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AI Governance in Pharmacovigilance: EU AI Act Compliance

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Executive Summary

The integration of **artificial intelligence (AI)** into **pharmacovigilance (PV)** – the science of monitoring and ensuring drug safety – has accelerated dramatically in recent years. Leading PV software platforms such as **Oracle Argus Safety, Veeva Vault Safety, and ArisGlobal LifeSphere** offer AI-enabled capabilities to automate case intake, coding, signal detection, and reporting. While these innovations promise efficiency gains, they also create new regulatory challenges. In response, regulators are developing robust **AI governance frameworks**. In the EU, the AI Act establishes a risk-based framework. High-risk obligations should be assessed for each intended use and operator role; they do not follow from PV or GxP status alone. For example, **Article 17** requires a quality management system for providers of high-risk AI systems. Applicable pharmacovigilance and data-protection duties require a separate assessment. This report examines how an “AI Governance and Compliance Layer” can be integrated into PV systems (notably Argus and Veeva) to meet these obligations. We analyze the historical context of PV regulation, current state of AI adoption in drug safety, and the specifics of the EU AI Act. We present comparative analyses of PV platforms, industry case studies of AI implementations, and detailed recommendations for design, validation, monitoring, and documentation of AI tools in PV. Recommended controls include validation like other GxP systems ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)), ongoing monitoring for data drift ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)), and **full auditability**. These controls do not establish an absence of compliance failures. We conclude with future outlook: as AI capabilities (e.g. LLMs) continue evolving, PV operators must proactively adapt their quality systems in line with both traditional safety regulations and new AI-specific laws.

Introduction and Background

Pharmacovigilance (PV) is defined as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems” (www.who.int). In practice, PV departments in pharmaceutical companies and regulatory agencies collect and analyze **Individual Case Safety Reports (ICSRs)** to identify signals of drug-induced harm, ensure benefit–risk balance, and comply with global regulations (e.g. ICH E2B, EU Good Pharmacovigilance Practices). Mastery of large, complex safety data is essential to patient safety and public health. As drug development and treatment personalization expands, case volumes have grown (the global PV market is projected at **\$9.2 B** in

2024, rising to ~\$19 B by 2032 at ~9.3% CAGR (www.globenewswire.com) (www.globenewswire.com)) and data sources have diversified (clinical trials, post-market studies, social media, EHRs, etc.). These trends strain manual processes and create a strong incentive to apply AI and automation.

AI in PV has matured over the past decade. Early automation focused on digitizing workflows and simple database queries, but recent AI (especially NLP and machine learning) can ingest unstructured narratives, code adverse events (e.g. MedDRA, WHO Drug), de-duplicate reports, and even draft narratives or periodic reports (intuitionlabs.ai). For example, Oracle's next-generation Argus Safety platform explicitly uses "artificial intelligence (AI) and machine learning (ML) to enhance efficiency, accuracy, and compliance" of end-to-end case processing (docs.oracle.com). Veeva's Vault Safety introduced an *AI-powered Intake* module ("Safety.AI" in 2019) that automatically extracts data from emails, faxes, and documents to pre-populate case fields (ir.veeva.com). ArisGlobal's LifeSphere Safety offers "AI-powered" automation across PV, including **"advanced intake [to] streamline the collection of safety data using GenAI and LLMs"** (www.arisglobal.com) and "touchless case processing" via end-to-end automation. These product descriptions should be distinguished from independently measured deployment outcomes; this article does not establish an industry-wide automation rate or an absence of compliance failures.

However, the adoption of **AI agents** (including ML models and generative LLMs) calls for clear oversight. The January 2026 [EMA–FDA guiding principles](#) underpin future AI guidance across the medicines lifecycle. They should not be presented as a new PV-specific inspection mandate. Evaluate binding GxP duties separately and assess each AI use against the AI Act's classification criteria and the organization's provider or deployer role.

This report provides a deep-dive analysis of how to construct an **AI Governance and Compliance Layer** for pharmacovigilance. We focus on Oracle Argus Safety and Veeva Vault Safety (as leading PV platforms) in the context of the EU AI Act, with a roadmap dated 14 October 2026. We survey historical PV regulation, technical landscape of PV systems, AI use cases in safety, and then detail regulatory and governance frameworks. We review published market forecasts and expert insights, and include case studies (e.g. Pfizer's AI pilot, major biopharma AI deployments (intuitionlabs.ai)). Through this analysis, we lay out best practices for integrating AI: from design and validation (treated under GxP principles (pmc.ncbi.nlm.nih.gov)) to documentation (technical files, bias reports, logs (pharmacystandards.org) (pharmacystandards.org)) to continuous monitoring (control plans, drift detection (pmc.ncbi.nlm.nih.gov)).

