# CAP'25-Sweden PharmaVantage Global Partner Report:

# Implementation Of AI In Supply Chain For AstraZeneca

Prepared for AstraZeneca

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# Executive Summary

AstraZeneca is at a pivotal moment where artificial intelligence (AI) can significantly enhance its global pharmaceutical operations. This report provides a strategic roadmap to optimize AstraZeneca's AI investment, balancing internal and external solutions to achieve operational excellence, cost savings, and improved compliance. Our analysis has identified three primary recommendations that form the foundation of this strategy.

**1. Maintain the 60-40 Internal-External AI Split (with Optimization):**

- Continue leveraging internal AI for sensitive data management, ensuring security and compliance in critical areas like pharmacovigilance.
- Utilize external AI solutions for high-speed, commodity functions, such as data processing and analytics, where efficiency is critical.
- This balanced approach maximizes control over proprietary data while benefiting from the scalability and speed of external AI vendors.

**2. Implement Vertex AI as the Preferred External Vendor:**

- Vertex AI offers advanced machine learning capabilities that align with AstraZeneca's goals for scalable, high-performance AI.
- As an external partner, Vertex AI can support fast, scalable analytics and pattern recognition without compromising data security.
- This partnership ensures that AstraZeneca remains at the forefront of AI innovation while maintaining cost efficiency.

**3. Optimize Workforce Allocation:**

- Reduce reliance on full-time employees (FTEs) for routine, non-core tasks by automating processes through AI.
- Prioritize high-value roles where human expertise is essential, such as data oversight and regulatory compliance.
- This workforce optimization reduces operational costs without sacrificing quality.

**Strategic Impact and Business Value:**

Implementing these recommendations will deliver substantial strategic benefits to AstraZeneca, enhancing cost efficiency, compliance, and speed across its global operations. By reducing reliance on full-time employees (FTEs) for routine tasks, AstraZeneca can significantly lower labor costs while maintaining data integrity through automated processes. Additionally, the strategic use of external AI for high-volume tasks minimizes infrastructure expenses, ensuring cost-effective scalability.

Enhanced compliance and data security are also critical outcomes of this strategy. Internal AI systems provide secure handling of sensitive patient data, minimizing the risk of data breaches and maintaining stringent regulatory standards. Meanwhile, Vertex AI offers scalable, compliant AI solutions that align with industry regulations, further strengthening AstraZeneca's compliance framework.

Moreover, the recommendations will accelerate time to market for AstraZeneca's products. Automated signal detection and data processing in pharmacovigilance streamline adverse event reporting, significantly reducing response times. Faster analysis and improved

decision-making capabilities in the supply chain enhance overall operational agility, ensuring that AstraZeneca can respond quickly to emerging challenges and opportunities.

All in all, this AI strategy positions AstraZeneca as a leader in data-driven pharmaceutical innovation. By optimizing the balance between internal and external AI, adopting Vertex AI for advanced analytics, and streamlining workforce allocation, AstraZeneca can achieve sustainable growth, enhanced compliance, and significant cost savings. These initiatives will not only improve operational efficiency but also strengthen AstraZeneca's commitment to patient-centric healthcare and global industry leadership.

## Current Conditions

AstraZeneca has consistently positioned itself at the forefront of AI innovation and pharmaceutical advancement. As part of its ongoing commitment to operational excellence and patient safety, the company is leveraging artificial intelligence to significantly streamline its pharmacovigilance processes. The current objective is to reduce the processing time from 18 weeks to 6 weeks by the end of the year, with a long-term target of achieving a two week turnaround time. This transformation underscores AstraZeneca's strategic vision to enhance efficiency, responsiveness, and regulatory compliance through cutting edge technology.

AstraZeneca leverages both proprietary and third party AI technologies to enhance its pharmacovigilance and clinical operations. Internally developed AI systems - particularly knowledge graphs- play a central role in synthesizing initial patient intake information, integrating current trial data, and projecting estimated trial outcomes. These domain-specific tools are tailored to AstraZeneca's internal processes and enable rapid, context-rich-decision making across the clinical lifecycle.

In parallel, AstraZeneca strategically incorporates third party AI solutions, such as ChatGPT and ClincialBERT, to complement its internal capabilities. These tools are primarily utilized at scale to process large volumes of historical data, extract insights from scientific literature, and support broader data analysis efforts. This hybrid approach allows the company to balance precision and scalability, ensuring both depth and breadth in data driven insights.

## Industry Research

### AstraZeneca's AI Strategy

AstraZeneca has its own guiding principles when it comes to the use of AI and data science. While AI is entrenched within the Pharmaceutical Biotechnology Industry AstraZeneca uses these principles to ensure their main focus is on patient safety. Their five principles are that any AI implemented within their company must be:

1. Accountable:
2. Private & Secure
3. Explainable & Transparent
4. Human Centric & Socially Beneficial
5. Findable, Accessible, Interoperable, & Reusable

These principles guided our research into our decisions of where and how we should implement AI into their supply chain and clinical trials. With our focus being to enhance drug safety by predicting potential risks early through AI-driven automation we had researched three different possibilities of AI implementation: Automation For regulatory Submission, Data Validation and Cleansing Signal Detection and Risk Assessment. With the help of our industry partners, we narrowed our research topic and scope to just Signal Detection and Risk Assessment (SDRA).

Throughout our project, with the help of our key leader Joseph Dremmock (Senior Director: Process & Governance for R&D IT) we were fortunate to combine our research with engaging in in-depth conversations with several key leaders at AstraZeneca. These individuals brought diverse expertise across AI, patient safety, product development, and supply chain operations. Their insights were critical in helping us understand not only the feasibility of our proposed solution but also the broader strategic context in which it would need to operate. Each leader offered unique perspectives that helped shape our approach, refine our focus, and build a deeper appreciation for the complexities of implementing AI in a global pharmaceutical organization.

