Agentic AI in Pharmacovigilance

Transforming Drug Safety Operations Through Autonomous Intelligence

Capgemini invent

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Executive Summary

Pharmacovigilance (PV) is undergoing a profound transformation, evolving from a compliance-centered function into a strategic, data-driven discipline. Traditionally, PV has served as the cornerstone of drug safety, ensuring the detection, assessment, and prevention of adverse effects throughout a product's lifecycle. However, the landscape is changing rapidly. Regulatory requirements are becoming more stringent, and the volume of safety data is exploding, as illustrated by more than 2.5 million Individual Case Safety Reports (ICSRs) submitted annually to the US Food and Drug Administration's (FDA's) FAERS database.

This surge in data volume and complexity has pushed PV beyond its historical role as a reactive, compliance-driven process. Today, it is evolving into a proactive enabler of patient safety and a critical component of global health strategy. Organizations are seeking advanced technologies to manage this data deluge, accelerate signal detection, and ensure real-time regulatory compliance.

Agentic AI represents a transformative leap forward. Unlike traditional automation or rule-based systems, Agentic AI leverages autonomous intelligent agents capable of perceiving, reasoning, planning, and acting independently across PV workflows. Imagine an autonomous PV analyst that never sleeps, continuously monitoring diverse safety data streams, adapting to evolving regulatory frameworks, and delivering actionable insights with minimal human intervention.

This white paper explores how Agentic AI is redefining pharmacovigilance by creating an autonomous, intelligent safety ecosystem. This paradigm shift enhances operational efficiency, strengthens regulatory compliance, and ultimately improves patient outcomes. By integrating technologies such as natural language processing, machine learning, and autonomous decision-making, Agentic AI positions PV as a future-ready discipline, one that is predictive, adaptive, and strategically aligned with global health imperatives.

Quantified Business Impact

Speed and Efficiency

Agentic AI dramatically accelerates pharmacovigilance workflows by automating repetitive tasks such as data entry, coding, and narrative generation. Processes that once required up to eight hours of manual case processing can now be completed in approximately 30 minutes[1]- a 94% reduction in turnaround time. This efficiency not only clears backlogs but also enables PV teams to focus on complex medical assessments and strategic risk management.

Accuracy and Compliance

Beyond speed, Agentic AI significantly enhances data integrity and regulatory performance. Accuracy rates improve from 60% to 95%[2], reducing costly errors and rework while strengthening the reliability of safety profiles. Automated scheduling and proactive alerts ensure 100% on-time submissions compared with previous rates of around 85%[3], eliminating compliance risk and reinforcing trust with global health authorities.

Cost Savings and Proactive Safety

The financial impact is equally compelling. Organizations can achieve a 40–60%[4] reduction in operational costs within 12 months by scaling PV operations without proportional increases in headcount. At the same time, AI-driven analytics accelerate signal detection by up to 70%[5], enabling earlier identification of emerging risks and proactive intervention, ultimately safeguarding patient safety and preserving market access.

Industry Validation

A leading pharmaceutical company deployed Agentic AI for case intake, reducing processing backlogs by 75% within 6 months while maintaining 100% regulatory compliance across FDA, EMA, and MHRA submissions.[6]

Introduction & Background

The Pharmacovigilance Challenge

Global Drug Safety Monitoring: The Complexity Challenge

Pharmacovigilance today operates in an environment of unprecedented scale and complexity. Regulatory authorities such as the US Food and Drug Administration (FDA) receive more than 2.5 million Individual Case Safety Reports (ICSRs) annually [1] through FAERS alone, a volume that continues to grow as global reporting obligations expand. This surge in data places immense pressure on PV teams to process, validate, and analyze cases quickly without compromising accuracy or compliance.

