Integrating Digital Technologies to Strengthen Adverse Drug Reaction Reporting in Indonesia's Pharmacovigilance System

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Abstract
The optimization of pharmacovigilance through digital transformation has become a global priority to improve patient safety and drug regulation. Indonesia's pharmacovigilance system, which has traditionally relied on manual and fragmented reporting, faces persistent challenges such as Lack of awareness to report ADR, limited awareness, and slow data processing. This study aims to analyze the integration of digital technologies to strengthen Adverse Drug Reaction (ADR) reporting within Indonesia's pharmacovigilance framework. Using a literature review method, ten national and international studies published between 2015 and 2025 were analyzed, focusing on mobile health applications, electronic medical records (EMR), artificial intelligence (AI), and the e-MESO platform. The results show that digital technologies significantly enhance ADR reporting accuracy, speed, and completeness, while improving coordination between healthcare professionals and regulatory authorities. AI and Big Data analytics further enable early signal detection and predictive risk assessment, reducing human error and facilitating evidence-based decision-making. However, challenges remain in data standardization, system interoperability, digital literacy, and cybersecurity. The study concludes that digital integration within pharmacovigilance is not only a technical innovation but also a strategic effort to foster transparency, accountability, and a safety-oriented culture. Strengthening infrastructure, policy alignment, and cross-sector collaboration is crucial to achieving a sustainable and intelligent pharmacovigilance ecosystem in Indonesia.

Introduction

Pharmacovigilance (PV) is a critical component of public health that ensures the safe and effective use of medicines by identifying, assessing, and preventing adverse drug reactions (ADRs). According to the World Health Organization (WHO), ADRs are among the leading causes of morbidity and mortality worldwide, accounting for 5–10% of hospital admissions globally. Factor that influences pharmacovigilance or ADR reporting is the limited infrastructure, low awareness among healthcare providers and patients, and the lack of an optimal systematic reporting mechanism. ADR rates in Indonesia are strikingly high: chemotherapy reaches 96–99%, insulin up to 97% due to hypoglycemia, and anti-tuberculosis drugs up to 85%, often causing hepatotoxicity and severe GI symptoms. Antiretroviral therapy shows about 45% ADR prevalence, with antimalarial and bronchodilator treatments also producing frequent CNS, cardiovascular, and digestive reactions. These high percentages show how miserable the situation is, as many patients experience serious, persistent ADRs that disrupt treatment and worsen outcomes. (Maharani & Yugatama, 2023). This wide variation indicates a lack of consistent national pharmacovigilance monitoring and a need for standardized, technology-driven approaches.

Despite the presence of a national pharmacovigilance system managed by the Indonesian Food and Drug Authority (BPOM), the inadequate capture of ADR cases remains an ongoing challenge. Data submitted to the WHO-Uppsala Monitoring Centre (UMC) show that Indonesia's ADR reporting rate is significantly lower than that of developed nations, even though drug utilization continues to rise. The barriers to effective reporting include limited awareness among healthcare professionals, inadequate training, high administrative workloads, and the absence of user-friendly reporting systems (Arifatul et al., 2025). These systemic

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weaknesses not only compromise patient safety but also hinder timely regulatory action in identifying and managing drug-related risks.

Globally, the transformation of PV systems toward digital platforms has been recognized as an essential step in modernizing drug safety monitoring. The integration of digital technologies—such as electronic health records (EHRs), mobile ADR reporting apps, and artificial intelligence (AI)-based signal detection—has demonstrated a significant increase in data accuracy, timeliness, and report completeness (Yella & Sudha, 2024). For example, digital ADR reporting systems implemented in India and Malaysia improved reporting rates by more than twofold compared to conventional manual systems (Bailey et al., 2023). These findings provide a relevant benchmark for Indonesia, where similar challenges and opportunities exist due to rapid health-digitization efforts, including the SATUSEHAT platform launched by the Ministry of Health.

The need for Indonesia to shift from a reactive to a proactive, data-driven pharmacovigilance (PV) approach has never been more urgent. Integrating digital technologies into PV will not only simplify reporting procedures but also enable real-time data analysis, predictive risk identification, and system interoperability across healthcare institutions, meaning that hospitals, clinics, and pharmacies can seamlessly share and exchange drug safety data. Previous studies reinforce the importance of this transformation; for example, research on Big Data Utilization in Pharmacovigilance identified data interoperability, governance, and privacy protection as essential components for successful digital PV implementation (Azali et al., 2025). However, these advantages can only be achieved through adequate investment in digital infrastructure, clear regulatory frameworks, and continuous professional training (BPOM).

