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Pharmacovigilance in the Post-COVID Era: Lessons Learned and Paradigm Shifts from the Indian Experience

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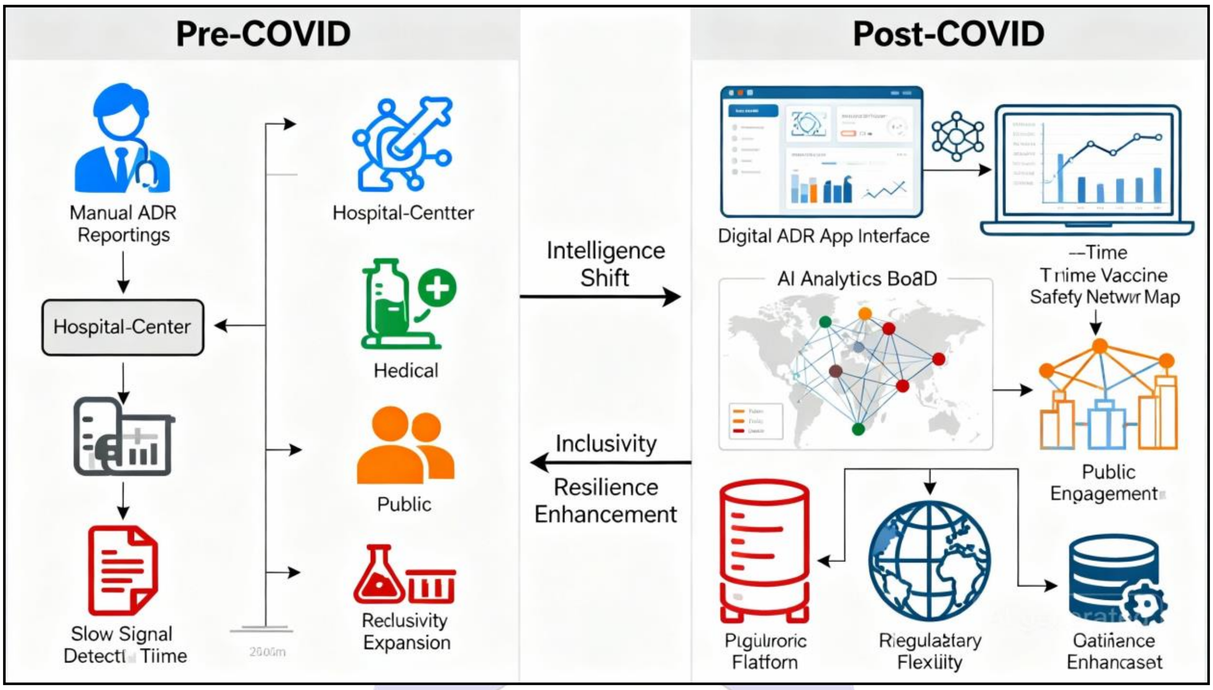
Abstract

The COVID-19 pandemic fundamentally redefined pharmacovigilance (PV) systems worldwide, serving as both a challenge and a catalyst for innovation. In India, the crisis accelerated the digital transformation of drug safety surveillance, leading to the rapid adoption of real-time adverse drug reaction (ADR) reporting, vaccine safety monitoring, and enhanced data transparency. The pandemic highlighted the need for agile governance, public engagement, and technology-driven vigilance to manage large-scale therapeutic interventions effectively . Key developments included the strengthening of the Pharmacovigilance Programme of India (PvPI), integration of artificial intelligence (AI) for signal detection, and the emergence of patient-centered reporting platforms. The Indian experience underscores a paradigm shift from traditional, compliance-based pharmacovigilance to a **data-driven, citizen-inclusive, and AI-assisted ecosystem**. This evolution not only improved national drug safety responsiveness but also positioned India as a model for resilient, intelligent, and participatory pharmacovigilance in the post-pandemic era.

Graphical abstract

Comprehensive visualization of India's transformation from traditional to AI-driven, inclusive pharmacovigilance in the post-COVID era.



Introduction

The terms pharmacovigilance (PV) can be characterized as the area of science and activity that is connected to the identification, evaluation, interpretation, and prevention of adverse events or any other potential drug-related issues. It has been one of the pillars of the health of the population as it ascertains that the benefits of medicines exceed the harms during their lifecycle (1). Pharmacovigilance is of particular importance in such a multifaceted and densely populated state as India. As the consumption of pharmaceuticals doubles exponentially, and as the modern and the alternative systems of medicine are integrated, there has never been as strong a need as ever to have a sound PV framework. Certainly, effective pharmacovigilance not only prevents patients against avoidable adverse drug reactions (ADRs) but also enhances the health care system through promoting rational drug use, creating confidence in healthcare interventions, and making informed regulatory decisions (2). The pharmacovigilance situation in India prior to the COVID-19 pandemic had a number of inherent issues. Although the Pharmacovigilance Programme of India (PvPI) was introduced in 2010 under the Central Drugs Standard Control Organization (CDSCO), there was still the issue of underreporting of ADRs. Research found that a large percentage of medical workers were either unaware or unmotivated to report ADRs, usually because of the time factor, the lack of the feedback system or even lack of training in pharmacovigilance practices (3). Moreover, there was a lack of coordination between hospitals, regulatory authorities, pharmaceutical industries and regional centers in terms of their PV infrastructure that was fragmented. The manual reporting system and use of paper based data collection also compromised the timely identification and analysis of safety signals. Consequently, the role of India in the global pharmacovigilance database was disproportionately low, even though the country had a large number of patients and had extended pharmacogenetic diversity (4). The beginning of the COVID-19 pandemic served as the global stress test of the pharmacovigilance systems in the world, including in India. Crunching out and introducing new therapeutics and vaccines under emergency use authorities brought new challenges to drug safety surveillance like never before. Simultaneously, the pandemic increased the pace of digital transformation in the healthcare field, triggering the paradigm shift in the collection, analysis, and communication of pharmacovigilance data (5).

The experience of India during the pandemic and the post-pandemic period contributes much to the understanding of how pharmacovigilance can develop to address the crises in health in the future. The pandemic also caused changes in the PV infrastructure, the regulatory framework, and the engagement of the population, stimulating closer cooperation between the public health institution, the technology partners, and the pharmaceutical industry (5). Also, it highlighted the importance of transitioning away from conventional, reactive PV models to proactive and predictive pharmacovigilance, in which the real-world data, big data analytics, and AI algorithms are at the heart of the declaration of the possible risk before it becomes the threat to the public health (6).

