3Analytics

BUSINESS WHITE PAPER

Leveraging Agentic AI Architecture

for EudraVigilance Signal Management

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Introduction

As part of regulatory compliance, all Pharma and Biotech companies must continuously monitor safety data from multiple authorities—including EudraVigilance, FAERS and national databases—to detect emerging risks and ensure patient safety. With the new mandate to monitor EudraVigilance data alongside FAERS and internal sources, life-sciences companies now face a dramatic expansion in both the scope and pace of pharmacovigilance obligations. This means -

- Safety teams must digest far higher volumes of individual case reports and aggregate analyses on an ongoing basis– driving up staffing needs, training costs and cross-functional coordination efforts
- Compliance executives should establish new governance forums, escalation pathways and audit trails to assure regulators of timely signal validation
- Business owners worry that any delay or misstep could trigger fines, inspection findings or reputational damage– making the effective integration of EudraVigilance not just a technical challenge but a critical board-level risk and resource management issue
- **Technical teams must implement robust system integrations and automated pipelines to support continuous EudraVigilance data ingestion, standardization and analysis**

On 25 July 2025 the EMA updated its "Monitoring EudraVigilance: legal basis and guidance" page to reflect that the longstanding pilot phase of signal detection by MAHs is now being replaced by a full, permanent requirement. From now on, **Marketing Authorisation Holders must continuously monitor EudraVigilance database for all medicinal products they have authorised in the EEA** — not just those on a limited pilot list

Challenges

- **Resource & Cost Management**

  Allocating sufficient budget and headcount to handle frequent data pulls, manual reviews and training– without spiraling OPEX or compromising other safety initiatives.

- **Governance & Audit Readiness**

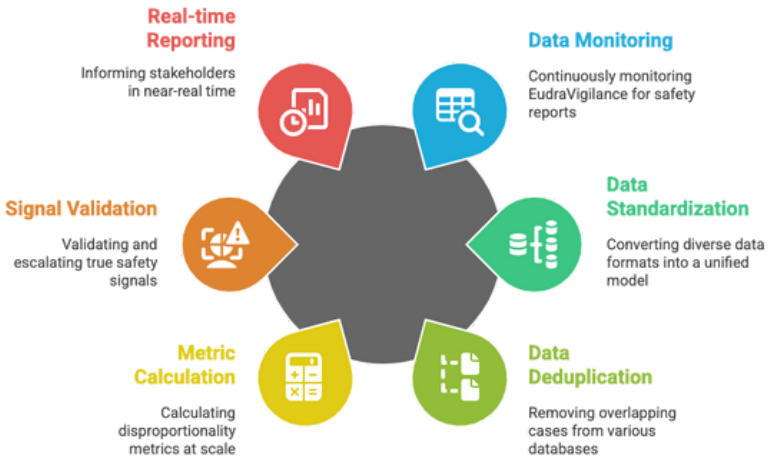
  Updating SOPs, roles and escalation pathways to cover new EudraVigilance monitoring duties, and maintaining immutable audit trails to satisfy EMA/NCA inspections.

- **Cross-Functional Coordination**

  Aligning PV, IT, Compliance and Finance teams around new workflows—avoiding silos, handoff delays and communication gaps that slow signal validation.

- **Regulatory Risk Exposure**

  Ensuring no missed or late signals in a 24/7 monitoring world, where even a single oversight can trigger fines, warning letters or reputational damage.