Regulatory Landscape: GxP, PV Guidelines, and the EU AI Act

Existing PV and GxP Regulations

Pharmacovigilance arises from GxP regulations ensuring drug safety. Key standards include ICH guidance (e.g. **E2B(R3)** for standardizing ICSRs, E2C/GVP for aggregate safety reports) and EU Good Pharmacovigilance Practices (GVP). Health authorities (EMA in EU, FDA in US, MHRA in UK) require manufacturers to operate validated safety databases, maintain a **Safety Management System (SMS)** or Quality Management System (QMS) for PV, and adhere to specific timelines (serious case reports in 15 days, PSURs/DSURs, etc.) (www.who.int). Data integrity (ALCOA/Q principles) and computerized system validation (e.g. CSV under 21 CFR Part 11) are foundational.

Crucially, PV regulations hold companies fully responsible for **all** steps in the safety workflow, whether manual or automated. For example, if AI automates case classification, the company remains liable for any errors.

Emergence of AI Governance Needs

As AI tools enter PV, regulators emphasize that existing GxP principles must also cover AI pipelines. Computerized systems (including AI/ML components) must be validated to be “*reliable, fit for its intended purpose, and compliant with regulatory requirements*” ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/35811111/)). Validation documentation must include training data sets, code, testing results, and a control plan for risk ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/35811111/)) ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/35811111/)). Internal audits, Quality Risk Management (per ICH Q9), and compliance monitoring extend to these AI modules. Current guidance (from agencies and industry groups) reinforces practices such as maintaining a central inventory of AI tools for audit, the notion of a “walled garden” test environment mirroring production for regulators to inspect ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/35811111/)), and the need to demonstrate explainability (per GxP audit trails) ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/35811111/)).

The AI Act requires a use-specific assessment. Document the intended purpose and test the two routes in **Article 6**:

- **Annex I product route:** the AI must be a covered product or its safety component, and the product must require third-party conformity assessment under the listed Union legislation. Ordinary PV intake, coding, or database automation should not be classified solely because it is GxP-critical or processes health data. Qualifying medical-device AI requires assessment against both conditions.
- **Annex III route:** identify a listed intended use, then assess Article 6(3). Its exception concerns systems without significant risk, including no material influence on decision-making, that perform a qualifying narrow procedural, improvement, pattern-detection, or preparatory task. Profiling natural persons remains high-risk. Document an exemption assessment and meet the applicable registration requirement.
- **Product-route qualifications:** Article 6(1a) excludes solely non-safety assistance, performance, efficiency, automation, convenience, or quality-control uses from safety components; paragraph 1b restores that status where failure or malfunction would endanger health and safety. Paragraph 1c addresses third-party assessment required solely for non-health-and-safety risks.

Identify the operator role before assigning duties. **Article 17** addresses providers of high-risk systems; it is not a universal QMS duty for every AI system or deployer. Assess applicable GxP duties separately. For high-risk systems using model training, **Article 10** requires relevant, sufficiently representative training, validation, and testing data that are, to the best extent possible, free of errors and complete in view of the intended purpose. It also requires examination and mitigation of relevant bias, rather than an absolute guarantee of unbiased data.

Roadmap as of 14 October 2026: the Commission’s **current application timeline** distinguishes provisions already applicable from future high-risk requirements. Prohibitions and the original AI-literacy provisions began applying on 2 February 2025; governance and general-purpose-model provisions began on 2 August 2025; most other rules became applicable on 2 August 2026. The **AI Omnibus**, which entered into force on 27 July 2026, amended parts of this framework, including AI literacy. Annex III high-risk requirements apply from **2**

December 2027, and Annex I regulated-product high-risk requirements from **2 August 2028**. Check [Article 111 transition provisions](#) for systems already on the market or in service; these dates do not automatically require every existing system to be reassessed on the same day.

Implications for Pharmacovigilance

Table 1 is a planning aid for systems that qualify as high-risk. Apply each provision to the relevant operator role when it becomes applicable, subject to transition rules. It is not a universal list of legal duties for all PV automation.

