Digital Transformation of Pharmacovigilance in India: Current Landscape and Future Horizon

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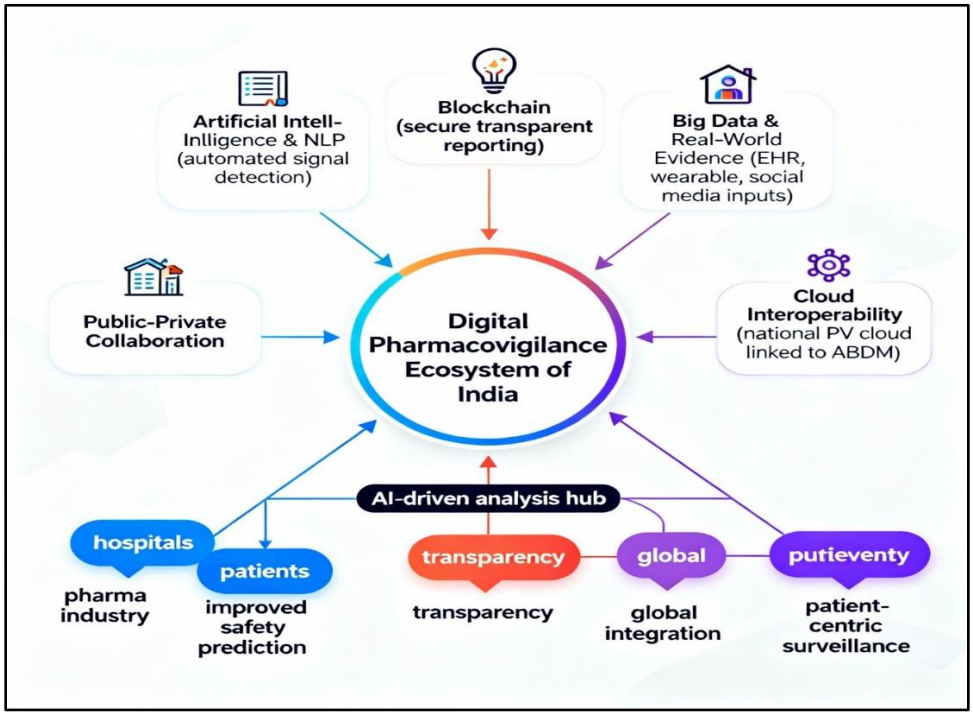
Graphical Abstract
India's AI-driven digital pharmacovigilance ecosystem integrating blockchain, big data, and cloud interoperability for predictive drug safety.



***Abstract*—A digital integrated and predictive and data-driven ecosystem of pharmacovigilance is also a paradigm shift within India compared to traditional manual reporting. It is transforming with the development of artificial intelligence, machine learning, natural language processing and analytics of big data in conjunction with regulatory updates via the Central Drugs Standard Control Organization, Indian Pharmacopoeia Commission), and the Pharmacovigilance Program of India. Integration of national digital health systems, such as the Ayushman Bharat Digital Mission, interoperability standards, such as FHIR and MedDRA, and their implementation by the healthcare networks are making data flow across them fluid. The emergence of mobile-based ADR tools, cloud computing and blockchain technologies has contributed to the increased efficiency of reporting, transparency and the ability to trace data. Although these progresses have been made, the following issues remain, such as fragmented data systems, insufficient digital literacy, imbalanced infrastructure, and the fear of compliance with the Digital Personal Data Protection Act, 2023. Standardization, capacity building of workforce, and sustainable cross-sector collaboration have to be considered by India to realize a fully predictive vision of pharmacovigilance by 2030. Further development of India can lead to a successful model of smart, patient-centered drug safety surveillance that can be enhanced through additional regulatory leadership and technological incorporation.**

I. INTRODUCTION

The process of pharmacovigilance (PV) in India has reached a decisive stage of the digital revolution, which is conditioned by technological innovation, the modernization of regulations, and the world trend toward data-based healthcare. Pharmacovigilance systematic process of identifying, evaluating, interpreting and preventing adverse drug reactions (ADRs) has always been relying on manual reporting and human-based analysis [1]. Past Indian PV activities were organized under the Pharmacovigilance Program of India (PvPI), which was set by the Indian Pharmacopoeia Commission (IPC) under the umbrella of Central Drugs Standard Control Organization (CDSCO). The system of reporting was mostly based on paper-filled ADR forms which were filled by healthcare professionals and uploaded manually to databases including Vigiflow, global database supported by the WHO-Uppsala Monitoring Centre [2]. Although this structure contributed to some fundamental data, it was usually underreported, slow to detect signals, and unable to integrate stakeholders. In the last three years, however, a paradigm shift has been witnessed as digital transformation has started to transform the pharmacovigilance as a reactive science to a predictive one [3]. The regulatory agencies of the world, including the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), have adopted highly developed digital systems like the Sentinel System or EudraVigilance modernization project which incorporates big data analytics, real-world evidence (RWE), and AI-assisted signal detection. Such efforts have inspired the same hopes in India, where artificial intelligence (AI), machine learning (ML), and natural language processing (NLP) intermingling with the pharmacovigilance processes is increasingly becoming apparent [4]. Vats, Kumar, and Pareek in their research article From Detection to Prediction: The Evolving Role of AI in Pharmacovigilance Systems find that AI-based PV tools can now be used to support automated processing of cases, unstructured data mining, and early signals generation, hence improving both speed and accuracy. The pharmaceutical and biotechnology industries in India are some of the largest generic drug manufacturers in the world that have developed enormous repositories of safety data that can be digitized and analyzed through algorithms [5]. These structures are essential in modernizing pharmacovigilance since they enable the integration of data in healthcare silos which has remained a major challenge in the Indian environment. The interoperability guidelines of The NDHM, based on the international FHIR standards, will presumably enable the movement of ADR data between hospitals, pharmaceutical companies, regulators, and PvPI centers to move freely. However, there are still a number of issues hampering complete digital implementation [6]. Indian pharmacovigilance ecosystem is still described by the heterogeneous data format, inconsistent reporting, and the lack of data quality control. Even rural and semi-urban areas which constitute a significant portion of healthcare consumption in India continue to be underrepresented in ADR reporting. According to Mohanan in his Taylor and Francis book Artificial Intelligence and Biological Sciences, bottlenecks such as data silos and poor digital literacy levels among medical workers are still very serious [7]. Furthermore, the privacy of data and security of the Internet that were enhanced by the Digital Personal Data Protection (DPDP) Act, 2023 demand that PV systems implement safe and ethical data processing. The COVID-19 pandemic (20202022) turned into a pivot that revealed these systemic gaps and, at the same time, encouraged the use of digital. The pharmacovigilance system was under massive pressure, at times of vaccine rollout and emergency drug approvals, to capture, verify, and analyze ADR data within real-time [8]. The old method of manually reporting was seen to be insufficient, and as such, there was a rush to test and experiment with digital and mobile reporting systems. This trend has persisted in the post-pandemic era, including more focus on AI-driven monitoring services, mobile ADR applications, or cloud-based reporting structures. In the report published by the Indian Pharmacopoeia Commission in 2024, ADR reports through mobile-based application were reported to be rising at a rapid rate, with the ADR PvPI app and SUGAM being the most frequently used programs, which signifies the rising digital interest among healthcare workers [9]. The other aspect of digital PV landscape development in India is the fact that Ayurveda and traditional medicine are being incorporated in the

