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Pharmacovigilance in Modern Healthcare: Recent Advances and Future Directions

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Abstract: *Pharmacovigilance (PV), or "the science and activities relating to the detection, assessment, understanding, and prevention of adverse drug reactions (ADRs) or any other drug-related problems" as per the WHO definition, has increasingly become an integral part of modern medicine. The evolution of therapeutics from small molecules to biological entities such as biologics, biosimilars, gene therapy and mRNA vaccines has expanded the frontier of PV, transforming it into a proactive rather than a passive practice, which relied solely on spontaneous reports. In this review, we look at the historic development and current regulatory paradigm of PV and highlight some of the key advancements in PV over the last 5 years. We emphasize how new technologies such as artificial intelligence (AI), machine learning (ML) and natural language processing (NLP) have been coupled with real-world evidence (RWE), big data analytics and patient reporting systems to enhance detection of signals and subsequent risk management processes. PV during the COVID-19 pandemic and real-time vaccine safety monitoring under Emergency Use Authorization (EUA) serves as a turning point that sped up near-real time safety assessment. We discuss other aspects such as issues with reporting under the current systems, variability in data sets, ethical considerations with AI, and a gap between developed and low and middle-income countries. Future trends in harmonized global systems of PV, integration of technology, use of block chain in tracking pharmaceuticals, wearable devices and patient personalized safety monitoring using pharmacogenomics, will be addressed. Evidence from regulatory documents, literature and technological trends will be synthesized to illustrate the journey of PV from a safety net to a predictive, patient-centered discipline critical for safe medicines in the 21 st century.*

Keywords: Pharmacovigilance; Adverse drug reactions; Signal detection; Artificial intelligence; Real-world evidence; Drug safety; Risk management; COVID-19 vaccines

I. INTRODUCTION

The safe use of medicines is a fundamental tenet of contemporary healthcare. Despite pre-marketing clinical trials; a significant proportion of adverse drug reactions (ADRs) come to light only once a medicinal product has been administered to the general population, where administration is wider, more long-term and more diverse than that experienced in trials [1,2]. Pharmacovigilance (PV) has therefore evolved into an essential scientific discipline and tool with which to protect the public. PV is officially defined by the WHO as "The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem" [3].

The genesis of contemporary PV is inseparable from the Thalidomide disaster of the early 1960s which revealed the tragic cost of failed post-marketing surveillance, leading to the inception of the WHO Programme for International Drug Monitoring in 1968 [4]. From there the discipline has evolved from passive spontaneous reporting systems to a complex, multi-agency structure involving regulatory bodies, marketing- authorisation holders, healthcare professionals and an increasing involvement of the public [5]. The Uppsala Monitoring Centre (UMC) acts as a repository of global PV and collates millions of Individual Case Safety Reports (ICSRs) in the global VigiBase database [6].

ADRs represent a significant global health issue. ADRs are thought to be responsible for 3-7% of hospital admissions in high-income countries, along with significant morbidity, mortality and financial cost [7,8]. A systematic review by Bouvy et al. Calculated that over 197,000 deaths a year were attributable to ADRs within the EU alone, costing in the

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region of €79 billion [9].These figures underline PV as an integral element of quality healthcare, and not simply a peripheral regulatory function.

The last 5 years has seen an unprecedented period of change within PV. The COVID-19 pandemic forced regulators to develop real-time tracking and monitoring systems for vaccines, involving billions of doses, leading to a significant development in data capture and safety surveillance [10,11]. Concurrently, use of Artificial Intelligence (AI), machine learning and big data analytics have rapidly expanded into signal detection, case processing and causality assessment [12]. Social media listening, patient reported outcomes and EHR data integration further contribute to existing safety monitoring systems [13]. This review discusses these developments and considers existing limitations and future perspectives for PV over the next 10 years.

