

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 significant efficiency gains (e.g. up to 30–50% of case processing automated (^[1] [intuitionlabs.ai](#))), they also create new regulatory challenges. In response, regulators are developing robust [AI governance frameworks](#). In the EU, the AI Act (Regulation (EU) 2024/1689) – the world’s first comprehensive AI law – imposes horizontal obligations for all AI systems, layered atop existing pharmacovigilance regulations (such as E2B(R3), GVP, and GDPR) (^[2] [pharmacystandards.org](#)). Key provisions include strict data governance, documentation, testing, and incident-reporting requirements for “high-risk” AI. 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. Ultimately, we find that with proper governance (including validation like any GxP system (^[3] [pmc.ncbi.nlm.nih.gov](#)), ongoing monitoring for data drift (^[4] [pmc.ncbi.nlm.nih.gov](#)), and [full auditability](#)), AI can be deployed in pharmacovigilance without compromising compliance. 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 (^[5] [www.globenewswire.com](#)) (^[6] [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 (^[7] [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 (^[8] [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 (^[9] [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**” (^[10] [www.arisglobal.com](#)) and “touchless case processing” via end-to-end automation. These innovations have yielded substantial productivity gains: industry pilots report queuing **30–50%** of case processing activities automated by AI (^[11] [intuitionlabs.ai](#)), with turnaround times shrinking from days to hours. Crucially, *no major company has reported regulatory compliance issues* from these AI deployments, provided proper validation and oversight are maintained (^[11] [intuitionlabs.ai](#)).

However, the adoption of “**AI agents**” (including ML models and generative LLMs) in PV also brings new regulatory scrutiny. In 2026, pharmacovigilance teams are expected not just to *use* AI, but to *explain and control* it. Both the U.S.

FDA and European regulators now demand that AI/ML-driven PV systems be governed, validated, monitored, and audit-ready like any other **GxP computer system** (^[11] [medium.com](#)). In early 2026, the FDA and EMA jointly released guiding principles emphasizing that PV AI must be *explainable, traceable, and inspection-ready* (^[11] [medium.com](#)). Meanwhile, the EU's horizontal **Artificial Intelligence Act** (the "AI Act") was finalized (in 2024) to set mandatory rules for all AI in the EU. Under this law, many PV-relevant AI applications will fall into "high-risk" categories requiring extensive compliance measures.

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 (2026 implementation). We survey historical PV regulation, technical landscape of PV systems, AI use cases in safety, and then detail regulatory and governance frameworks. We compile data (market forecasts, adoption stats) and expert insights, and include case studies (e.g. Pfizer's AI pilot, major biopharma AI deployments (^[12] [intuitionlabs.ai](#)) (^[13] [intuitionlabs.ai](#))). Through this analysis, we layout best practices for integrating AI: from design and validation (treated under GxP principles (^[3] [pmc.ncbi.nlm.nih.gov](#))) to documentation (technical files, bias reports, logs (^[14] [pharmacystandards.org](#)) (^[15] [pharmacystandards.org](#))) to continuous monitoring (control plans, drift detection (^[4] [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. The thalidomide tragedy highlighted why such strict oversight is needed: *"no patient suffers avoidable harm"* (^[16] [pmc.ncbi.nlm.nih.gov](#)).

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"* (^[17] [pmc.ncbi.nlm.nih.gov](#)). Validation documentation must include training data sets, code, testing results, and a control plan for risk (^[18] [pmc.ncbi.nlm.nih.gov](#)) (^[19] [pmc.ncbi.nlm.nih.gov](#)). 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 (^[20] [pmc.ncbi.nlm.nih.gov](#)), and the need to demonstrate explainability (per GxP audit trails) (^[21] [pmc.ncbi.nlm.nih.gov](#)).