current pharmacovigilance systems. The proposed interdisciplinary approach is deemed to enhance the pharmacovigilance system in India, as it will widen the data sources and enhance cross-domain learning. Worldwide, real-world data (RWD) and real-world evidence (RWE) based on big digital databases which may include EHRs of hospitals, wearables, and even social media platforms are increasingly defining the future of pharmacovigilance [10]. Pharmacovigilance through the use of RWE is a growing area of research focus in India, with such initiatives as the Digital Health Repository of the Indian Council of Medical Research (ICMR) and the 2024 Health Data Management Policy supporting the idea. These databases, when integrated with PvPI systems, would help identify real-time signals, predictive safety analytics, and the risk assessment with the assistance of the AI [11].

Meanwhile, analysts point out that the digital transformation should not be limited to technology but should be based on governance, capacity building, and ethics as well. In the article, Recent Developments in Microbiology, Biotechnology and Pharmaceutical Sciences, Sundararavadivadijan, Mohan and Rengarajan (2025) observed that successful digital PV necessitates alignment of regulations, trained manpower and sustainable model of investment. The reason why this transformation is worth studying is that this approach will fill the apparent gap between the traditional pharmacovigilance work in India and the current digital paradigm [12]. Although isolated cases of digital adoption presence, where automated signal detection and mobile ADR reporting can be found, no single national approach covering the governance of digital pharmacovigilance exists. The necessity of the modernization of PV systems does not just concern the efficiency, but also the readiness of the population to address the health crisis, as well as the high reaction to the signs of drug safety in the next emergencies. Its overall goal, thus, is to imagine and execute a strategic digital journey based on AI-centered automation, data systems of interoperability, and cross-sector partnership that will make India the model of efficiency, transparency, and predictability in pharmacovigilance by 2030. The present situation in Pharmacovigilance in India [13]. The system of pharmacovigilance is currently multi-dimensional in India, which can be viewed as an indicator of the increasingly complex pharmaceutical sphere and the rapid adoption of digital health transformation in the country. By 2025, the PV landscape of India is at a critical point and is based on well-developed institutional structures yet is also aiming at moving toward a more integrated, data-driven, and predictive safety monitoring environment. Regulatory innovation, international cooperation, the formation of digital infrastructure, and the increased acknowledgment of the significance of patient safety are influencing such a change in the priorities of managing the health of the population [14]. The heart of the Indian pharmacovigilance system is a system of institutions and regulatory agencies that organize drug safety efforts in the country. Central Drugs Standard Control Organization (CDSCO) is the very top-most regulatory agency that is under the Ministry of Health and Family Welfare and is in charge of providing safety, efficacy, and quality of medical products. Since 2011, this is run by the IPC, the national ADR monitoring coordination center, as the PvPI. It works under the supervision of CDSCO and with the World Health Organization-Uppsala Monitoring Centre (WHO-UMC) and incorporates India data in the world pharmacovigilance database, Vigibase [15]. The triad of institutional bodies (CDSCO, IPC, and WHO-UMC) constitutes the core of the pharmacovigilance system in India as the safety signals discovered on the national level are used to create the global drug safety information. The PvPI currently carries more than 600 AMCs throughout the country, which are found in medical colleges, tertiary care institutions, and regional drug surveillance centers. These centers gather, confirm and send ADR data to the IPC where they are aggregated nationally and sent to the WHO database. The PvPI model focuses on multi-tier coordination, local data collection in hospitals, regional and national analysis to form an ecosystem that allows balancing between grassroots and centralized management [16]. This partnership with the WHO-Uppsala Monitoring Centre utilizing Vigiflow, a secure online program of ADR entry and management, has improved the contributions of India to the global pharmacovigilance activities, thus being in line with the global standards including ICH E2E and E2D guidelines. The pharmacovigilance infrastructure serving India has become very diverse over the last few years, indicating that both the