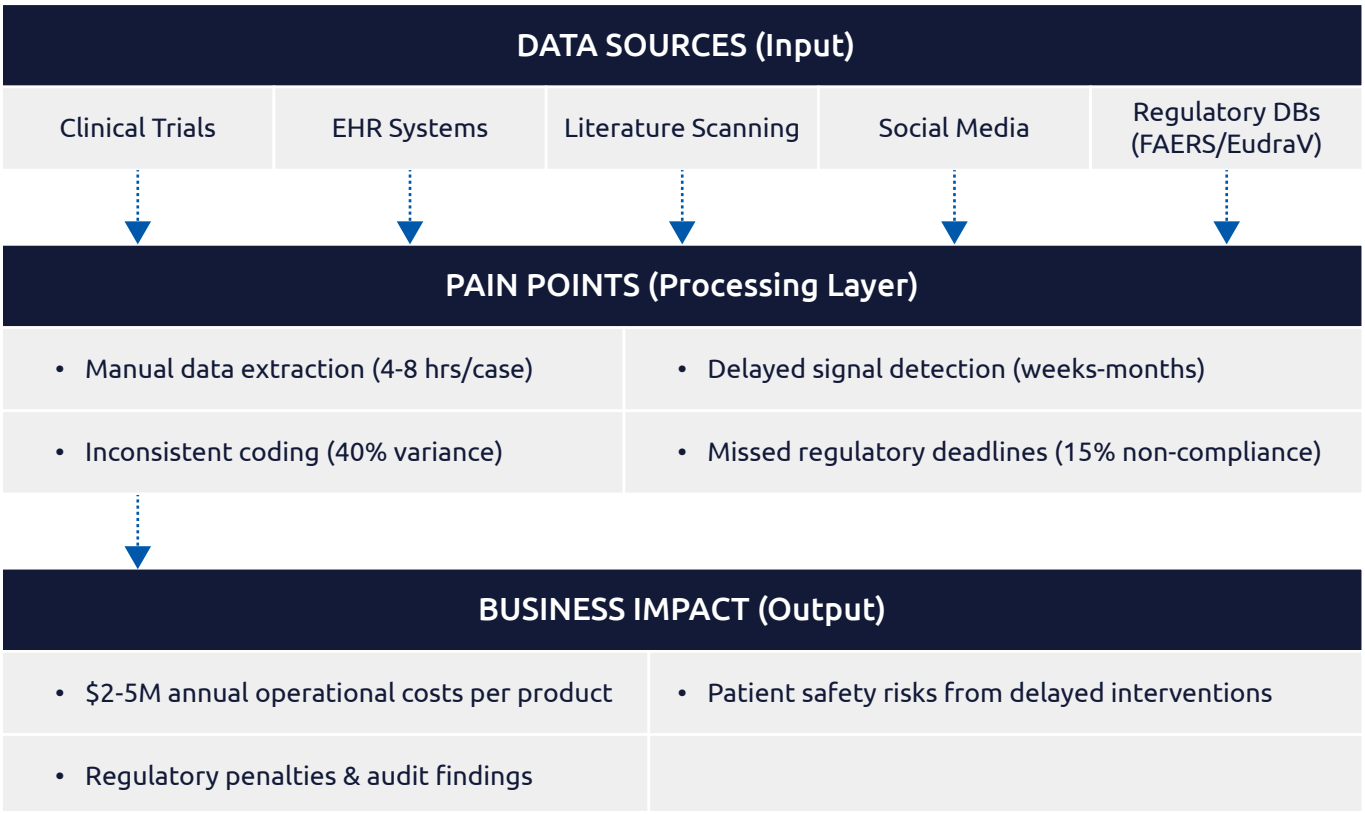
Fragmented Data Sources and Evolving Regulations

Safety information now originates from a wide array of sources, including clinical trials, electronic health records (EHRs), patient registries, published literature, and even social media platforms. Integrating these heterogeneous datasets into a coherent and reliable safety narrative presents a formidable challenge. Compounding this issue are rapidly evolving regulatory frameworks, such as the FDA's 2023 discussion paper on AI/ML in drug development and European Medicines Agency's (EMA's) draft guideline on AI-enabled medicines. These developments demand not only regulatory compliance but also robust governance, transparency and explainability across AI-driven processes.

Compressed Timelines and Operational Pressure

Global PV operations must adhere to stringent regulatory timelines, including 15-day expedited reporting for serious adverse events and 90-day periodic submissions across multiple jurisdictions. These deadlines leave little room for manual inefficiencies or data inconsistencies. As a result, organizations are increasingly compelled to adopt advanced automation and intelligent systems to ensure timely, accurate reporting while maintaining full traceability and audit readiness.