Thus, the main objective of this review is to uncover the paradigm changes, innovations, and policy lessons that were gained by India in the pharmacovigilance response in the post-COVID period. In this paper, the author critically evaluates the ways in which the Indian PV system had to adapt to the previously unknown challenges, the technological and organizational changes that restructured drug safety monitoring, and which strategies could inform the future preparedness (7). This review will provide an in-depth perspective of how pharmacovigilance can move beyond a compliance-based model to a smarter, patient-focused and globally harmonized system that is able to provide a solution to protect the health of the populace in an increasingly complicated therapeutic environment (8).

Before COVID-19 Pharmacovigilance the Indian Landscape.

The pharmacovigilance situation in India was in the process of consolidation, but until the outbreak of the COVID-19 pandemic, it was slowly developing. As a sign of the increasing role of drug safety in the expanding pharmaceutical market, India introduced Pharmacovigilance Programme of India (PvPI) in July 2010 at the auspices of the Central Drugs Standard Control Organization (CDSCO) at the Ministry of Health and Family Welfare, Government of India (9). The program was mandated to have the Indian Pharmacopoeia Commission (IPC) which was referred to as the National Coordination Centre (NCC) whose main aim was to monitor adverse drug reactions (ADRs) and to ensure that the benefits of medicines surpassed the risks. The PvPI was an historic move in India ensuring the intent to enhance patient safety and harmonize national pharmacovigilance practices with international standards (10).

PvPI operational structure was multi-tiered with National Coordination Centre (IPC) as the main center, Zonal and Regional Pharmacovigilance Centres, and Adverse Drug Reaction Monitoring Centres (AMCs) situated in the medical colleges and hospitals around the country. These centers were charged with the role of gathering, evaluating, and reporting the data on ADR to the NCC to be assessed and reported to the World Health Organization-Uppsala Monitoring Centre (WHO-UMC) in Sweden (11). In 1998, India formally joined the WHO Programme of International Drug Monitoring (PIDM) which permitted it to send national ADR data to the world safety database, VigiBase. With the help of this collaboration, India sought to strengthen its drug safety signal detection system and have an active role in the global pharmacovigilance network (12).

The pre-COVID pharmacovigilance system in India was associated with a number of operational issues despite such extensive structural changes. Underreporting of ADRs was one of the most challenging problems that reduced the usefulness of national drug safety surveillance. ADR reporting rate was significantly lower than it is in developed countries, and this could be explained by insufficient knowledge and incentives of the medical staff. ADR reporting was considered by many clinicians as another administrative burden and not a vital part of the patient care (13). Additionally, most of the reports were based on the tertiary care and urban healthcare facilities, which resulted in a hospital-based bias that did not reflect on the drug safety information of primary care facilities and the rural population, where a significant percentage of the Indian population is spread. The process of reporting was very manual as well as paper based and thus led to delays in data transmission, incomplete documentation and the inconsistency in signal assessment (14). The ADR forms were physically presented to AMCs where the data was manually inputted into national systems causing major time delays between the occurrence of events, reporting and analysis. This restricted the capacity of the program to identify early warning signals or control the emergent safety concerns in real time. Moreover, information sharing and cross-interoperability between various healthcare industries, namely allopathic, Ayurveda, Yoga, Unani, Siddha, and over-the-counter drugs markets was minimal, which resulted in a fragmented representation of drug safety within the diverse Indian healthcare industry(15) . The other significant weakness was that there was low level of pharmacovigilance literacy among healthcare workers and the general population. Pharmacovigilance was not a fundamental part of medical and pharmacy education, and was only trained in a few schools. Consequently, most practitioners were not knowledgeable or confident about identifying and reporting ADRs (16). The involvement of pharmaceutical companies in post-marketing surveillance was also uneven since very few ADRs were reported by clinical practice or by patients. Disjointed communication among the regulatory agencies, manufacturers, and healthcare providers also acted as a barrier to the development of a systematic drug safety surveillance system (17). Even more challenges were encountered in the pharmacovigilance implementation in rural and remote areas. Inadequate infrastructure, low access to the internet and lack of electronic medical record systems limited the collection of data and the submission of ADR on time. In addition, the utilization of traditional medicine was common in these areas, but ADR reporting systems by AYUSH practitioners or the informal care providers were in essence non-existent (18). As such, the national pharmacovigilance system was unable to real-world reflect safety profiles of most of the commonly used traditional/non-prescription preparations. In India, institutional advancement was consistent but operationally inefficient as the pre-COVID pharmacovigilance situation occurred. Although the creation of PvPI and cooperation with WHO–UMC provided a solid basis of drug safety monitoring, the system was in a disjointed, reactive, and mostly manual state (19). The main barriers that limited the potential of pharmacovigilance in protecting the population health were underreporting, absence of awareness, deficiency in rural outreach, and insufficiency of technological integration.

Nevertheless, all these difficulties, in their turn, became driving forces of change as the COVID-19 pandemic revealed the vulnerability of the old system and required quick digitalization, data-based decision-making, and community involvement (20). Table provides a comparative analysis of the pharmacovigilance (PV) ecosystem in India before and after the COVID-19 pandemic to outline the significant change thereof. India had a predominantly manual, compliance-driven, hospital-based PV framework that was data fragmented, with a low level of public awareness and hinders ADR reporting procedures before 2020. Conversely, the post-COVID period brought in a new paradigm shift of digitally empowered, predictive, and patient-centered model (21). The main developments are the introduction of artificial intelligence and big data analytics to identify real-time signals, building interoperable e-reporting systems, and the development of ADR monitoring to rural and community scales. This shift highlights the successful shift of the country to active compliance rather than reactive compliance in the form of proactive intelligence that depicts a robust, open, and internationally integrated pharmacovigilance system that can respond to future health emergencies (22).