manual and electronic reporting systems can be found. The main source of data collection is spontaneous reporting by healthcare professionals with a supplementary cut of targeted spontaneous reporting, cohort event monitoring, and post-marketing surveillance studies [17]. ADR information can now be made on various platforms: Vigiflow platform, paper-based form that is provided at healthcare facilities, and mobile-based reporting systems, including the ADR PvPI mobile application and SUGAM, a CDSCO-operated digital platform that provides regulatory submissions. The innovations have enhanced accessibility among healthcare professionals and the populace, enhancing a greater involvement in the pharmacovigilance initiatives. Additionally, the Indian Pharmacopoeia Commission has extended the PvPI with special subprograms including Medical device subprograms, MvPI, the Hemovigilance Program of blood and plasma safety and the program, Adverse Events Following Immunization (AEFI) surveillance program [18].

Management, standardization, and sharing of data remains highly important in the effectiveness of the pharmacovigilance system in India. The data management practices have become better with the implementation of international generic standards like the MedDRA (Medical Dictionary for Regulatory Activities) to code the ADR and ICH E2B(R3) to use electronic data exchange. However, interoperability is an issue that has been persistent [19]. Several hospitals and healthcare facility still utilize differentiated data systems that do not have uniformity of digital interfaces. This restricts the possibility of PvPI and CDSCO to do real-time analytics or inter-institutional comparisons. Such advances will create the foundation of a universal, interoperable pharmacovigilance ecosystem that will be able to connect patient-level data across healthcare networks [20]. Pharmacovigilance reporting process in India is usually organized in a way that ADRs are recorded at the first stage by health professionals, reviewed by AMC pharmacovigilance personnel, with their validation at the national stage carried out by PvPI analysts, and sent to WHO-UMC. This kind of automation will be able to give high-risk cases priority and make decisions faster which is one of the most important steps to predictive pharmacovigilance. PvPI Annual Report, the DQI of Individual Case Safety Reports (ICSRs) in India has significantly increased due to the increase in training and awareness of data completeness but underreporting is still a problem in rural areas and in the private healthcare workforce [21]. Another pillar in the pharmacovigilance system in India is the involvement of the pharmaceutical industry. The compliance in the industry is governed by Schedule Y of Drugs and Cosmetics Rules, 1945, which requires post-marketing safety monitoring of all drugs in the market. Pharmaceutical companies are required to have a pharmacovigilance unit, periodic safety update reports (PSURs), and serious adverse event reporting within certain time constraints. The GVP Guidelines (2023) that CDSCO has provided also expand the responsibilities of the industry to include quality systems, training, and record keeping [22]. The Indian status as one of the biggest exporters of generic medicines in the world has also forced the local players to suit with the global regulatory standards. The major firms like Sun Pharma, Dr. Reddy labs, Cipla and Lupin have embraced the use of global safety databases like Oracle Argus and ArisG to meet the process of reporting both locally and internationally. Small and mid-sized pharmaceutical companies, however, are frequently prone to hindrances in remaining in compliance because of financial and technical constraints [23]. Pharmacovigilance now has new instruments and technologies introduced by digitization, and it is a slow but unmistakable transition to automation and analytics. The Vigiflow system has been the major countrywide database on the ADR management, although relatively new applications like ADR PvPI, SUGAM and IHIP have been launched with mobile accessibility and cloud data management. Case deduplication, data mining, and early signal detection are being piloted with artificial intelligence and data visualization dashboards are being utilized to study reporting trends and geographic patterns of ADRs. PvPI operations include now basic analytics tools to provide insights about drug-event relationship, time-to-onset analysis, and clustering of adverse reactions [24]. With these improvements, even with the increased digital pharmacovigilance systems, their uptake is mixed throughout the ecosystem. India has a digital PV transformation that is largely successful due to its unending investment in infrastructure, skills, and data governance. Fears of data privacy,

particularly in the wake of the adoption of the DPDP Act, 2023, present some delicate considerations of balancing the privacy of patients with the public interest of open transfer of data. With the current trajectory of India pharmacovigilance ecosystem, which is yet to gain full maturity, there might be a definite step towards predictive, integrated, and real-time safety monitoring [25]. Institutional bases are robust, technology facilitators are developing and the policy environment is now more open to innovation. Nevertheless, to achieve the maximum potential of the digital pharmacovigilance, it will be needed to ensure more joint work of regulators, healthcare institutions, and industry with the help of effective training programs and awareness of the population [26]. Finally, the pharmacovigilance system in India is shifting to become a learning health system where the system constantly adapts, analyzes, and foresees safety issues via digital intelligence as opposed to a traditional system that is more compliance-driven. It is the institutional maturity, regulatory prospective and digital aspiration of India that can make it a global leader in pharmacovigilance by 2030 with a framework that not only protects patients but also supports evidence-based, smarter regulation decisions in the largest generics market globally [27].

