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Review Article

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Post-Market Surveillance Evolution: Pharmacovigilance 2.0 and the future of global Drug Safety

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Abstract

Pharmacovigilance (PV) plays a critical role in ensuring the safety of drugs and vaccines after marketing authorization. Traditionally, PV systems relied heavily on spontaneous adverse drug reaction (ADR) reporting, which often faced challenges such as underreporting, fragmented data sources, and delays in signal detection. The COVID-19 pandemic highlighted these shortcomings, creating an urgent need for more efficient, technology-driven systems. This led to the emergence of "Pharmacovigilance 2.0," characterized by the integration of artificial intelligence (AI), real-world evidence (RWE), big data analytics, and digital platforms, including mobile applications, for active and predictive safety surveillance. In India, the Pharmacovigilance Programme of India (PvPI) has strengthened ADR reporting networks, signal detection capabilities, and risk communication mechanisms. Meanwhile, in the United States, the FDA's Sentinel 2.0 system utilizes advanced analytics to proactively monitor post-market drug safety in near real time. This article explores the evolution of PV systems in both countries, comparing key innovations, highlighting regulatory advancements, identifying existing challenges, and proposing future directions for achieving harmonized, globally efficient drug and vaccine safety frameworks.

Keywords: Pharmacovigilance 2.0; Real-World Evidence; AI in Drug Safety; PvPI; FDA Sentinel; Adverse Drug Reaction Reporting; Post-Market Surveillance

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1. Introduction

Pharmacovigilance (PV) is defined as the science and activities concerned with the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems Although pre-approval clinical trials generate crucial safety data, these studies involve limited sample sizes and controlled conditions that may not reveal rare or long-term adverse effects. (1) Therefore, post-marketing safety surveillance is vital to identify risks that emerge when drugs are used in larger and more diverse populations.

Historically, PV has relied on spontaneous reporting systems such as India's Pharmacovigilance Programme of India (PvPI) and the United States Food and Drug Administration's (FDA) Adverse Event Reporting System (FAERS). These systems, while foundational, face inherent limitations: low reporting rates, lack of real-time data, and delayed signal detection. In response, regulatory bodies are increasingly adopting modern approaches termed "Pharmacovigilance 2.0" characterized by proactive monitoring, AI-driven analytics, and integration of real-world evidence RWE. (2)

This review provides a comparative overview of traditional and modern PV frameworks in India and the U.S., examines the transformative impact of digital tools, and explores challenges and opportunities shaping the future of global pharmacovigilance. (3)

2. Methodology

This review article adopted a narrative synthesis approach to explore the evolution of post-market surveillance (PMS) and the emergence of Pharmacovigilance 2.0. A comprehensive literature search was performed across PubMed, Scopus, Web of Science, Google Scholar, and official regulatory portals such as the FDA, EMA, WHO, and the Indian Pharmacopoeia Commission (IPC). Publications from 2015 to 2025 were retrieved using keywords including pharmacovigilance, post-market surveillance, artificial intelligence in drug safety, real-world evidence, FDA Sentinel, and PvPI. Inclusion criteria encompassed peer-reviewed articles, regulatory

guidelines, technical reports, and policy documents focusing on PMS frameworks, digital health innovations, and regulatory perspectives in India and the United States. Studies lacking methodological relevance or regulatory context were excluded. Literature selection involved identification, eligibility screening, and critical appraisal to extract information on historical evolution, technological advancements, patient-centric approaches, and global harmonization efforts. Evidence from scientific studies, policy reports, and regulatory documents was synthesized to present a comprehensive understanding of pharmacovigilance transformation and future directions for drug safety monitoring.