Table . Comparative Overview of Pharmacovigilance in India Before and After the COVID-19 Pandemic: Evolution from Compliance to Intelligence

S.No.	Parameter	Pre-COVID PV (Before 2020)	Post-COVID PV (After 2021)	References
1	Governance Framework	Centralized under CDSCO and IPC; limited inter-agency coordination	Strengthened CDSCO–IPC collaboration with dynamic governance and shared accountability	(23)
2	Regulatory Approach	Rigid, compliance-based monitoring	Flexible, adaptive, and innovation-driven regulations (e.g., EUA)	(24)
3	Data Reporting System	Manual ADR reporting forms and offline submission	Fully digital, real-time e-reporting via portals and apps	(25)
4	Data Management	Fragmented and delayed aggregation	Integrated National PV Data Grid with AI-assisted analytics	(26)
5	ADR Monitoring Centres (AMCs)	~250–300, mostly urban and tertiary hospitals	600+ AMCs including rural, private, and district hospitals	(27)
6	Public Involvement	Minimal public participation	Citizen-inclusive PV through apps, telemedicine, and awareness programs	(28)
7	Use of Technology	Basic databases and Excel-based tracking	AI, ML, NLP, IoT, and blockchain for predictive PV	(29)
8	Signal Detection	Manual review by experts	AI-driven real-time signal detection and validation	(30)
9	Data Transparency	Limited public access	Open-access ADR dashboards and regular safety bulletins	(31)
10	Vaccine Safety	Conventional post-marketing surveillance	Active, real-time COVID-19 vaccine safety monitoring network	(31)

11	International Collaboration	Limited WHO-UMC engagement	Active participation in WHO Global Vaccine Safety Initiative	(32)
12	AYUSH/Herbal Drug PV	Neglected or minimal	Formal frameworks for herbal, AYUSH, and biosimilar vigilance	(33)
13	Pharmacogenomics	Largely absent	Integration of pharmacogenetic safety profiling	(34)
14	Community Involvement	Restricted to tertiary healthcare settings	Community health workers trained for local ADR reporting	(35)
15	Training & Capacity Building	Occasional workshops and CME programs	Continuous e-learning and national PV certification programs	(36)
16	Public Awareness	Low patient literacy and ADR awareness	National awareness campaigns and social media engagement	(37)
17	Data Integration	No link between PvPI and hospital EMRs	Full interoperability with SUGAM, EHRs, and eHealth platforms	(38)
18	Cybersecurity	Minimal digital risk	Implementation of secure data systems under DPDP Act	(39)
19	Speed of Response	Weeks to months	Near real-time ADR alert generation and dissemination	(40)
20	Post-Marketing Surveillance	Primarily reactive	Proactive and predictive post-marketing risk detection	(41)
21	Innovation Ecosystem	Largely government-led	Rise of PV-tech startups and private innovation ecosystems	(42)
22	Rural Surveillance	Poor ADR reporting from rural areas	Strengthened through decentralization and CHW involvement	(43)
23	Big Data Utilization	Limited to descriptive statistics	Predictive analytics for drug safety and repurposing insights	(44)
24	Vaccine Hesitancy Management	Unaddressed in PV framework	Dedicated modules for misinformation and risk communication	(45)
25	Tele-Pharmacovigilance	Non-existent	Operational tele-PV platforms enabling remote ADR reporting	(46)
26	Outcome Focus	Compliance and documentation	Patient safety intelligence and continuous improvement	(47)
27	Overall Evolution	Fragmented, manual, and hospital-centric PV system	Intelligent, integrated, patient-centered, and AI-assisted PV ecosystem	(48)

The figure 1 is a clear representation of the transformational changes in the pharmacovigilance (PV) systems after the COVID-19 pandemic. Prior to the pandemic, the PV framework remained mostly traditional with limited data reporting, poor status of database integration, inadequate technological implementation as well as poor international cooperation. Nevertheless, the post-COVID period provoked the paradigm shift due to a strong increase in the need to detect adverse events quickly, monitor their safety and usage of vaccines, and share data in real-time As observed in the chart, the five parameters data reporting, adverse event management, database integration, global collaboration, and technology use have grown significantly after the pandemic. This advancement indicates the use of AI-based analytics, cloud-based PV databases, mobile ADR reporting applications, and global data-sharing networks. The change highlights the role of COVID-19 as an agent of digital transformation, regulatory modernization, and drug education among the population in Pharmacovigilance (49).

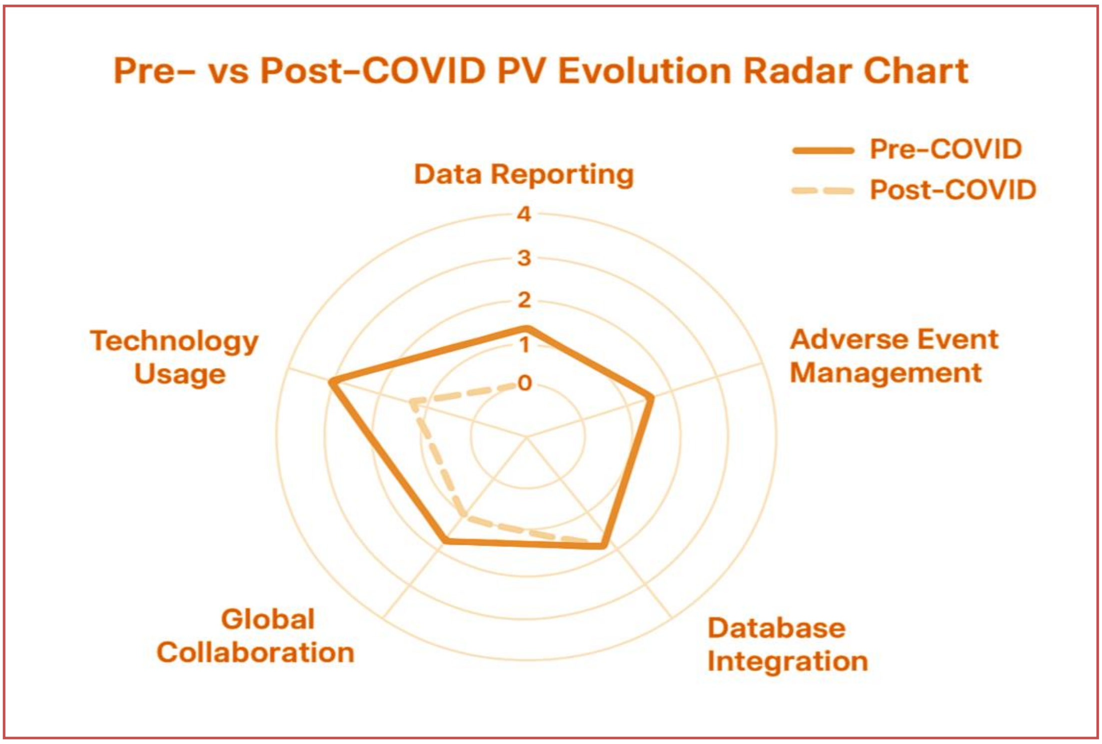


Figure 1: Radar chart showing the comparative evolution of pharmacovigilance systems before and after COVID-19 across key performance dimensions.