PV Ecosystem Complexity



The diagram provides a high-level view of the pharmacovigilance (PV) workflow, illustrating how raw safety data moves through successive processing stages and ultimately influences business outcomes. It highlights the interconnected nature of PV operations and explains why traditional, manual approaches are increasingly unsustainable. At the top, diverse data sources feed into the system, ranging from structured clinical trial records to unstructured inputs such as social media content and regulatory databases. These inputs then flow through a processing layer where operational pain points emerge, such as manual data extraction, inconsistent coding, and delayed signal detection. Finally, the output layer reflects the consequences of these inefficiencies, such as high operational costs, compliance risks, and potential patient safety concerns. This flow underscores the urgent need for automation and AI-driven solutions to streamline processes, improve accuracy, and enable proactive risk management.

The Transformation Imperative

Traditional PV systems were designed for an era of limited data volumes and predictable regulatory frameworks. Today, they face an unprecedented challenge of scale and complexity. With millions of ICSRs, diverse real-world evidence sources, and global regulatory variations, manual and semi-automated processes cannot keep pace. These legacy systems struggle with:

- **Data Overload:** Structured and unstructured safety data from EHRs, social media, and clinical trials.
- **Regulatory Velocity:** Frequent updates and expectations from regulatory agencies such as the FDA and EMA increasingly demanding near real-time compliance.
- **Operational Bottlenecks:** High dependency on human review, leading to delays and increased risk.

What is Agentic AI?

Agentic AI

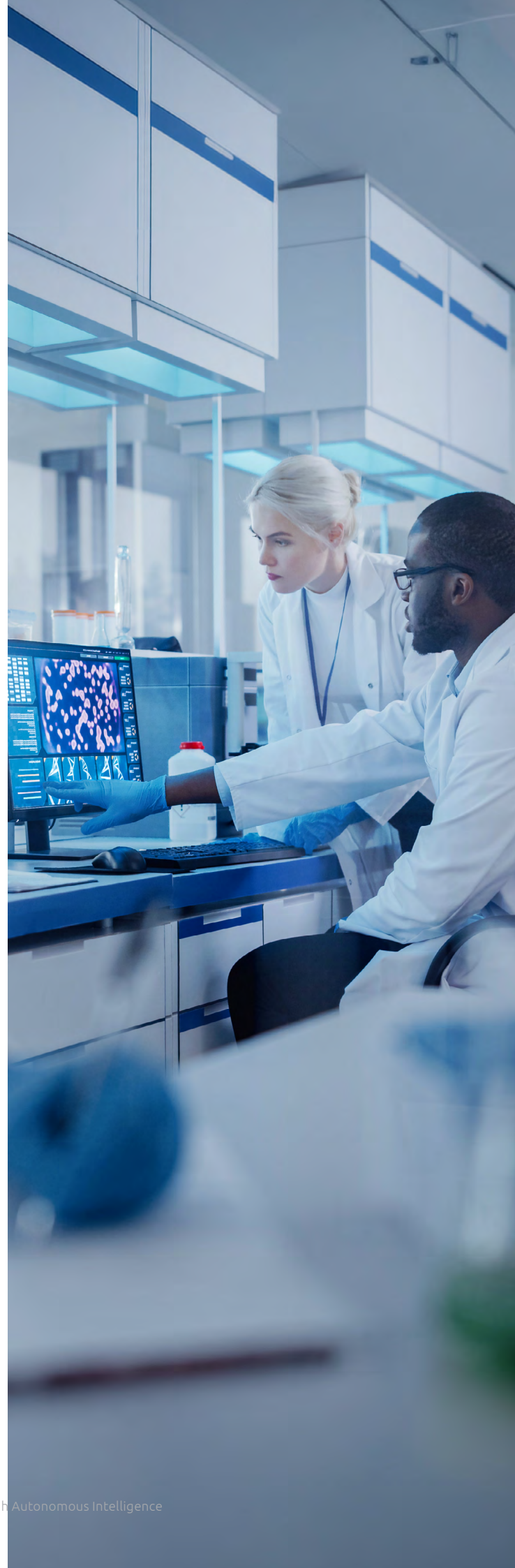
Agentic AI refers to autonomous intelligent systems that can perceive, reason, plan, and act independently without constant human oversight. These systems go beyond traditional automation by embedding adaptive intelligence. They learn from every interaction, improving decision-making over time, and dynamically responding to new, evolving scenarios.

