White Paper

Enhancing Patient Safety:

A Paradigm Shift Through Early AI Adoption in Pharmacovigilance Workflows

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Introduction

In the high-stakes, ever-evolving landscape of pharmacovigilance (PV), the imperative to ensure patient safety is spurring innovative approaches. Traditional PV operations typically start at 'Case Processing,' but the persistent challenge of underreported adverse drug reactions (ADRs) demands a paradigm shift. The FDA's estimate that only 1–10% of ADRs reach the Adverse Event Reporting System (FAERS) underscores a need for a more proactive strategy.

This paper stems from the US FDA Discussion paper on 'Using Artificial Intelligence and Machine Learning in the Development of Drug and Biologic Products[1],' which highlighted the applications for PV beginning at the Case Processing stage. However, the emphasis on identifying adverse events remains a pivotal precursor to effective processing. The vast unstructured data, often beyond a company's control, poses a considerable hurdle in this endeavor. Despite the FDA's recognition of AI/ML's potential, the focus on identifying AEs for Individual Case Safety Report (ICSR) submission remains limited.

Four years ago, Genentech's US Patient Safety team embarked on a groundbreaking initiative named 'AI Technology Enhancing AE Detection' (ATHENA). This initiative sought to apply AI/ML earlier in the PV workflow, specifically targeting the point of patient interaction. The goal was clear – to decrease the risk of missed adverse events due to human error and enhance patient safety outcomes.

A call to rethink AE reporting in Patient Support Programs (PSPs)

Patient Support Programs (PSPs), while rich in valuable data, have traditionally been overlooked for safety purposes. The ATHENA initiative challenged this convention, recognizing the untapped potential within PSP data to identify adverse events buried beneath the surface. The traditional focus on downstream processes, particularly case processing, presented a missed opportunity for efficiencies and increased patient safety. ATHENA's vision was to shift the focus upstream, addressing the challenges PSPs present to ongoing pharmacovigilance.

Why did we undertake this ambitious initiative? Each year, Genentech's US safety team reviews more than 1.4 million documents arising from PSPs for potential safety events. These 1.4 million documents each represent a potential patient interaction that Genentech works to ensure is not burdened by administrative activities. Automating the review process was intended to decrease the risk of missed adverse events due to human error.

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1 U.S. Food and Drug Administration. "Using Artificial Intelligence and Machine Learning in the Development of Drug and Biological Products." May 2023. Available from: https://www.fda.gov/media/167973/download.