The COVID-19 Catalyst: How the Pandemic Transformed PV

Strengthening PvPI's Governance Structure

The post-COVID-19 era was a major breakthrough in the development of the Indian system of pharmacovigilance, particularly in enhancing the governance framework of the Pharmacovigilance Programme of India (PvPI). The difficulties of the pandemic showed that the current regulatory framework involves a more complex and opaque structure with a lack of technology that can react quickly to arising drug safety concerns. As a reaction, the Central Drugs Standard Control Organization (CDSCO) and the Indian Pharmacopoeia Commission (IPC) made a series of collaborative changes following 2021 to increase the operational effectiveness, accountability, and responsiveness of the national pharmacovigilance network (50). Such initiatives were to shift the PV system in India to be a far more proactive system based on data, with a global harmonized system that enables real-time decision making based on the masses public health. The partnership of CDSCO and IPC turned out to be the pillar of pharmacovigilance reform in India. Although CDSCO remained as the national regulatory body, the national regulatory body in matters related to drug approval, licensing, and enforcement, the IPC, which became the National Coordination Centre (NCC) in the field of PvPI, became more active in digital transformation, agency coordination, and advanced data analytics (51). Both bodies together created a common communication structure between zonal office, state regulatory, and Adverse Drug Reaction Monitoring Centres (AMCs). Through this integration, the flow of safety data was enhanced, and consistency of signal detection, signal evaluation and regulatory action was improved. Among the key innovations of this time, one can single out the digitalization of the ADR reporting systems via the portals, including SUGAM and eADR, and the mobile-based applications created by PvPI (52). These electronic instruments made the submission of ADR faster and more convenient both among healthcare professionals and patients, minimized delays and maximized the visibility of data. Capacity building was another area that the IPC aimed at and this was done through special training programs that were given to pharmacovigilance officers, hospital pharmacists and industry representatives, and thus enhanced the human resource base of the national PV network. The other important change was the establishment of regulatory flexibility of emergency-use authorizations (EUAs), particularly due to the COVID-19 vaccination effort and using repurposed therapeutics (53). In order to understand the urgency of the need to guarantee both access and safety, CDSCO and PvPI established adaptive regulatory pathways, which focused on post-authorization safety monitoring. Pharmaceutical companies with EUA status had to provide periodic Safety Update Reports (PSURs) and risk management plans (RMPs) frequently, and any new safety signal had to be identified and evaluated as quickly as possible (54). Moreover, PvPI and the Co-WIN digital platform were introduced to expand the vaccine safety monitoring network in India and combine it with the National Adverse Event Following Immunization (AEFI) program. This strategy demonstrated that regulatory flexibility, directed by science and transparency, may keep the people trustful and help avoid patient harm even in crisis situations. Besides digital and regulatory reforms, IPC also came up with new Standard Operating Procedures (SOPs) aimed at quick signal control and the determination of causality, which would speed up the process of recognizing and analyzing potential safety issues. These SOPs standardized procedures in the entire ADR monitoring centers allowing homogeneity and consistency in the evaluation of causality (55). The new architecture also capitalized on automated tools of analysis to identify the new trends in ADR data to enable an early intervention and minimize the risk. A Rapid Signal Assessment (RSA) process was created to review time sensitive information as quickly as possible and a Signal Review Panel (SRP) which consisted of pharmacologists, clinicians, and epidemiologists was created to guarantee scientific integrity in decision-making. Such improvements of procedures made pharmacovigilance in India a predictive rather than a reactive field, which can anticipate and prevent risks before they turn into nationwide health problems (56). An international ADR data repository that consolidates the input of PvPI, AEFI, and industry reports further harmonized the data and allowed the responsiveness of the regulation. In these actions, India was able to show how a developing state could transform its governance structure in pharmacovigilance by integrating regulatory control with digital health intelligence. The further development of PvPI in 2021, in this way, is a role model of resilience and reformation, demonstrating that the system of pharmacovigilance may be efficient, patient-centered, and globally aligned by means of strategic governance, flexibility in regulation, and integration of technologies. The International Optimization and Indian Leadership (57). The introduction of artificial intelligence (AI) in pharmacovigilance is one of the most disruptive changes during the post-COVID period that has redefined the concept of adverse drug reactions (ADRs) detection, analysis, and prediction. The conventional pharmacovigilance system that mainly relied on manual reporting, clinical assessment, and retrospective data analysis procedures commonly suffered underreporting, data dispersion and time delays in signal identification and regulatory intervention. The pandemic highlighted the shortcomings of such reactive solutions and paved the way to the implementation of AI-based predictive pharmacovigilance, which is an active model that leverages machine learning (ML), natural language processing (NLP), and big data analytics to detect possible safety issues before they become potential sources of public health hazards (58). This shift has been especially massive in India as a part of the wider digitalization of health initiative through efforts like the Ayushman Bharat Digital Mission (ABDM) and modernization of the Pharmacovigilance Programme of India (PvPI).Machine learning algorithms have emerged as powerful tools in predicting ADRs from clinical, prescription, and real-world data sources. By analyzing large datasets comprising electronic health records (EHRs), laboratory findings, prescription patterns, and patient demographics, ML models can detect subtle correlations between drug exposure and adverse outcomes that may escape human observation. These algorithms continuously learn and improve as new data become available, enhancing their predictive accuracy over time (59). For instance, supervised learning models can classify drugs based on their likelihood of causing specific adverse reactions, while unsupervised models can cluster unknown drug-event associations for further investigation. In the Indian context, such predictive modeling has begun to be explored in collaboration with major academic medical centers and research institutions. The use of AI for signal detection not only accelerates risk identification but also optimizes resource allocation, allowing regulatory authorities and healthcare providers to focus on high-priority safety concerns (60).