Meanwhile, in the EU the regulatory environment is undergoing a generational shift. In July 2024, the EU formally adopted the **Artificial Intelligence Act** (Regulation (EU) 2024/1689), which entered into force on August 1, 2024. Unlike

sector-specific PV rules (“vertical” regulation for drug safety), the AI Act is a *horizontal* law covering *all* industries (^[12] [pharmacystandards.org](#)). It establishes a risk-based regime for AI: **high-risk** applications must meet strict obligations (data governance, documentation, transparency, human oversight, incident reporting, etc.), whereas low-risk AI have minimal requirements and some uses (e.g. harmful content generation) are outright prohibited. The Act introduces new legal roles and burdens: e.g., “Providers” and “Deployers” of AI have different responsibilities, and an expanded Quality Management System is required to cover AI (e.g., per Art. 17 each AI system must be integrated into QMS procedures) (^[22] [pharmacystandards.org](#)).

Notably, **almost all AI systems in pharmaceutical PV are likely to be classified as high-risk** under the AI Act. According to EU guidelines, any AI used as a safety component of a medical product or any AI in software requiring medical-device conformity falls under high-risk criteria (^[23] [www.iqvia.com](#)) (^[24] [www.iqvia.com](#)). In practice, while PV case management software itself may not be a “medical device,” certain PV applications (such as AI-assisted diagnostics or risk assessment) could be. Even if not formally a device, AI tools processing health data may be treated with caution: industry analysts expect that **“almost all of your GxP-critical systems”** will be treated as high-risk under the new law (^[22] [pharmacystandards.org](#)). Consequently, PV organizations must bring their AI systems into compliance “parallel” to GxP: the AI Act’s “horizontal” obligations sit on top of GxP/MDR/GDPR requirements (^[2] [pharmacystandards.org](#)). For example, Article 10 of the AI Act (data governance) mandates that providers of high-risk systems use representative, error-free, and unbiased training datasets (^[14] [pharmacystandards.org](#)) ; Article 11 requires comprehensive technical documentation akin to a CSV validation package (preserved for 10 years) (^[15] [pharmacystandards.org](#)) ; Article 73 obligates reporting of “serious incidents” caused by high-risk AI to national authorities, mirroring vigilance reporting (^[25] [pharmacystandards.org](#)).

Key timelines: The AI Act’s provisions are phased in from 2025 through 2027, creating a “ticking clock” for compliance (^[26] [pharmacystandards.org](#)). Non-EU providers are in scope if the AI is “placed on the market” or “put into service” in the EU. In effect, global pharma companies must now satisfy both sets of rules. (A helpful analogy dubbed the AI Act a “City Building Inspector” inspecting AI wiring throughout the hospital building, even beyond where the “Hospital Electrical Inspector” of GxP has purview (^[27] [pharmacystandards.org](#)).

Implications for Pharmacovigilance

In practice, the convergence of PV and AI regulation imposes concrete demands on PV practitioners. Table 1 (below) summarizes some AI Act obligations with PV relevance:

| 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 (^[28] 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) | Ensure training/validation datasets are <i>relevant, representative</i> , complete, error-free, and bias-mitigated (^[14] pharmacystandards.org). | Use diverse, high-quality AE datasets (across populations) for model training. Implement formal data cleaning and bias assessment reports. |
| Technical Documentation (Art. 11, Annex IV) | Create a comprehensive “technical file” (GxP validation pack with AI-specific docs) that details system design, intended purpose, performance tests. Must be retained 10 years (^[15] pharmacystandards.org). | Expand traditional CSV documentation: include AI model architecture, training/validation data provenance, bias analyses, robustness tests. |
| Post-Market Monitoring & Incident Reporting (Arts. 72–73) | For high-risk AI systems, continuously monitor performance (PMS) and report any <i>serious incidents</i> (system malfunctions causing harm) to authorities (^[25] pharmacystandards.org). | Treat critical AI failures (e.g. misclassification causing patient risk) as reportable events. Augment PV quality system for ongoing model monitoring (detect data drift, errors). |
| Human Oversight & Transparency | High-risk AI must allow appropriate human oversight and be sufficiently transparent/explainable in operation. | Ensure PV staff can review and override AI outputs. Maintain clear audit trails (e.g. logs of AI decisions) and documentation to allow explainability. |
| Quality Management System (Art. 17) | Update the firm’s QMS to integrate AI-specific processes (governance, ownership, workflow control). | Revise SOPs to cover AI lifecycle (e.g. change control for model updates, vendor audits), embed AI oversight in PV Master File. |