AI Act Provision	Requirement	Implications for PV/Examples
Risk Management (Art. 9)	Establish a risk management system for AI. Must assess not only patient safety risks but also fundamental rights and societal impacts (pharmacystandards.org).	Extend PV risk assessments: e.g. analyze biases affecting patient subgroups, data privacy risks, and social implications of PV AI models.
Data Governance (Art. 10)	Training, validation, and testing data must be relevant, sufficiently representative, and, to the best extent possible, free of errors and complete in view of intended purpose (Article 10).	Assess data coverage, quality gaps, and relevant bias; a named bias report is a recommended documentation method.
Post-Market Monitoring & Incident Reporting (Arts. 72–73)	Distinguish internal deviations and near misses from legally reportable serious incidents; assess operator duties and sectoral exceptions (Article 73).	Investigate failures internally. Apply the statutory definition and reporting procedure described under Operational Controls; patient risk alone is not an automatic Article 73 trigger.
Quality Management System (Art. 17)	Providers of high-risk AI systems must put a QMS in place to ensure compliance (Article 17).	Identify whether the organization is a provider or deployer; integrate applicable controls with existing quality procedures.

Table 1: Selected high-risk AI Act obligations and PV planning implications, subject to operator role, application date, and transition rules.

PV organizations should formalize AI ownership, validation, documentation, and ongoing monitoring. Separate these recommended governance controls and existing GxP duties from high-risk AI Act obligations that depend on classification, operator role, and application date.

AI Applications and Trends in Pharmacovigilance

AI Use Cases in PV

AI is being applied across the pharmacovigilance lifecycle (Figure 1). Key use cases include:

- **Case Intake Automation:** AI (NLP, machine vision) tools extract structured data from incoming reports (emails, PDFs, phone transcripts). Oracle's *Safety One Intake* and Veeva's *Vault Safety.AI* are examples that auto-populate fields (patient info, drugs, events) from diverse sources ([ir.veeva.com](#)). This reduces manual entry and speeds throughput (Veeva reports intake time reduction, allowing PV staff to “focus on verification” ([ir.veeva.com](#))). ArisGlobal's LifeSphere likewise emphasizes “*touchless case processing*” with AI-driven intake and NLP ([www.arisglobal.com](#)).

- **Medical Coding & Triage:** AI models can suggest MedDRA coding and WHODrug codes for symptoms and products. Rule-based or ML approaches flag seriousness (e.g. “hospitalization”, “death”) to prioritize cases. Early systems used fixed rules, but modern solutions can learn from historical cases to improve coding accuracy.
- **Signal Detection and Analysis:** AI and data mining help identify safety signals from aggregate data. For example, Oracle Empirica Signal uses statistical algorithms, and Uppsala Monitoring Centre’s vigiRank (an AI-based ranking) prioritizes signals by combining factors like report novelty and completeness (intuitionlabs.ai). Machine learning can sift through multimillion-line datasets to highlight emerging patterns faster than traditional methods.
- **Aggregate Reporting and Regulatory Submission:** AI can assist in generating aggregate reports (PBRERs/PSURs) and regulatory submissions by auto-populating sections from safety databases. It can also check E2B(R3) message completeness and consistency.
- **Advanced Analytics and Predictive Modeling:** ML is used to model patient cohorts, predict adverse outcomes, and support benefit–risk evaluation. Such predictive analytics remain more research-focused but are gaining interest for pharmacometrics and post-market surveillance.
- **Literature and Social Media Monitoring:** Natural language processing and web scraping tools continuously scan scientific literature, social media, and other open sources for new AE information. AI-based literature review systems triage and extract relevant safety data for case creation or signal detection.

A feasibility pilot described in Schmider et al.’s [2019 publication](#) tested three commercial vendors’ proposed solutions. It supported the feasibility of AI-assisted extraction from adverse-event source documents and evaluation of case validity. The publication year should not be treated as the pilot’s execution date, and the pilot does not establish a 2026 industry-wide automation rate or compliance outcome.

These use cases motivate a practical recommendation: evaluate efficiency together with extraction quality, error handling, and human oversight.

Workflow overview: Case intake, coding, triage, signal detection, and reporting are the use cases described above.