Similar to this, natural language processing (NLP) has also brought about a novel dimension of pharmacovigilance by facilitating the automatic extraction of ADR information in the unstructured text data. There is an immense body of useful drug safety knowledge beyond the official clinical reports; in physician notes, discharge reports, patient forums online, and social media platforms. This has been especially handy in the surveillance of post-marketing which patients are increasingly contributing their treatment experiences in the online world. NLP systems can distinguish between actual ADR indicators and irrelevant conversations by using sentiment analysis and the context and produce early warnings about any budding safety trends (61). NLP-based pharmacovigilance could be a good solution to real time monitoring of drug safety at a community level in India where the social media penetration is high and the interaction between patients and social media is on the increase. Such tools are slowly finding acceptance by PvPI and other regulatory bodies to enhance the traditional ADR databases with patient-reported outcomes. Big data analytics also enhances the AI use in pharmacovigilance, as it combines various types of data streams, such as clinical trial outcomes, pharmacogenomic, and post-marketing surveillance data, into the comprehensive safety information. The volume and depth of the data created throughout the COVID-19 pandemic and especially by vaccination initiatives, emergency-use drugs, and real-world treatment plans, demonstrated the need of high-capacity data analytics structures (62). Newer computational models can be used to examine millions of data points to determine trends in the occurrence of ADRs over time and space and to determine rare adverse events and drug interactions across populations. Notably, the study of drug repurposing in the post-COVID environment has also become possible with the help of big data analytics. Using AI-based analytics, mining of safety and efficacy data on existing drugs has discovered new therapeutic uses of old drugs, thus streamlining the discovery effort without compromising on safety oversight. These measures will not only boost the effectiveness of pharmacovigilance but will also lead to strategic pharmaceutical innovation, which will fit the vision of India being a global pharmacovigilance hub (63). The combination of AI, NLP, and big data analytics has therefore transformed pharmacovigilance to be a reactive/case-based science to a predictive/evidence-driven science. In India, the Indian Pharmacopoeia Commission, CDSCO and digital health researchers are discussing the frameworks of incorporating AI-based signal detection into the national ADR database. The future of pharmacovigilance is in the ability to develop intelligent systems that are able to continuously and automatically learn - systems that can process a wide range of data, respond to new health risks, and assist in making regulatory decisions more accurately than ever before (64). With the predictive pharmacovigilance becoming AI-driven, it is likely to establish a healthcare setting in which the safety of drugs is no longer observed but can be predicted, guaranteeing quicker responses and safer patient therapy with drugs on all levels of the healthcare system. Inclusion of Public Participation. During the post-COVID period, pharmacovigilance in India has become a more patient-focused and inclusive form of activity rather than a clinician- and regulator-led activity. The pandemic highlighted the value of treating the general population as the active participants of adverse drug reaction (ADR) monitoring. Due to the emergence of digital health technologies, the personal interaction of patients with pharmacovigilance has improved significantly via mobile apps, telemedicine, and online health platforms (65). With the help of the Central Drugs Standard Control Organization (CDSCO), the Indian Pharmacovigilance Programme (PvPI) launched user friendly ADR reporting applications and online platforms, where patients and caretakers can report side effects in real time. Social media has also become an important additional source of data to pharmacovigilance. Natural language processing (NLP) is being applied to mine such platforms as Twitter, Facebook, and online patient forums to identify the early signs of bad events. Through this social approach to listening, the usual geographical limits of pharmacovigilance have been extended to other non-clinical scenarios, providing a quicker and more comprehensive overview of the drug safety trends in everyday practice (66).

The public awareness initiatives have played a critical role in fostering a culture of shared responsibility for drug safety. Nationwide campaigns supported by the Ministry of Health, IPC, and WHO ave emphasized the importance of ADR reporting, particularly in rural and semi-urban regions. Community health workers (ASHAs and ANMs) have been trained to recognize and report ADRs, thereby strengthening the grassroots surveillance network (67).

Policy and Regulatory Paradigm Shifts

Following the COVID-19 pandemic, an evolutionary breakthrough in the pharmacovigilance (PV) system in India occurred, which is marked by prospective policy changes and an enhanced regulatory ecosystem. The crisis not only revealed the structural loopholes but also offered a chance to redefine drug safety governance in a more responsive, transparent, and worldwide manner. In addition to enhancing the dedication of India to patient safety, these paradigm shifts made the country a promising member of the global pharmacovigilance society. Among the greatest changes, the strengthening of the Pharmacovigilance Programme of India (PvPI) in structure should be considered (68). A number of post-2021 reforms were proposed under the joint accountability of the Central Drugs Standard Control Organization (CDSCO) and the Indian Pharmacopoeia Commission (IPC) to coordinate better between the national authorities, healthcare facilities, and pharmaceutical companies. The crisis that was experienced during the pandemic particularly with emergency-use authorizations (EUAs) to vaccines and antiviral drugs raised the issue of flexibility in regulation without compromising rigorous post-marketing safety monitoring. This resulted in the creation of active structures which enabled conditional approvals under the real-time safety monitoring and constant data analysis (69). Also, the PvPI introduced new standard operating procedures (SOPs) to allow quick signal detection, data triage, and causality. The automation, the use of digital platforms, and artificial intelligence tools were combined to enhance the pace of the ADR reporting and facilitated the flow of data within hospitals, partners in the industry, and regulatory agencies. These innovations helped a great deal in minimizing the reporting lag time as well as enhancing the quality and accuracy of safety assessment. Consequently, the model of pharmacovigilance in India changed to a reactive model to become a proactive and technology-focused system that may react quickly to the arising safety issues. The world interaction of India also enhanced significantly at this time (70). The country was instrumental within the World Health Organization Global Vaccine Safety Initiative (GVSI) whereby the country provided data and methodologies that enhanced global vaccine safety surveillance. It was a win-win alliance that not only strengthened the foreign positions of India but also facilitated sharing of experience with other countries that had the same predicament in terms of capacity building in pharmacovigilance. Moreover, India also offered its technical assistance and training modules to low and middle-income countries (LMICs), establishing itself as a regional pharmacovigilance excellence hub in South Asia and the rest of the world (71). The development of specific vigilance systems of herbal, AYUSH, and biosimilar products was also another milestone. As the Indian market is very large in terms of acceptability of traditional and biologically derived medicines, the new regulations were directed to the implementation of various therapeutic systems in the same PV structure. This holistic practice typifies the Indian healthcare diversity and also make sure that medicinal products, be it modern, traditional or biotechnological must be put under strict safety evaluation. The post-COVID policy and regulatory paradigm shifts is an indicator of the fact that India is becoming more inclusive, technology-facilitated and globally compatible in the pharmacovigilance ecosystem. India has established an example of robust and responsive 21 st century drug safety surveillance by enhancing the quality of governance, adopting digital innovation and international co-operation (72). Issues with the Post-COVID Pharmacovigilance Landscape. Although the pharmacovigilance