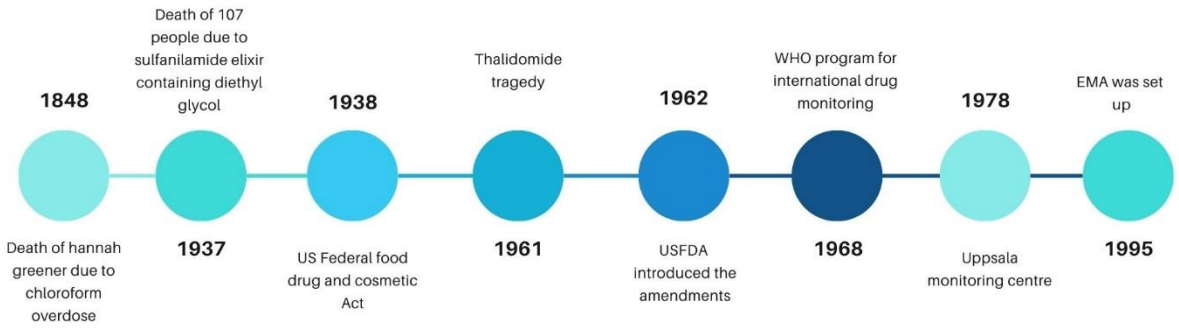

Figure 1. Historical Overview of Pharmacovigilance

3. Background

The concept of pharmacovigilance took shape in the 1960s, following the thalidomide incident, which exposed the necessity for organized systems to oversee drug safety. In its early phase, pharmacovigilance primarily depended on voluntary reporting of adverse drug reactions (ADRs) by healthcare providers. (4) "Although these systems helped identify numerous safety issues, they also suffered from limitations such as:

- High under-reporting rates.
- Inconsistent data quality.
- Delayed signal detection.
- Lack of patient engagement.

Global regulatory authorities responded by establishing pharmacovigilance frameworks, such as the U.S. FDA Adverse Event Reporting System (FAERS), the European Medicines Agency (EMA) Eudra Vigilance, and the WHO Uppsala Monitoring Centre (VigiBase). These systems created international databases, allowing cross-country collaboration. (5)

In recent years, the growing availability of real-world data (electronic health records, insurance databases, wearable devices, mobile health apps, and even social media) has pushed pharmacovigilance into a new era. This shift is collectively referred to as Pharmacovigilance 2.0 a more dynamic, technology-enabled, and patient-inclusive form of global drug safety. (6)

4. Objectives

The present review article aims to comprehensively examine the evolution of post-market surveillance and pharmacovigilance, tracing their historical development and pivotal milestones in advancing drug safety monitoring. It further seeks to elucidate the concept and significance of Pharmacovigilance 2.0, emphasizing its transformative potential in shaping next-generation pharmacovigilance systems. In addition, the review explores the role of emerging technological innovations and their implications for global drug safety oversight, while integrating regulatory perspectives from major international health authorities. Finally, it critically analyses the key challenges confronting pharmacovigilance practices and proposes potential future pathways to strengthen global pharmacovigilance frameworks for improved patient safety and public health outcomes.

5. India: The Pharmacovigilance Programme of India (PvPI)

The Central Drugs Standard Control Organisation (CDSCO) launched the Pharmacovigilance Programme of India (PvPI) in 2010, aiming to establish a nationwide mechanism for adverse drug reaction monitoring. By 2019, more than 400 ADR Monitoring Centres (AMCs) were operational across the country, coordinated by the Indian Pharmacopoeia Commission (IPC) as the National Coordination Centre. (7)

Data from India's PvPI are forwarded to the WHO's Uppsala Monitoring Centre to contribute to international drug safety databases. The program uses paper-based forms, online reporting portals, and more recently, the Med Safety mobile app. Despite these advances, challenges persisted. (8)

- Limited awareness among healthcare professionals and patients. (9)
- Underreporting of ADRs due to lack of incentives and training.
- Manual data processing leading to delays in signal detection.

6. United States: FDA Adverse Event Reporting System (FAERS)

The U.S. FDA operates the FAERS database to collect voluntary ADR reports from healthcare professionals, patients, and manufacturers. FAERS supports post-market safety evaluations and informs regulatory actions such as safety labelling changes or product recalls. (10)

However, like PvPI, FAERS is primarily passive in nature, leading to similar limitations:

- High volume of unstructured reports requiring manual review.
- Incomplete data fields (e.g., missing patient demographics).
- Delayed identification of emerging safety signals.