Industry Adoption and Benefits

The pharmacovigilance automation market is expanding rapidly. A 2025 market study projects the global PV automation market will generate “hundreds of millions” in revenue from 2025–2034 ([finance.yahoo.com](#)), driven by rising safety regulations and AE volumes. Regionally, North America currently dominates (~45% of the PV automation market in 2024 ([finance.yahoo.com](#))) thanks to high R&D spending, with Asia-Pacific growing fastest. By function, the largest revenue share (~42%) is in automated case processing and reporting ([finance.yahoo.com](#)); notably, **regulatory compliance automation** is identified as the fastest-growing segment (CAGR peak) ([finance.yahoo.com](#)). Among technologies, NLP is expected to grow fastest (as diverse unstructured AE narratives are ingested) ([finance.yahoo.com](#)), although RPA holds the largest share today (36%) ([finance.yahoo.com](#)).

Large biotechs and pharma are key adopters. For example, Merck has migrated from legacy safety DBs to **Veeva Vault Safety** which embeds AI for case intake and tracking (intuitionlabs.ai). Oracle's Argus Safety (now "Safety One Argus") likewise now offers cloud-based AI modules (e.g. NLP intake, AI **translation**) (pmc.ncbi.nlm.nih.gov) (intuitionlabs.ai). One press release notes that Oracle has introduced "AI-driven language translation for case data" in Argus (2024) to allow faster global case processing (intuitionlabs.ai). ArisGlobal's LifeSphere claims multiple top-10 pharmas as customers, emphasizing its "AI-forward" credibility (www.arisglobal.com). There are also specialized service vendors: companies like IQVIA, Accenture, and Cognizant offer outsourced PV services underpinned by AI; IQVIA, for instance, highlights its end-to-end AI solutions for drug safety (from trials to post-market) (intuitionlabs.ai).

Published feasibility evidence supports examining AI-assisted PV tasks, but does not establish how much of industry-wide PV work is automated in 2026. The [Schmider et al. pilot](#) addresses extraction and case validity; it should not be used as a measure of task automation, time savings, or fully automated cases across the industry.

Pharmacovigilance Platforms: Argus, Veeva, LifeSphere, and AI

Many PV professionals use commercial safety databases, including Oracle Argus Safety, Veeva Vault Safety, and ArisGlobal LifeSphere Safety. ArisGlobal is the LifeSphere vendor, as identified in [Nordic Capital's primary announcement](#). Table 2 compares these platforms; it does not imply a Veeva ownership relationship with ArisGlobal.

Platform	Vendor	Deployment	Core AI/Automation Features	Examples/Notes
Oracle Argus Safety	Oracle (Safety One Argus)	Cloud (OCI) & On-prem	- AI/ML case intake and data extraction (Safety One Intake) (docs.oracle.com) - AI-driven language translation (2024) (intuitionlabs.ai) - Signal management (Oracle Empirica)	Long-established PV DB in 25+ countries (docs.oracle.com). Safety One Argus (2026) explicitly "using AI/ML to enhance efficiency..." (docs.oracle.com). Widely used by top pharmas and CROs.
Veeva Vault Safety	Veeva Systems	Cloud (Vault)	- Vault Safety.AI for automated case intake (NLP from docs, emails) (ir.veeva.com) - Integrated cloud suite (Case mgmt, submissions) - RPA for workflows (customer style)	Veeva's integrated cloud system includes Safety and SafetyDocs. Vault Safety.AI was announced in 2019. (ir.veeva.com).

Platform	Vendor	Deployment	Core AI/Automation Features	Examples/Notes
LifeSphere Safety	ArisGlobal	Cloud (LifeSphere PV Suite)	- Advanced Intake with GenAI/LLMs (www.arisglobal.com) - “LifeSphere Cognitive” suite (NLP intake, ML for prioritization, report automation) (intuitionlabs.ai) - Touchless case processing	Market-leading PV platform (www.arisglobal.com). Promotes “AI-powered autonomous intelligence” in PV.

Table 2: Comparison of Leading Pharmacovigilance Systems and Their AI Capabilities. Sources: Oracle Argus documentation (docs.oracle.com); Veeva press releases (ir.veeva.com); ArisGlobal website (www.arisglobal.com); industry reports (intuitionlabs.ai) (intuitionlabs.ai).