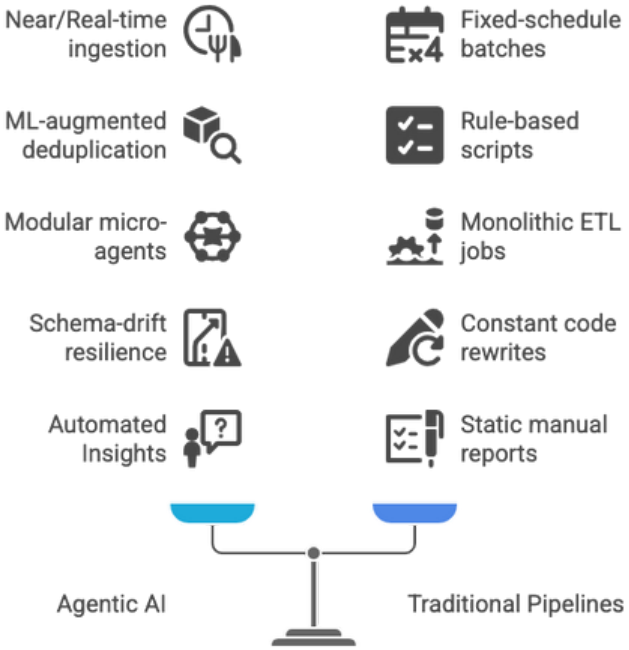


Integrated Technical System is critical

- **Continuous Data Refresh & Latency –** Automating near-real-time ingestion from EudraVigilance (ICSRS, eRMRs, line listings) alongside FAERS and national sources, while handling portal rate limits and large payloads.
- **Data Standardization & Quality –** Converting heterogeneous formats (E2B(R3) XML, CSV, Excel) into a unified model, reconciling MedDRA/WHO-Drug terminologies and preventing “garbage in, garbage out.”
- **Scalability & Resilience –** Designing pipelines that auto-scale for growing portfolios and evolving data schemas, while detecting and adapting to schema drift or portal interface changes.
- **Automated Monitoring & Alerting –** Building built-in health checks for data freshness SLAs, pipeline failures and schema changes, with real-time alerts to minimize downtime and manual firefighting.

AI-Driven Solutions

AI-driven agentic architectures transform pharmacovigilance by autonomously ingesting, standardizing and analyzing safety data the moment it's available– enabling near real-time signal detection, self-healing pipelines and conversational insights. This marks a fundamental shift from traditional batch-based ETL workflows, which suffer from latency, rigid maintenance cycles and manual complexity.



Real-time Ingestion
Agents fetch new safety data instantly upon release, eliminating batch delays

Modular Micro-agents
Independent components you can update, scale or swap without disrupting the system

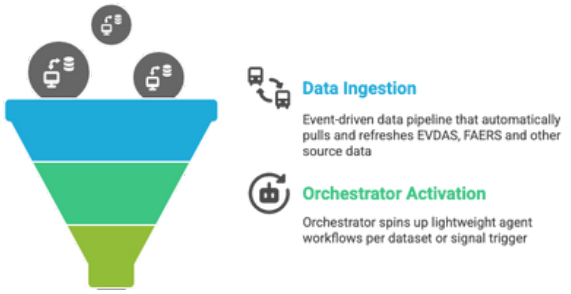
ML-guided Deduplication
Probabilistic matching collapses duplicate reports more accurately than static rules

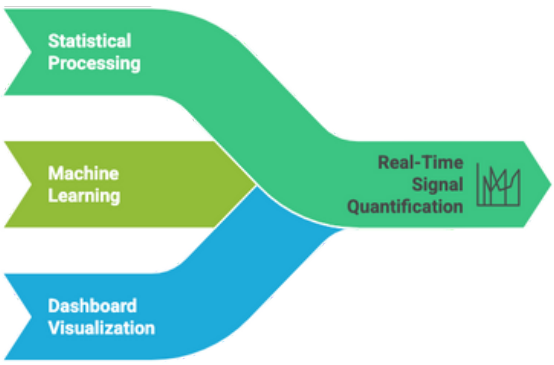
Schema-drift Resilience
Automated detectors spot and adapt to format changes, cutting maintenance overhead

Event-driven Orchestration
Workflows trigger exactly when needed, optimizing compute and speeding throughput

Automated Monitoring
Built-in health checks and alerts ensure data freshness and compliance continuously

