Whitepaper

AI Agents Transforming Case Intake in Pharmacovigilance

Author

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Executive Summary

Adverse event (AE) reporting is at the heart of patient safety. Yet, the current pharmacovigilance (PV) case intake process is slow, costly, and prone to error. This whitepaper introduces an AI-powered Case Intake solution that uses a multi-agent architecture to automate intake, triage, translation, and reporting. The system improves speed, accuracy, and compliance while reducing costs by up to 30–50%.

By replacing fragmented manual workflows with intelligent automation, pharma companies can process cases in minutes instead of hours, achieve 24×7 global coverage, and enhance data quality for better decision-making.

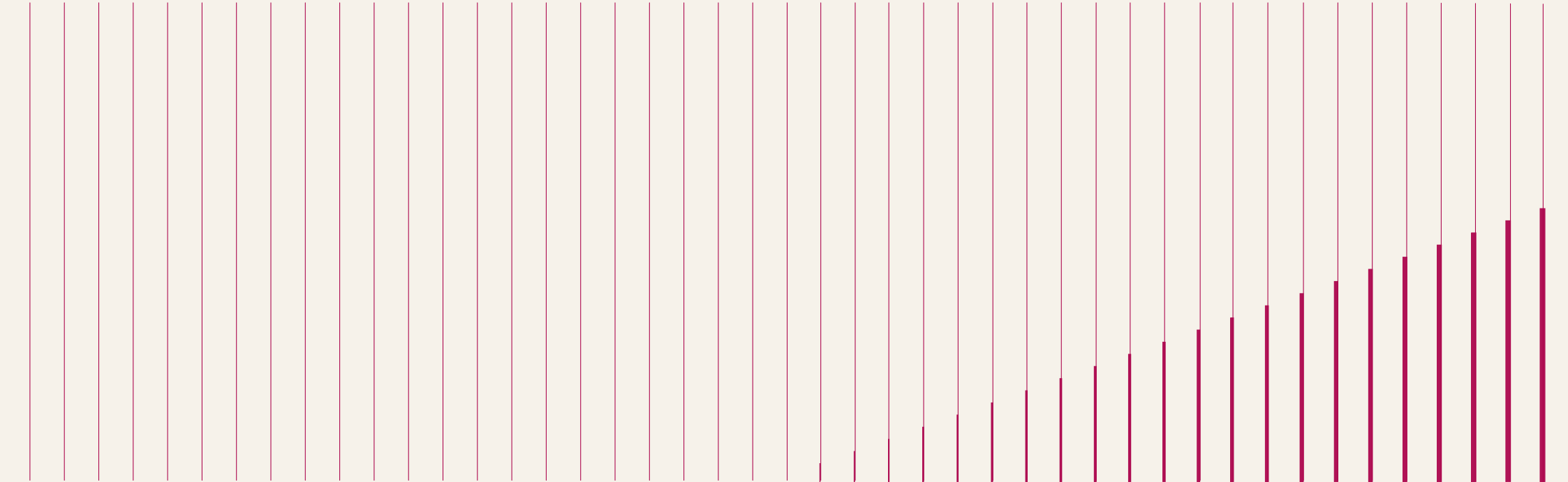
The Real-World Challenge

Pharmacovigilance is a vital discipline that ensures drugs on the market remain safe for patients through continuous monitoring of adverse events. Yet, the intake process, the initial capture and review of adverse event data is a major pain point for pharma companies. Over the past five years, there have been several attempts to automate these tasks, but with Gen AI and Agentic AI, new possibilities for efficiency and automation are emerging.

Costs related to case intake are enormous, eating up 60-70% of pharmacovigilance budgets. More than just money, poor intake practices can cause errors in patient or product data, missed or late reports, and duplicates that waste time. Inaccurate intake also delays risk identification, meaning safety signals emerge later than they should. The regulatory environment makes this even tougher: missing a 7-day or 15-day adverse event reporting deadline can trigger inspections, audits, or financial penalties from agencies like the FDA, EMA, or MHRA.

Moreover, pharma companies operate across global markets with different languages, formats, and regulatory rules. Diverse data inputs complicate standardization and create a risk of low-quality or inconsistent safety data. The sheer volume of reports also grows as portfolios expand and products reach more patients. Teams struggle to keep up with this rise, leading to backlogs and operational inefficiencies. This pressure slows down follow-up investigations and could expose companies to legal challenges or reputational damage.