Data insights: These platforms primarily aid adverse-event case management, but automation is expanding into signal management and analytics. Oracle’s Empirica Signal and Uppsala Monitoring Centre’s Vigilize should be attributed separately. UMC describes **Vigilize** as supporting signal detection, assessment, and communication. Many vendors now highlight “AI-enabled compliance”: Oracle’s Safety One Argus advertises streamlined reporting via AI (docs.oracle.com), and Veeva’s materials emphasize meeting reporting deadlines by removing manual bottlenecks (ir.veeva.com).

Despite vendor claims, PV systems still require rigorous validation and auditability when AI is added. In practice, new AI modules need to comply with 21 CFR Part 11/Annex 11, be validated to the level of risk, and have their outputs harmonized with regulatory standards (e.g., ensuring E2B(R3) case reports remain correct). We summarize some **observations and recommendations** on AI in these platforms:

- **Integration of AI vs GxP Compliance:** Each platform provides AI features (e.g. ML triage, NLP coding). However, companies must treat these as extensions of the computerized PV system. That means including them in the system’s Validation Master Plan (VMP), qualification scripts, and Change Control. For example, if Argus’ intake AI is updated, it should follow the change-control lifecycle, and its performance bench-tested before release.
- **Data Integrity and Audit Trails:** All AI decisions/processes must be traceable. Systems should log not only the final data entry but also how the AI derived it. This may include showing confidence scores or model versions for each auto-populated field. Audit logs (already mandatory in PV DBs) must be extended to capture AI-related metadata.
- **Consistent Coding Dictionaries:** When AI assists with MedDRA/WHO coding, companies must ensure that the AI’s suggestions use current code dictionaries synchronized with the database. This ensures consistency with regulatory reports.
- **Vendor Collaboration:** Many companies rely on third-party PV software. Under regulatory guidance, PV process owners should have agreements ensuring AI components are held to compliance standards (pmc.ncbi.nlm.nih.gov). This may entail auditing the vendor’s software development lifecycle or obtaining evidence of their validation and data-quality processes.

AI Governance and Compliance Practices in PV

Building an “AI governance and compliance layer” means adapting corporate governance processes to include AI risk management. The following practices are organizational recommendations. Treat AI Act references as conditional on intended-use classification, provider or deployer role, application date, and transition provisions; assess GxP duties separately.

Governance Framework and Organizational Roles

A robust AI governance framework defines **roles and accountability**. Key roles include:

- **AI Steering Committee/Internal Governance Board:** Cross-functional team (PV, QA/Compliance, IT/AI, Legal) that sets AI policy, reviews new projects, and monitors ongoing AI risk.
- **AI Process Owner:** The PV specialist responsible for overseeing AI systems; ensures GxP integration, validation, and change control. This person maintains the list of AI tools in use (like a PV system inventory) for audit readiness (pmc.ncbi.nlm.nih.gov).
- **AI Validator/Quality Assurance:** Sets validation standards for AI (drawing on GAMP5 for computer systems and NIST AI guidelines). Ensures all AI models are validated (with documented fit for purpose tests) (pmc.ncbi.nlm.nih.gov).
- **Data Steward:** Oversees training and input data quality, data governance, and bias assessment. Map Article 10 requirements where they apply to a qualifying high-risk system.
- **IT/DevOps (MLOps) Team:** Implements secure development and continuous integration/continuous deployment (CI/CD) pipelines for AI models, including controls for model versioning, environment isolation, and logging.

Organizationally, the governance layer should augment the existing PV quality system with appropriate AI procedures, such as model validation and change control. Under [Article 17](#), providers of high-risk AI systems must establish a QMS ensuring compliance. Do not assign that provider duty universally to every AI user or every PV system.

Risk Management and Validation

All AI/ML components must pass through the same risk-based validation framework as other PV systems (pmc.ncbi.nlm.nih.gov). The magnitude of effort is proportional to potential patient impact. The following steps are recommended controls. AI Act duties referenced here apply only where the system classification, operator role, application date, and transition rules bring them into scope:

1. **Risk Assessment:** Extend the PV assessment to model reliability, data integrity, privacy, and bias. For a qualifying high-risk system, assess the applicable Article 9 requirements; GxP criticality alone does not determine AI Act classification ([Article 6](#)).
2. **Validation Protocol:** Develop validation scripts and acceptance criteria for AI modules. For example, an AI case intake system must be tested on a representative sample of reports (including outlier cases) to verify extraction accuracy. Metrics for performance (precision/recall for key fields, false negative/positive

rates) should be established.