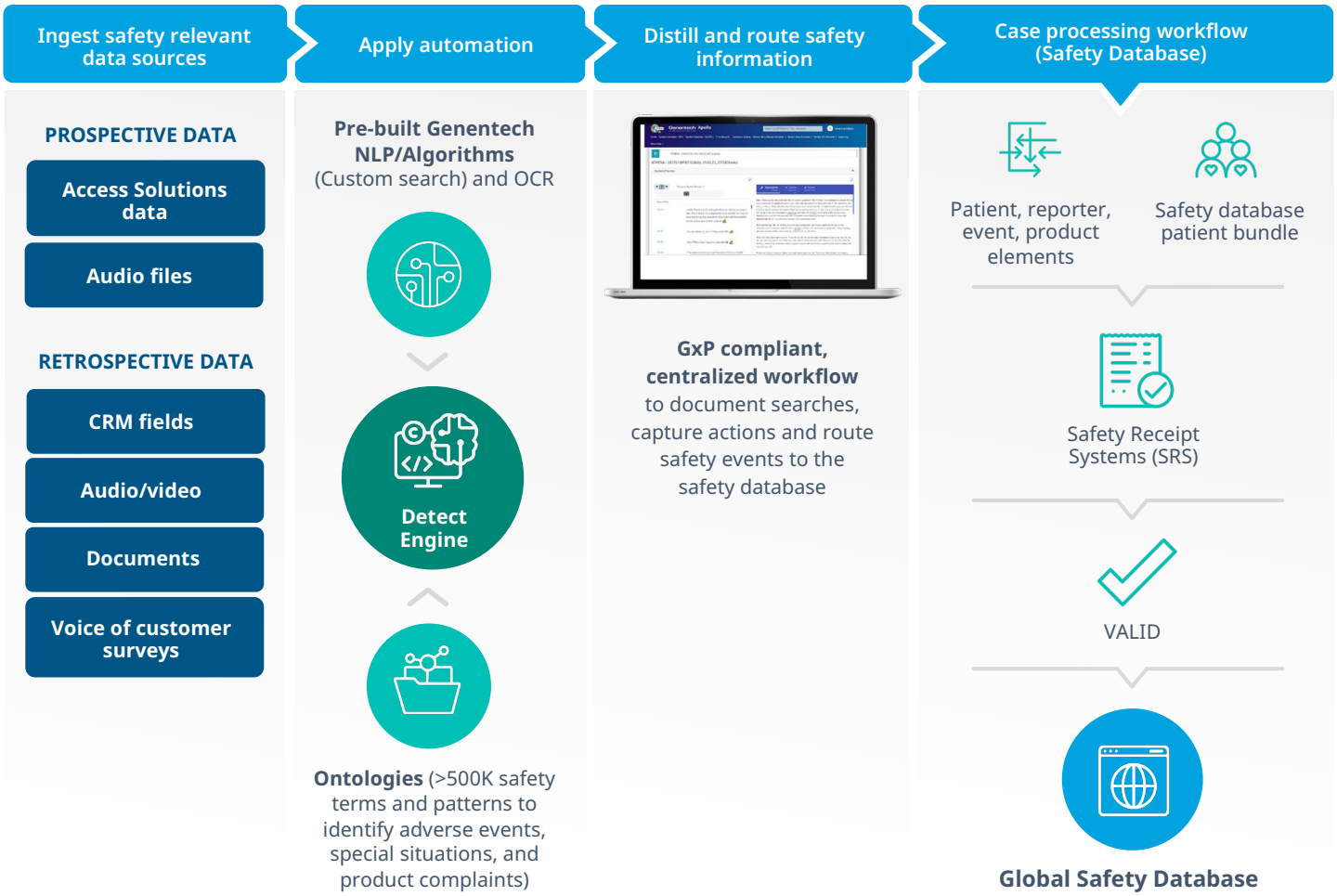
ATHENA initiative overview: collaborative innovation

The ATHENA initiative represents a collaborative effort to revolutionize adverse event detection. By applying AI/ML technology earlier in the workflow, ATHENA sought to eliminate manual labor, identify adverse events, and lay the groundwork for a more patient-centric healthcare paradigm. This shift in perspective is about collaboration among various entities to collectively solve a common problem. The emphasis is on utilizing data and technology collectively to drive positive outcomes.

AI technology was applied through IQVIA Vigilance Detect, a pharmacovigilance platform that features continuous learning capabilities, vast ontologies, and demonstrated efficiency in reducing noise, and eliminating human error. The collaboration between human expertise and advanced AI/ML controls ensured a seamless transition to automation while maintaining a vigilant human touch.

PATIENT SAFETY DATA DISTILLING THROUGH THE PV WORKFLOW FASTER

AI/ML technology is embedded upstream of the case processing workflow (using IQVIA Vigilance Detect) to optimize review



Shaping a patient-centric approach

ATHENA's impact extends beyond operational metrics. It champions a patient-centric approach by deflecting manual administrative activities upstream. This redirection of effort allows providers and Access Solutions to dedicate more time to patients' needs, fostering a more personalized patient experience. Beyond the numbers, ATHENA has enabled more humanized interactions, making patient safety a collective responsibility.

The technological core: IQVIA Vigilance Detect

The technological backbone of ATHENA lies in IQVIA's Vigilance Detect solution. Developed over 13 years, this technology has evolved by constantly building a bank of ontologies supporting Natural Language Processing (NLP). Its success is rooted in a sophisticated combination of AI, NLP, and automation, processing more than four million records annually. The Baseline Ontologies, fine-tuned for safety, enable the system to detect adverse events, product complaints, off-label use, and other potential risks with precision.