**Strategic Problem Overview for SDRA**

From our own research and conversations with AstraZeneca's leadership team, several key insights and strategic goals emerged that directly influenced the evolution of our project. First and Foremost, SDRA must increase patient responsibly. Secondly the quality of the AI and its implementation is more important than being first to market with a brand new AI system, lastly the AI system must increase the efficiency of their current employees allowing them to increase their efficiency and get drugs to market faster saving more patients' lives. These insights lead us to developing short-term and long-term key requirements for the SDRA AI that would help guide our recommendation.

**Short-Term SDRA AI Key Requirements:**

1. **Regulatory Compliance is Non-Negotiable:** A consistent message from every leader we spoke with was the importance of ensuring that any AI system, especially one operating in the SDRA space, adheres to global regulatory standards. Both the FDA and EMA

impose stringent requirements, and as AI technologies continue to evolve, so too do the compliance expectations. Our model had to be built with regulatory compatibility at its core to have any chance of real-world adoption.

2. **Effectiveness Must Match or Exceed Manual Methods:** Currently, statistical trends in the SDRA process are manually generated by experts. For an AI model to be trusted and adopted, it must not only replicate this accuracy but also offer added value whether in speed, scalability, or consistency. Leaders underscored the importance of rigorous validation and ongoing monitoring to ensure model performance remains high over time. This requirement is necessary to increase patient safety. When SDRA is able to decrease the time needed to create the models it will allow for adverse events to be detected sooner and allow for more patients to be saved faster.

**Long-Term SDRA AI Key Requirements:**

1. **Adaptable to the Changes:** As technology advances AI is rapidly evolving and advancing. Any AI model that is currently implemented must be able to be updated to ensure that when a new system workflow is created using AI it will not have to be disrupted due to changing technology. Not only are there technological advancements but regulatory advancements as well. The FDMA and EMA are constantly updating their process and rules regarding AI and the use of patient data. Ensuring the AI system can update with current changes ensues that the money invested into development will not be wasted.
2. **Interoperability and Integration are Essential:** The leaders emphasized that AI systems must integrate seamlessly into AstraZeneca's existing digital infrastructure. The company is working toward an interconnected ecosystem of AI tools, where different

models support and complement each other. Any proposed solution would need to plug into this ecosystem without causing disruptions or requiring major system overhauls.

3. **Tangible Impact on Time to Market:** One of AstraZeneca's primary goals in adopting AI is to accelerate the drug development lifecycle. Our model would only be deemed valuable if it could demonstrably reduce the time it takes to bring a drug to market. This focus shaped how we thought about performance metrics and model evaluation criteria throughout the project.

These conversations were more than just informative; they were foundational. The perspectives, feedback, and challenges shared by AstraZeneca's leaders gave our team a much stronger sense of purpose, helping us move from theoretical innovation to a practical, strategic recommendation grounded in the realities of the pharmaceutical industry.

**AI Utilization in Pharmaceutical Biotechnology Industry**

Artificial intelligence (AI) is a transformative technology shaping numerous industries, including pharmaceutical biotechnology. Its rapid development has revolutionized research and development (R&D), clinical trials, manufacturing, and pharmacovigilance (Coherent Solutions, 2025). AI's ability to process vast datasets with speed and accuracy has made it indispensable for identifying drug candidates, optimizing clinical trials, and enhancing patient safety (ITRex Group, 2024).

Within the biopharmaceutical space, AI is playing a pivotal role across multiple functions. In drug discovery and development, AI algorithms can analyze massive datasets including genetic information, protein structures, and chemical properties to identify viable drug candidates much faster than traditional methods. In clinical trials, AI is improving patient recruitment, optimizing

trial design, and enabling real-time monitoring of patient outcomes. In clinical trials, AI assists in patient recruitment, optimizes trial design, and supports real-time monitoring of patient outcomes, reducing the risk of bias and human error (Dorian, 2023). Furthermore, AI in manufacturing enhances production processes, quality control, and waste reduction, while AI-driven pharmacovigilance systems detect adverse events and predict risks through natural language processing (NLP) and machine learning. To understand AstraZeneca's position in this evolving landscape, we examined the AI strategies of its main competitors, focusing on internal versus external AI development. Companies either build in-house AI capabilities for greater control and integration or collaborate with external vendors for specialized expertise and faster deployment (Pharmaceutical Processing World, 2023).

**Pfizer:**

**Internal AI for Prototyping and Data Integration:** Pfizer has established internal AI frameworks in partnership with AWS, enhancing data integration and prototype development. These collaborations reduce development time, speed up minimum viable product (MVP) creation, and consolidate data efficiently (Amazon Web Services, 2024).

**External AI for Disease Modeling and Drug Development:** Pfizer also partners with external companies, such as CytoReason, for AI-driven disease modeling. These collaborations support data-driven drug development without requiring extensive internal resource allocation (Reuters, 2024).

**Bayer:**

**Internal AI for Medical Coding Automation and Radiology Support:** Internal AI Solutions: Bayer has implemented AI for automating medical coding and supporting radiological diagnostics. These solutions streamline workflows and increase diagnostic accuracy, contributing to improved healthcare delivery (Wall Street Journal, 2024).

**External AI for** A**griculture AI and Healthcare Model Monetization:** Bayer collaborates with Microsoft to develop AI solutions in agriculture and healthcare, leveraging Bayer's proprietary data to optimize processes and generate additional revenue through Microsoft's platform (Bayer, 2025).

**Novartis:**

**Internal AI for Data Analytics and Clinical Trial Optimization:** Novartis utilizes internal AI tools for data analytics and clinical trial management, significantly reducing processing times and improving decision-making (Dataiku, n.d.).