3. **Data Quality Controls:** Align with AI Act Article 10. Ensure training/validation datasets are aligned with intended use. For instance, if an NLP model is meant to process EU case reports, its training corpus should include EU language variants and case styles. Formal data cleaning and documentation (data lineage) are essential (pharmacystandards.org). Each critical dataset should have metadata (provenance, date range, language coverage).
4. **Bias and Ethical Review:** Assess performance across relevant subgroups, document possible bias, and plan mitigation. [Article 10](#) requires examination of relevant bias and appropriate detection, prevention, and mitigation measures. A “Bias Assessment Report” is a recommended way to organize evidence, not a statutory document title.
5. **Technical Documentation:** Prepare an AI technical file (per Article 11) encompassing design specifications, data governance, risk analysis, test reports, and monitoring plans (pharmacystandards.org). This becomes part of the PV computerized system master file and should be audit-ready. As one expert puts it, think of it as a “*GAMP 5 Validation Package, but supercharged with new legal requirements.*” (pharmacystandards.org) Table 3 (below) illustrates the expanded content required.

Document Type	Traditional GxP (CSV)	AI Act (High-Risk AI)
System Specifications	User Requirements, Functional Specs	General description of intended purpose, scope (pharmacystandards.org)
Design Documentation	Design Specs, Architecture	Detailed AI/ML design (models, architecture)
Validation Protocols & Reports	OQ/PQ protocols	Added AI-specific tests (accuracy, robustness, bias metrics) (pmc.ncbi.nlm.nih.gov)
Traceability Matrix	Traceability matrix (requirements → tests)	Augmented with AI components and risk controls
Training Data & Data Sheets	(Not in CSV)	Data provenance, preprocessing, representativeness
Change Control Records	Change history	Log of model version changes, retraining events
New Additions		
Bias Assessment Report (recommended format)	N/A	Evidence of relevant bias examination and mitigation (pharmacystandards.org)
Fundamental Rights Risk Analysis	Compliance/Risk eval for safety/patients	Consider privacy, fairness, legal/regulatory risks
Vigilance/Incident Plan (PMS)	CAPA records, complaint handling	Monitoring and escalation plan that distinguishes deviations, risk notifications, and legally reportable serious incidents
Logging and Record-Keeping Plan	Audit trail adherence	AI-specific logging schema (Art. 12 requirement)

Table 3: Expanded Validation/Documentation Requirements for High-Risk AI in PV (compared to traditional GxP validation). References: AI Act Articles 10–11 (pharmacystandards.org) (pharmacystandards.org), ISPE GAMP 5, and observance of data integrity best practices.

Table 3 illustrates recommended documentation planning for qualifying high-risk AI, subject to the applicable role and date; adopting AI in PV may involve additional documentation on top of the standard life-cycle docs. In particular, risk-based validation for AI emphasizes metrics of model **reliability, accuracy, and robustness** (pmc.ncbi.nlm.nih.gov). For example, Monte Carlo or adversarial testing might be employed to ensure an NLP model handles rare/unseen cases. All these outputs become part of the regulatory artifact.

Operational Controls and Monitoring

After validation, AI systems enter production under strict controls. Key elements include:

- **Control Plan and Monitoring:** As an internal governance control, informed by [Glaser and Littlebury's discussion](#), maintain a defined **Control Plan** documenting expected model performance and thresholds. Continuously monitor for “drift” (data pattern changes) or degradation. For example, unexpectedly higher rates of “unmapped terms” might signal model obsolescence. Any performance deviation should trigger investigation, retraining, or rollback.
- **Logging and Traceability:** Maintain detailed logs of AI input/output and decision rationale. For qualifying high-risk systems, assess applicable AI Act record-keeping obligations (pharmacystandards.org) and GCP audit trails. Logs should include model version ID, timestamp, input data checksum, output, and proximity scores if applicable. This ensures anomalies can be retroactively examined in audits or inspections (pmc.ncbi.nlm.nih.gov) (pmc.ncbi.nlm.nih.gov).
- **Walled-Garden (Controlled Environment):** Some industry thought leaders suggest keeping a “walled garden” sandbox of each AI model (with its training and test data) for regulator review (pmc.ncbi.nlm.nih.gov). In practice, this might mean preserving a sealed copy of the AI model and data exactly as certified, which can be inspected during audits (mirroring the production environment). This aids in regulatory transparency (EMA expects algorithm/dataset review for benefit–risk support (pmc.ncbi.nlm.nih.gov)).
- **Change Control for AI Updates:** Validate proposed model changes and document the assessment before release. Under [Article 43\(4\)](#), a substantial modification triggers a new conformity assessment for a previously assessed high-risk system. Predetermined learning changes documented at the initial assessment are not automatically substantial modifications. Where notified-body certificates apply, [Article 44](#) limits their stated validity to five years for Annex I systems and four years for Annex III systems; extensions require reassessment under the applicable procedure. Any annual internal review is an organizational control, not a general annual recertification mandate.
- **Incident Reporting:** Investigate deviations, errors, and near misses through internal quality procedures. Apply [Article 3\(49\)](#) separately: a serious incident involves an AI incident or malfunction leading directly or indirectly to death or serious harm to health, serious and irreversible critical-infrastructure disruption, infringement of Union-law fundamental-rights obligations, or serious harm to property or the environment. Potential patient risk alone does not automatically meet this definition. When applicable,

