VIEW POINT

PHARMACOVIGILANCE AND AI: ENHANCING DRUG SAFETY WITH AUTOMATION LEVERAGING ARTIFICIAL INTELLIGENCE FOR EFFECTIVE DRUG MONITORING AND REGULATORY COMPLIANCE

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1. Introduction to Pharmacovigilance (PV)

Definition

Pharmacovigilance (PV) involves the **monitoring, detection, assessment, and prevention** of adverse effects or any other drug-related problems. It ensures that medicines remain **safe, effective, and compliant** with global regulatory frameworks.

Importance

PV plays a critical role in **patient safety and regulatory adherence.** Several well-known examples highlight its impact:

Valsartan contamination with NDMA (a carcinogen) led to **global recalls and stringent regulatory measures** after PV investigations.

Nimesulide restrictions for children under 12 due to PV-reported **adverse effects** like GI bleeding, ulcers, and clotting.

Challenges in Pharmacovigilance

PV plays a critical role in **patient safety and regulatory adherence.** Several well-known examples highlight its impact:

Massive Data Volumes

The pharmaceutical industry handles **millions of adverse event (AE) reports,** making manual analysis **time-consuming and prone to human error.**

Regulatory Complexity

Stringent compliance requirements require **rapid reporting and high accuracy** in anomaly detection.

Multi-Channel Reporting

Adverse events are captured from **emails, call transcripts, social media, literature, and regulatory filings,** making analysis **challenging without automation.**

2. AI in Pharmacovigilance: Transforming Drug Safety Monitoring

Why AI?

AI provides a **scalable, efficient, and intelligent approach to drug safety monitoring,** addressing industry pain points:

a) Automated AE Detection

Reduces **manual workload and response time.**

b) Real-Time Signal Detection

Identifies safety signals faster, improving **proactive decision-making.**

c) AI-Driven Pattern Recognition

Detects hidden trends in **real-world evidence.**

d) Elimination of Redundancies

Minimizes **duplicate reporting** and ensures data accuracy.

Core AI Capabilities in Pharmacovigilance

1. **Natural Language Processing (NLP):** Extracts AEs from **unstructured reports, clinical notes, and social media.**
2. **Machine Learning (ML):** Identifies risk patterns and prioritizes cases based on severity.
3. **Robotic Process Automation (RPA):** Automates **case processing workflows** (e.g., ICSR submissions).
4. **Chatbots & Virtual Assistants:** Handles **initial patient or HCP reports** and **pre-triage** events.

3. AI powered anomaly detection approach: Infosys AI solution

Context & Industry Challenges: Pharmaceutical firms face a rapidly growing volume of **multi-channel safety data**. The existing **manual approach to anomaly detection** is:

Unscalable

Human review is **resource-intensive** and **slow.**

Inefficient

High chances of **missed signals** or **compliance risks.**

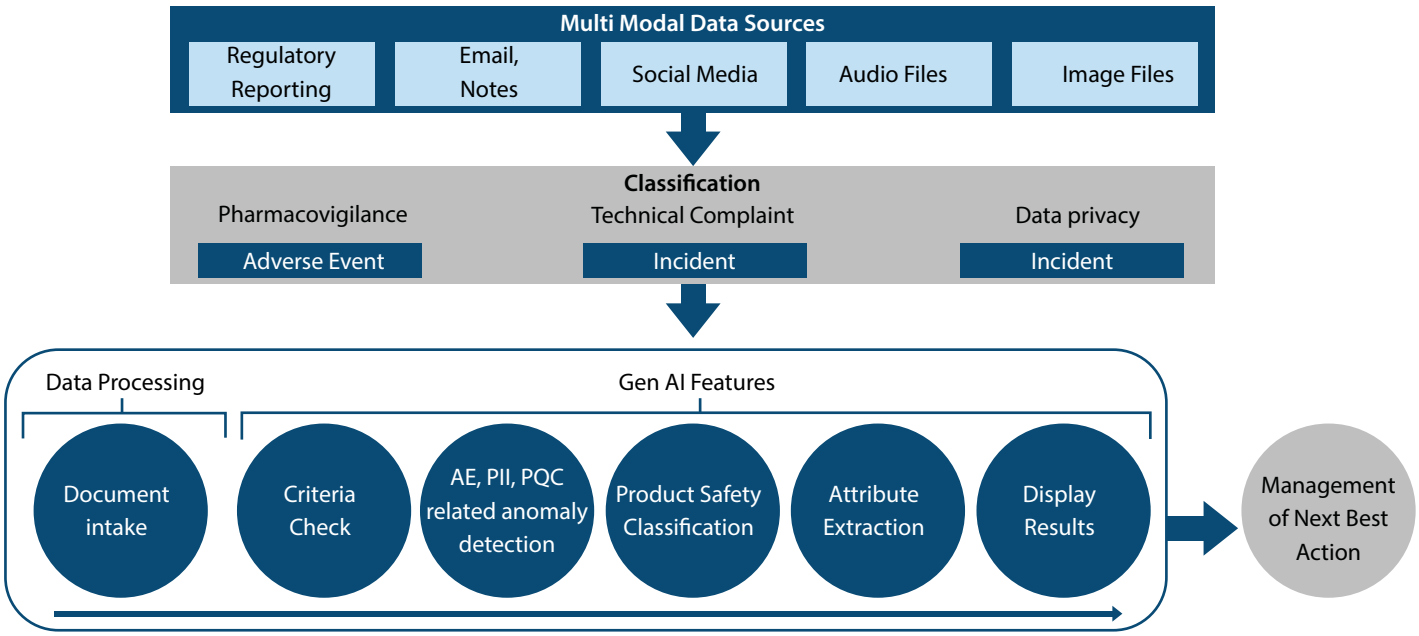
Regulatory Risk-Prone

Failure to handle PII correctly, AE or PQC can lead to regulatory penalties.

Infosys proposes a Gen AI & Agent AI powered anomaly detection framework to streamline PV processes.

- **Automated anomaly detection** across **AEs, PII, and technical complaint.**
- **AI powered summarization:** Generate **structured reports** for regulatory submissions.
- **PII Anonymization:** Ensures compliance with **maintaining traceability** for internal audits.
- **Proactive risk monitoring:** A flags early patterns warning to prevent escalations.

Process Overview for detecting anomalies from multi-modal data sources - Text, Audio, Images, etc.



Technology stack.

Generative AI & Agentic AI
Automates safety case classification and triage.

FastHTML framework
Accelerates AE data extraction and structuring.

OCR and AI vision models
Detects anomalies text. images and outcomes.

4. Strategic Differentiators & Future Roadmap

Key Differentiators

a) Operational Excellence:
AI aligns with PV **governance & compliance standards.**

b) Scalable Architecture:
Easily expands to new **PV use cases** like **medication error detection.**

c) AI-Driven Decision Support:
AI predicts **potential safety issues before they escalate.**

Future Roadmap

ICSR Database Integration:
Maps AI-extracted fields to regulatory reporting systems.

MedDRA & WHO Dictionary Mapping: Standardizes terminology for **global compliance.**

AI-Driven Image Analysis:
Uses OCR to **detect anomalies in scanned documents.**

Conclusion

Pharmacovigilance is undergoing a **transformational shift** with AI-powered automation. **Generative AI, NLP, and ML** are revolutionizing **anomaly detection, case processing, and regulatory reporting. Gen AI-based anomaly classification and summarization framework** enhances **efficiency, accuracy, and compliance,** positioning pharmaceutical companies for **next-generation drug safety and regulatory excellence.**

* **AI in PV is no longer an option—it's a necessity for future-ready pharmacovigilance.**

About the Authors

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Jayadhar Gundu bringing a unique blend of business acumen and technical expertise drawn from over 7 years of experience across diverse sectors. With a robust background in life sciences consulting and the manufacturing domain, he has delivered transformative solutions in supply chain management. His proficiency in process improvement has led to significant operational gains and enhanced performance for clients. As a responsible AI practitioner he is committed to ethical AI deployment, ensuring that AI technologies are used responsibly and effectively to benefit the life sciences industry.

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Sapna is a seasoned life sciences consultant with over nine years of experience in R&D, Project and Quality Management, Data Analysis, and Computer System Validation (CSV). She has successfully led projects in safety and quality, driving continuous process improvements to enhance client performance. Passionate about innovation, she is eager to explore AI technologies and their responsible application in the life sciences industry.

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