**External AI for Document Automation and Healthcare Data Processing:** Novartis partners with companies like Yseop to automate clinical documentation and streamline data processing, maximizing productivity and research efficiency (PharmaVoice, n.d.).

Pharmaceutical companies strategically balance internal AI development with external collaborations. Internal investments typically focus on data management and process optimization, while external partnerships target specialized analytics and drug development (Prismetric, 2024). Success in AI implementation often depends on aligning technology with company goals rather than purely on internal versus external approaches (FastDataScience, 2024).

AstraZeneca's current strategy of maintaining a 60/40 split between internal and external AI development has proven effective. By leveraging both internal innovation and external partnerships, AstraZeneca can remain agile and responsive to industry changes while minimizing costs and maximizing innovation potential (Microsoft News, 2019).

**Internal vs. External AI Options**

**Internal AI Development Pros & Cons:** Developing AI capabilities internally represents a major strategic undertaking for AstraZeneca. While it requires a significant investment of time, capital, and technical resources, the potential long-term advantages can be substantial particularly for a company operating in a highly regulated industry. (Coherent Solutions, 2025). One of the most compelling benefits of internal AI development is end-to-end customization. Unlike third party solutions that often offer generalized or pre-configured features, internal development allows AstraZeneca to build a platform that is specifically aligned with its workflows, data architecture, and strategic priorities. This means that the AI system can seamlessly integrated with AstraZeneca's existing databases, clinical safety frameworks, and regulatory compliance frameworks. It also allows for the incorporation of proprietary algorithms, internal knowledge bases, bases, reflecting AstraZeneca's institutional expertise and evolving alongside the organization over time (FastDataScience, 2024).

Internal development also promotes enhanced data security and ownership. By keeping the entire development process in house, AstraZeneca maintains full control over sensitive clinical and safety data, reducing risks associated with external data sharing and third party vulnerabilities a critical consideration in the context of pharmacovigilance and patient safety data (ITRex Group, 2024). Additionally, internal development encourages organizational learning and AI capability building. As teams work through the design and implementation phases, they gain

valuable experience that strengthens AstraZeneca's internal data science, software engineering, and risk analytics capabilities skills that are transferrable across other functions and innovation initiatives. However, the benefits of internal AI development come with significant challenges, most notably in terms of time, complexity, and cost. Developing a robust AI system from scratch is a resource-intensive process that typically requires cross-functional collaboration between IT, data science, pharmacovigilance, compliance, and clinical operations teams. The project lifecycle from initial planning and model design through testing, validation, and deployment can span months or even years, depending on scope and scale. In terms of financial investment, internal development carries a high upfront cost.

The total estimated budget is approximately $650,000, though the final amount can vary based on system complexity and enterprise-wide integration needs. There is also the risk for potential obsolescence of the AI system due to technological advancements or regulatory changes. While these figures represent a significant investment, it is important to view them in the context of long-term strategic value. A well designed, internally developed AI system can deliver operational efficiencies, reduce the risk of costly late-stage failures, and support faster regulatory submissions ultimately accelerating time to market for life saving therapies. It also enhances AstraZeneca's ability to respond proactively to safety issues, improving patient outcomes and reinforcing trust with regulators and stakeholders (Dorian, 2023).

**External AI Development Pros & Cons:** Engaging external AI vendors presents a strategically viable option for AstraZeneca, particularly when quick execution and cost predictability are critical. Unlike internal development, which demands significant upfront investment and long-term resource commitment, external AI solutions offer a more agile approach. By leveraging the expertise of established vendors, AstraZeneca can rapidly

implement AI systems tailored to specific use cases, without the need to build foundational infrastructure in-house. This is particularly beneficial for short-term projects or areas where rapid deployment is essential, such as enhancing data analysis capabilities for clinical trials or drug discovery (Prismetric, 2024). One of the most notable benefits of external AI is cost transparency Working with vendors who have established pricing models enables AstraZeneca to forecast expenses accurately, aiding budget management and minimizing financial risk. This predictability helps budget planning and reduces financial risk. Furthermore, external AI solutions are inherently scalable, allowing AstraZeneca to adapt to changing project demands by adjusting service levels rather than reconfiguring internal systems. This flexibility is crucial in the dynamic pharmaceutical landscape, where research needs can shift based on emerging data or new regulatory requirements (PharmaVoice, n.d.).

Another advantage is the ongoing expert support from AI vendors. Rather than maintaining a dedicated internal team to manage system updates and enhancements, AstraZeneca can rely on vendors for continuous maintenance and optimization, ensuring the latest technologies are seamlessly integrated (Microsoft News, 2019). However, outsourcing also presents challenges, primarily concerning data security. Entrusting proprietary clinical and safety data to third-party vendors carries potential risks, especially regarding compliance with data protection regulations. Additionally, externally developed AI systems may lack full customization since they are designed to address broader industry needs rather than AstraZeneca's specific workflows. Vendor lock-in is another concern; transitioning to a different provider can be both costly and technically challenging. Furthermore, vendors often retain intellectual property rights over core algorithms, which may hinder future innovation (Bayer, 2025).

Despite these limitations, external AI development remains an attractive option when time to implementation is paramount or when specialized expertise is required. By carefully selecting reputable vendors and establishing clear data governance protocols, AstraZeneca can mitigate risks while taking advantage of the speed and scalability that external AI solutions provide. This balanced approach allows the organization to remain agile in an increasingly competitive and data-driven pharmaceutical landscape.