These challenges aren't hypothetical. Failing to handle AE reports properly impacts patient safety, triggers regulatory sanctions, and harms brand trust. Pharma companies can't afford mistakes or delays. They need an approach that scales, improves accuracy, and speeds data processing without ballooning costs. That's where automation and AI enter as critical enablers of modern pharmacovigilance.



Global Industry Outlook

The global pharmacovigilance (PV) market 1 is valued at approximately $6.8 billion to $10.36 billion in 2025, depending on the estimated source. Within the industry, adverse event (AE) intake and processing makes up a major part of the cost burden, accounting for 60–70% of overall operational PV expenses. This high share is driving pharma companies to adopt automation, which is now becoming standard practice. Leading organizations report achieving 30–50% cost savings through automated case intake and processing systems, transforming traditional workflows and reducing non-automated labor. Industry giants like IQVIA, ArisGlobal, and RxLogix are at the forefront of these advancements, offering scalable platforms that support outsourcing and advanced automation.

Tech Mahindra's multi-agent model stands out for its local expertise and modular scalability, helping companies efficiently manage global safety operations while keeping up with complex regulations and regional needs. With stricter compliance standards and the rising volume of pharmacovigilance activities, integrating automation is no longer a choice; it's become central to staying competitive, controlling costs, and delivering reliable drug safety outcomes across multiple international markets.

Reinventing Case Intake with AI

Tech Mahindra's AI-powered Case Intake solution provides a practical way forward for pharmacovigilance teams drowning in non-automated workloads. The platform uses a multi-agent system that divides the intake process into specialized tasks handled by dedicated AI agents working together. This method transforms raw, unstructured data into structured, validated cases quickly and reliably.Here's how it works:

- **Multi-Agent Intelligence**
  Specialized AI agents work side by side to extract, classify, translate, and check regulatory details for each case. Each agent does its job, so case intake happens faster and with more accuracy. Together, they keep information moving smoothly from start to finish.

- **Omnichannel Coverage**
  The solution gathers reports from all kinds of sources—emails, handwritten forms, phone calls, even social media. No matter where safety data comes in, it gets picked up and ready for review. This keeps the process complete and reliable.