An Analogy to Illustrate the Concept

Imagine a tireless pharmacovigilance analyst who never sleeps, processes thousands of safety cases simultaneously, and continuously learns from every decision. This analyst doesn't simply follow static rules, it adapts instantly to new regulatory requirements, predicts emerging risks, and proactively manages compliance obligations. Unlike conventional tools, Agentic AI operates as a self-directed entity, capable of orchestrating complex workflows, prioritizing tasks, and delivering actionable insights in real time.

Key Characteristics of Agentic AI

- **Perception:** Interprets both structured and unstructured data from multiple sources including ICSRs, EHRs, and social media.
- **Reasoning:** Applies advanced algorithms to detect patterns, assess risk, and make informed decisions.
- **Planning:** Strategically organizes tasks to optimize efficiency and regulatory compliance.
- **Action:** Executes processes autonomously, including case intake, coding, narrative generation, and regulatory submissions.



Traditional AI vs Agentic AI

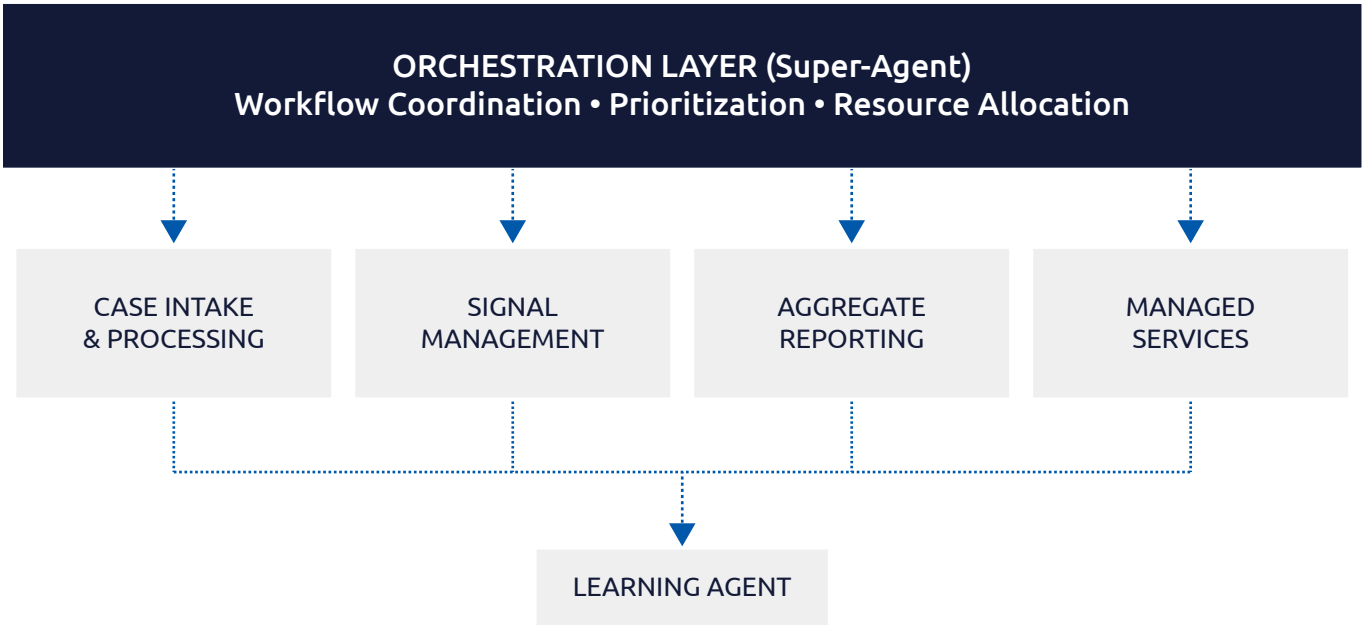
Understanding the distinction between Traditional AI and Agentic AI is essential to appreciating the significant leap in capability and autonomy that Agentic AI brings to pharmacovigilance. While Traditional AI focuses primarily on static, rule-based automation, Agentic AI introduces adaptive, self-directed intelligence that transforms workflows from rigid processes into dynamic, context-aware systems.