**Criteria for External AI:**

To ensure that the chosen external AI vendor can effectively support the development of the SDRA AI system, it is essential to evaluate their capabilities against a set of clearly defined criteria. These criteria are designed to guarantee that the external solution aligns with AstraZeneca's strategic goals while maintaining the highest standards of accuracy, security, and adaptability. A thorough evaluation will minimize risks and ensure that the selected vendor can deliver a robust, scalable, and compliant AI solution.

The first and critical criterion is Automated Efficiency, focusing on continuous monitoring accuracy and proactive risk detection. Given the dynamic nature of pharmacovigilance and safety data management, the AI system must be capable of automating data ingestion and analysis, minimizing manual intervention, and maintaining consistency in monitoring adverse events. The vendor's solution should include sophisticated algorithms capable of detecting emerging risks in real-time, offering automated alerts, and generating comprehensive reports. By implementing efficient automation, AstraZeneca can ensure that safety data is continuously monitored, significantly reducing the time required to detect potential safety signals and address emerging risks.

Equally important is the criterion of Data Security, which involves maintaining compliance with stringent regulations and safeguarding patient information. The selected vendor must adhere to global data protection standards, such as GDPR and HIPAA, by incorporating robust encryption protocols, secure data storage, and controlled access mechanisms. Regular security audits, vulnerability assessments, and transparent data governance practices are essential components of a trustworthy vendor's approach. Since pharmacovigilance involves handling sensitive clinical and patient data, any compromise could lead to legal consequences and reputational damage. Even thought we do not recommend the vendor have access to any patient data, they will still have access to some AstraZeneca's data. Therefore, the vendor must demonstrate a proven track record of maintaining data integrity and security across similar projects.

The final criterion, suitability for SDRA, focuses on the vendor's ability to deliver a solution that adapts effectively to diverse data inputs while conducting comprehensive risk analysis. The SDRA system must integrate data from multiple sources, including clinical trials, real-world evidence, and spontaneous adverse event reports. The chosen AI platform should be flexible enough to handle structured and unstructured data, allowing for efficient data fusion and analysis. Furthermore, the system must be capable of performing in-depth risk assessments, drawing from heterogeneous data sets to identify potential safety concerns accurately. This adaptability ensures that AstraZeneca can leverage the AI system for both ongoing safety monitoring and post-market surveillance.

Ultimately, selecting the right external AI vendor requires a balanced consideration of automated efficiency, data security, and suitability for SDRA specific applications. Vendors who meet these criteria will be better positioned to support AstraZeneca's AI strategy, delivering

solutions that not only enhance safety monitoring but also align with the company's commitment to data-driven, patient-centered innovation. Through diligent vendor selection, AstraZeneca can optimize the development of the SDRA AI system while mitigating potential risks associated with external collaborations.

**Strategic Benefits of AI SDRA**

One of the most promising areas for AI adoption at AstraZeneca is in SDRA. This area, which plays a critical role in patient safety and regulatory compliance, stands to benefit enormously from AI-driven efficiencies. This opportunity is driven by the five R's of AstraZeneca: Right patient, Right Tissue, Right Safety, Right Commercial and Right Target. Using these principles that lead us to believe that SDRA has three main implications for AstraZeneca.

**Faster Creation of Regression Models:** Traditionally, creating regression models for risk assessment has been a manual, time-consuming task. With AI, these models can be generated automatically and continuously updated as new data becomes available. This not only speeds up the process but also improves accuracy and responsiveness. Earlier deployment of these models enables faster identification of trends and anomalies, which supports better decision-making.

**Predictive Analytics to Determine Potential Problems:** AI systems can analyze historical data to identify patterns that might predict future problems. This predictive capability allows AstraZeneca to implement preventive measures before issues escalate. It can also enhance scenario planning, support more efficient resource allocation, and help meet regulatory requirements more effectively.

**Faster Advert Detection:** AI enables AstraZeneca to detect potential safety issues faster by analyzing structured and unstructured data from sources such as clinical reports, EHRs, and

social media. This faster detection allows the company to address issues proactively, minimizing risk and reducing delays in the drug development timeline. Early detection also reduces financial losses associated with late-stage failures or post-market safety issues.

The adoption of AI is no longer a question of "if" but "how" for biopharmaceutical companies. Those that can effectively harness AI across key areas while balancing internal and external capabilities will be best positioned to lead in innovation, speed to market, and patient impact. AstraZeneca's current approach to AI development has served it well, and SDRA represents a high-impact area for continued investment. By integrating AI-driven tools for signal detection, risk modeling, and predictive analytics, AstraZeneca can further reduce time-to-market, improve drug safety, and ultimately save more lives.

# Recommendations & Next Steps for SDRA Implementation

**Our recommendation for AstraZeneca are as follows:**

1. Maintain the 60-40 split of external vs internal AI while prioritizing external AI for speed and efficiency, and internal AI for data security
2. The external AI vendor to be supported by Google Cloud Platform's Vertex AI for its reliability, scalability and ability to self train internal model
3. Reduce the contractor FTE from 10 to 3 to reduce cost and human intervention. The 3 FTEs are to be focused on risk mitigation strategies (detailed further in the report)

## Internal vs External AI Models: Optimal Sourcing Strategy

To maximize the effectiveness of AI-driven Signal Detection and Risk Assessment (SDRA) while balancing security, scalability, and efficiency, AstraZeneca should maintain its current 60% internal and 40% external AI model implementation strategy, with a refined functional partitioning to optimize performance. This hybrid approach leverages the strengths of internal AI models for handling sensitive pharmacovigilance (PV) data, ensuring regulatory compliance and seamless integration with internal processes, while utilizing external AI tools for rapid, scalable, and automated tasks such as data intake and visualization (Figure 1). By prioritizing internal models for core SDRA functions and external models for augmentation, AstraZeneca can enhance operational efficiency, maintain data security, and align with global regulatory expectations (e.g., FDA, EMA, GDPR, HIPAA). Additionally, reducing contractor full-time equivalents (FTEs) from 10 to 3 will streamline costs and focus human resources on critical risk mitigation strategies, as detailed elsewhere in this report.