Table 1: Key EU AI Act Requirements and Their Implications for Pharmacovigilance (2026). Sources: EU AI Act (Reg. 2024/1689) articles and official guidance (^[25] [pharmacystandards.org](#)) (^[14] [pharmacystandards.org](#)) (^[15] [pharmacystandards.org](#))

pharmacystandards.org) (^[28] pharmacystandards.org).

The net effect is that PV organizations must **build an AI-governance layer** on top of their case management systems. This entails: formalizing roles (identifying who is the “Provider” vs. “Deployer” of any AI tool); expanding quality documentation (e.g. adding bias reports, logging plans, fundamental rights risk analysis to technical files (^[29] pharmacystandards.org)); and instituting ongoing vigilance for AI components. While these requirements may appear daunting, they are largely an extension of existing GxP practices. Indeed, the same article notes: “None of these [AI governance] activities is novel. All reflect existing processes within well-functioning pharmacovigilance programmes.” (^[21] pmc.ncbi.nlm.nih.gov) (^[17] pmc.ncbi.nlm.nih.gov). Nevertheless, the explicit legal mandate makes this a top priority for PV compliance.

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 (^[30] ir.veeva.com). This reduces manual entry and speeds throughput (Veeva reports intake time reduction, allowing PV staff to “focus on verification” (^[31] ir.veeva.com)). ArisGlobal’s LifeSphere likewise emphasizes “touchless case processing” with AI-driven intake and NLP (^[32] 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 (^[7] 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.

These applications have moved beyond pilots into production. A 2021 pilot at Pfizer tested multiple AI systems for auto-extracting case data and initial assessment; it proved “AI tools can accurately extract key data (drugs, events, patient info) and even determine case validity” (^[12] intuitionlabs.ai). Following such successes, top pharma (Roche, Novartis, AstraZeneca, J&J, Merck, etc.) have implemented AI-driven PV platforms. Many have adopted ArisGlobal LifeSphere, marketed as “AI-Forward” with cognitive modules, or Veeva Vault Safety with AI intake. Some have reported handling COVID-19 vaccine report surges by combining RPA bots (for data transfers) with AI (for processing) (^[33] intuitionlabs.ai). Anecdotally, companies achieving 30–50% automation claim dramatically shorter processing times, “with no reported major compliance issues” (^[1] intuitionlabs.ai) when proper validation is applied.

These real-world deployments underline a key insight: **AI integration solves pressing PV efficiency needs**, but must be matched by commensurate oversight. As one industry analysis notes, “AI integration is a natural evolution for PV — it addresses inefficiencies and positions drug safety monitoring for the growing challenges of the 21st century.”^[34] (intuitionlabs.ai).

Figure 1: Sample AI use cases in pharmacovigilance workflows (case intake, coding, triage, signal detection, reporting). Image credit: [Pharmacovigilance analytics infographic]^[35] www.pharmacovigilanceanalytics.com — shows AI accelerating detection of adverse effects by leveraging advanced analytics.

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^[36] (finance.yahoo.com), driven by rising safety regulations and AE volumes. Regionally, North America currently dominates (~45% of the PV automation market in 2024^[37] (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^[37] (finance.yahoo.com); notably, **regulatory compliance automation** is identified as the fastest-growing segment (CAGR peak)^[37] (finance.yahoo.com). Among technologies, NLP is expected to grow fastest (as diverse unstructured AE narratives are ingested)^[38] (finance.yahoo.com), although RPA holds the largest share today (36%)^[39] (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^[40] (intuitionlabs.ai). Oracle’s Argus Safety (now “Safety One Argus”) likewise now offers cloud-based AI modules (e.g. NLP intake, AI **translation**)^[41] (pmc.ncbi.nlm.nih.gov)^[42] (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^[42] (intuitionlabs.ai). ArisGlobal’s LifeSphere claims multiple top-10 pharmas as customers, emphasizing its “AI-forward” credibility^[43] (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)^[44] (intuitionlabs.ai).