II. DRIVERS AND ENABLERS OF DIGITAL TRANSFORMATION

Regulatory requirements, application of technologies, international benchmarking, and joint work of various stakeholders are the driving forces behind the digitalization of pharmacovigilance in India. These drivers and enablers have been coming together to redefine the collection, analysis, and utilization of drug safety data to make pharmacovigilance no longer a highly reactive and manual system, but rather, an intelligence driven system. It is not just a technological change but also a cultural and institutional one that indicates the general Indian commitment to e-Governance, digital health reform and harmonization of regulatory science internationally [28]. First in this change is an intense regulatory initiative of the Government of India. Digital pharmacovigilance was based on the national initiatives like the Digital India Mission (2015) that targets the digitization of the government services and later the NDHM now the ABDM that was introduced in 2020. All of these elements allow facilitating a flow of data between hospitals, laboratories, and regulatory agencies, which is a necessary requirement to achieve efficient pharmacovigilance [29]. These guidelines ease the secure and standardized allotment of ADR-related data between clinical locations and PvPI and CDSCO. In the case of pharmacovigilance, this implies going beyond lone ADR reports to data streams, which are complete and real-time and which can improve the precision and timeliness of signal identification. Meanwhile, regulators such as the CDSCO and the IPC have been in motion to make pharmacovigilance respond to the larger digital transformation agenda in the country [30]. The GVP Guidelines (2023) pays much attention to the implementation of the automation tools and online databases in the safety monitoring. The SUGAM portal has developed into a single platform on electronic submissions where online submissions are done such as ADR reporting, licensing, and regulatory communications in reducing delays in administration and enhancing transparency in the administration of CDSCO [31]. Further, India is also a member of international fora like the ICH, thus its digital pharmacovigilance systems are also consistent with the international standards of data exchange, including ICH E2B(R3) and MedDRA coding systems. Adding to regulatory momentum are potent technological enablers which are changing the process of pharmacovigilance. AI and ML are being utilized to automate and optimize traditionally manual operations such as signal detection, data triage and case validation. An example of this is that AI algorithms that have been trained on historical adverse event data can find hidden trends that can be used to tell of emerging drug safety concerns before they can be reported through traditional means [32]. Signal detection systems based on machine learning can constantly scan real world data sources including hospital records, digital prescriptions and social media to aid regulators and companies in identifying warning signals of adverse events. NLP has become a changer of the game in the automation of ICSR processing. As the majority of ADR data is provided in unstructured text clinical notes, patient feedback, or spontaneous reports, NLP can be used to extract all the relevant information, including the names of the drugs, symptoms, and the timelines among others

with high accuracy. Research, such as Vats, Kumar, and Pareek (2025) in the World Journal of Pharmaceutical Research has revealed that case triaging on NLP takes less time than manual case triaging by up to 40 percent with an increase in throughput without affecting the integrity of data [33]. Developing RPA and combining it with AI and data visualization tools, pharmacovigilance teams can guarantee efficiency in operation as well as in depth. All these tools will transform the paradigm of non-between dynamic and predictive Pharmacovigilance where the emphasis is put on predicting the possible risk of safety rather than recording ADRs [34]. In the world, digital transformation of pharmacovigilance in improved markets has offered good role models to the Indian digital revolution. The EudraVigilance system which is the EMA-mediated pharmacovigilance system of the European Union is a flagship example of the digitization of large-scale pharmacovigilance [35]. The modernization project of the EudraVigilance system had automated data validation, electronic submissions of ICSRs and real-time analytics dashboards to detect signals. Through these reforms, EU regulators have been able to simplify the process of safety reporting and improve their cooperation with MAHs. The U.S. Food and FDA has also changed its pharmacovigilance ecosystem using the FAERS Modernization Initiative, incorporating cutting-edge analytics and the Sentinel System a big-data-powered surveillance network, which uses electronic health records, insurance claims, and clinical trial data to detect post-market safety concerns. The models have been inspirational in India through PvPI and CDSCO. In 2024, PvPI started to consider a pilot project of AI-assisted signal detection tools, and this is akin to the Sentinel implementation of the FDA, but using de-identified data of partner hospitals [36]. Similarly, there are ongoing initiatives to create a national pharmacovigilance dashboard with real-time visualization functions which enable regulators to have a detailed picture of the ADR rates by drug group, geography, and demographics [37]. The pharmacovigilance ecosystem has been widened with regulators, healthcare providers, as well as academic institutions, CROs, and technology startups. Universities and research centers have started to create a specific pharmacovigilance and regulatory science to educate people in AI, data analytics, and clinical safety monitoring. As an example, the partnership between the Indian Council of Medical Research ICMR, AIIMS and PvPI has resulted in joint research projects on real-world evidence analytics and ADR trend modeling [38]. The CROs and pharmacovigilance service providers, including IQVIA, Accenture and TCS, have been critical in bringing about the digital pharmacovigilance workflow both to Indian and multinational pharmaceutical companies. Their services include data curating, automation, and AI-enhanced analytics to ensure the industry players meet the requirement of global safety reporting effectively. Health-tech startups are also pacing the pack with AI chatbot-based innovative solutions to report on ADRs, cloud-based safety data stores, and blockchain-based drug traceability systems. Indicatively, PV technology youngsters in Bengaluru have begun integrating ADR modules in telemedicine and electronic prescription, building an ecosystem where real-time adverse events will be notified by patients and clinicians [39].

Assistance of the WHO-Uppsala Monitoring Centre also goes on to improve the global status of India in pharmacovigilance. India has also become one of the largest contributors to the WHO Vigibase database, which is an indicator of the increased awareness of ADR and the ability to report it using digital means [40]. By doing this, the Indian regulators have access to international signal detecting devices such as Vigilyze to compare international data with national safety trends. Simply put, the policy innovation, technological integration, and cross-sectoral collaboration constitute the drivers of the digital transformation of pharmacovigilance in India. The regulatory framework of the government through its digital health policies offers the regulatory structure, AI, ML, NLP, and RPA serve as the technological driver, and partnerships are used to ensure that the system is flexible, inclusive, and competitive on the global level [41]. With ongoing support in terms of policy introduction and capacity building, the digital pharmacovigilance system in India can soon become a digital pharmacovigilance system, competing with such leaders in the pharmaceutical industry as the FDA Sentinel and the EMA EudraVigilance, as well as the digital pharmacovigilance systems of other countries [42].