Agentic Architecture





Case Study

Problem Statement

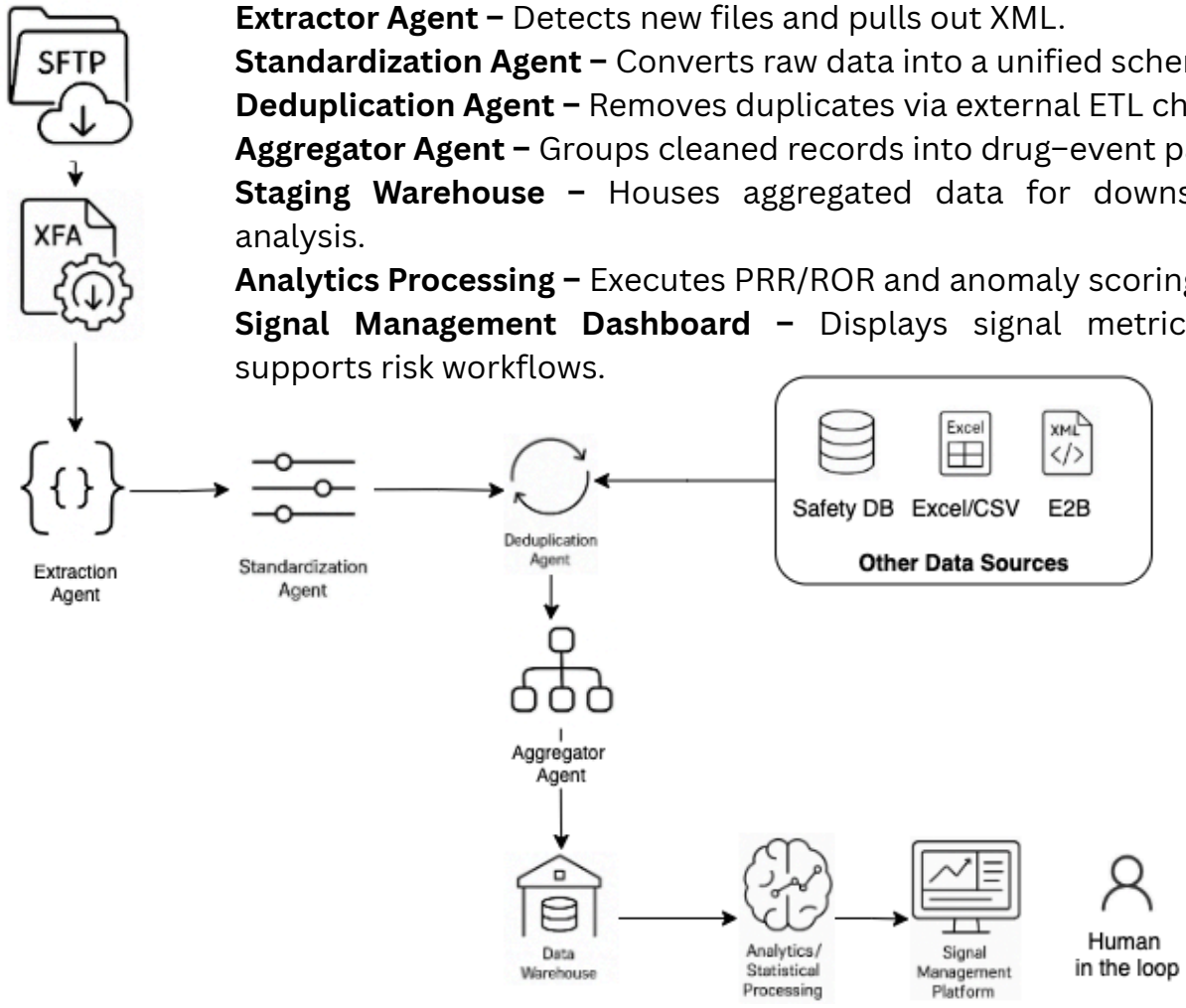
A large-sized life-sciences company was responsible for monitoring EudraVigilance reports via EVWeb, extracting data from CIOMS-style XFA (Xeons) forms, and generating safety signals. Their pharmacovigilance team spent large portions of each week manually downloading XML and PDF case files, parsing complex form structures, and aggregating results in spreadsheets for disproportionality analysis.