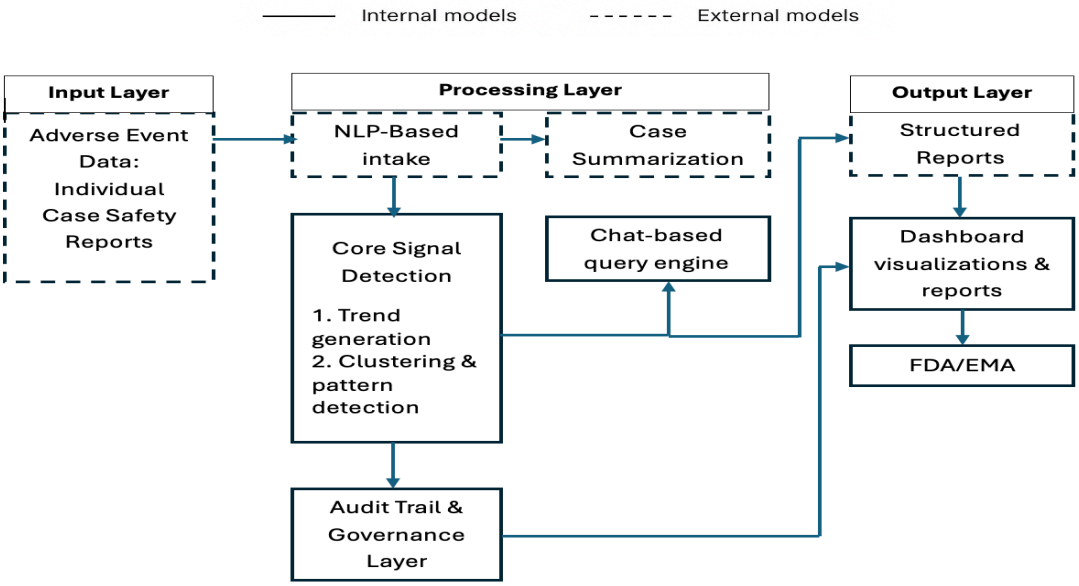


Figure 1

| Platform | DataRobot | Vertex AI | Palantir |
|---|---|---|---|
| **Automated Efficiency Management** | Requires periodic human intervention | AutoML and MLOps automate training and monitoring | Limited automation, requires continuous monitoring |
| **Data Security** | Moderate (enterprise-grade security) | High (leverages Google Cloud security) | High (focus on data governance and compliance) |
| **Suitability for SDRA** | Ideal for rapid risk analysis with pre-built models | Best for tailored risk detection models with robust automation and security | Best for combining data from multiple sources and providing actionable insights |

Figure 2

**Maintain a 60- 40 Internal/External AI Split**

Internal AI models should be prioritized for processing sensitive PV data, regulatory trend analysis, and decision-making logic to ensure data security and alignment with AstraZeneca's internal R&D, safety, and legal frameworks. These models are critical for handling adverse event processing, regulatory trend detection, and signal confirmation, where data sensitivity and compliance are paramount. External AI tools, specifically Google Cloud Platform's Vertex AI, should be leveraged for automated data intake, natural language processing (NLP), and visualization dashboards to enhance speed and scalability. Vertex AI was selected after evaluating external vendors, including DataRobot and Palantir, due to its superior reliability, scalability, and self-training capabilities tailored for SDRA use cases. While DataRobot and Palantir offer robust data security, they fall short in automated efficiency and adaptability for SDRA-specific requirements (Figure 2). This functional partitioning ensures that internal models safeguard proprietary and regulated data, while external tools accelerate non-sensitive, high-volume tasks.

**Streamline Human Resources for Risk Mitigation**

To optimize resource allocation and reduce operational costs, AstraZeneca should reduce contractor FTEs from 10 to 3, focusing the remaining personnel exclusively on implementing and overseeing risk mitigation strategies. These strategies, detailed in the risk mitigation section, include bias detection, model drift monitoring, and compliance-focused explainability. The reduced FTEs will work closely with the Model Risk Committee to ensure robust governance, validate AI outputs, and address anomalies through the AI Incident Response Plan. This lean approach enhances efficiency while maintaining rigorous oversight of AI-driven SDRA processes. To operationalize this strategy, AstraZeneca should develop an AI Use Case

Evaluation Matrix to systematically assess which SDRA tasks are best suited for internal versus external AI models. The matrix should score use cases based on four key criteria:

**Data Sensitivity**: Prioritize internal models for handling sensitive PV data to comply with GDPR and HIPAA.

**Model Adaptability**: Evaluate the ability of models to adapt to evolving adverse event patterns and regional behaviors.

**Explainability Requirements**: Ensure outputs meet regulatory standards for auditability and transparency.

**Time-to-Value**: Assess the speed and efficiency of model deployment for operational needs.

This matrix will provide a clear framework for assigning use cases, such as adverse event processing to internal models and NLP-based case intake to external tools like Vertex AI. By implementing this strategy, AstraZeneca can maintain its leadership in ethical AI adoption, ensuring a secure, scalable, and compliant approach to SDRA that drives innovation while safeguarding patient safety and regulatory trust.