The table below compares Traditional AI and Agentic AI across five key capabilities, highlighting a fundamental shift in how intelligence is applied and operationalized. Traditional AI typically relies on rule-based, predefined workflows designed for single-task automation. These systems require frequent human oversight and manual updates to static models and often struggle to adapt to regulatory changes or variations in data. In contrast, Agentic AI enables autonomous decision-making through contextual reasoning. It orchestrates collaboration among multiple intelligent agents across end-to-end workflows, and continuously learns from outcomes and feedback. Rather than operating under constant human control, Agentic AI functions with strategic human guidance, dynamically adapting to evolving regulations and complex data environments. This evolution positions Agentic AI as a transformative force, moving beyond automation to enable intelligent, self-directed pharmacovigilance operations.

Capability	Traditional AI	Agentic AI
Operation	Rule-based, predefined workflows	Autonomous decision-making with contextual reasoning
Scope	Single-task automation	Multi-agent orchestration across end-to-end workflows
Learning	Static models, manual updates	Continuous learning from outcomes and feedback
Autonomy	Constant human oversight	Strategic guidance, minimal intervention
Adaptability	Rigid, breaks with changes	Adapts to regulatory updates and data variations

Agentic AI in Pharmacovigilance: Transforming Core Functions

Unified Multi-Agent Architecture



Continuous improvement across all functions

The diagram presents a Unified Multi-Agent Architecture designed for pharmacovigilance automation. At the top is the **Orchestration Layer** (Super-Agent), which acts as the central controller. This layer is responsible for workflow coordination, prioritization, and dynamic resource allocation across all PV functions. Beneath the Orchestration Layer are four specialized functional agents each focused on handling distinct tasks: **Case Intake & Processing, Signal Management, Aggregate Reporting**, and **Managed Services.** These agents operate semi-independently but remain tightly synchronized through the orchestration layer to ensure efficiency and compliance. At the foundation of the architecture is a **Learning Agent**, which continuously monitors outcomes and feedback from all functions, driving iterative improvements and adaptive intelligence across the system. Together, this unified architecture enables scalability, real-time decision-making, and proactive risk management by combining autonomous execution with centralized oversight and continuous learning.

Impact Across PV Functions

PV Function	Traditional Process	Agentic AI Solution	Proven KPI
Case Intake	4-8 hrs manual extraction, 60% accuracy	Automated document processing (15+ languages)	30 min, 95% accuracy[2,3]
Case Triage	Inconsistent classification, missed deadlines	Global rules engine, auto-prioritization	100% on-time reporting[4]
Signal Detection	Weekly batch processing, 30% false positives	24/7 monitoring, statistical analysis (ROR/PRR)	70% faster, 12% false positives[6]
Signal Assessment	Manual literature review, subjective causality	Automated context retrieval, causal inference models	4 weeks earlier detection[24]
Aggregate Reports	Manual query building, template linking	NLP query generation, auto-template selection	85% time reduction[14]
Data Quality	Periodic validation, 40% coding variance	Continuous monitoring, intelligent MedDRA coding	98% duplicate detection[15]
Compliance	Reactive tracking, 15% missed deadlines	Real-time audit trails, proactive alerts	Zero audit findings[19]
Managed Services	9-5 support, delayed incident response	24/7 AI Customer Service Hub, auto-triage	60% faster resolution[13]

Real-World Validation

The practical impact of Agentic AI in PV is evident across multiple operational domains

Case Study 1 - Case Processing: A mid-size pharmaceutical company reduced its case backlog from 2,000 to 200 cases within 4 months, achieving 94% reduction in case processing time.[7]

Case Study 2 - Signal Management: A global pharmaceutical organization detected a rare cardiovascular safety signal 4 weeks earlier than traditional methods would have allowed, enabling a proactive label update ahead of regulatory inquiry, potentially avoiding market restrictions.[8]

Case Study 3 - Regulatory Intelligence: Automated monitoring of FDA/EMA/MHRA guidance reduced manual effort by 60%, ensuring continuous compliance with evolving regulatory requirements.