(PV) system in India has achieved significant advances in the digitalization, policy change, and community involvement following the COVID-19 pandemic, there are still a number of challenges that define its current transformation. These obstacles are important to maintaining the momentum achieved due to the pandemic and making sure that pharmacovigilance in India is sustainable, fair, and sustainable. Among the most significant threats, there is data privacy and cybersecurity. The security of sensitive health and patient data has become a significant issue with the large-scale implementation of electronic reporting systems, mobile applications, and cloud-based PV databases (73). The privacy of individuals, data breaches, and cyber threats may not only interfere with the privacy of individuals, but also with the validity of the pharmacovigilance system. Misinformation and vaccine hesitancy is also another burning concern and it became one of the major obstacles during and post-pandemic. Although social media sites are useful in providing real-time information about safety, they have also been used to disseminate unverified information regarding drug and vaccine safety. This two-sided situation offers a challenging dynamic to the pharmacovigilance authorities, who have to overcome false information with evidence-backed communication. Overcoming this problem can be achieved by building the public trust through regular distribution of the confirmed safety information and participation of the community leaders in the awareness campaigns. Another issue is the automation versus human expertise (74). The combination of artificial intelligence (AI) and machine learning (ML) applications has certainly made signal detection and ADR evaluation efficient. Yet, excessive dependence on algorithms may result in the failure to notice context-specific details that can be explained by professional pharmacologists and clinicians. Therefore, ensuring a balance between automated analytics and human judgment by an expert is one of the most significant concerns to prevent the possible misunderstanding or neglect in safety assessment. Lastly, there is still no parity of pharmacovigilance infrastructures between rural and urban areas, which impedes national coverage (75). Metropolitan regions can enjoy the benefits of improved reporting systems and highly prepared healthcare providers, whereas rural regions are in a bad state of awareness, insufficient internet connectivity, and trained PV personnel. The solution to this gap involves capacity-building exercises, decentralized reporting hubs, and community-based sensitization programs with the participation of the ASHA and the ANM workers. The pharmacovigilance situation in the post-COVID phase of India indicates not only positive changes but also according to the traditional challenges. It is only under such concerted efforts that the PV system in India can be maintained in to a globally resilient model that keeps the drug safety and public confidence in the years to come (76).

The table 2 points to the complex issues that appeared in the pharmacovigilance (PV) environment of India in the post-COVID-19 period and the related measures that need to be undertaken to enhance the system. The high-level of digitalization and the mass vaccination efforts have revealed such vulnerabilities as lack of privacy in the data, the misinformation, and the under-reporting of the adverse events. Moreover, rural-urban differences, lack of training, and poor inter-agencies coordination have also led to the inefficiency of ADR reporting (77). The proposed strategic actions to implement in order to solve these problems are digital integration, capacity building, and community engagement. The implementation of AI-driven analytical tools, encrypted cloud solutions, and national databases can boost the real-time signal recognition and provide data security to a considerable degree. On the same note, integrating pharmacovigilance modules in healthcare education and increasing the involvement of both the public and private institutions will enhance awareness and responsibility. Lastly, the means of public communication like mobile apps in different languages and campaigns about the national PV system- are essential to create transparency and trust in the national PV system (78).

Table 2: Challenges and Strategic Solutions in Post-COVID Pharmacovigilance

S.No.	Key Challenge	Underlying Cause	Proposed Solution / Strategic Response	References
1	Data privacy & cybersecurity	Rapid digitalization without robust data protection	Enforce DPDP Act, adopt encrypted cloud PV systems	(79)
2	Misinformation & vaccine hesitancy	Spread of unverified content on social media	Deploy AI-driven social listening and verified dashboards	(80)
3	Rural–urban disparity	Limited PV awareness and poor internet access	Train ASHA/ANM workers; develop offline ADR reporting tools	(81)
4	Over-reliance on automation	AI misclassification and bias risk	Combine AI data analytics with expert human validation	(82)
5	Fragmented stakeholder coordination	Weak inter-agency data sharing	Integrate PvPI with EHR, CDSCO, and state health networks	(83)
6	Inconsistent ADR reporting	Lack of standardized templates and user training	Implement national e-ADR reporting framework	(84)
7	Limited pharmacovigilance literacy	Inadequate PV inclusion in medical curricula	Introduce PV modules in medical, pharmacy, and nursing education	(85)
8	Insufficient signal detection	Overwhelming data from multiple sources	Adopt AI/ML algorithms for real-time signal prioritization	(86)
9	Under-reporting of ADRs	Fear of legal consequences and lack of incentives	Encourage voluntary reporting through awareness and recognition programs	(87)
10	Shortage of skilled PV professionals	Limited training and exposure	Establish specialized PV training centers and online certification courses	(88)
11	Lack of global data harmonization	Incompatible databases and coding standards	Adopt ICH-E2D and MedDRA coding for uniform reporting	(89)
12	Post-vaccine adverse event tracking gaps	Weak follow-up mechanisms	Use integrated Co-WIN and PvPI linkages for real-time AEFI reporting	(90)

13	Delayed data analysis	Manual review and limited computational power	Automate analysis using big data and NLP tools	(91)
14	Public distrust in regulatory systems	Poor communication and transparency	Promote open-access ADR dashboards and public reports	(92)
15	High workload on PV centers	Surge in data volume post-pandemic	Implement distributed cloud analytics and automated triaging	(93)
16	Limited collaboration with private hospitals	Voluntary participation only	Mandate PV participation for all NABH-accredited hospitals	(94)
17	Language and literacy barriers	Reports often in regional languages	Enable multilingual ADR reporting apps and AI translation	(95)
18	Budgetary and resource constraints	PV underfunded in public health programs	Create dedicated PV funds under National Health Mission (NHM)	(96)
19	Poor feedback to reporters	Lack of acknowledgment mechanisms	Automate acknowledgment and case-status updates to reporters	(97)
20	Ethical and data ownership issues	Ambiguity over patient consent	Include digital consent modules in reporting software	(98)
21	Cross-border ADR tracking issues	Absence of regional cooperation	Establish SAARC PV collaboration for data sharing	(99)
22	Limited public engagement	PV awareness confined to professionals	Launch "Safe Medicine India" campaigns via mass media	(100)