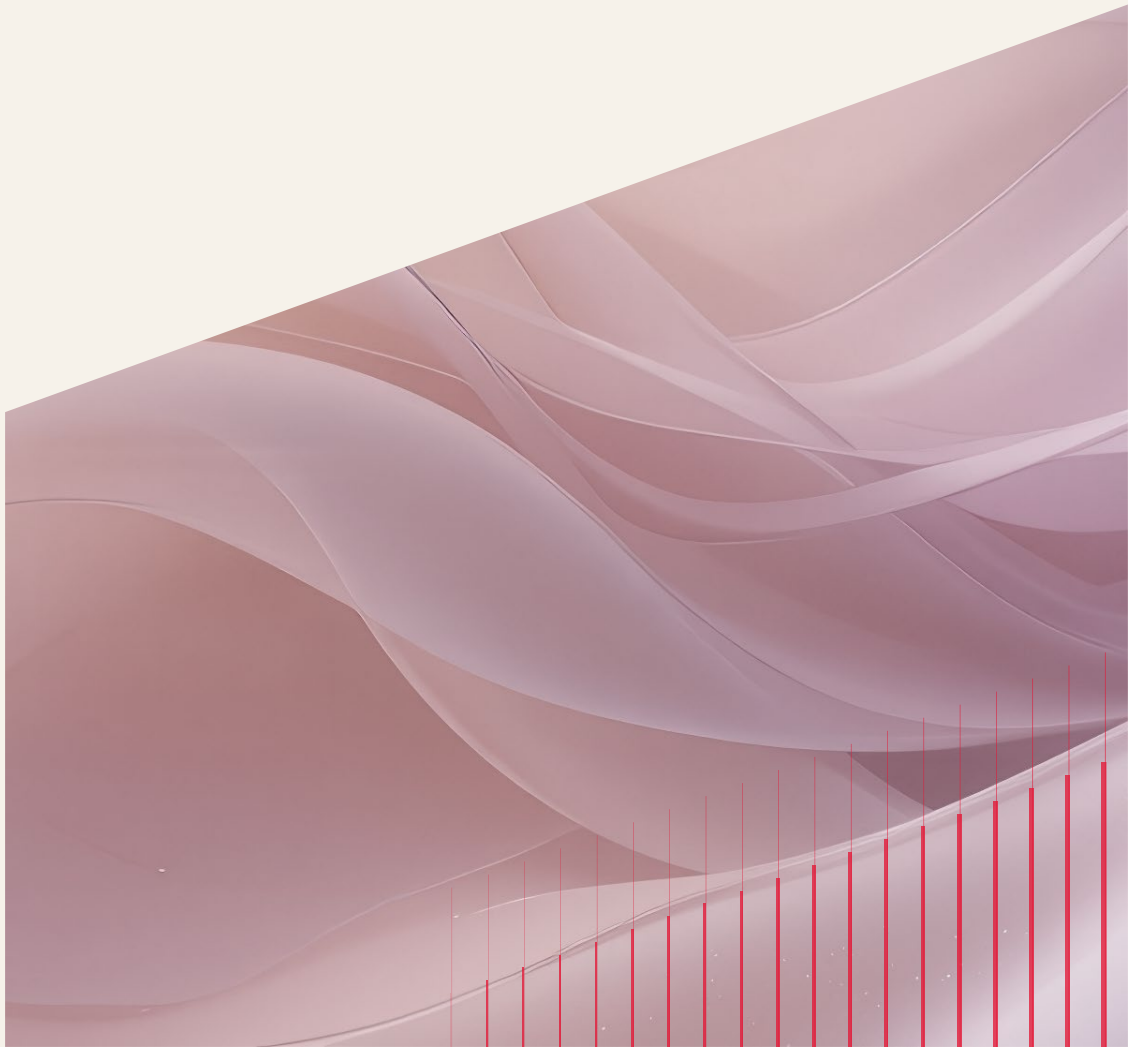
- **Built-In Compliance**
  AI spots serious adverse events quickly and flags them for priority action. Every reporting deadline is tracked to help avoid missed timelines or penalties. Built-in checks mean safety data always meets regulations.

- **Real-Time Translation**
  The system instantly turns foreign-language safety reports into clear, structured English for easy use. Teams can process global cases without waiting for manual translation. Language barriers don't hold up safety anymore.

- **Duplicate Detection**
  AI checks the database for repeated entries and flags duplicate cases right away. This clears out clutter and keeps safety reviews focused and efficient. Data quality stays high, making audits much simpler.

- **Performance Dashboards**
  Live dashboards show turnaround times, compliance rates, and more all in one place. Safety teams get up-to-date stats to track progress and fix problems fast. Decision-making is simpler with real numbers on hand.

- **Flexible Deployment**
  The platform sets up easily like using it as SaaS or picking your favorite cloud, like AWS, Azure, or GCP. Deployment fits into any IT scenario so teams can work their way. Flexibility means it grows with your business worldwide.



Differentiators That Drive Performance

Every feature, from omnichannel intake to real-time dashboards, plugs into your workflow without fuss. You get fault tolerance and local flexibility so operations keep running, even when things go wrong.

Feature	Why It Matters
Multi-Agent Architecture	Enables modular, scalable automation with fault tolerance.
Omnichannel Intake	Captures data from all relevant sources, reducing blind spots.
Regulatory Intelligence	Ensures timely and compliant reporting.
Translation & Transcription	Supports global operations and multilingual submissions.
Duplicate Detection	Cuts down on rework and improves data integrity.
Dashboards	Empowers teams with real-time insights and audit readiness.
Cloud Flexibility	Fits seamlessly into existing IT ecosystems.

Technical Architecture Overview

The technical architecture of an AI-powered pharmacovigilance case intake system is built with clear, layered functionality. The input layer ingests diverse data streams such as emails, voice recordings, scanned adverse event forms, and web portal submissions, ensuring all possible sources are captured. The processing layer features a multi-agent AI engine that specializes in fast extraction, case triage, real-time translation, and automatic validation, improving speed and consistency while minimizing manual steps.