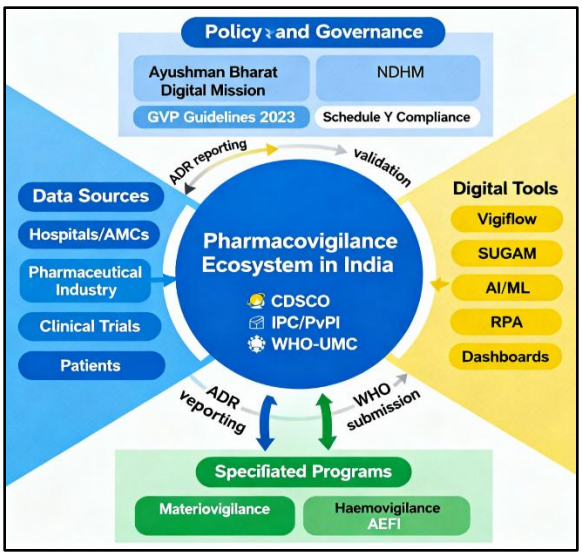


Figure: Digital pharmacovigilance ecosystem in India integrating policies, data sources, and advanced safety tools

III. CHALLENGES IN DIGITAL PV IMPLEMENTATION

Although the introduction of the digital PV in India has a great potential and scope of innovation, it has several structural, regulatory, technical, and human-resource challenges that keep hampering its complete implementation. when India increased the pace of its initiatives to digitalize drug safety monitoring within the framework of the ABDM and increase the PvPI, the challenge of introducing large-scale and multi-source data systems and staying in compliance with the regulations became clearer [43]. The identified challenges are based on the data quality, regulatory ethics, human capacity, and economic infrastructure, which are the main obstacles on the way to a healthy, AI-driven pharmacovigilance ecosystem in India. The reliability, consistency and completeness of ADR data are the basic pillars of pharmacovigilance. Nevertheless, the current ADR ecosystem in India is very fragmented. These reports are obtained through various sources which are hospitals, pharmacists, clinical trials, patients and industry but are usually documented in some inconsistent format [44]. There is also persistent semi-manual entry that is used by many hospitals, particularly those in the public sector, and nomenclature, drug nomenclature, and completeness of cases are very significant barriers to automated data aggregation. The Journal of Pharmacovigilance and Drug Safety, almost 30 40 percent of the ADR notifications under PvPI include incomplete or unclear clinical information, including absent timelines, dosages, or outcomes, diminishing their analytical quality. Interoperability of data is also a major issue [28]. EHRs and HIS have extended the scope of data dissemination to several digital silos, which are usually not compatible with other silos. The standard application programming interface (APIs) are absent in most EHRs in Indian hospitals to share data with PvPI or CDSCO systems. Even though the Health Data Management Policy (2024) under ABDM has given way to FHIR-based interoperability standards, their adoption is still uneven particularly among smaller and rural healthcare facilities. Consequently, centralization of ADR data in centralized systems such as Vigiflow is frequently done by hand, which is counterproductive to automation [45].Further, the use of non-standardized data dictionaries and the use of less standardized terminologies like MedDRA or SNOMED CT make it difficult to link data in a meaningful way and cross-analyze it. No less urgent are the regulatory or ethical issues of digital pharmacovigilance especially in the area of data privacy and cybersecurity. The implementation of the DPDP Act, 2023 has provided new compliance expectations to be implemented by health data processors, such as the explicit patient consent, limitation of purpose and minimization of data. Although these measures are necessary towards protecting patient privacy, it also makes pharmacovigilance operations more complicated since the ever-flowing medical information, that provides signals, is sensitive [46]. The tension between the interests of the population and the rights of data individuals now presents a challenge to regulators and healthcare providers - the main issue in the digital health regulation. In DPDP Act, the pharmacovigilance bodies are expected to anonymize or pseudonymize patient information prior to processing, but India has yet to establish standardized technical specifications or anonymization guidelines specifically applied to the pharmacovigilance applications [47]. Moreover, PV systems that are based on the cloud are efficient but have cybersecurity threats. The instances of unauthorized access, data leakage, and ransomware intrusion in healthcare databases point to the importance of

applying high-quality encryption, access management, and security monitoring in real-time. The same can be said about the ethical implications of AI-based pharmacovigilance systems where algorithmic bias and non-transparent decision-making can affect the interpretation of its ADR patterns and signal prioritization. There is still no regulatory control over these AI systems, and this forms a grey area of compliance and responsibility [48]. The other important issue is the problem of capacity building and skill gaps among the pharmacovigilance experts. PV needs to transform digitally, which means that it needs both expertise in drug safety science and new skills in data analytics, artificial intelligence, coding, and informatics a skill set that is still scarce in the pharmacovigilance workforce of India. Part of the ADR monitoring centers continues to depend on the old fashioned reporting mechanisms and manual input of data in the databases, with little access to the digital platform such as Vigiflow, the ADR PvPI app, or the artificial intelligence [30]. PvPI internal assessment established that electronic case processing or data analytics were only formalized in 45% of AMC personnel.