7. Limitations of Traditional PV

Both PvPI and FAERS share common limitations:

- **Underreporting:** Studies estimate that over 90% of ADRs go unreported in passive systems.
- **Data Fragmentation:** ADR data are rarely linked with clinical or prescription records. (11)
- **Reactive Approach:** Signals are detected retrospectively rather than predicted in advance. (12)

These constraints necessitated the transition to more dynamic, technology-driven pharmacovigilance frameworks.

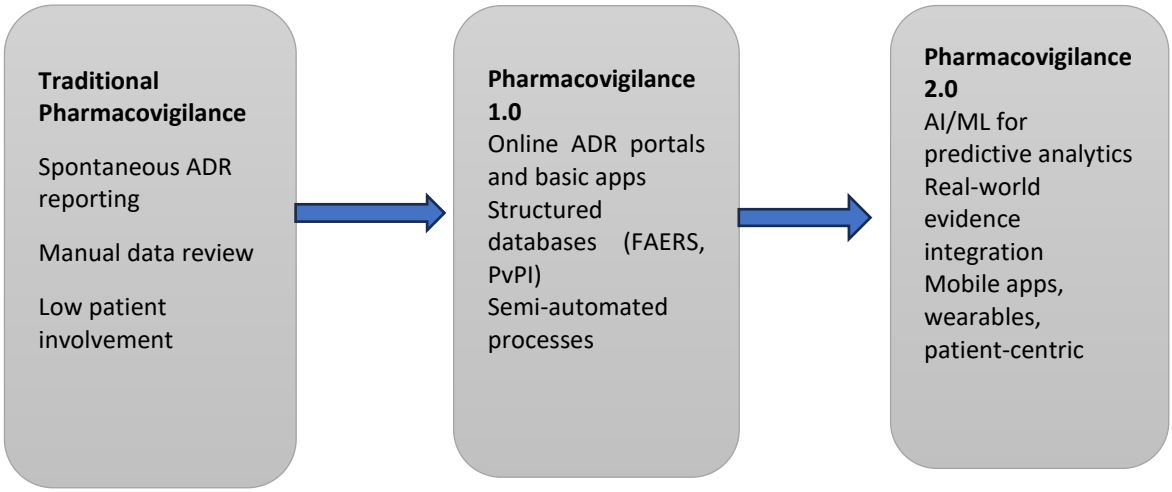

Figure 2. Evolution of Pharmacovigilance

8.Pharmacovigilance 2.0: Modern Trends (2020–2025)

Pharmacovigilance 2.0 marks a major transformation from passive reporting to proactive, technology-driven safety surveillance toward active surveillance and predictive analytics. By leveraging AI, machine learning, and RWE, PV 2.0 enables regulators to detect potential safety issues faster and engage patients more effectively. (13)

8.1 Role of Emerging Technologies (Blockchain, Cloud, IoT)

Emerging Digital Tools Beyond AI:

In addition to artificial intelligence and real-world evidence, novel digital infrastructures are shaping the future of pharmacovigilance. Blockchain technology is being explored to ensure secure, transparent, and tamper-proof recording of adverse event data across stakeholders. (14) Cloud-based platforms enable real-time global sharing of safety information. (15) reducing duplication of efforts between regulators and industry. Similarly, the Internet of Things (IoT) through wearable devices and connected health apps generates continuous patient safety data, supporting a shift from episodic to continuous monitoring. (16) These technologies complement AI-driven analytics and are expected to strengthen trust, interoperability, and timeliness in post-market surveillance. (17)

Real-world evidence (RWE) is gathered from sources like electronic health records, insurance claims databases, and various registries. This data provides insights into drug performance in routine practice, beyond controlled clinical trial settings. (18)

- **United States:** The FDA's RWE framework (2021) supports regulatory decision-making using data from healthcare databases covering over 100 million patients. Sentinel 2.0 integrates these datasets for continuous, real-time safety monitoring. (19)
- **India:** PvPI is planning integration with the National Digital Health Mission (NDHM) to link ADR reports with patient health records, creating opportunities for broader safety evaluations. (20)

8.1.1 AI and Machine Learning for Signal Detection

AI enhances pharmacovigilance by

- Automating case triage and disproportionality analysis.
- Mining unstructured text (e.g., EHR notes, social media) using natural language processing (NLP).
- Predicting safety risks earlier than manual methods.