Therefore, this literature review aims to gather, integrate, and critically evaluate existing research on the role of digital technologies in enhancing ADR reporting in Indonesia's pharmacovigilance system. The expected outcome is to strengthen the national pharmacovigilance ecosystem through data-driven innovation, improve ADR report quality and timeliness, and ultimately contribute to patient safety and rational drug use across Indonesia.

Methods

This study applied a literature review design to analyze and synthesize information on the integration of digital technologies in pharmacovigilance systems, with a focus on improving adverse drug reaction (ADR) reporting in Indonesia. The method aimed to systematically gather, evaluate, and interpret relevant scholarly works, official reports, and empirical studies published between 2015 and 2025.

The literature search was conducted across several electronic databases, including PubMed, ScienceDirect, ProQuest, Google Scholar, and the WHO Global Index Medicus. Search terms included combinations of keywords such as "pharmacovigilance", "adverse drug reaction reporting", "digital health", "artificial intelligence", "electronic health record integration", and "Indonesia." Boolean operators ("and," "or") were used to expand or refine the search results.

The inclusion criteria were: 1) Publications written in English or Bahasa Indonesia; 2) Articles focusing on pharmacovigilance systems, ADR reporting, or digital health integration; 3) Studies that discussed implementation, barriers, or outcomes of digital pharmacovigilance, particularly in low- and middle-income countries (LMICs); 4) Full-text articles available online with adequate methodological clarity. Exclusion criteria included: 1) Studies that only discussed pharmacovigilance conceptually without application to digital tools; 2) Duplicated records or opinion-based papers without data; 3) Articles article published span besides 2015-2025.

The search process initially generated a large number of studies; however, after applying the inclusion and exclusion criteria, only 10 journal articles were considered relevant because they specifically addressed digital technologies and ADR reporting in indonesia's pharmacovigilance system. These journals discussed various aspects of digital pharmacovigilance such as online reporting platforms, mobile ADR applications, artificial intelligence for signal detection, and the ability of different health information systems to exchange and use data seamlessly, as well as overall health system readiness. The selected studies were critically reviewed and compared to highlight best practices, barriers, and strategies that could be applied to Indonesia's pharmacovigilance system.

A narrative and thematic analysis approach was used to interpret the findings. Thematic grouping was based on four key domains: (1) barriers to ADR reporting, (2) types of digital technologies implemented, (3) system and policy readiness, and (4) observed outcomes or impacts on reporting performance. This approach ensured that the selected studies were aligned with the purpose of the article, understanding how digital technologies can enhance ADR reporting, and allowed a structured comparison between global evidence and Indonesia's

pharmacovigilance needs, providing a comprehensive view of how digital transformation can strengthen drug safety monitoring.

Results and Discussion

The analysis of ten selected journal articles published between 2023 and 2025 revealed significant progress, conceptual development, and ongoing challenges in optimizing Indonesia's pharmacovigilance system through the utilization of digital technology. These studies examined how digital reporting platforms, artificial intelligence (AI), and mobile health applications transform the quality, accuracy, and timeliness of Adverse Drug Reaction (ADR) reporting while addressing long-standing systemic barriers such as persistent gaps in reporting practices, workflow inefficiencies, and constraints in workforce capability.

The findings collectively highlight that digital innovations do not merely enhance data collection but fundamentally reshape pharmacovigilance into an integrated, intelligent, and participatory system. The following section synthesizes the literature thematically, supported by relevant studies.