This gap is further aggravated by lack of organized training programs in digital pharmacovigilance at the medical and pharmacy institutions. Although organizations like the IPC and ICMR have started having workshops and certificate courses on pharmacovigilance and regulatory informatics, the number is very low and cannot satisfy the demand [49]. The only way of overcoming this digital literacy gap is to integrate curriculum in universities, in addition to regular training of regulators, healthcare providers, and industry safety teams. Another serious impediment to the process is the economic and infrastructural limitations of digital pharmacovigilance. Interoperability of the pharmacovigilance systems also demands long term investments in both the hardware and software and also network connections, which most smaller hospitals and regional AMCs have a hard time covering [50]. The lack of even digital infrastructure in India contributes to this gap: cities with tertiary care units have ADR modules integrated into EHR, whereas rural hospitals usually have little to no access to the internet to report online. Therefore, the underreporting is still heavily biased towards urban areas, which distorts the national pharmacovigilance data and restricts representativeness. The high price of the standardized IT system which has to meet the global data exchange standards like the ICH E2B(R3) puts small and medium-sized pharmaceutical companies off [51]. Wider companies have embraced commercial pharmacovigilance applications, such as Oracle Argus and ArisG, but small companies tend to use manual systems or piecemeal solutions. Devoid of an infrastructure that is shared and supported by the government or PPPs, these organizations stand a chance to be uncompliant and not integrated into the world drug safety networks [52]. Another economic problem related to it is the sustainability of digital investments. Maintenance and technical upgrades are not regular after the end of the period of funding and creates gaps in the flow of the data [53]. The absence of standardized procurements and maintenance policies among the AMCs is also a factor of inefficiency and redundancy of infrastructure. In addition to these structural issues is the fact that there is little knowledge of pharmacovigilance of the healthcare professionals and the general population. Although there are the availability of digital reporting instruments such as the ADR PvPI app, the adoption levels are small. ADR reporting is considered time wasting or secondary to patient care by many physicians and unawareness of patients is the common awareness on the part of patients themselves regarding their roles in pharmacovigilance [54]. This cultural stigmatization is another hindrance to the attainment of a fully digitally inclusive PV system. India must be addressed through a multi-pronged approach in order to overcome these challenges. It will be necessary to strengthen the process of data standardization by ensuring that MedDRA and FHIR protocols are nationwide adopted, have a robust privacy framework that is compatible with the DPDP Act, invest in cybersecurity infrastructure, and capacity-building measures through national digital literacy programs [55]. PV training should become a part of medical education, and the long-term financial support of the digital infrastructure platform can change the PV approach to a continuous learning health program that improves drug safety and patient outcomes. Simply put, though India has gone a long way in establishing the pillars of digital pharmacovigilance, systemic hurdles such as

disjointed information systems to insufficient staff readiness continue to hinder the transformation process on a grand scale [56]. The task to come is not only technical in nature but also institutional and educational: building an ecosystem capable of facilitating innovation and at the same time making it equitable, data-over-information, and ethically governed. These limitations will be important to overcome in case India becomes a leader in intelligent pharmacovigilance around the world at the end of the decade [57].

S. No	Challenge Area	Specific Challenge	Description	References
1	Data Quality	Incomplete ADR reports	Missing timelines, dosages, or outcomes reduce analytical value.	[58]
2	Data Quality	Inconsistent data formats	ADRs reported from hospitals, patients, and industry differ in structure.	[59]
3	Data Quality	Fragmented data sources	Multiple reporting channels without standard integration hinder aggregation.	[60]
4	Data Quality	Lack of standardized terminology	Inconsistent use of drug names, MedDRA, SNOMED CT limits analysis.	[61]
5	Data Integration	EHR-HIS incompatibility	Hospital systems often cannot directly share ADR data with PvPI.	[62]
6	Data Integration	Manual intervention required	Integration into central systems like Vigiflow needs human effort, slowing automation.	[63]
7	Interoperability	Inconsistent adoption of FHIR standards	Many hospitals, especially rural, do not implement standard APIs.	[64]
8	Interoperability	Poor cross-platform compatibility	Limits aggregation, analysis, and signal detection.	[65]
9	Regulatory	DPDP Act compliance	Data privacy laws require anonymization/pseudonymization, complicating PV operations.	[66]
10	Regulatory	Ethical tension	Balancing patient privacy with public health reporting needs.	[67]
11	Regulatory	Limited AI oversight	Algorithmic bias and “black-box” models raise accountability concerns.	[68]
12	Cybersecurity	Cloud-based data risks	Threats include unauthorized access, ransomware, and data leaks.	[69]
13	Human Resources	Skill gaps	Limited expertise in AI, coding, analytics, and informatics among PV staff.	[70]
14	Human Resources	Low adoption of digital tools	Many AMCs still use manual reporting workflows.	[71]
15	Human Resources	Inadequate training programs	Universities and AMC training insufficient for digital PV demands.	[72]

16	Infrastructure	Uneven digital infrastructure	Rural hospitals often lack internet or EHR systems for online reporting.	[73]
17	Infrastructure	Hardware and software costs	Smaller hospitals cannot afford interoperable IT systems.	[74]
18	Economic	Small pharma limitations	SMEs struggle to implement ICH E2B(R3)-compliant PV software.	[75]
19	Economic	Sustainability of funding	Short-term grants and donor projects create discontinuities in PV operations.	[76]
20	Economic	Maintenance gaps	Lack of standardized procurement/maintenance policies leads to inefficiency.	[77]
21	Awareness	Low physician engagement	ADR reporting often viewed as secondary or time-consuming.	[78]
22	Awareness	Low patient participation	Patients unaware of reporting mechanisms or their role in PV.	[79]
23	Standardization	Lack of nationwide MedDRA adoption	Hinders uniform data coding and global comparability.	[80]
24	Standardization	Non-uniform terminologies	Difficulties in cross-system analysis and regulatory reporting.	[81]
25	Cultural / Institutional	Resistance to change	Traditional workflows dominate; adoption of digital PV remains slow.	[82]