Lessons Learned from the Indian Experience

The after effects of COVID-19 have provided India with a special chance to look back into its pharmacovigilance (PV) history and understand what the most important lessons are that may be applied to the development of a more reactive and sustainable system of drug safety. The pandemic was a stress test, which revealed vulnerabilities, but also led to innovations, cooperation, and flexibility in the PV sector of the country. The lessons learned in Indian experience show that the combination of actions of the state, industry, health care professionals, and citizens can enhance pharmacovigilance in both a national and international context (101). The ability to create the force of the public-private cooperation has been one of the most important lessons. The collaboration involving the regulatory agencies, including the Central Drugs Standard Control Organization (CDSCO), the Indian Pharmacopoeia Commission (IPC), the pharmaceutical industry, and the technological partners resulted in outstanding progress in the field of data collection and reporting. The development of such an initiative as the SUGAM portal and the PvPI mobile applications resulted in the creation of the digital ecosystem that facilitated the submission, assessment, and monitoring of adverse drug reactions (ADRs) (102). The platforms did not only enhance efficiency but also promoted transparency, accountability, and real time decisions. The collaboration of the state and corporate world contributed to the fast exchange of data as well, allowing responding to safety-related signals much faster during the pandemic. The other useful lesson is the benefits of the decentralization that enhance reporting timeliness and data diversity. India managed to reach the hinterland of the pharmacovigilance activities through empowering the regional PV centers, hospitals, and even community health workers. The connection of data into decentralized networks allowed the expedited ADR reports, localized analysis, and enhanced the coverage of the drug safety trends on the national level (103). This model has been important in the representation of safety information of the diverse population in India as it represents the variation in genetic, dietary and environmental conditions which affect drug response. The other pillar of the PV success in India was capacity building as well as ongoing training. The IPC and PvPI have put a lot of funds in workshops, webinars and certification programs to enhance the technical skills of the medical professionals, pharmacists and regulatory officials. These efforts have enabled the improvements of ADR reporting, the improvement of causality determination, and the creation of a culture of vigilance among medical practitioners. Lastly, the Indian experience reiterated the need to create community engagement as the background of sustainable Pharmacovigilance (104). Democratization of drug safety monitoring through the empowerment of patients, caregivers and community health workers to be actively involved in reporting ADRs has contributed to the disciplined monitoring of drug safety. Awareness campaigns at the grassroots level which are being facilitated by workers of ASHA and ANM, have played a major role in propagating ADR literacy in the rural areas where there is limited access to formal healthcare systems. With digital platforms, decentralization, capacity building and people engagement, India has provided the basis of a pharmacovigilance model that is not only effective and transparent but also people-centric- establishing a standard that can be followed by other countries in the attempt to achieve a comprehensive and participatory drug safety surveillance (105).

The New Frontier: Patient-Centric and Predictive Pharmacovigilance

The predictive and patient-focused models of pharmacovigilance are changing the future of pharmacovigilance in India as the country is moving towards a change in perspective regarding a paradigm shift in favor of traditional reactive models of pharmacovigilance. The post-COVID era has increased the pace of the use of new technologies and personalized treatment methods allowing identifying the drug risks early enough and enhancing therapeutic safety and empowering patients as active participants of healthcare. This new frontier signifies a significant shift in the response to adverse drug reactions (ADRs) to its prediction, which is data-powered and digitally innovative and patient-driven (106).

The area of change is the greatest transformation of the reactive to the predictive type of pharmacovigilance. Traditionally, the collection of retrospective ADR data relied on hospitals and care providers, and frequently led to the late identification of warning indicators. Nowadays, ADRs may be predicted and prevented by combining artificial intelligence (AI), machine learning (ML) with real-world data analytics. With prescription data, patient data, and clinical history, predictive algorithms will be able to identify high-risk medications or populations, and then implement early intervention and risk reduction measures (107).

The other novel development is genomics and pharmacogenetic safety monitoring which is a personalized approach. The increased interest that India has developed in genomic studies and bioinformatics has provided new opportunities to learn about individual differences in drug metabolism and response. It is now possible to use the pharmacogenetic data to determine patients genetically predisposed to adverse reactions, which leads to the creation of more specific drug prescriptions and changes in dosage. This accuracy based method not only increases the safety but also the efficacy of therapy especially in chronic diseases where patients have to take long-term medications (108).

Artificial intelligence, wearable gadgets, and the Internet of Things (IoT) provide additional opportunities of real-time pharmacovigilance. Smartwatches, biosensors, and linked medical devices will be able to watch vitals parameters every minute e.g. heart rate, blood glucose or oxygen levels and send the data directly to PV databases. All findings that deviate or show abnormal responses can be sent as alerts to the health professionals ensuring that they can respond quickly to possible ADRs. This is a significant advancement to proactive patient safety because it indicates a transition of episodic monitoring to continuous surveillance (109).

Besides, telehealth and digital therapeutics have also become part of post-marketing drug surveillance. The popularization of telemedicine platforms both during and after the pandemic has introduced the opportunity to clinicians to monitor the experience of taking medication remotely, especially in rural or underserved areas. Digital therapeutics software-based intervention programs created to prevent, manage, or treat diseases are able to provide useful real-world safety data that supplements traditional PV systems. Such a combination of telehealth and pharmacovigilance guarantees that even those patients that are not located in the traditional medical facility can have access to a safety net (109).

The proposed AI-Integrated Pharmacovigilance Network Model figure 2 is an improvement of the model that is bound to transform the sphere of drug safety surveillance in the post-COVID period. This network is a system that incorporates several sources of data such as mobile reporting applications, cloud-based storage, AI-based analytics, and tracking on social media and integrates them into one digital pharmacovigilance network. Negative event reports made by the medical staff and the general population are analyzed using AI algorithms to identify signals at an early stage, predict patterns, and evaluate risks. The model will allow real-time sharing of data and make decisions to respond better to emerging drug safety signals by connecting the PvPI to regional pharmacovigilance centers. Scalability, accuracy, and constant surveillance are ensured by the use of AI and cloud technologies, and the social media analytics is used to detect the unreported or trending unfavorable events. Altogether, this combined system enables an evidence-based, open, and proactive pharmacovigilance system and keeps up with the international digital health standards (110).