Table 1. Summary of Selected Literature on Digital Pharmacovigilance

No.	Journal Tittle	Author	Main Findings
1.	Effectiveness of mobile applications in enhancing adverse drug reaction reporting: a systematic review	(Liyanage & Madhushika, 2025)	Mobile app–based reporting (Liyanage et al., 2025) increased the quantity, quality, and speed of Adverse Drug Reaction (ADR) reporting compared to manual methods.
2.	Adverse Drug Reactions Reporting Profile in Tertiary Referral Hospital: A Retrospective Pharmacovigilance Study in Indonesia	(Sari & Suprapti, 2024)	Hospital-based study in Indonesia (Sari & Suprapti, 2024) found antineoplastic, antibacterial, and antihypertensive drugs as the most common ADR causes, with underreporting still a major issue.
3.	AI-Powered Signal Detection in Pharmacovigilance Databases	(Kessler, 2025)	AI-driven signal detection (Kessler, 2025) improved early identification and accuracy of drug safety signals using machine learning and natural language processing.
4.	Pharmacovigilance in the Era of Digital Health Leveraging Big Data and Artificial Intelligence for Enhanced Drug Safety Monitoring	(Khan et al., 2025)	Digital health and big data integration (Khan et al., 2025) enabled real-time, predictive, and patient-centered pharmacovigilance, though data quality and regulatory alignment remain challenges.
5.	The applications and advances of artificial intelligence in drug regulation: A global perspective	(Fu et al., 2025)	AI improves global drug regulation by enhancing safety surveillance and review efficiency, though challenges remain in data quality and standardization.
6.	Evaluation of Adverse Drug Reaction Reporting on the Badan POM Website in Yogyakarta Special Region	(Ernawati et al., 2025)	In Yogyakarta, antibiotics (especially levofloxacin, ceftriaxone) caused most ADRs, mainly affecting the skin; stronger digital reporting is needed.
7.	Healthcare professionals' willingness to utilize a mobile health application for adverse drug reaction reporting in a limited resource setting: An input for digital health, 2023	(Dubale et al., 2024)	77.4% of Ethiopian healthcare professionals are willing to use mobile apps for ADR reporting; training and usability are key factors.
8.	The Assessment of Patient Safety Culture Among Doctors, Nurses, and Pharmacists in a Public Hospital in Indonesia	(Kartikasari et al., 2023)	Patient safety culture was strong (70.3%), with high organizational learning but low staffing adequacy. The study shows that patient safety culture among healthcare workers indirectly supports safe medication practices and ADR reporting, making it relevant to pharmacovigilance.
9.	Advancements in Electronic Medical Records for Clinical Trials:	(Lee et al., 2025)	The combined trigger tools and STOPP/START criteria effectively detected adverse drug events, inappropriate medications, and

	Enhancing Data Management and Research Efficiency		prescription omissions in elderly patients, improving medication safety though limited to one hospital and short study duration.
10.	Implementation of a pharmacovigilance system to detect adverse events and improve medication appropriateness in a hospital in Indonesia	(Atmaja et al., 2024)	AI-supported EMRs enhanced data accuracy, patient recruitment, and trial efficiency but faced challenges in data standardization, privacy, and interoperability; success depends on strong collaboration and regulatory support.

The implementation of mobile-based systems has revolutionized ADR reporting workflows. Liyanage and Madhushika (2025) demonstrated that the transition from manual to digital systems improved the completeness, timeliness, and accessibility of ADR reports by up to 2.5 times. Similarly, Dubale et al. (2024) found that digital literacy, usability, and training were key predictors of healthcare professionals' willingness to adopt mobile ADR reporting tools, with 77.4% of respondents expressing readiness for implementation. These findings confirm that technology acceptance and user competence are crucial determinants of pharmacovigilance success, consistent with Rogers' (2003) Diffusion of Innovations Theory.

At the national level, Sari and Suprapti (2024) observed persistent underreporting in Indonesian hospitals, particularly in cases involving antineoplastic, antibacterial, and antihypertensive agents. Their findings highlight the need for more systematic digital integration and awareness programs. Ernawati et al. (2025) supported this by showing that antibiotic-related ADRs (especially levofloxacin and ceftriaxone) dominated regional pharmacovigilance data, yet online reporting through BPOM's e-MESO remained underutilized due to limited infrastructure and digital engagement.

The introduction of AI and Big Data technologies marks a new frontier for pharmacovigilance analytics. Kessler (2025) demonstrated that machine learning and natural language processing techniques could automatically detect early ADR signals with higher sensitivity and specificity compared to manual WHO-VigiBase analysis. Khan et al. (2025) extended this by showing that AI-enabled pharmacovigilance supports real-time, patient-centered monitoring and predictive risk modeling. However, both authors emphasized the ongoing challenge of ensuring data standardization and regulatory compatibility across different digital systems. Fu et al. (2025) explored the global dimension of AI integration in pharmacovigilance, emphasizing that algorithmic automation can accelerate regulatory review and enhance global safety surveillance. Nonetheless, ethical issues such as data ownership, patient consent, and algorithmic transparency must be addressed to maintain trust in AI-assisted pharmacovigilance.