IV. VISION FOR DIGITAL PHARMACOVIGILANCE IN INDIA

A potent combination of AI, blockchain, big data analytics, and cloud interoperability technologies is also redefining the future of PV in India, and together these technologies are expected to turn drug safety monitoring into more of a proactive, predictive, and open ecosystem rather than a reactive component of the regulatory process. The vision of digital pharmacovigilance in India will have reached a level of global benchmarking, data-driven, and closely linked to the ABDM and international databases of safety by the year 2025-2030 [83]. This is not just a technological change but a strategic change that is based on the values of patient-centricity, transparency and collaborative innovation. The conventional methods of PV are based on the use of manual review of cases and retrospective analysis, whereas the upcoming systems will use machine learning algorithms and NLP to process large datasets of structured and unstructured information provided by various sources. Predictive pharmacovigilance will help to detect potential safety-related risks at the earliest stage and even earlier than they can be observed at the population level [84]. The NLP can be used to extract vital data of cases, including drug names, dosage, symptoms, and outcomes, using AI-driven systems to process single case safety reports, the unstructured clinical notes, and patient complaints. Supervised and unsupervised learning models are then used to analyze these data to be able to identify anomalous patterns or new drug-event associations. An example is the Indian Pharmacopoeia Commission (IPC) has started to look at AI-enabled signal prioritization tools based on the FDA Sentinel System that constantly tracks real-life data to detect trends in drug safety [85]. Traditionally labor-intensive literature monitoring is also being automated with the aid of AI-based text mining, which examines scientific literature, preprints, and case studies that may contain reports of adverse events. These functions will not only enhance the speed and precision, but also enable the pharmacovigilance specialists to concentrate on more advanced clinical and regulatory evaluation instead

of data repetitive tasks [86]. The addition to AI in this change is the possibility of the implementation of the blockchain technology to improve the transparency, traceability, and information integrity in the Indian pharmacovigilance system. Blockchain provides a ledger that is immutable to store all the stages of the ADR reporting process since the first submission by healthcare providers or patients to its validation by the regulatory authorities [87]. Through decentralization of data storage blockchain can avoid unauthorized changes, provide auditability, in addition to full traceability of the report. Practically, blockchain might form the basis of a National PV Blockchain Network that exists between hospitals, pharmaceutical firms, PvPI centers, and regulators and they engage in interaction on a shared platform with specified permissions [88]. All the ADR reports processed into the system would create a record of the data with a timestamp, which would be immutable and as a consequence would ensure data integrity throughout the reporting chain. In addition, compliance workflows (i.e., sending notifications when safety updates or regulatory deadlines need to be met) can be automated with the help of smart contracts. An ecosystem of pharmacovigilance based on blockchain would also enhance the credibility of the population by ensuring that ADR data is safely stored and audited publicly [89]. In line with these developments, there is the increase in the significance of big data and RWE in pharmacovigilance. The future of PV in India will be more and more based on the complexification of various sources of data EHRs, wearable devices, telemedicine platforms, and even social media to create a complete picture of drug safety in the state of the art. The ICMR and NHA are already on the path to creating a National Health Data Repository which will become a vital basis of RWE-based analytics on PV [90]. The integration of EHR can be used to track patients longitudinally and this allows pharmacovigilance systems to identify delayed or cumulative ADRs that may otherwise be not detected in clinical trials. In the meantime, wearable gadgets (smartwatches and biosensors) provide ongoing data on physiological indicators, which can act as precursors of adverse responses to particular medications [91]. Monitoring social media, which is also driven by NLP and sentiment analysis, could be used to supplement the traditional reporting systems due to the ability to detect the public discourse about the side effects of the drug almost in real time. These techniques have been confirmed by the FDA and EMA worldwide and the digital infrastructure of ABDM in India can now provide a platform on which to build large scale integration [92].

One of the main facilitators to this vision is the introduction of cloud-based interoperable platforms that would centralize the pharmacovigilance operations in one digital ecosystem. To the future Indian PV architecture, a National Pharmacovigilance Cloud is likely to be integrated with the NDHM/ABDM digital health stack using FHIR-compliant APIs. This will enable the flow of ADR data in hospitals, pharmacies, and pharmaceutical firms, into a centralized, analytics-friendly environment [93]. Cloud computing facilitates scalability, fast processing of data and access to safety-related information in real-time regardless of geographies. Integrity with other international platforms, including Vigibase (WHO-UMC), FAERS (FDA), and EudraVigilance (EMA), also contributes to the fact that India will act as an active provider of pharmacovigilance intelligence to the outside world. Nevertheless, to achieve such interdependent infrastructure, there must be a robust governance and security model. Since the sensitive patient data will be stored on cloud systems, the adherence of India to the DPDP Act, 2023 will be of utmost importance [94]. Multi-layer encryption, role-based access control, and zero-trust frameworks-based secure cloud systems should be adopted in order to guarantee privacy and accountability. Digital pharmacovigilance in the future is conditional upon the robustness of the public-private collaboration models that will be able to maintain the innovation and scalability [95]. The digital transformation of pharmacovigilance needs the involvement of the technological capacity and financial resources of the private sector, yet these institutions of the public sector, CDSCO and IPC, have already established the basic groundwork in the form of PvPI [96]. The top pharmaceutical firms in India already engage with technology businesses to introduce intelligent solutions of PV with using RPA to process data and AI algorithms to triage cases. Joint projects might go a step further and include blockchain-based ADR registries joint pilot projects, AI ethics frameworks

on pharmacovigilance, and common data sandboxes, which enable testing of the algorithms in a controlled and anonymized setting. Academia, in turn, is equally important as it should design multidisciplinary training programs that will bridge pharmacology, data science, and regulatory informatics [97]. To rule out concerns on the sustainability of these initiatives, India may implement the PPPs models used in the IMI of the European Union that funds massive research on digital pharmacovigilance. These frameworks would spread costs, promote innovation and form an ecosystem in which the government would provide oversight and the private sector would provide the technological development. The vision of the digital pharmacovigilance in India, in the long term, is in line with the objective of developing a learning health system a continuously evolving network in which all ADR reports, clinical observations, and patient outcomes would contribute to the general knowledge and enhance health safety recommendations [97]. In 2030, assuming that India manages to incorporate these innovations into a national PV system, it might be one of the first countries to succeed in intelligent drug safety surveillance not only detecting but also predicting threats, shortening response time, and guaranteeing the best pharmaceutical safety of its citizens and the whole world [98].