Business & Technical Challenges

- **Tedious Manual Processing** - Pharmacovigilance specialists devoted 20+ hours per week to case-report downloads, form parsing and data entry.
- **Error-Prone Workflows** - Manual extraction from varied XFA templates led to inconsistent mapping and rework.
- **Delayed Signal Detection** - Long batch cycles meant emerging safety signals were identified days later, increasing compliance risk.
- **Lack of Data Visibility** - The team had no unified dashboard to explore drug–event pairs or review case summaries in real time.

Agentic AI Solution Overview

Consolidated Ingestion Zone – Central drop server for raw XFA forms.
Extractor Agent – Detects new files and pulls out XML.
Standardization Agent – Converts raw data into a unified schema.
Deduplication Agent – Removes duplicates via external ETL checks.
Aggregator Agent – Groups cleaned records into drug–event pairs.
Staging Warehouse – Houses aggregated data for downstream analysis.
Analytics Processing – Executes PRR/ROR and anomaly scoring.
Signal Management Dashboard – Displays signal metrics and supports risk workflows.



Outcomes & Benefits

Drug–Event Level Visibility
Users can explore safety data at the granular drug–event pair level, aiding in precise signal detection.

Consolidated Case Summaries
All relevant ICSR data is grouped and summarized, giving a 360° view of each drug–event combination.

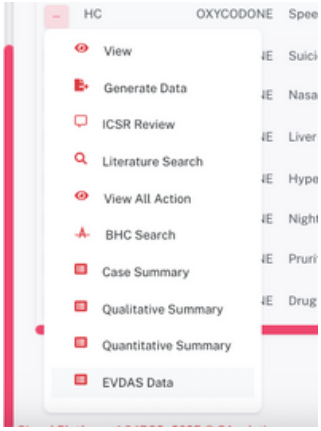
Navigable FDES Aggregations
Users can seamlessly access and compare Full Data Extraction Set (FDES) aggregations across time and source systems.

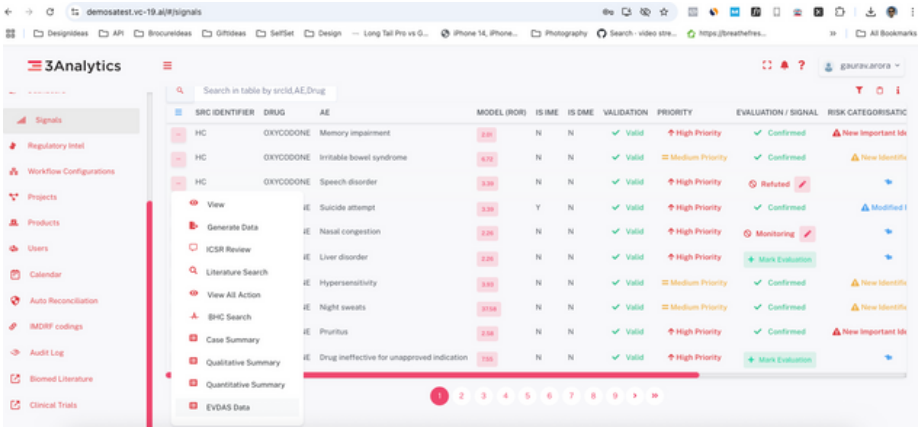
Significant Time Savings
Automations reduce manual review time by 40-60%, enabling safety teams to focus on analysis, not curation.

Unified Analytical View
Statistical signals, source patterns, and timelines are displayed together—enabling cross-dimensional insights.

Improved Signal Assessment
Integration of disproportionality metrics (PRR, ROR) and anomaly scoring provides robust signal qualification.

Proactive Risk Analysis
Advanced filters and trend detection help flag potential safety issues before they escalate.





Conclusion

Agentic AI architecture transforms signal-management from a reactive, manual process into a proactive, self-optimizing platform – delivering real-time insights, reducing noise, and ensuring continuous compliance with evolving regulatory mandates. By decomposing the pipeline into specialized agents for ingestion, standardization, deduplication and analytics, organizations gain scalability, resilience and the agility to adapt without costly rewrites.

Call to Action

Ready to turn your signal-detection challenge into a competitive advantage? Contact our team today to schedule a personalized demo of our agentic AI platform and see how you can streamline EudraVigilance integration, accelerate signal validation and safeguard patient safety with confidence.