An integration layer connects seamlessly with established industry safety systems like Argus, Aris Global, and Veeva, allowing for smooth data exchange and regulatory workflow. On top, the output layer generates structured, error-checked Individual Case Safety Reports (ICSRs), ready for regulatory use with clean, standardized data. This architecture is flexible for deployment including SaaS options or private cloud environments such as AWS, Azure, or GCP making it easy for organizations to scale across global operations and adapt to different IT requirements

Turning Innovation into ROI

AI automation leads to dramatic gains in pharmacovigilance case intake. Intake turnaround time improves from 4-6 hours to just 30 minutes, valid case rates rise from 70-80% to 95%, and the share of auto-populated fields increases from 30% to 85%, cutting manual effort by half. Compliance rates climb to 98%, duplicate detection accuracy goes up to 95%, and the system can process up to 150-200 cases per day compared to just 30-40 before. This means faster throughput, better safety reporting, and more value for teams and budgets.

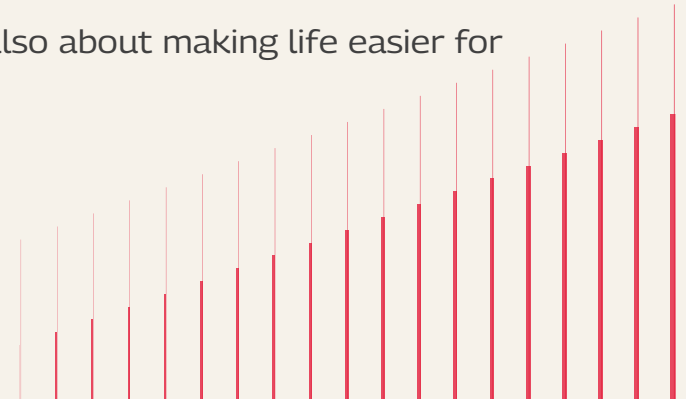
Business Impact

Metric	Manual Baseline	AI-Powered Outcome	Result
Intake Turnaround	4-6 hours	<30 minutes	90% faster
Valid Case Rate	70-80%	>95%	30% improvement
Auto-Populated Fields	<30%	>85%	50% less manual entry
Compliance Timeliness	85-90%	>98%	Reduced risk
Duplicate Detection	60-70%	>95%	Less rework
Intake Capacity	30-40/day	150-200+/day	400% efficiency gain

Pilots in motion with Fortune 500 pharma companies

Fortune 500 pharma leaders face real pressure to handle adverse events quickly and bring down the cost and time it takes to manage safety cases. Tech Mahindra's answer is an agentic AI platform that automates case intake through every channel whether the event comes in by email, phone, or form using smart agents that specialize in the task at hand. A master agent then takes over to automate critical steps like translation, adverse event sorting, and medical coding, keeping the process smooth and accurate.

For these customers, it's not just about cutting costs (which went down by 30%), it's also about making life easier for business teams, who reported a 50% boost in their overall experience and workflow.



Moving Pharmacovigilance Forward

Pharmacovigilance demands quick response and precision yet traditional non-automated case intake just isn't enough for the pace and complexity of today's drug safety landscape. As the volume and variety of adverse event reports keep rising, pharma teams face growing pressure to avoid errors, reduce costs, and meet regulatory deadlines without compromise.

Tech Mahindra's AI-powered Case Intake solution addresses each of these needs head-on, turning intake into a smart, automated sequence that works around the clock and across all channels.
By blending specialized agents for tasks like extraction, translation, and coding with a master agent for oversight, the platform achieves reliable accuracy and speed and helps business teams do more, with less manual intervention. By shifting from reactive, error-prone processes to proactive, intelligent workflows, pharmacovigilance becomes both safer and more scalable, ready for the global demands of tomorrow. For any pharma organization looking to future-proof its operations, the path forward is clear: automation is not an option, it's a necessity.

Endnotes

Precedence Research. (2024, October). Pharmacovigilance market size to hit USD 22.25 billion by 2034

https://www.precedenceresearch.com/pharmacovigilance-market

About the Author

Nitin Jindal heads the go-to-market for Life Sciences solutions across the major markets for Tech Mahindra. He brings in a rich two decades of experience in the IT industry, with primary focus in leading service line consulting and sales teams across healthcare, pharmaceutical, and MedTech sectors. He has driven comprehensive strategic partnerships with hyperscalers alongside domain-centric collaborations and made significant impact in the domain.

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