- **FDA:** Artificial intelligence is used in Sentinel 2.0 to enhance detection of safety signals while reducing incorrect alerts.
- **India:** PvPI is piloting AI-driven tools, especially for electronic prescription data.

8.1.2 Mobile & Digital ADR Reporting:

Patients can now take an active role in reporting drug safety issues through the use of mobile applications

- **India:** The Med Safety app enables ADR reporting in multiple Indian languages and links to the WHO global database. (21)
- **USA:** The FDA's MedWatch app and the V-safe program (COVID-19 vaccine monitoring) allow real-time ADR submission and follow-up surveys. (22)

Social media platforms (Twitter, Facebook) are also being explored for signal detection, especially for vaccines and consumer health products.

9. Patient-Centric Pharmacovigilance

9.1 Patient Empowerment in Safety Monitoring
Pharmacovigilance 2.0 emphasizes the role of patients not merely as data providers but as active collaborators in drug safety. Mobile health apps, online patient communities, and wearable devices empower patients to share real-time experiences, enriching databases with context-specific information such as lifestyle, adherence, and quality-of-life outcomes. (23) Patient-reported data capture adverse effects that may be overlooked in clinical settings, particularly for rare events or vulnerable populations. This cultural shift from physician-centric to patient-inclusive pharmacovigilance is essential to building responsive and transparent safety systems. (24)

9.2 Pandemic-Driven Acceleration:

The COVID-19 pandemic accelerated PV modernization worldwide. The swift deployment of vaccines called for real-time safety tracking, leading to the implementation of...

Digital dashboards for daily ADR tracking.

- AI models to identify emerging safety patterns.
- Patient-reported outcomes via mobile platforms.

9.3 Comparative Insights: India vs USA:

- Both India and the U.S. are transitioning toward technology-enabled pharmacovigilance, but at different stages of maturity

9.3.1 Similarities:

- Adoption of digital ADR reporting tools.
- Increased patient involvement.
- Collaboration with WHO-Uppsala and ICH initiatives.

9.3.2 Differences:

- **FDA Sentinel 2.0:** Fully operational AI and RWE integration.
- **PvPI:** Rapid digital expansion, with pilot AI programs and NDHM integration underway.

Table 1. Comparison of Traditional Pharmacovigilance and Pharmacovigilance 2.0 (2020–2025)

Parameter	Traditional PV (Pre-2020)	Pharmacovigilance 2.0 (2020–2025)
Data Sources	Spontaneous ADR reports (FAERS, PvPI)	Real-world evidence (EHR, claims, registries)
Technology Use	Manual data review, paper/online forms	AI, machine learning, digital dashboards
Patient Involvement	Limited (forms, helplines)	Mobile ADR apps, V-safe, Med Safety App
Global Collaboration	WHO-Uppsala linkage	ICH, EMA integrated frameworks
Signal Detection	Retrospective, delayed	Predictive, real-time monitoring
Challenges	Underreporting, fragmented data	Data privacy, AI bias, interoperability

9.3.3 Challenges and Opportunities

Challenges:

- **Data Privacy:** Compliance with global frameworks like GDPR and HIPAA is critical.
- **Algorithm Bias:** AI tools may inherit bias from training datasets.
- **Interoperability:** Remains limited due to the absence of uniform data-sharing standards between different regions."

Opportunities:

- Predictive analytics for early detection of ADRs.
- Integration of wearable device data (e.g., heart rate, glucose monitors).
- WHO's Pharmacovigilance 2030 vision for global harmonization.

10. Post-Market Surveillance Evolution (Pharmacovigilance 2.0 and the Future of Global Drug Safety):

10.1 Current Updates (2024–2025)

- **Use of Artificial Intelligence (AI) & Machine Learning:** Regulators (FDA, EMA) are adopting AI for faster detection of safety signals.
- **Real-World Data (RWD) & Real-World Evidence (RWE):** Increasingly used in regulatory decisions (from electronic health records, mobile apps, wearables).
- **FDA Sentinel Initiative & EMA Eudra Vigilance:** Actively monitoring millions of patients for adverse events.
- **WHO VigiBase Expansion:** Now the world's largest ADR database with stronger global participation.
- **India's PvPI:** Strengthening ADR reporting and global collaboration.