**Cost Justification: AI vs Human Contractors**

Transitioning from a contractor-based manual labor model to an AI-driven approach for Signal Detection and Risk Assessment (SDRA) offers AstraZeneca significant cost savings, enhanced scalability, and improved operational efficiency. The current model relies on 5–10 full-

time equivalent (FTE) contractors, incurring annual costs of $500,000 to $1,000,000, driven by per-person expenses of approximately $100,000 per year. In contrast, an AI-driven model, leveraging token-based processing, cloud infrastructure, and minimal human oversight, is projected to reduce annual costs to $50,000–$75,000. This shift yields potential savings of $450,000–$925,000 annually, with a payback period of less than 12 months. By adopting AI, AstraZeneca can achieve 10x scalability, 24/7 availability, and alignment with its commitment to innovative, cost-effective pharmacovigilance solutions, all while maintaining compliance with global regulatory standards (e.g., FDA, EMA, GDPR, HIPAA).

Internal AI Implementation Cost:

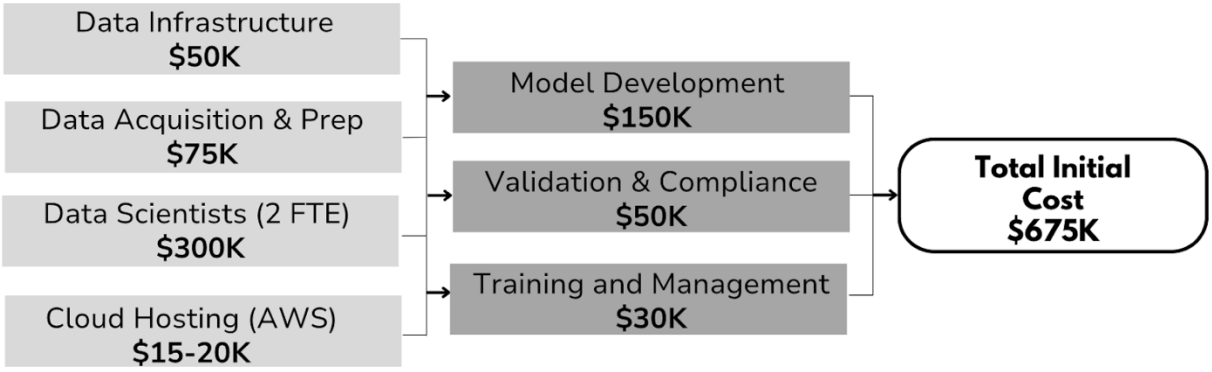


Figure 3

**Cost Breakdown and Analysis**

**Current Human Contractor Costs (Figure 4)**

**Per-Contractor Cost**: $100,000 per year per FTE.

**Total Annual Cost**: 5–10 FTEs for global SDRA operations result in a cost range of $500,000–$1,000,000 annually.

**Limitations**: The contractor-based model is labor-intensive, lacks scalability for handling large data volumes, and introduces latency in signal detection, potentially impacting patient safety and regulatory reporting timelines.

## Projected AI Implementation Costs (Figure 3)

AstraZeneca's established access to real-world data from prior drug launches significantly reduces upfront data procurement costs, positioning the company to implement AI at the lower end of the cost spectrum compared to industry benchmarks provided by consulting firms and AI development companies. The projected annual costs for an AI-driven SDRA model are as follows:

**Token-Based Processing**: Approximately $3,000 per year for 150,000 conversation turns (e.g., using models like those offered by OpenAI or similar providers).

**Data Storage and Processing**: Estimated at $30,000 per year, leveraging cloud-based solutions for secure, scalable data management compliant with GxP standards.

**Google Cloud Platform (GCP) Vertex AI and Hosting**: Estimated at $15,000–$25,000 per year, depending on scale, due to Vertex AI's reliability, self-training capabilities, and suitability for SDRA use cases.

**Total Annual AI Cost**: $50,000–$75,000, significantly lower than the contractor-based model.

## Financial and Operational Benefits

**Annual Savings**: The AI-driven model delivers potential savings of $450,000–$925,000 per year compared to the current contractor-based approach.

**Payback Period**: With implementation costs offset by savings, the payback period is less than 12 months, making the transition a financially sound investment.

**Scalability and Efficiency**: AI enables 10x scalability, allowing AstraZeneca to process larger volumes of adverse event data with 24/7 availability, reducing latency and enhancing signal detection accuracy.

**Strategic Alignment**: By reducing reliance on human contractors and leveraging AI, AstraZeneca reinforces its leadership in ethical and innovative pharmacovigilance, aligning with industry trends toward automation and cost optimization.

To validate this cost justification and ensure long-term success, AstraZeneca should conduct a comprehensive Total Cost of Ownership (TCO) and Return on Investment (ROI) analysis over a three-year horizon. This analysis should compare the costs of maintaining full-time human analysts versus AI augmentation, factoring in: Onboarding and training costs for contractors versus AI model setup, Latency and throughput differences between manual and AI-driven processes, Compute scaling requirements for AI infrastructure as data volumes grow, Ongoing maintenance and retraining costs for AI models to address model drift and ensure performance. This analysis will provide a robust financial framework to guide the transition, ensuring that AstraZeneca maximizes cost savings, operational efficiency, and regulatory compliance while maintaining its commitment to patient safety and innovation in SDRA.

| Year | Contractor Cost | AI Cost+3 FTE | Net Savings | Cumulative Savings |
|---|---|---|---|---|
| Y1 | $500K–$1M | $350K–$375K | $150K–$625K | $150K–$625K |
| Y2 | $500K–$1M | $352K–$378K (5% inflation) | $148K–$622K | Up to $1.5M |
| Y3 | $500K–$1M | $355K–$382K (additional 5%) | $145K–$618K | Up to $2.4M |

Figure 4

**Contractor FTE Role Optimization for SDRA**

To support the implementation of AI in Signal Detection and Risk Assessment (SDRA), AstraZeneca must establish a robust risk governance framework to address critical risks such as model drift, data leakage, bias, hallucination, and regulatory non-compliance. By reducing the contractor full-time equivalent (FTE) count from 10 to 3 and redirecting their focus to three key risk mitigation strategies, AstraZeneca can optimize resource allocation while ensuring algorithmic transparency, human oversight, and ethical integrity. These three FTEs will work under the guidance of an internal Model Risk Management Committee to implement layered safeguards, including explainable AI modules, data pseudonymization, human-in-the-loop (HITL) review processes, and version-controlled model registries. This strategic realignment will enhance the efficiency, compliance, and reliability of AI-driven SDRA, reinforcing AstraZeneca's commitment to patient safety and leadership in innovative pharmacovigilance.