The application of Vigilance Detect is not a standalone process but a holistic approach. It seamlessly integrates automation techniques, such as NLP and machine learning, with human-assisted machine learning. The end-to-end workflow ensures centralized and standardized routing of information, bringing efficiency to the process. The success of Vigilance Detect lies not just in its technological prowess but in its ability to enhance human decision-making and identify AEs embedded in reported data.

Supervised learning for continuous enhancement

Indeed, human-led governance in the context of applying AI and ML to drug development was one of the FDA's three key areas of focus. US Patient Safety's commitment to a human-in-the-loop approach is embodied in ATHENA's use of supervised learning — a method that ensures human expertise remains integral to the AI/ML controls and contribute to continuous improvement. The feedback loop allows for pattern recognition, trend identification, and ongoing refinement of the system. This iterative process ensures that ATHENA evolves with changing needs and emerging patterns, underscoring the adaptability of the model.

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Impact evaluation: unveiling operational efficiency

Upstream impact

ATHENA's journey from 2019 to 2022 witnessed a substantial reduction in the percentage of documents requiring manual review. The transition from **100% to 58% in manual review effort** signifies a paradigm shift towards increased automation. In 2022, ATHENA achieved a **90% efficiency gain over human effort** in the initial review of digital documents, highlighting the tangible benefits of early AI adoption.

Downstream impact

Downstream, ATHENA's impact is evident in the reduced invalid individual case safety reports, **reflecting a 50% decrease since 2019.** This outcome is attributed to the minimization of invalid cases entering the safety receipt system and the enhanced accuracy of potential adverse event assessments.

Automated adverse event detection influence extends to a deflection of redundant data from case intake and processing teams, streamlining the entire PV workflow and freeing up resources for other activities.

UPSTREAM IMPACT

90% Efficiency

In 2022, **90% efficiency over human effort** in an initial review of digital documents.

94% Efficiency

In 2022, **94% efficiency over human effort** in benefit call recording investigations.

550,000 Digital documents identified

18,000 Adverse events identified

60,000 Calls reviewed

60,000 calls equating to 33,000 hrs were reviewed which if performed manually, would need 22 people or 4,100 working days.

DOWNSTREAM IMPACT

50% Reduction

Since 2019, individual case safety reports from Access Solutions have been **reduced by 50% due to fewer invalid cases.**

96% of Documents

In 2022, **96% of documents did not contain potential AEs** and were not sent to the drug safety database.

QUALITATIVE IMPACT

Reduction in non-value add activity, more meaningful utilization of professional resources.

Qualitative impact

Beyond quantitative metrics, ATHENA has brought about a qualitative transformation by reducing non-value-adding activities. This shift allows for a more meaningful utilization of professional resources, redirecting focus from mundane administrative tasks to activities contributing to improved patient safety oversight and outcomes.

Navigating challenges: the path forward

Despite ATHENA's success, navigating the intricacies of implementing advanced technologies in PV is not without challenges. Technological agility, customization impediments, system integration capabilities, and patient privacy concerns require ongoing consideration. Striking the right balance between harnessing the power of AI and safeguarding patient privacy is also essential for sustained success.

Conclusion: advancing patient safety through synergistic innovation

In conclusion, the ATHENA initiative stands as a testament to the transformative potential of collaborative innovation in patient safety. It vividly demonstrates the feasibility and efficacy of applying AI/ML technology early in the drug safety lifecycle, particularly within PSPs. ATHENA's success underscores the paramount importance of collaboration, where diverse entities converge to protect patient safety and optimize outcomes.

This model accentuates collaboration, recognizing that AI/ML technology serves to augment human decision-making and automate tasks, thereby freeing up time for more valuable PV activities. The adoption of early AI in pharmacovigilance aligns seamlessly with the industry's commitment to patient-centricity and represents a significant leap toward a more proactive and holistic healthcare approach.

The ATHENA initiative demonstrates the feasibility and efficacy of applying AI/ML technology early in the drug safety lifecycle, particularly within PSPs.