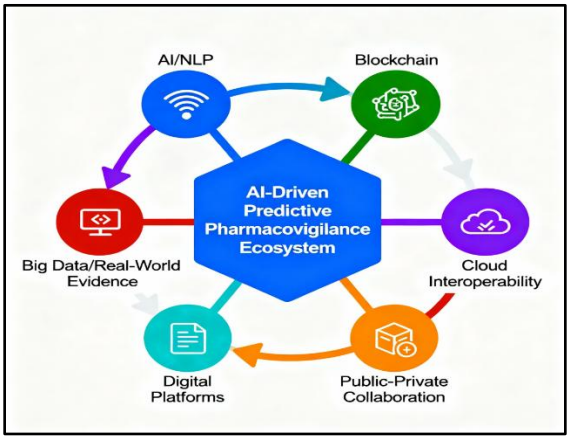


Figure: Future-ready digital pharmacovigilance ecosystem for India: AI, blockchain, big data, and interoperability for proactive drug safety

V. POLICY RECOMMENDATIONS AND STRATEGIC ROADMAP

Digital technologies have brought the modernization of PV and this is the first time in history when it is possible to improve patient safety, simplify the process of reporting and increase the level of regulatory control [99]. In order to accomplish these, it is important to have a detailed strategic framework to cover governance, capacity building, standardization, stakeholder engagement and performance evaluation. In the heart of successful digital PV is a robust governance structure that outlines clearly the roles and responsibilities and accountability systems of all stakeholders such as regulatory authorities, pharmaceutical companies, health providers and the patients [100]. This structure must make sure that it follows the national and international laws, make the decision-making open, and offer the avenues of managing ethical data and data protection. With the introduction of well-defined governance, the regulatory authorities can more effectively coordinate the pharmacovigilance efforts, reduce the threats, and promptly Liaise with emerging safety issues. It is also important to build human and institutional capacity building [101]. There is a need to train health workers, data managers, and regulatory staff and offer knowledge sharing programs to help them acquire the skills necessary to navigate through digital PV systems [102]. The importance of these programs should be on the interpretation of digital safety signals, the use of advanced analytics tools, and following the standard reporting protocol. A culture of excellence and accountability throughout the ecosystem can be developed by encouraging further professional growth and certification in digital PV. The use of internationally accepted standards, including FHIR health exchange data and ISO IDMP product information, can be used to ensure that data of different origins can be harmonized. Structured datasets, code sets, and standardized terminologies facilitate correct, timely, and full observance of safety signals, ease the decision of regulatory bodies, and international cooperation [103]. it is integrated with electronic health records, mobile health applications, and digital reporting tools that improve the quality of data and can allow an almost real-time monitoring of adverse events. These may be

recognition schemes, feedback systems, integration with clinical decision support systems, or even games to motivate attendance. Reporting procedures could also be simplified by making user interfaces intuitive, developing mobile applications and automated workflows to help reduce barriers to entry and to collect more and better safety data [104]. The evaluation of the effectiveness of digital PV initiatives needs the strong system of evaluation metrics. These measures are supposed to determine the number and quality of adverse event reports, system usability, timeliness of signal detection, and patient safety outcome as a result of interventions. Gaps, optimization of the working process, and decision-making should be identified with the help of regular audits, performance dashboards and benchmarking against international standards [103]. Also, the constant observation and the ongoing improvement of the digital PV systems within the frames of these assessments are necessary to make sure that the digital PV systems are versatile, scalable, and capable of adapting to new technological trends and regulations. To conclude, the digital revolution of pharmacovigilance is a challenging task requiring a holistic approach based on a robust governance, capacity building, interoperability standards, stakeholder involvement and effective evaluation mechanisms [104]. With such strategic roadmap in place, regulatory bodies and healthcare stakeholders will be in a position to build the most efficient, proactive and patient-centered pharmacovigilance ecosystem. Not only does this enhance the safety of the medicines, but it also creates confidence amongst the people in the system, improves the system as well as making the country a pioneer in PV in the world [105].

VI. CONCLUSION

Pharmacovigilance ecosystem is undergoing a digital revolution that has never been witnessed in India, which entailed a combination of technology, policy, and collaboration to create an active, proactive and patient-centric safety surveillance system. The combination of artificial intelligence, blockchain, big data analytics, and interoperable cloud systems through regulatory programs like the Ayushman Bharat Digital Mission and Good Pharmacovigilance Practices Guidelines (2023) indicate the pivotal change in the conventional reporting to smart-based drug safety governance. Nevertheless, the ability to achieve this vision is tied to the successful fight against the issues associated with data fragmentation, interoperability, workforce readiness, and ethical AI implementation. The capacity to maintain the momentum will be essential by strategic investments into digital infrastructure, standardized frameworks and capacity building. Through ongoing regulatory insight and cross-sectoral cooperation, India can become a global example in digital Pharmacovigilance that would convert the regulation of drug safety into a learning and adaptive health system that protects the patients and improves the community confidence.

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