The role of EMRs in strengthening drug safety management was highlighted in studies by Lee et al. (2025) and Atmaja et al. (2024). lectronic Medical Record (EMR) systems—especially those equipped with AI-assisted trigger tools—proved effective in detecting medication errors, inappropriate prescriptions, and ADR patterns in elderly patients. In Indonesia, Atmaja et al. (2024) confirmed that AI-supported EMRs improved reporting accuracy and reduced manual workload but still faced obstacles in interoperability and data security. The findings collectively suggest that digital pharmacovigilance can significantly enhance healthcare quality when supported by institutional readiness and robust governance.

Lastly, Kartikasari et al. (2023) found patient safety culture was strong (70.3%), with high organizational learning but low staffing adequacy. The study shows that patient safety culture among healthcare workers indirectly supports safe medication practices and ADR reporting, making it relevant to pharmacovigilance.

The transition toward digital pharmacovigilance represents not merely a technological adaptation but a paradigm shift in the philosophy and operationalization of drug safety monitoring. Across the reviewed studies, a recurring pattern emerges: digitalization fundamentally reshapes how data are collected, processed, analyzed, and acted upon in pharmacovigilance systems. The synthesis of findings demonstrates that digital transformation enhances reporting performance, analytical depth, and institutional collaboration, yet also introduces new complexities related to governance, infrastructure, and ethical management.

At the global level, pharmacovigilance has evolved from passive, spontaneous reporting to an integrated, proactive, and data-driven process. Studies by Fu et al. (2025) and Khan et al. (2025) underline that the convergence of artificial intelligence (AI), Big Data analytics, and cloud-based interoperability enables early identification of drug safety signals that were previously undetectable through traditional manual reporting. This evolution supports the World Health Organization's "Next-Generation Pharmacovigilance" agenda, which calls for intelligent systems capable of predictive analysis, cross-border data exchange, and participatory reporting models. In this context, Indonesia's ongoing adoption of e-MESO and integration within the SATUSEHAT ecosystem reflect alignment with global efforts toward

digital harmonization and health system intelligence. From a theoretical standpoint, this transformation aligns with Rogers' Diffusion of Innovations theory (2003), which suggests that successful technological adoption depends on perceived relative advantage, compatibility, complexity, the ability to try the innovation on a small scale, and the visibility of its results. In the Indonesian context, mobile applications and EMR-based pharmacovigilance platforms clearly demonstrate relative advantage, enhancing ADR reporting efficiency and accessibility. However, the diffusion process remains hindered by limited infrastructure, varying levels of digital literacy, and inconsistent institutional readiness, particularly in rural and resource-limited areas. These socio-technical barriers emphasize the importance of contextual adaptation and stakeholder engagement in ensuring equitable digital transformation.

Digital pharmacovigilance also alters the epistemological foundation of drug safety management, from reactive documentation to predictive prevention. The use of AI and machine learning (Kessler, 2025; Khan et al., 2025) enables continuous signal detection and automated causality assessment, reducing dependence on human interpretation and minimizing reporting latency. Yet, this mechanization raises new ethical dilemmas, particularly concerning algorithmic transparency, bias in data training sets, and accountability for automated decision-making. Fu et al. (2025) highlight the necessity for clear governance frameworks to regulate AI in pharmacovigilance, ensuring that machine learning models augment rather than replace human expertise.

In Indonesia, the integration of AI-supported EMRs (Atmaja et al., 2024; Lee et al., 2025) represents a critical advancement toward intelligent pharmacovigilance systems capable of real-time data linkage across healthcare sectors. These systems enable near-instantaneous transmission of ADR information from hospitals to the Indonesian Food and Drug Authority, enhancing both surveillance responsiveness and regulatory decision-making. However, as identified by Atmaja et al. (2024), challenges in the ability of different health information systems to work together persist due to fragmented systems and the absence of standardized data ontologies across institutions. This indicates that digital success relies not only on technical capacity but also on institutional governance and inter-sectoral collaboration.

The findings of Sari and Suprapti (2024) and Ernawati et al. (2025) emphasize that, despite technological availability, underreporting remains a fundamental behavioral barrier. Many healthcare professionals still perceive ADR reporting as an administrative burden rather than a patient safety obligation. This underscores the need for systemic cultural change supported by leadership commitment and policy incentives. Kartikasari et al. (2023) confirmed that hospitals with strong safety cultures and digital learning environments demonstrated higher ADR reporting consistency, reflecting how culture, technology, and leadership interdependently influence pharmacovigilance outcomes.