Business Value & ROI

Three Pillars of Value

The value of Agentic AI in pharmacovigilance can be understood through three foundational pillars: **Operational Excellence, Regulatory Compliance**, and **Strategic Advantage**. Together, these pillars represent a holistic transformation of PV operations.

Operational Excellence focuses on driving efficiency and scalability by automating labor-intensive tasks, improving data quality, and reducing rework. **Regulatory Compliance** ensures organizations meet global reporting obligations with precision, leveraging proactive alerts, complete traceability, and audit-ready workflows to eliminate compliance risks. **Strategic Advantage** goes beyond cost savings to deliver competitive benefits, accelerating time-to-market, enabling earlier signal detection, and unlocking significant financial impact. These pillars are interdependent, creating a value framework in which speed, accuracy, and foresight converge to strengthen both patient safety and business performance.

Operational Excellence

Agentic AI delivers a step-change in efficiency by automating high-volume, repetitive tasks across pharmacovigilance workflows. Case processing times shrink by nearly 80%, reducing turnaround from eight hours to just 30 minutes. This acceleration clears operational backlogs and enables PV teams to focus on strategic medical assessments. Data quality improves by 70%[4], thanks to intelligent coding, validation, and consistency checks across global submissions. Enhanced initial quality reduces rework by 50%, saving time and resources. Critically, scalability becomes achievable, as organizations manage up to three times the case volume without proportional increases in headcount, ensuring resilience during product launches or safety crises.

Regulatory Compliance

Compliance is non-negotiable in pharmacovigilance, and Agentic AI enables organizations to stay ahead of evolving requirements. Automated scheduling and proactive alerts ensure 100% on-time[1] reporting across major agencies such as the FDA, EMA, MHRA, and JPMA. Post-implementation audits report zero critical findings, reflecting robust governance and traceability. Every AI-assisted action is logged, creating complete audit trails for transparency and inspection readiness. Furthermore, predictive compliance monitoring prevents 95%[9] of potential issues before submission deadlines, significantly reducing regulatory risk and reinforcing trust with health authorities.

Strategic Advantage

Beyond operational gains, Agentic AI delivers measurable business impact. Organizations achieve 40–60% reductions[10] in PV operating costs within the first year, translating into $2–3 million annual savings[11] per product for mid-sized pharmaceutical companies. AI-driven signal detection enables identification of emerging risks up to three to four weeks earlier than traditional approaches, supporting proactive risk mitigation[12] that protects both patient safety and market access. At the same time, streamlined PV processes accelerate time-to-market for new therapies, giving companies a competitive edge in an increasingly dynamic and innovation-driven life sciences landscape.

Industry Benchmark

Industry benchmarks indicate that organizations implementing Agentic AI in pharmacovigilance achieve rapid ROI within 8–12 months, driven by headcount optimization and reduced compliance risk. Automated workflows consistently deliver 40–60% reduction in operating costs, generating $2–3 million in annual savings per product for mid-sized companies. These gains are attributable to autonomous case processing, real-time regulatory adherence, and proactive risk mitigation, which together help prevent costly penalties and preserve market access. Earlier signal detection, combined with accelerated PV processes, further shortens time to market and strengthens long-term competitive positioning.

Conclusion

Agentic AI fundamentally transforms pharmacovigilance from a labor-intensive, reactive compliance function into a proactive, intelligent safety ecosystem. By deploying autonomous agents that operate continuously across case processing, signal detection, and regulatory reporting, organizations shift from managing backlogs to preventing safety issues before they escalate. Technology no longer simply accelerates existing workflows, it enables entirely new capabilities including predictive signal detection, real-time regulatory intelligence, and adaptive compliance monitoring. This paradigm shift empowers PV teams to focus on strategic medical assessment and risk evaluation while AI manages operational complexity, ultimately delivering faster insights, stronger compliance, and most importantly, better patient safety outcomes.

Beyond operational efficiency, Agentic AI positions pharmacovigilance as a strategic differentiator within the life sciences industry. Organizations that embrace this transformation realize measurable benefits including cost reductions, accelerated time-to-market, and enhanced regulatory confidence, while building a future-ready safety infrastructure. As global regulations continue to evolve and data volumes surge, the ability to adapt intelligently and act autonomously will define long-term competitive leadership.

The future of pharmacovigilance is autonomous, intelligent, and proactive. The time to act is now.

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