In sum, by 2026 AI has become established in PV pipelines, with broad industrial trials completed and many production workloads. Survey data (semi-confidential) suggest PV teams now routinely use AI for up to half of their routine tasks^[1] (intuitionlabs.ai). This makes AI governance no longer optional: **inspections are no longer asking if AI is used, but how it is controlled**^[45] (medium.com).

Pharmacovigilance Platforms: Argus, Veeva, LifeSphere, and AI

Many PV professionals leverage commercial safety databases. Historically, Oracle Argus Safety (originally Relsys product) and ArisGlobal LifeSphere Safety dominated the market, with Veeva Vault Safety (launched 2019) gaining share, especially after Veeva’s 2023 acquisition of ArisGlobal. Each platform is now embedding AI/automation capabilities. Table 2 compares these leading tools.

| Platform | Vendor | Deployment | Core AI/Automation Features | Examples/Notes |
|---------------------|---------------------------|-----------------------|---|---|
| Oracle Argus Safety | Oracle (Safety One Argus) | Cloud (OCI) & On-prem | <ul style="list-style-type: none"> - AI/ML case intake and data extraction (Safety One Intake)^[8] (docs.oracle.com) - AI-driven language translation (2024)^[42] (intuitionlabs.ai) - Signal management (Oracle Empirica) | <ul style="list-style-type: none"> Long-established PV DB in 25+ countries^[46] (docs.oracle.com). Safety One Argus (2026) explicitly “using AI/ML to enhance efficiency...”^[8] (docs.oracle.com). Widely used by top pharmas and CROs. |

| Platform | Vendor | Deployment | Core AI/Automation Features | Examples/Notes |
|--------------------|--------------------------------|-----------------------------|--|---|
| Veeva Vault Safety | Veeva Systems | Cloud (Vault) | <ul style="list-style-type: none"> - Vault Safety.AI for automated case intake (NLP from docs, emails) ([9] ir.veeva.com) - Integrated cloud suite (Case mgmt, submissions) - RPA for workflows (customer style) | Veeva's integrated cloud system includes Safety and SafetyDocs. Customers include Merck, etc ([47] intuitionlabs.ai). Vault Safety.AI launched 2020 to "speed case processing." ([9] ir.veeva.com). |
| LifeSphere Safety | ArisGlobal (now part of Veeva) | Cloud (LifeSphere PV Suite) | <ul style="list-style-type: none"> - Advanced Intake with GenAI/LLMs ([10] www.arisglobal.com) - "LifeSphere Cognitive" suite (NLP intake, ML for prioritization, report automation) ([7] intuitionlabs.ai) - Touchless case processing | Market-leading PV platform ([43] www.arisglobal.com). Adopted by Roche, Novartis, AZ, J&J for global safety ([13] intuitionlabs.ai). Promotes "AI-powered autonomous intelligence" in PV. |

Table 2: Comparison of Leading Pharmacovigilance Systems and Their AI Capabilities. Sources: Oracle Argus documentation ([8] docs.oracle.com); Veeva press releases ([9] ir.veeva.com); ArisGlobal/Veeva websites ([32] www.arisglobal.com); industry reports ([42] intuitionlabs.ai) ([7] intuitionlabs.ai).

Data insights: These platforms primarily aid adverse-event case management, but automation is expanding into signal management and analytics. For example, Oracle maintains **Empirica Signal** (incorporating ML analytics) and **VigiLyz** (UMC's algorithmic tool), while LifeSphere partners include UMC. Many vendors now highlight "AI-enabled compliance": Oracle's Safety One Argus advertises streamlined reporting via AI ([8] docs.oracle.com), and Veeva's materials emphasize meeting reporting deadlines by removing manual bottlenecks ([31] 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 ([17] 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. We detail the core practices and domains needed.

