White Paper

Demanding More from AI Governance in Drug Safety

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Source: IQVIA

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Artificial Intelligence (AI) usage continues to expand in the pharmaceutical space with many drug companies considering how to implement this technology to increase efficiency and enhance decision making across the lifecycle of a drug, the Marketing Authorization Holders (MAHs) must also ensure compliance amid an evolving regulatory landscape. Regulators have encouraged the use of AI in drug development and manufacturing, but their guidance remains largely in draft form and is subject to change as new insights come to light.

The regulatory climate: where do we stand?

As of January 2025, 69 countries had proposed or implemented >1,000 AI-related policy initiatives and legal frameworks.[1] Published in 2024, the EU AI Act addresses healthcare and therein, high-risk AI systems; it is the world's first and arguably most influential comprehensive legal framework for AI. It sets a global benchmark by adopting a risk-based approach and imposing obligations proportionate to the potential impact of AI systems.

Despite calls from major European tech leaders to delay its rollout, the European Commission has made it unequivocally clear: **there will be no pause, no grace period, and no delay in the implementation of the EU AI Act**. The first set of rules came into force in February 2025, and key obligations for high-risk AI systems, i.e., those deemed to pose significant risks to fundamental rights, health, or safety, will become binding from August 2, 2026. At the same time, the commission has emphasized that **organizations do not need to wait for detailed prescriptions to act**. Companies are expected to proactively align with the intent of the Act, and failure to do so could result in significant penalties: up to €35 million or 7% of global annual turnover.

In 2025, the U.S. government issued two memoranda — M-25-21 and M-25-22 — directed toward federal agencies, which firmly established the country's pro-innovation stance on AI. These documents made it clear that AI adoption is encouraged, provided it is supported by robust, risk-based assessments. Japan has echoed a similar position, emphasizing innovation while maintaining a strong focus on risk management. The message is clear: **regulatory clarity is not a prerequisite for responsibility**. Organizations are encouraged to move forward confidently, provided they adhere to the guiding principles and frameworks already established.

Furthering the cause, the European Medicines Agency (EMA), U.S. Food and Drug Administration (FDA), and U.K. Medicine and Healthcare products Regulatory Agency (MHRA) have all released draft frameworks. The Council for International Organizations of Medical Sciences (CIOMS) XIV Working Group is developing a framework using current regulatory guidelines that focuses on the use of AI in the field of PV and drug safety. MAHs can use this existing draft framework as a practical bridge between the EU AI Act and U.S. guidance to prepare for and maintain compliance and monitoring of AI solutions for patient safety.

The challenges: what are we up against?

Successfully implementing AI across drug safety and PV processes requires circumventing several obstacles. First, there is the issue of trust. Generative AI solutions employ Large Language Models (LLMs), which, due to the black box nature of this software, results in an inherent lack of transparency and control. It is difficult to explain how an LLM produces the results it does, why it makes the decisions it makes, or where that information comes from. For most MAHs, establishing trust and confidence in an AI model that lacks full explainability is disconcerting, and though validating a model and enacting controls is a major step towards increasing trust, this inherent risk presents the first hurdle for many.

Likely the most significant challenge of leveraging AI in safety is overcoming the deeply entrenched legacy human workflows. Some MAHs have been using the same safety processes for years, either internally or through a CRO, making the prospect of implementing new approaches and managing those changes daunting. But AI in safety is more than just a technical shift; it's a cultural shift. Without reimagining your operations to accommodate AI, your business model will struggle to reach its potential, and at worst it will fail.

Implementing AI into drug safety practices requires a multi-disciplinary collaboration between developers, data analysts, computer scientists, PV experts, and business operations to guarantee that the AI is working as intended before, during, and after deployment. PV and safety use cases evolve over time and thus, AI demands continuous human oversight with cross-functional expertise, necessitating at least some AI fluency across skillsets.

Finally, due to the relative newness of AI implementations in drug safety and a lack of formal guidelines, MAHs likely do not have existing knowledge of how to validate dynamic AI. Common questions might include: *How do we incorporate model development assumptions and evaluation metrics relevant to generative AI Systems? What evaluation metrics are appropriate? What statistical measures should be implemented? How do we ensure regulators are satisfied with our validation technique? How will this perform with real-world data?*

The solutions: how do we safely move the dial from traditional to generative AI?