**Strategic Role Optimization for FTEs**

The three retained FTEs will focus on executing a three-tiered risk governance strategy, ensuring that AstraZeneca's AI-driven SDRA system meets regulatory standards, delivers reliable outputs, and upholds ethical principles. Their roles are designed to balance automation with human expertise, fostering trust among regulators, internal stakeholders, and patients.

1. **Align AI Systems with FDA and EMA Guidelines**

   The first FTE will lead efforts to ensure that AstraZeneca's SDRA AI systems comply with global regulatory standards, including those set by the FDA, EMA, and PMDA. This involves developing a robust AI validation framework based on industry-recognized standards, such as Good Machine Learning Practice (GMLP) and Good Automated Manufacturing Practice (GAMP), to verify model performance, ensure consistent outputs, and maintain quality throughout the system lifecycle. The FTE will facilitate early and proactive engagement with regulatory authorities to align expectations, minimize approval friction, and address compliance concerns, building credibility for AstraZeneca's AI-driven approach. To support regulatory audits, the FTE will oversee the implementation of comprehensive traceability and auditability mechanisms, including version-controlled model registries, detailed decision logs, and explainable AI modules that document the data source, model version, and processing logic for every output. These efforts will ensure that AI-generated signals meet stringent requirements (e.g., E2B(R3), MedDRA) and foster trust with internal and external stakeholders, positioning AstraZeneca as a leader in compliant AI adoption.

2. **Ensure Reliable Outputs Through Continuous Monitoring and Collaboration**

   The second FTE will focus on maintaining the reliability and integrity of AI outputs by

establishing continuous monitoring protocols and fostering cross-functional collaboration. This includes implementing systems to detect and mitigate issues such as model drift, false positives, and data anomalies, which could compromise the accuracy of signal detection. The FTE will define clear thresholds for HITL intervention, ensuring that critical or ambiguous cases are escalated to pharmacovigilance experts for review, thereby preserving ethical integrity and regulatory compliance. Working closely with the Model Risk Management Committee, the FTE will oversee performance metrics, implement corrective actions, and maintain a robust human-AI collaboration framework. These measures will ensure that AstraZeneca's AI-driven SDRA system delivers dependable, high-quality outputs, enhancing patient safety and regulatory trust while minimizing operational risks and supporting 24/7 scalability.

3. **Leverage Ethical and Diverse Real-World Datasets**

   The third FTE will ensure that AI models are trained on validated, diverse real-world Individual Case Safety Report (ICSR) datasets, encompassing a wide range of patient populations, clinical scenarios, and adverse event patterns to enhance model robustness and reduce bias. Unlike the industry trend, where 60% of pharmaceutical AI systems rely on synthetic datasets that often miss rare edge cases, AstraZeneca will prioritize authentic clinical data to capture critical signals. The FTE will conduct regular bias testing using well-defined fairness metrics to identify and address disparities in model performance across demographic groups (e.g., age, gender, ethnicity), ensuring equitable and accountable AI-driven decisions. By integrating these evaluations into a continuous monitoring cycle, the FTE will align AI outputs with scientific integrity and regulatory

expectations, reinforcing AstraZeneca's commitment to ethical AI practices and patient-centric pharmacovigilance.

AstraZeneca should communicate this role optimization plan to external vendors, such as Cognizant and TCS, to implement the reduction of contractor FTEs from 10 to 3 and align their responsibilities with the three-tiered risk governance strategy outlined above. The FTEs will collaborate with vendors to integrate validation frameworks, monitoring protocols, and ethical data practices into the SDRA AI system. Additionally, AstraZeneca should establish a timeline for the Model Risk Management Committee to conduct its first review, ensuring alignment with the proposed safeguards and regulatory requirements. This streamlined, strategic approach will optimize resources, enhance compliance, and position AstraZeneca as a leader in ethical, efficient, and innovative AI-driven pharmacovigilance.

## Risk Mitigation Strategy

Implementing AI for Signal Detection and Risk Assessment (SDRA) introduces critical risks around data privacy, regulatory compliance, model bias, and explainability. This strategy defines mitigation mechanisms for each risk class, ensuring AstraZeneca aligns with FDA, EMA, GDPR, and HIPAA expectations, while maintaining its leadership position in ethical AI adoption.

### Regulatory Uncertainty

Implementing AI for Signal Detection and Risk Assessment (SDRA) introduces risks around regulatory compliance, particularly with FDA, EMA, GDPR, and HIPAA expectations. To ensure alignment with regulatory reporting standards such as E2B(R3) and MedDRA,

AstraZeneca will align SDRA AI model outputs with structured regulatory templates used in existing submissions. Compliance-focused explainability modules will be implemented, detailing the source of data, model version, and processing logic summary for each output. Biannual regulatory readiness simulations will test AI-generated reports against compliance standards. To address data privacy and security concerns under GDPR and HIPAA, sensitive adverse event data will undergo pseudonymization and tokenization before any interaction with third-party models, and no identifiable data will be used in prompt construction or external API calls. Model audit logs and outputs will be stored locally with GxP-compliant encryption and access control to prevent leaks and ensure compliance.