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 (^[48] 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) (^[17] pmc.ncbi.nlm.nih.gov).
- **Data Steward:** Oversees training and input data quality, bias mitigation, and data governance policies implementing Article 10 requirements (^[14] pharmacystandards.org).
- **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 AI governance layer should augment the existing Quality Management System (ISO 13485, 9001 or equivalent for PV) to explicitly include AI procedures. For example, new SOPs might cover topics like “Validation of machine learning systems” and “Handling of algorithm updates.” The AI Act explicitly requires updating QMS SOPs to handle new AI-specific processes (per Art. 16–17 discussions (^[49] pharmacystandards.org)).

Risk Management and Validation

All AI/ML components must pass through the same risk-based validation framework as other PV systems (^[17] pmc.ncbi.nlm.nih.gov). The magnitude of effort is proportional to potential patient impact. The basic steps include:

1. **Risk Assessment (Article 9):** Extend existing PV risk assessments to AI use. Beyond usual data integrity and reliability risks, include algorithmic risks: e.g. a model might systematically miss hypoglycemia-related reports if trained mostly on headache reports. Article 9 of the AI Act requires considering “risks to fundamental rights and democracy” (^[50] pharmacystandards.org), though in PV the focus will primarily be on patient safety, privacy, and bias.
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 (^[14] pharmacystandards.org). Each critical dataset should have metadata (provenance, date range, language coverage).
4. **Bias and Ethical Review:** Perform periodic algorithmic bias assessments. This means analyzing AI outputs across subgroups (e.g. age, gender, geography) to detect systematic biases. Document the findings in a “Bias Assessment Report” as mandated by Article 10 (^[14] pharmacystandards.org) (^[15] pharmacystandards.org). For example, if an AI algorithm downplays adverse events reported in elderly patients, this must be identified and mitigated (e.g. by augmenting training data).
5. **Technical Documentation:** Prepare an AI technical file (per Article 11) encompassing design specifications, data governance, risk analysis, test reports, and monitoring plans (^[15] 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.” (^[15] 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 (^[14] 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) (^[18] 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 | | |

| Document Type | Traditional GxP (CSV) | AI Act (High-Risk AI) |
|----------------------------------|--|---|
| Bias Assessment Report | N/A | Formal analysis and mitigation of data bias (^[14] 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 | Plan for monitoring AI performance and reporting glitches (AI Act Art.73) |
| 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 (^[14] [pharmacystandards.org](https://www.pharmacystandards.org)) (^[15] [pharmacystandards.org](https://www.pharmacystandards.org)), ICH GAMP5, and observance of data integrity best practices.

Table 3 illustrates that adopting AI in PV means layering 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** (^[51] 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 [39] recommends, 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. This satisfies AI Act record-keeping obligations (^[15] [pharmacystandards.org](https://www.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 (^[21] pmc.ncbi.nlm.nih.gov) (^[20] 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 (^[20] 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 (^[21] pmc.ncbi.nlm.nih.gov)).
- Change Control for AI Updates:** Model updates (re-training, parameter tweaks, data refresh) must follow Change Control. Only well-validated updates may be promoted. The AI Act proposes annual re-certification for high-risk systems, so PV should track versions and re-validation cycles.
- Incident Reporting:** Promptly treat any AI-related failure that causes or risks patient harm as a **serious incident**. Under Article 73, if the AI system is high-risk, the *provider* must report such events to national authorities (^[25] [pharmacystandards.org](https://www.pharmacystandards.org)). For example, if an AI triage algorithm erroneously filters a case of Stevens-Johnson syndrome, PV would document this as a safety failure of the system and report per GVP/AI Act rules.
- 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 Pilot (2018):** Pfizer tested three commercial AI solutions to auto-extract case data using their historical database. The pilot found AI could accurately identify key fields and assess case validity (^[12] intuitionlabs.ai). This real-world study validated the feasibility and guided selection of vendors for deployment (^[12] intuitionlabs.ai).
- **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 (^[33] 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) (^[52] intuitionlabs.ai). This platform – a form of “cognitive RPA” – standardized workflows and data sources, boosting efficiency of distributed safety teams (^[52] 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 (^[42] intuitionlabs.ai). Veeva’s Safety.AI launched in 2020, and by 2025 is a core part of their Vault Safety Suite (^[9] ir.veeva.com). ArisGlobal promoted “MultiVigilance” (touchless processing) and “Advanced Intake” (GenAI) in product announcements as of 2024 (^[32] 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.” (^[21] pmc.ncbi.nlm.nih.gov). The new challenge is aligning them with AI-specific imperatives (the AI Act’s “bigger baton” effect (^[2] pharmacystandards.org)).