While traditional AI has been broadly adopted (and validated for pharmacovigilance), users are only beginning to understand how generative AI technology behaves in routine use and real-world scenarios and how to evaluate it. The only meaningful difference in transitioning from traditional to generative AI is the insertion of a trust layer — AI governance — combined with a deep understanding of how these technologies differ in behavior and risk.

AI governance

Validation is just one component of ensuring AI quality. What is needed is something that looks at the entirety of an AI model to establish regulatory adherence every step of the way, often referred to as AI governance. The guiding principles of AI governance include the following considerations:

Is the AI model following a risk-based approach?

What is the likelihood of something going wrong and how will it be addressed if something does go wrong?

Is this AI model high, medium, or low risk, and what are the potential consequences of said risks?

What are the consequences of failure?

How do all the controls and user interfaces that touch this process impact the risks? Where is a human interacting with the model?

Are they in the loop or are they in command?

What is the appropriate level of human oversight needed? When and how will a review for equity and bias take place?

To ensure an AI initiative is going to withstand the pressure of real-world use, it is important to account for transparency. Your technology provider should prioritize transparency in terms of how the system was designed and how the AI model or models were selected. A provider should also advise on what controls are in place to mitigate risk and any known limitations with the models. The MAH will hold the ultimate responsibility for the AI that is used in their system and will need to document all AI usage information within the PV System Master File (PSMF). Working with a transparent and knowledgeable AI provider will aid an MAH as they strive to uphold the expectations of regulators and maintain continuous compliance.

Because data privacy is so important, a major focus should be on ensuring that patient data is subject to the strictest security controls, preventing data leakage and/or patient reidentification. MAHs must ask technology providers how they can be sure their data will not be used to train current or future models and will need assurance that their data is privatized and secured. Stakeholders must constantly be looking at risk and evolving regulations in this area as well as expecting updates on how their provider is responding to new regulations or technology changes in regular governance meetings.

Furthermore, with LLMs and AI, it is important that the data leveraged is diverse and representative of a global population. Every stakeholder from developers, prompt engineers, and end-users have their part to play in ensuring bias is not propagated in the design or deployment of technology. Consciousness review of geographical and gender parity and underrepresentation of populations is a necessity to ensure fairness and equity.

Though AI governance in drug safety is a highly complex and involved process, it is merely the evolution of good data and risk governance, which PV professionals have been committed to for a long time. Embedding AI governance by design empowers trust in an AI-enabled safety system and streamlines the path toward success. On the other hand, reverse engineering governance into an existing system is incredibly challenging and costly. By implementing AI governance from the outset, workflows will be thoughtfully designed, robustly engineered, and strategically positioned for compliance.

MAHs should be prepared to furnish both an AI governance grid and a risk-based credibility assessment to auditors and inspectors that demonstrates how they have sought to align with the existing AI guidelines for drug safety. In concert, these elements are more likely to inspire trust from regulators and other stakeholders.

