketing sleight of hand, **"agent washing",** the rebranding of old chatbots and automation as agents. Of the thousands of vendors now claiming agentic capability, it reckons only around **130 are the real thing.**

None of this means the direction is wrong. When Anthropic released Claude Sonnet 5 in June 2026, it described a model that could "make plans, use tools like browsers and terminals, and run autonomously at a level that, just a few months ago, required larger and more expensive models". The capability is arriving, and it is getting cheaper by the month.

For a sector built on oversight and accountability, this is familiar ground. The organisations that get value from agents will be those that let their **agents earn autonomy slowly,** under close supervision. The question is no longer whether AI can act on its own, but how much we should let it, and under what controls. Industries that already live under strict oversight, drug safety among them, may be better prepared for it than most.

> *"Most businesses do not need an autonomous agent tomorrow. They need one repetitive task done reliably, with a human still in the loop. That is where the value actually starts"*
>
> **Amit Jaitly,** Director of JMC Solutions

EMRN's AI Workplan Celebrates its 3rd Birthday: Here's How it Evolved

Next month marks three years since the **European Medicines Regulatory Network** began formalising its approach to AI through its **AI workplan.** The workplan was born from the ambition to better understand AI's potential across the medicines lifecycle but has since evolved into a practical framework for building **regulatory structures** and **stakeholder forums** to support responsible adoption at scale.

> *"By building on strong collaboration and shared principles, EMA is helping ensure that AI delivers tangible benefits for patients and public health - safely, effectively, and at scale"*
>
> **Peter Arlett,** Head of Data Analytics at the European Commission

Developed under the **HMA-EMA Big Data Steering Group,** the workplan was designed to help the network use AI safely across medicines regulation while managing risks to human and animal health. Its vision extends beyond a single agency, promoting a **coordinated European regulatory framework** that uses AI for productivity, process automation, stronger data insights and better decision-making.

Over the past three years, the EMRN's AI work has shifted from **exploration** to **implementation.** Early efforts focused on understanding how AI could support the medicines lifecycle and where regulatory risks might emerge. Since then, the network has built **internal expertise,** developed **guiding principles** for LLMs, created an AI Observatory for horizon scanning and translated this experience into practical guidance for regulators and industry.

This matters because the EMRN extends beyond the EMA, bringing together national competent authorities across the EEA with the EMA and HMA to regulate medicines. This **coordinated** approach helps create **consistent** expectations across Europe rather than fragmented interpretations between national regulators.

Stakeholder engagement has become a defining feature of the workplan. HMA and EMA's **multi-stakeholder AI workshop** brought together regulators, patients, HCPs, academia and industry to discuss real use cases, regulatory expectations and the wider legal environment. The workshop concluded that the EMRN had already begun implementing its workplan across guidance, technology and policy.

International alignment is also strengthening. The EMA and FDA have published joint principles for **Good AI Practice** in drug development, signalling that European regulators are not developing expectations in isolation. For globally operating companies, this convergence will become increasingly important as AI becomes embedded in development, safety monitoring and regulatory operations.

Entering its fourth year, the EMRN's AI workplan will continue to evolve. Europe's medicines regulators are no longer focused solely on what AI might do, but on building the **governance, guidance** and **collaborative structures** needed to use it responsibly, creating clearer expectations and greater regulatory **predictability.**

MethodHub and Datafoundry Join Forces to Integrate AI with Pharmacovigilance

As AI adoption increases across the PV industry, inter-firm **technology partnerships** are becoming an increasingly common route to modernising drug safety operations. Rather than going through the costly, and often risky process of building every capability in-house, organisations tend to prefer combining **specialist AI platforms** with established PV expertise to create more intelligent, scalable safety ecosystems.

The latest example comes from the strategic partnership between **MethodHub Software** and **Datafoundry,** which aims to deliver AI-powered PV solutions for pharmaceutical, biotechnology and life sciences organisations. MethodHub is bringing their expertise in pharmacovigilance operations, regulatory compliance and global service delivery, while Datafoundry brings their purpose-built AI tools developed specifically for the niche of drug safety. Together, these firms want to help organisations move away from fragmented, manual workflows towards evermore **interconnected** and **automated** PV workflows.

Among the technologies included are **Safety AI,** for end-to-end case management, **Signal AI** to support more efficient signal detection while reducing false positives, and **AI-powered literature monitoring** software with multilingual capabilities. Combined with MethodHub's regulatory expertise, these tools have the potential to improve **efficiency, consistency** and **compliance** with global regulatory expectations from agencies like the FDA and EMA.

This partnership not only reflects the wider shift taking place across the industry but also highlights how AI implementation is increasingly becoming an **ecosystem** rather than a single software purchase. As adverse event volumes grow exponentially, and regulatory expectations become more complex, PV is becoming a **strategic function** where automation, intelligent data analysis and AI-assisted decision support play a crucial role. Success now depends not just on deploying technology, but on **combining validated AI** platforms with **experienced PV** professionals, **governance frameworks** and **regulatory wisdom** to support safe, compliant adoption.

For PV teams, this demonstrates how strategic partnerships with technology firms can yield real tangible benefits by automating tedious tasks and improving data processing, all to allow specialists to focus on the highest value scientific and clinical priorities.

> *"Through our partnership with Datafoundry, we are bringing together cutting-edge AI platforms, domain expertise, and scalable service delivery to help clients build future-ready, intelligent PV ecosystems"*
>
> *Ahobilam Nagasundaram,* CEO and Executive Director of MethodHub Software Ltd

Genesis Makes AI Evidence Synthesis Platform and Releases it for Free

Finding, reviewing and **synthesising scientific evidence** is one of the most time-consuming tasks in life sciences, and also one of the most crucial. Whether supporting pharmacovigilance, regulatory submissions or other medical affairs, teams often spend weeks manually reading literature, screening publications and **tracking new evidence.**

> *"Run it yourself. Run it with Genesis. Or have Genesis run it for you"*
>
> Genesis Research Group

Genesis Research Group is hoping to change that with its **EVID AI evidence synthesis** platform, designed to bring the entire evidence review process into a single platform. And best of all, it's being released **free of charge** to life science organisations and eligible researchers until the end of 2026.

Developed by Genesis scientists and refined through two years of use on real client projects, users of the platform can perform **rapid evidence searches,** targeted **literature reviews,** ongoing **surveillance** and full **systematic reviews** without switching between multiple disconnected tools. It has been developed around real-world workflows across healthcare economics and outcomes research, real world evidence, medical affairs and market access.

The decision to release the platform for free for the remainder of 2026 is largely a strategic one. Instead of generating revenue from this software immediately, Genesis wants to encourage organisations to experience the platform firsthand, demonstrate its value and likely provide valuable **feedback** data to continuously improve the software.

Evidence synthesis is particularly well suited to this broader industry shift towards AI and automation, because AI can **accelerate literature identification** and **organisation** while leaving the critical interpretation and decision making with experienced professionals. However, despite the potential benefits, AI-assisted evidence synthesis is not without risk. If search strategies are poorly designed or AI systems overlook relevant studies, important evidence could be missed, which will lead to biased conclusions being drawn. As with any GxP adjacent AI application, human **oversight, validation** and **transparency** remain essential to secure scientific integrity and confidence.

For pharmacovigilance teams, this is another example of AI being applied to one of the industry's most labour-intensive activities. **Faster evidence reviews** and **continuous literature surveillance** have the potential to improve efficiency while allowing specialists to spend more time analysing safety data instead of searching for it.

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