Implications and Future Directions

Immediate Challenges

Pharmacovigilance organizations face a “dual-inspection” paradigm. Auditors may simultaneously enforce GVP and AI Act rules. As the pharmacy standards guide colorfully puts it, firms must “pass both inspections”: the specialty (EMA) inspector focusing on PV impact, and the “City Inspector” for AI code compliance (^[27] pharmacystandards.org). This compels PV teams to rapidly upgrade their QMS and SOPs:

- **GxP & AI Convergence:** Existing CSV practitioners must learn AI-centric concepts like ML model drift, bias, and interpretability. Conversely, AI teams must embed GxP mindsets. Cross-training and hiring “AI compliance” expertise is becoming common. According to one regulator, this is “the most critical strategic concept”: determining who is provider vs deployer and what their liability is (^[53] pharmacystandards.org).
- **Budget and Resources:** Implementing an AI compliance layer requires investment in tools (e.g. MLOps platforms with audit features), staff training, long-term documentation. The regulatory timeline (2025–2027) is relatively short for many companies still exploring AI in PV. There may be resource constraints, especially in smaller pharma or CROs.
- **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

Despite challenges, the long-term outlook is promising. The global push for **responsible AI** suggests frameworks will become more harmonized across jurisdictions. The EU AI Act may influence FDA/CFR updates (already FDA has “Guiding Principles” culminating in 2026 with articulate transparency expectations (^[11] medium.com)). Initiatives like ICH’s planned “Guideline on AI/ML” may further standardize expectations globally beyond the EU. Industry consortia

(TransCelerate AI in PV) are already drafting best practices for “assurance-ready” AI (^[54] www.transceleratebiopharmainc.com).

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:** Public–private partnerships (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.

In summary, by 2026–2028 the landscape will likely resemble 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. The EU AI Act (2026) codifies what many in PV have intuitively practiced under GxP: robust validation, data integrity, and auditability. 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 (^[17] pmc.ncbi.nlm.nih.gov); ensuring training data are representative and bias-mitigated (^[14] pharmacystandards.org); maintaining a “technical file” with enriched documentation (bias reports, performance metrics) (^[15] pharmacystandards.org); and embedding monitoring (drift detection, incident reporting) into the safety workflow.

These measures will enable PV organizations to deploy AI solutions (for case intake, coding, signals, etc.) with confidence that they can “withstand regulatory scrutiny” (^[55] medium.com). Indeed, early adopters already report significant efficiency improvements without compliance lapses (^[1] intuitionlabs.ai). The emerging regulatory doctrine is clear: **inspections in 2026 and beyond demand proof of AI oversight, not simple black-box use** (^[45] medium.com). Pharmaceutical companies must therefore pro-actively align their AI-enabled pharmacovigilance with both GxP and AI Act obligations.

Looking ahead, the AI Act’s influence may extend well into PV and life sciences innovation. It effectively makes responsible AI a core aspect of “patient safety.” Companies that invest now in a rigorous AI governance layer – embedding explainability, transparency, and data quality from the ground up – will not only comply with the law but likely achieve better outcomes through trustworthy AI. In essence, AI governance in PV is about building “*defensible, compliant AI workflows for regulatory inspections*” (^[11] medium.com). By doing so, PV teams can harness the full benefits of AI (faster signal detection, predictive insight, global scalability) while ensuring no compromise on the ultimate goal: safeguarding patient health.

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