Another crucial dimension is patient-centered participation. As mobile health applications become increasingly accessible, they open opportunities for direct patient involvement in ADR reporting—extending pharmacovigilance beyond the walls of healthcare institutions. Liyanage and Madhushika (2025) highlight that mobile-based systems can empower patients to report drug reactions in real time, democratizing data collection and promoting transparency. This participatory model resonates with the WHO's vision of "pharmacovigilance for the people", which emphasizes inclusivity, equity, and shared responsibility in drug safety monitoring.

Digital transformation also intensifies concerns related to cybersecurity and privacy. The integration of large-scale health databases and cloud computing increases vulnerability to data breaches and unauthorized access. Studies by Atmaja et al. (2024) and Fu et al. (2025) emphasize that strong data governance frameworks—covering encryption, access control, and anonymization—are essential to protect patient confidentiality. In Indonesia, harmonization of BPOM's data protection standards with national electronic health record policies under SATUSEHAT remains a top priority to maintain public trust.

From a policy perspective, the reviewed literature indicates that successful implementation of digital pharmacovigilance requires a coordinated governance model that balances technological innovation with regulatory oversight. Effective collaboration between BPOM, the Ministry of Health, hospitals, and academic institutions can ensure system interoperability, ethical compliance, and resilience. Moreover, ongoing monitoring and evaluation mechanisms should assess digital pharmacovigilance performance, including metrics on data completeness, reporting timeliness, and signal detection accuracy.

Comparatively, similar challenges and opportunities are observed in other low- and middle-income countries (LMICs) such as India, Malaysia, and Ethiopia. These countries also experience limitations in infrastructure, digital literacy, and human resource capacity, yet have demonstrated that mobile applications, AI-enabled platforms, and integrated EHR systems can improve ADR reporting and pharmacovigilance outcomes when supported by strong governance and capacity-building initiatives. Indonesia's experience aligns with these LMICs, indicating that contextual adaptation, institutional readiness, and stakeholder engagement are critical for successful digital transformation.

Overall, the discussion demonstrates that digital transformation in pharmacovigilance is a multidimensional process that goes beyond technological adoption. It involves restructuring institutional workflows, strengthening human capacity, and redefining governance principles to ensure transparency, equity, and sustainability. By continuously improving interoperability, ethical data management, and workforce skills, Indonesia has the potential to become a regional model for digital pharmacovigilance in Southeast Asia.

Ultimately, integrating digital technology in pharmacovigilance should not only enhance data efficiency but also uphold core values of patient safety, accountability, and justice. Maintaining a balance between automation and human judgment remains central to ethical pharmacovigilance practice. As digital ecosystems mature, the challenge for Indonesia—and other LMICs—is to ensure that technological progress translates into tangible improvements in patient outcomes, institutional trust, and public health resilience.

Conclusion and Recommendations

Digital technologies, including mobile ADR reporting applications, AI-driven analytics, and EMR integration, have the potential to significantly enhance pharmacovigilance in Indonesia by improving the accuracy, timeliness, and completeness of adverse drug reaction reporting. However, successful implementation depends not only on technology but also on coordinated governance, institutional readiness, workforce capacity, and a strong patient safety culture. Comparisons with other low- and middle-income countries, such as India, Malaysia, and Ethiopia, highlight similar infrastructural and socio-technical challenges, emphasizing the need for contextual adaptation and stakeholder engagement. A multidimensional approach that integrates technology, human resources, policy, and patient participation is essential to strengthen Indonesia's pharmacovigilance system.

Suggestion to strengthen digital pharmacovigilance in Indonesia, the government and stakeholders should: 1) Strengthen Governance: Establish coordinated governance among BPOM, Ministry of Health, hospitals, and academic institutions to ensure system interoperability and regulatory compliance; 2) Build Human Capacity: Provide training and continuous professional development to improve digital literacy and effective use of ADR reporting tools; 3) Improve Infrastructure: Enhance digital infrastructure, particularly in rural and resource-limited areas, to support reliable data exchange and EMR integration; 4) Promote Patient Engagement: Encourage patient participation in ADR reporting through mobile health applications to foster a participatory pharmacovigilance culture; 4) Ensure Data Security and Monitoring: Implement strong data governance frameworks and continuous monitoring of reporting performance, including completeness, timeliness, and signal detection accuracy.

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