**AI Model Accuracy**

AI models for SDRA face risks of signal hallucination, false positives, and performance degradation, which could lead to unnecessary escalations or regulatory misreporting. To mitigate false positives, AstraZeneca will deploy threshold-based confidence scoring before raising alerts and require human-in-the-loop (HITL) validation before signals are submitted to health authorities. Decision traceability will be enabled via logs and statistical justifications, such as confidence intervals and clustering scores. To address model drift due to changes in drug usage patterns, adverse event types, or regional behaviors, monthly performance evaluations against a golden test set of adverse event cases will be scheduled. A model registry with version control, performance metrics, and update history will be maintained, alongside an automated retraining pipeline with rollback capabilities to counter negative drift. These measures ensure the accuracy and reliability of AI-driven signal detection.

### AI Governance & Bias Mitigation

Risks of model bias and lack of interpretability could undermine trust in AI outputs and miss critical adverse event signals, particularly life-saving outliers. Unlike 60% of pharmaceutical companies using synthetic datasets, AstraZeneca will avoid synthetic training data, which often omits rare signals, and instead use diverse, real-world ICSR data from various geographies and demographics to preserve outlier integrity. Bias detection layers will flag skewed inference distributions, and subgroup accuracy testing (age, gender, disease subtype) will ensure fairness. To enhance interpretability for stakeholders, natural language explanation layers will be integrated alongside statistical outputs, using interpretable-by-design frameworks. A "Why this signal?" module will explain temporal trends, risk comparisons with historical cohorts, and clustering rationale. For third-party vendor risks, only non-sensitive, anonymized case descriptions will pass through external APIs, with a vendor risk assessment file and SaaS security compliance attestations maintained. A Model Risk Committee will review model drift, errors, and updates, supported by an AI Incident Response Plan and an annual AI audit covering model validation, output traceability, and access logs to ensure robust governance and ethical AI adoption.

## Conclusion

To maintain its leadership in pharmaceutical innovation and operational efficiency, AstraZeneca should adopt a dual-track AI implementation strategy- leveraging internal AI models for core SDRA processes, while utilizing external AI platforms for dashboarding, large-scale data intake and augmentation of insights.

Internally developed AI solutions, such as knowledge graphs, are best suited for SDRA workflow due to their tailored design, deep integration with AstraZeneca's proprietary data, and alignment with regulatory and compliance frameworks. These models provide a controlled, secure, and interpretable environment for supporting critical decisions in patient safety and clinical trial oversight. Externally, incorporating platforms such as Vertex AI by Google offers a scalable and flexible infrastructure to support real time data ingestion, dashboard analytics and advanced model training. This external capacity enables AstraZeneca to manage high volume diverse datasets from global pharmacovigilance data to scientific literature, freeing up internal resources for domain-specific tasks. By strategically balancing internal control with external scalability, AstraZeneca can realize a significant efficiency gain, reducing full time employees (FTE) from 10 to 3, while maintaining high accuracy and responsiveness. This reduction not only delivers measurable cost savings but also serves as a proactive risk mitigation strategy, enhancing agility in the face of evolving regulatory requirements and global health challenges.

This hybrid AI framework positions AstraZeneca to sustain its competitive edge, scale innovations effectively, and reinforce its commitment to patient safety through smarter, faster, and more resilient pharmacovigilance systems.

# Appendix

**Cost calculation breakdown:**

1. **Token-Based Processing (OpenAI)**

Assumption:

a. One conversation turn = ~50 tokens
b. Total turns per year = 150,000

Calculation:

a. Total Tokens = 50 tokens/turn × 150,000 turns = 7,500,000 tokens/year
b. Cost per Token = $0.0004 (based on OpenAI pricing for GPT-4-turbo as of April 2024)
c. Total Token Cost = 7,500,000 tokens × $0.0004 = $3,000/year

**2. Data Storage & Processing**

Given Info:

a. Historical average over the last two years = ~$30,000/year
b. This includes:
    - Secure storage of adverse event data
    - Data cleaning, structuring, and transformation
    - Access provisioning for model inputs

Estimated Annual Cost: $30,000

**3. GCP Vertex AI + Hosting**

Assumption:

a. Using Google Cloud's Vertex AI for model orchestration and hosting
b. Costs include:
    - Model deployment
    - Inference processing
    - Usage-based compute (CPU/GPU)
    - API endpoints for integration

Cost Range:

a. Low-End Estimate: $15,000/year (small to medium-scale workloads)
b. High-End Estimate: $25,000/year (larger deployment or more parallel inference jobs)

**4. Total AI Cost Range**

Low-End Estimate:

a. Token Cost: $3,000
b. Data Processing: $30,000
c. Hosting (GCP): $15,000
d. Total = $48,000/year

High-End Estimate:

a. Token Cost: $3,000
b. Data Processing: $30,000
c. Hosting (GCP): $25,000
d. Total = $58,000/year

Thus, rounded total cost range = ~$50,000 to $75,000/year (including small contingency).

**5. Human-Based Contractor Cost**

Given Info:

a. $100,000 per year per overseas pharmacovigilance contractor
b. Estimated need: 5 to 10 contractors

Total Cost Range:

a. Low End (5 FTEs): 5 × $100,000 = $500,000/year
b. High End (10 FTEs): 10 × $100,000 = $1,000,000/year

**6. Projected Yearly Savings**

Calculation:

1. High-End AI Cost ($58,000) vs Low-End Human Cost ($500,000):

a. Savings = $500,000 - $58,000 = $442,000/year

2. Low-End AI Cost ($48,000) vs High-End Human Cost ($1,000,000):

a. Savings = $1,000,000 - $48,000 = $952,000/year

Therefore, Estimated Yearly Savings =

~$450,000 to ~$925,000/year

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