Article 73 requires providers to report immediately after establishing a causal link or its reasonable likelihood, and no later than 15 days after awareness. Widespread infringements and the critical-infrastructure category have an immediate, two-day maximum; deaths have an immediate report after causality is established or suspected and a ten-day maximum. An incomplete initial report may be followed by a complete report. **Article 26(5)** separately addresses deployer risk notifications, suspension of use, and immediate serious-incident notifications to the provider and relevant authorities; Article 73 applies accordingly if the provider cannot be reached. Article 73(9) limits reporting for qualifying Annex III systems subject to equivalent Union-law reporting, and Article 73(10) limits AI Act notifications for MDR/IVDR device AI to fundamental-rights incidents under Article 3(49)(c), to the designated national authority. Assess sectoral vigilance duties separately. A missed or misclassified PV report therefore needs investigation and a reporting assessment, rather than automatic Article 73 classification.

- **Personnel Training and Oversight:** Staff using AI tools need training on their capabilities and limitations. Importantly, a human in the loop must verify critical outputs (especially if mandated by regulations). Documentation of training and competency for PV staff on AI tools is another compliance element.

In short, the operational practice for AI in PV is to treat AI components as validated and auditable instruments, with continuous quality oversight integrated into the safety management process.

Case Studies and Examples

- **Pfizer feasibility pilot (published 2019):** [Schmider et al.](#) describe a pilot testing three commercial vendors' proposed AI solutions for extraction from adverse-event source documents and evaluation of case validity. This supports feasibility, rather than a claim of production deployment, an execution date inferred from copyright, or a demonstrated absence of compliance failures.
- **COVID-19 Vaccine Reporting (2020):** Some companies, like Pfizer, faced a global surge in ICSRs from vaccination campaigns. They quickly deployed Robotic Process Automation (RPA) bots for case intake and celebrated scalability wins ([intuitionlabs.ai](#)). This strategic use of automation (RPA + AI) exemplifies resilience: when PV volumes spiked, automated pipelines handled bottlenecks that manual processing could not.
- **Cross-Product Safety Integration:** At a global forum, a top-10 pharma reported deploying a new AI-enabled signal-detection system to unify surveillance across divisions (pharma, vaccines, consumer health) ([intuitionlabs.ai](#)). This platform – a form of “cognitive RPA” – standardized workflows and data sources, boosting efficiency of distributed safety teams ([intuitionlabs.ai](#)).
- **Leading Vendors:** Oracle has begun rolling out AI in Argus. In 2024–2025, new features include automated coding suggestions and language translation in Argus ([intuitionlabs.ai](#)). Veeva announced Vault Safety.AI in 2019 ([ir.veeva.com](#)). ArisGlobal promoted “MultiVigilance” (touchless processing) and “Advanced Intake” (GenAI) in product announcements as of 2024 ([www.arisglobal.com](#)). These illustrate the breadth of AI integration in the market.

Expert Opinion: Industry analysts emphasize that successful AI governance in PV is *fundamentally no different* from assuring any critical computerized system. One commentary notes, “None (of these [AI governance] activities) is novel. All reflect existing processes within well-functioning pharmacovigilance departments.” (pmc.ncbi.nlm.nih.gov). The new challenge is aligning them with AI-specific imperatives (the AI Act’s “bigger baton” effect (pharmacystandards.org)).

