Whitepaper: Pharmacovigilance & Adverse Event Monitoring FrameworkReal-Time Sovereign Multi-Agent Drug Safety Surveillance - w10

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Singularity IO Zurich, Switzerland

EXECUTIVE SUMMARY

Post-market drug safety monitoring is becoming increasingly complex due to growing patient populations, new therapies, and vast amounts of real-world data. Traditional pharmacovigilance systems are too slow, manual, and limited to detect emerging safety signals effectively.

This whitepaper presents a sovereign, multi-agent Pharmacovigilance Framework that enables continuous, real-time adverse event monitoring with superior speed, accuracy, and regulatory compliance.

Key Outcomes

- 50–70% faster adverse event signal detection
- Significant reduction in manual case processing workload
- Automated regulatory reporting and audit-ready documentation
- Multi-source data integration (EHR, registries, social media, wearables)
- Full explainability and human oversight mechanisms
- Complete data sovereignty on Swiss infrastructure

Built on the Singularity Agentic Platform running on Exoscale SKS, this framework helps pharmaceutical companies and regulators protect patients more effectively while reducing operational burden.

INTRODUCTION

Pharmacovigilance — the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects — is a critical pillar of drug safety. However, the volume and velocity of real-world data have outgrown legacy systems.

Sovereign Agentic AI offers a powerful new approach: intelligent agents that continuously monitor multiple data streams, detect potential safety signals early, automate case processing, and support rapid regulatory response — all while maintaining the highest standards of privacy and compliance.

This framework provides life sciences organisations with a complete blueprint for next-generation pharmacovigilance.

THE CHALLENGE

Current pharmacovigilance operations face serious limitations:

- Delayed signal detection (often months after first occurrences)
- High volume of manual Individual Case Safety Report (ICSR) processing
- Fragmented data sources with poor integration
- Limited ability to analyse complex patterns and drug-drug interactions
- Growing regulatory expectations for proactive risk management
- High operational costs and reliance on specialised PV professionals

Traditional rule-based and basic ML systems lack the reasoning capability required for modern safety surveillance.

OUR APPROACH – THE SOVEREIGN PHARMACOVIGILANCE AGENT CREW

The Singularity Pharmacovigilance Framework deploys a coordinated crew of autonomous agents:

- **Multi-Source Data Ingestion & Normalisation Agent**
- **Signal Detection & Pattern Recognition Agent**
- **Causality Assessment & Risk Evaluation Agent**
- **Automated Case Processing Agent**
- **Regulatory Reporting & Documentation Agent**
- **Continuous Learning & Knowledge Update Agent**

These agents work collaboratively in real time using stateful LangGraph orchestration and secure, privacy-preserving data access.

All operations run inside isolated sovereign namespaces on Exoscale SKS in Swiss data centers.

TECHNICAL ARCHITECTURE

Core Components:

- **Orchestration**: LangGraph for complex safety investigation workflows
- **Inference**: Ollama with domain-specific medical and safety models (GPU-accelerated)
- **Memory**: Qdrant vector database for historical cases and signal patterns
- **Automation**: n8n for integration with EudraVigilance, FAERS, EHRs, and other sources
- **Observability**: Full explainable AI audit trails and LangSmith-style tracing

Key Capabilities:

- Real-time multi-source signal detection
- Advanced causality assessment using medical reasoning
- Automated ICSR generation and submission
- Privacy-preserving federated analysis techniques

IMPLEMENTATION GUIDE

12-Week Pharmacovigilance Agent Crew Deployment Roadmap

Phase 1: Foundation (Weeks 1–3)

- Current PV process assessment and data source mapping
- Signal detection rule and threshold definition
- Singularity Platform tenant provisioning (Enterprise tier)

Phase 2: Agent Development & Validation (Weeks 4–8)

- Build and train core detection and assessment agents
- Retrospective validation on historical safety data
- Ethics, data protection, and regulatory review

Phase 3: Pilot, Scale & Handover (Weeks 9–12)

- Live pilot alongside existing PV system
- Performance benchmarking and model refinement
- Full governance framework and PV team training

EXPECTED BUSINESS IMPACT & ROI

Typical Results for Mid-to-Large Pharmaceutical Companies:

	Metric	Improvement	Annual Value
1	Signal Detection Speed	50–70% faster	Earlier risk mitigation
2	Manual Case Processing	-45% to -65%	Major team efficiency
3	Regulatory Reporting Time	-60% to -80%	Reduced compliance cost
4	Overall PV Operating Costs	-30% to -50%	CHF 2 – 8+ million
5	**Total Expected ROI**	**210–340%**	**Payback in 4–7 months**

REGULATORY COMPLIANCE & GOVERNANCE

The framework is purpose-built for the highest regulatory standards:

- Full compliance with EU AI Act (high-risk AI in pharmacovigilance)
- GVP (Good Pharmacovigilance Practices) alignment
- Automated generation of PSURs, DSURs, and RMP updates
- Comprehensive explainability and audit trails for Swissmedic, EMA, and FDA inspections

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CONCLUSION AND FUTURE OUTLOOK

The future of drug safety lies in intelligent, continuous, multi-agent surveillance systems that can detect risks faster and more accurately than humans alone. By deploying this framework on sovereign Swiss infrastructure, pharmaceutical companies can protect patients more effectively, reduce operational costs, and maintain full control over sensitive safety data.

Organisations that adopt sovereign Agentic Pharmacovigilance today will set the new industry standard for safety and

regulatory excellence.

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