- **Patient-Centric Approaches:** social media, mobile health apps, and patient-reported outcomes are now part of safety monitoring.

10.2 AI-Driven Safety Surveillance: FDA's Sentinel and ARIA Approach

The FDA's Sentinel Initiative- especially its ARIA component-continues to revolutionize drug safety monitoring by leveraging real-world data (RWD), like insurance claims and electronic health records (EHRs). It enables rapid safety analyses under real-world conditions and informs regulatory actions such as label changes and safety communications. (19)

- Sentinel has become one of the FDA's key platforms for generating real-world evidence (RWE) to assess product safety's
- The ARIA system conducts proactive drug safety signal detection using AI/analytics and a distributed database.

11. WHO's VigiBase & Enhanced Data Access Conditions

VigiBase, maintained by the WHO Uppsala Monitoring Centre (UMC), is the world's largest global pharmaco-surveillance database, now containing over 40 million adverse event reports from more than 180-member countries (as of February 2025).

In March 2025, WHO and UMC introduced a new Data Access Conditions framework to clarify who can access VigiBase and under what circumstances. This ensures transparent, responsible data sharing and builds trust among stakeholders.

Additionally, VigiBase Extract provides structured, standardized data (MedDRA, WHO Drug) for subscription-based access by researchers, regulators, and academia.

12. Future Outlook

Pharmacovigilance 2.0 will continue evolving toward predictive, patient-centric frameworks. As AI models mature and health record integration improves, proactive safety monitoring will become standard. Collaborative global networks between regulators (CDSCO, FDA, EMA, WHO) will be crucial for addressing cross-border safety concerns and harmonizing standards. (25)

12.1 Global Harmonization and Regulatory Convergence

The future of pharmacovigilance depends on harmonized frameworks that transcend national boundaries. Organizations such as ICH, WHO, and the International Coalition of Medicines Regulatory Authorities (ICMRA) are working toward common data standards and interoperable reporting platforms. Low- and middle-income countries are increasingly adopting digital pharmacovigilance systems, supported by global capacity-building initiatives. (26) Such convergence reduces duplication, fosters mutual recognition of safety signals, and ensures equitable participation in the global drug safety ecosystem.

13. Discussion

Pharmacovigilance 2.0 represents a paradigm shift from reactive to proactive drug safety monitoring. Unlike traditional spontaneous reporting, it leverages AI and ML for rapid signal detection and pattern recognition, improving predictive accuracy. Real-World Evidence (RWE) from electronic medical records, registries, and insurance data enhances understanding of safety profiles across diverse populations. Patient engagement through mobile apps, wearables, and social media enables timely adverse drug reaction reporting, while global data integration fosters international collaboration. (27)

Key initiatives exemplifying this evolution include the FDA's Sentinel Initiative, EMA's EudraVigilance, WHO's VigiBase, and India's PvPI, reflecting a global trend toward digital, data-driven pharmacovigilance. Challenges remain in data quality, interoperability, privacy, and validation of AI/ML models to prevent bias. (28)

Overall, Pharmacovigilance 2.0 enhances patient safety, accelerates signal detection, and supports informed regulatory decisions. Continued efforts in harmonizing standards, improving data sharing, and fostering patient-centric reporting are essential to fully realize its potential.

14. Conclusion

Pharmacovigilance 2.0 represents a transition from traditional, reactive reporting methods to proactive, analytics-based safety monitoring. The integration of Artificial Intelligence (AI) and Real-World Evidence (RWE) is transforming how safety signals are detected, validated, and communicated to regulators and the public. Both India and the USA have made significant progress, but their approaches reflect differences in healthcare infrastructure and regulatory maturity. Moving forward, harmonized international collaboration guided by WHO's Pharmacovigilance 2030 strategy will be essential to create a globally responsive, transparent, and proactive drug safety ecosystem.

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Conflict of Interest

The authors declare that they have no competing interests related to this work.

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