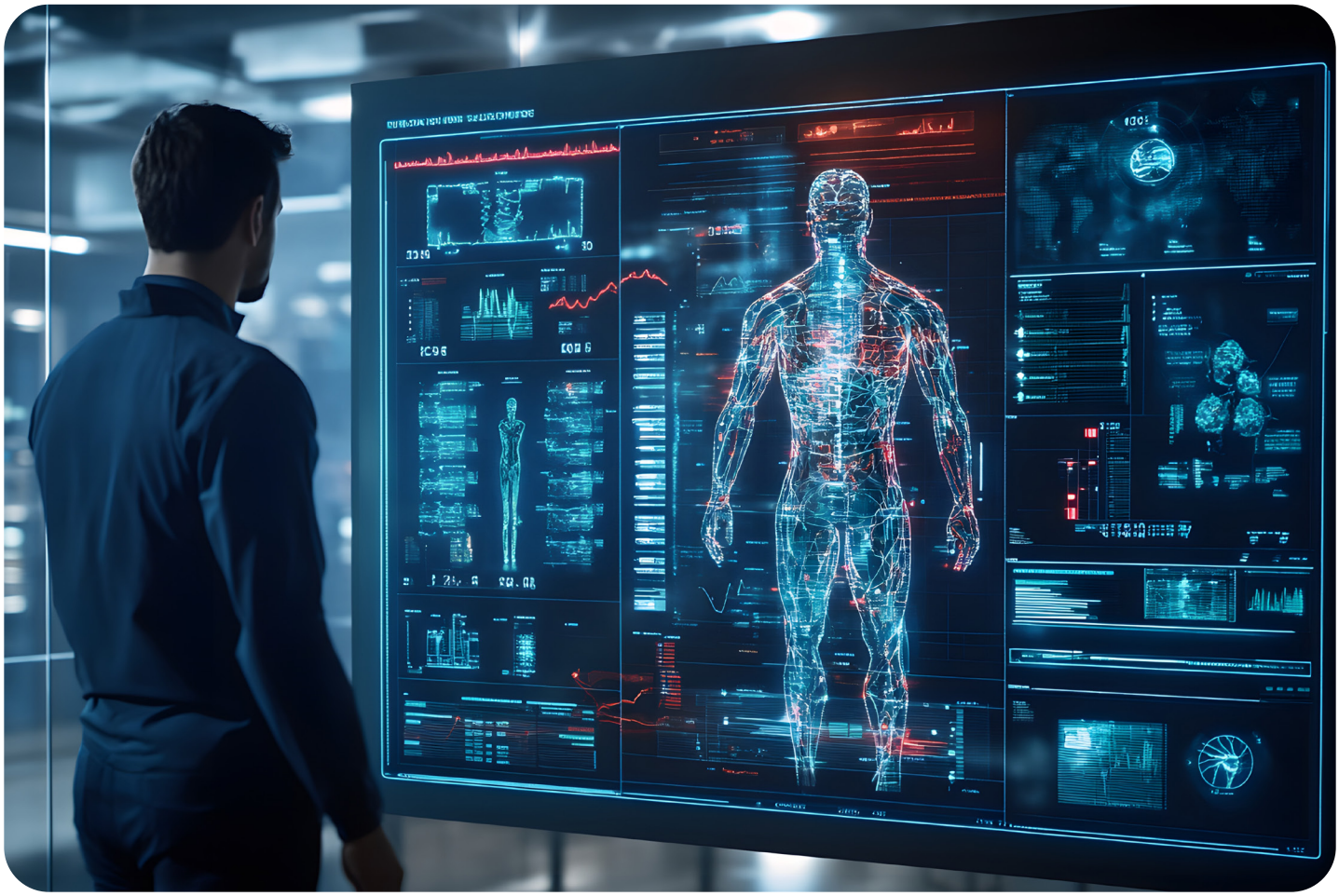
The partnerships: what questions should we be asking?

The AI space is noisy and there is no shortage of incredible technology. Choose partners who will evolve with you and the ecosystem. To determine whether a potential AI technology provider has the prowess to accommodate the implementation of AI, MAHs should assess a provider's understanding of the current AI legislation and how it is shaping the landscape of safety regulation. It is also essential to ensure the technology provider has a thorough conceptualization of how to assess risk in the context of patient safety and the MAH's use case. They must demonstrate that they have effective AI controls in place to support transparency and explainability, that they understand what documentation is required by regulators, and that they have a robust and proven strategy for validating GenAI.

With these capabilities in tow, a technology provider will be expertly suited to help validate and govern the implementation of AI.

The horizon: what's stopping you?

The era of generative AI is not on the horizon — it's already here. Regulators are not standing in the way; they are encouraging innovation, provided it is governed responsibly. The technology is available, the frameworks are emerging, and the opportunity is real. If you have a robust AI governance plan in place, then nothing should stop you from moving forward. The only real barrier now is hesitation. This is the moment to act. The future of drug and device safety will be shaped by those who lead with purpose, transparency, and people at the center.



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Marie Flanagan serves as the Regulatory and AI Governance Lead for IQVIA's Vigilance Detect (safety risk identification technology). In her 20-year tenure, she has held various leadership positions in Pharmacovigilance (PV) operational management, strategy, and consulting. Throughout the years, she has played a pivotal role in the integration of safety technology and services and the strategic expansion efforts of IQVIA's pharmacovigilance department. In her current role, she provides regulatory consultancy to safety technology teams and supports the AI governance embedded in safety technology from development through deployment.

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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07.2025.DPS.BCS2025-2242-07JUL