About the authors

JOANN EVANGELISTA
Head of Operations & Innovations, US Patient Safety Genentech

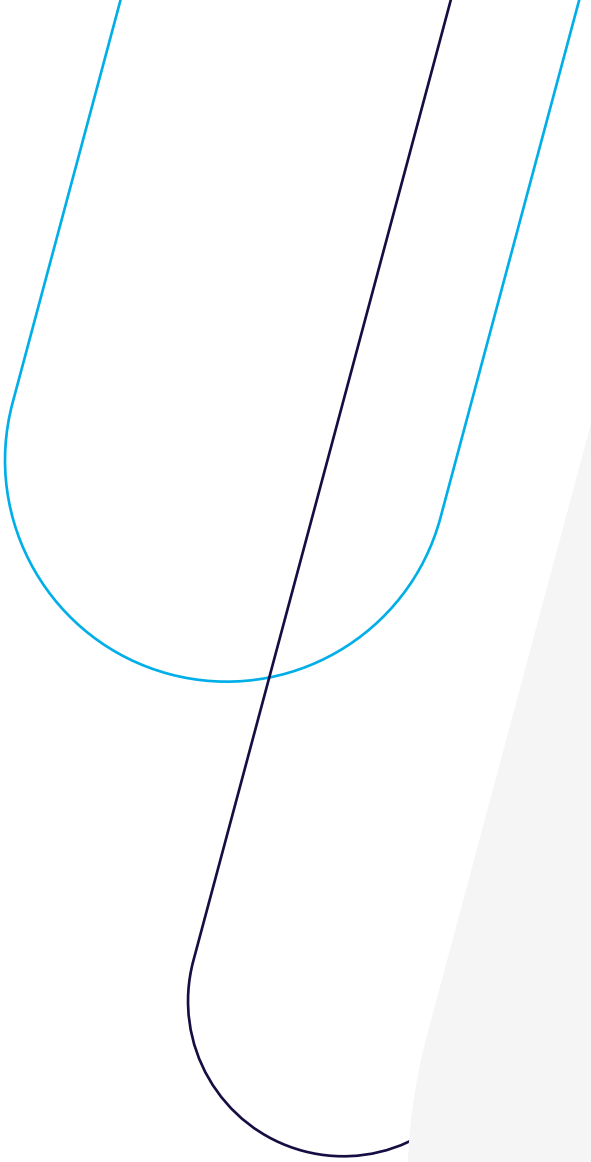
Joann is the Head of US Patient Safety Operations & Innovations at Genentech, with over 20 years of experience in a federally regulated landscape holding multiple positions in the Commercial and Medical Affairs organizations. She is a revered visionary leader and integrated systems thinker whose journey with Artificial Intelligence started seven years ago when AI in AE detection was at the edge of its adoption. She has cultivated an environment rich in technology using innovative approaches with AI and machine learning to sustain PV operational excellence in a rapidly changing environment. Joann's experiences and perspective have lent itself to assess multiple AI tools across high-risk PV areas to decrease exposure and increase compliance and efficiency.

MARIE FLANAGAN
Director, Offering Management
IQVIA Vigilance Detect

Marie serves as Director of Offering Management for IQVIA's Vigilance Detect (safety risk identification technology). In her 18-year tenure, she has held various leadership positions in PV operational management, PV strategy and consulting. Throughout the years she has played a pivotal role in the integration of safety technology and services and the strategic expansion efforts of IQVIA's pharmacovigilance department. In her current role, she supports the evolution of safety risk identification technology in response to evolving industry needs.

MEREDITH KILEY
Senior Manager Operations & Innovations, US Patient Safety Genentech

Meredith is an accomplished US Patient Safety Operations & Innovations Senior Manager at Genentech, renowned for her leadership and experience in a compliance driven environment. With an impressive tenure of 15 years within the Medical Affairs organization, she has held various pivotal roles, showcasing her versatility and expertise supporting multiple system integrations and enhancements which have increased ICSR compliance. Meredith's career is characterized by her commitment to integrating cutting-edge technological systems into the PV landscape, driving sustained operational excellence for nearly 10 years.



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