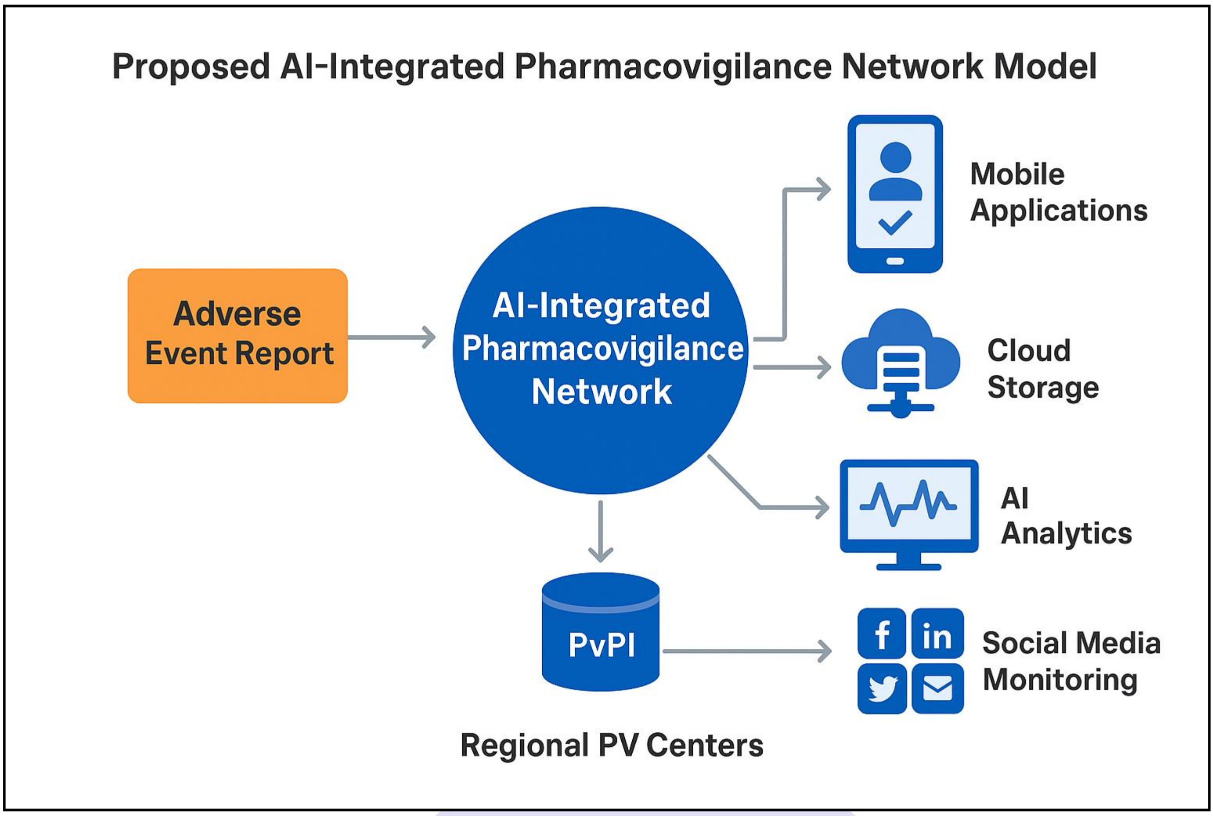


Figure 2: Proposed AI-Integrated Pharmacovigilance Network Model illustrating real-time data flow between adverse event sources, AI analytics, cloud systems, social media monitoring, and regional PvPI centers.

Future Directions for India The post-COVID pharmacovigilance (PV) transformation of India has been undertaken successfully and has established a good foundation to transform India as a world leader in drug safety. The experiences gained, technological advancements done and the policy changes undertaken throughout the recent years have placed India in the position to make radical steps to develop more integrated, intelligent and inclusive PV ecosystem. Going forward, the future of pharmacovigilance in India is pegged on four strategic pillars, which include data integration, education, innovation, and global leadership (111). An important measurement that follows is how a National Pharmacovigilance Data Grid can be developed in a seamless manner as part of the overall health AI infrastructure in the country. A single network like this would link hospitals, pharmacies, diagnostic centers, telehealth services, and health databases of the population. This data grid would connect pharmacovigilance insights, cross-linked with electronic health records (EHRs) and genomic data, in real-time by processing adverse drug reactions (ADRs) by using cloud computing and artificial intelligence. The aim is to come up with a predictive constantly learning system, which is able to foresee safety concerns and make clinical decisions in urban and rural healthcare environments (112). There is also the promotion of PV literacy as a principle element of medical teaching and community health education. Although the reporting infrastructure has improved, the success of pharmacovigilance is based on the awareness and participation. Incorporating PV modules into the medical, pharmacy, and nursing education will help to make sure that future health care professionals will receive training on how to identify, evaluate and report ADRs. In addition, community-based outreach activities, electronic awareness campaigns, and multilingual educational materials will assist in reaching the patients and caregivers and empower them to be active participants in drug surveillance. The promotion of PV analytic startups, which are supported by R&D,

is another promising area. The dynamic startup ecosystem in India (along with the missionary efforts of the government, such as Startup India or Digital Health Mission) offers productive grounds in terms of data science, AI-based safety analytics, and risk prediction modeling (113). Funding, incubating and regulatory alliances would help unlock the potential of local indigenous technologies that could support the local healthcare issues but also lead to the solidarity of global pharmacovigilance research. Finally, the long-term vision, which is called Vision 2030: India as a Global Pharmacovigilance Innovation Hub, has a vision of a country as a key catalyst in the development of global drug safety standards. This would help not only in increasing international cooperation but it would also guarantee that drug safety innovations by India are benefiting a wide variety of people globally (114).

Conclusion

The post-COVID age has transformed pharmacovigilance, as it is no longer a system that operates at regulatory compliance but a system that operates at an intelligence-based prediction and empowering patients. The experience of the pre-pandemic India and the post-pandemic India has demonstrated that the successful implementation of the digital transformation, policy-making process, and civic engagement can result in the creation of the robust and responsive drug safety system. The modernization of pharmacovigilance in the country, as evidenced by the shift towards manual reporting of ADRs to AI-enabled data-driven vigilance, can be taken as an example of modernizing pharmacovigilance in the entire world. India has focused on transparency, incorporation of technology, and involvement of a patient, which has helped it to establish a future-ready PV ecosystem that does not only identify risks in a short period of time but also predicts them. This change will be the pivotal move towards making therapeutics safer, making the public more trustful, and making the world more equipped to face the challenges of health in the future.