Implications and Future Directions

Immediate Challenges

Pharmacovigilance organizations should prepare for applicable GVP and AI Act oversight by documenting intended use, operator roles, and relevant legal duties. The following are organizational planning recommendations; they are not a universal dual-inspection mandate for all PV AI.

- **GxP & AI Convergence:** Cross-train PV, CSV, and AI teams in model drift, bias, interpretability, and applicable quality procedures. Identify provider and deployer roles before assigning legal duties. The Council on Pharmacy Standards educational material should not be attributed to a government drug regulator.
- **Budget and Resources:** Plan tools, staff training, and documentation against the roadmap dated 14 October 2026. The [Commission's amended schedule](#) puts Annex III high-risk requirements at 2 December 2027 and Annex I regulated-product high-risk requirements at 2 August 2028. These future dates do not postpone provisions already applicable or separate GxP duties. Assess resources against the actual system classification, role, and transition provisions.
- **Data Privacy and Ownership:** When AI models use health data, GDPR considerations apply. De-identification of case data used for algorithm training (if done inside EU) may be required, in addition to AI Act obligations. Also, reliance on cloud AI suppliers raises concerns about cross-border data flows and vendor qualification.

Future Outlook

Future harmonization remains an outlook, rather than an established legal outcome. The [EMA–FDA guiding principles](#) are intended to underpin future AI guidance. TransCelerate’s [Intelligent Automation Opportunities in Pharmacovigilance initiative](#) was completed as of April 2025, with no new solutions or updates planned. Its published assets remain available, including AI-based validation case-study themes, a technology matrix, and an industry survey; these outputs should not be described as an ongoing drafting programme.

For PV in particular, AI promises to extend beyond case processing. Future applications include real-time signal detection across worldwide data networks, patient-level risk profiling, and tailored risk mitigation communications. For instance, AI-driven signal detection could continuously ingest EHR and claims data to spot safety trends weeks before traditional means. Regulatory science is also using AI: the FDA and EMA proactively explore AI to support their own PV (e.g. advanced VigiBase analytics).

Key Imperatives for the Future:

1. **Proactive Governance:** Integrate AI oversight from project inception (“governance by design”), rather than retrofitting, as emphasized by recent thought leadership.
2. **Benchmarking and Metrics:** Agree on industry metrics for AI performance and compliance (accuracy, fairness). Align with regulators on “what good looks like.”
3. **Collaboration:** Regulatory collaboration (e.g. EMA-FDA AI principles (www.ema.europa.eu), multi-stakeholder workplans) will smooth global convergence and reduce duplication.
4. **Technology Bridge:** Investment in explainable AI (XAI), monitoring tools, and secure MLOps will ease compliance. For example, integrated model governance platforms can automatically log AI outputs and track data drift.

One possible future scenario is an “AI-augmented pharmacovigilance culture”: PV professionals routinely using AI assistants and inspectors equally versed in AI compliance. The AI Act acts as a catalyst for that transition, ensuring that as PV becomes more proactive (predicting and preventing adverse effects), it remains fully **accountable and transparent**.

Conclusion

The convergence of AI and pharmacovigilance presents both great promise and critical responsibilities. Leading PV platforms (Argus, Veeva, LifeSphere) are already embedding AI to automate case handling, yet this innovation must be tempered with rigorous governance. AI governance planning should distinguish existing GxP controls from AI Act duties that depend on classification, operator role, application date, and transition rules. Our analysis shows that an **AI Governance and Compliance Layer** – conceptualized as the overlay of processes, documentation, and controls – is not an abstract extra burden but an extension of existing quality practices for the digital age. Key actions include treating AI components as GxP computer systems requiring proportional validation (pmc.ncbi.nlm.nih.gov); ensuring training data are representative and bias-mitigated (pharmacystandards.org); maintaining a “technical file” with enriched documentation (bias reports, performance metrics) (pharmacystandards.org); and embedding monitoring (drift detection, incident reporting) into the safety workflow.

Validation, monitoring, documentation, and human oversight are governance controls, not proof that no compliance failures have occurred. The [EMA–FDA guiding principles](#) underpin future guidance; they do not establish a new PV-specific inspection mandate for 2026. Pharmaceutical companies should map their AI-enabled pharmacovigilance to the duties applicable to each system and operator.

Looking ahead, PV teams should connect each AI use to its intended purpose, evidence of performance, quality controls, and accountable owners. This provides a practical basis for assessing efficiency and safety without guaranteeing legal compliance or better clinical outcomes.

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Source links

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