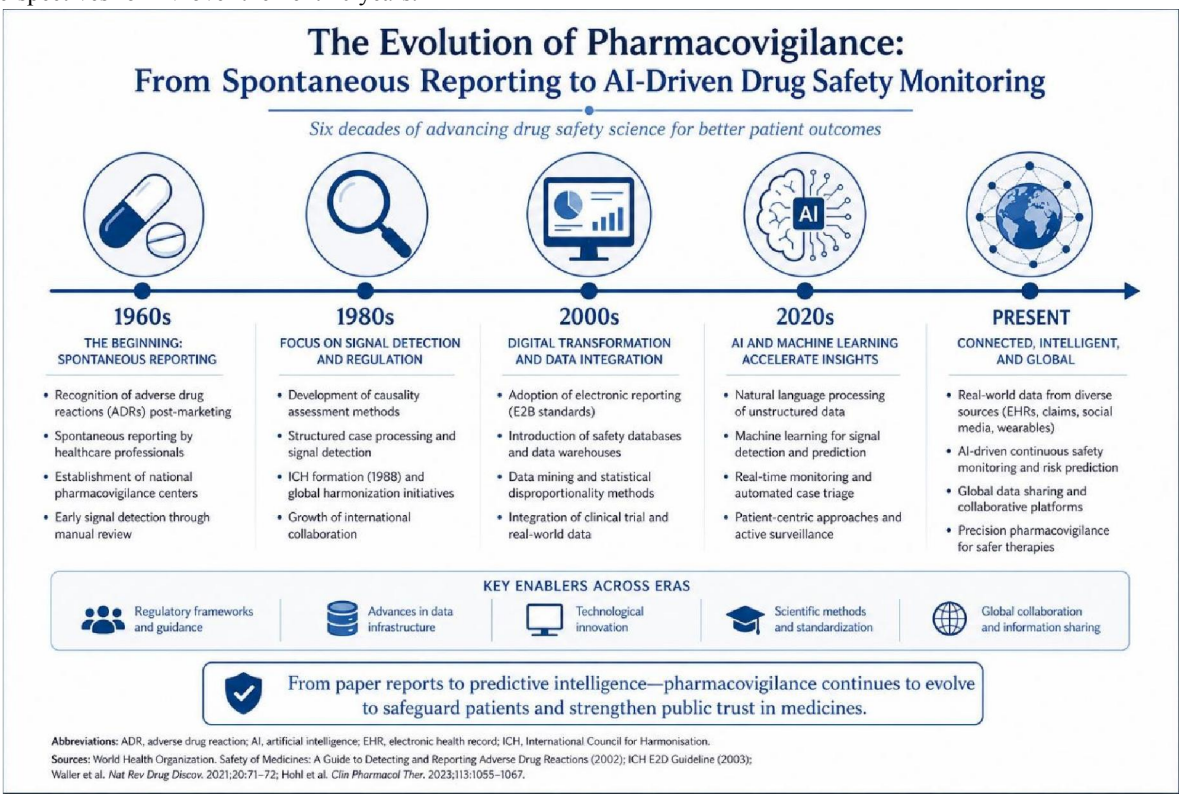

Figure 1. The evolution of pharmacovigilance from spontaneous reporting (1960s) to AI-driven, globally connected drug-safety monitoring.

II. HISTORICAL EVOLUTION AND REGULATORY FRAMEWORK

2.1 From Thalidomide to VigiBase

The thalidomide scandal resulted in approximately 10,000 births of phocomelic babies globally between 1957 and 1962 and fundamentally changed global drug regulation [4]. A response from the United States Food and Drug Administration (FDA) was the 1962 Kefauver-Harris Amendments, requiring proof of both safety and efficacy before marketing [14]. The World Health Organization's (WHO's) Pilot Research Project for International Drug Monitoring followed in 1968 involving ten countries; it provided the basis of what was to become VigiBase [3,6].

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2.2 Development of national and regional systems

Regional systems evolved over the following decades, each with their own strengths. Europe's system managed by the European Medicines Agency (EMA) with its EudraVigilance database, from 2017 made available to the public for aggregate ADR data and supports a network of national competent authorities under the Good Pharmacovigilance Practices (GVP) modules [15,16]. The US FDA maintains a reporting and investigation database (FDA Adverse Event Reporting System - FAERS) and has an active surveillance system using electronic health and claims data from over 100 million patients (Sentinel Initiative) [17]. The Japanese Pharmaceuticals and Medical Devices Agency (PMDA) operates the Medical Information Database Network (MID-NET) [18], whilst the Pharmacovigilance Programme of India (PvPI) launched in 2010 has expanded rapidly with over 350 ADR Monitoring Centres [19].

2.3 Harmonisation via ICH

A series of influential ICH guidelines: E2A (Clinical Safety Data Management); E2B (Electronic Transmission of ICSRs); E2D (Post-Approval Safety Data) and E2E (Pharmacovigilance Planning), have provided a common understanding and approach to global practice [20]. The latest ICH E2D(R1) review from 2023 standardizes solicited reporting expectations, digital data streams and patient- generated data [21].

Table 1. Major global pharmacovigilance systems and their characteristics.

Region / Country	Regulatory Body	Key Database	Distinctive Feature
Global	WHO–UMC	VigiBase	>35 million ICSRs; serves 170+ member
European Union	EMA	EudraVigilance	Mandatory electronic submission; public portal
United States	FDA	FAERS / Sentinel	Active surveillance via claims & EHR (>1 patients)
Japan	PMDA	JADER / MID-NET	Hospital-based EHR network with linked data
United Kingdom	MHRA	Yellow Card Scheme	Earliest patient-reporting system (since 2
India	CDSCO–IPC	VigiFlow (PvPI)	Rapidly expanding network of 350+ AMC
Canada	Health Canada	Canada Vigilance	Mandatory hospital reporting under Vane Law
Australia	TGA	DAEN	Public-access database for consumers a professionals

III. CORE METHODOLOGIES OF MODERN PHARMACOVIGILANCE

3.1 Spontaneous reporting systems

The workhorse of post-marketing surveillance, spontaneous reporting, although having many advantages in terms of coverage and cost-effectiveness, and sensitivity to detect rare events, suffer from chronic under-reporting, estimated to be as high as 94% by a seminal systematic review on signal detection by Hazell and Shakir [25].

The quality of spontaneous reports is variable, with incomplete reports of causal relationships leading to frequent difficulty in interpreting signals [26].

3.2 Signal detection and disproportionality analysis

Safety signal: A safety signal is "information that arises from one or multiple sources... Which suggests a new potentially causal association, or a new aspect of a known association" [27, WHO Working Group VIII CIOMS]. Quantitative signal detection involves calculations of disproportionality, e.g. PRR, ROR, BCPNN and

EBGM, all of which have characteristic sensitivities and specificities [28,29]. Complementary use of a suite of algorithms was shown by Bate and Evans to improve reliability, particularly of rare or delayed reactions [29].

3.3 Causality assessment

Causality assessment provides a translation from statistical association to a clinical judgement. The Naranjo algorithm and the WHO-UMC causality categories remain the standard, both rely on subjective interpretation and have only moderate agreement [30,31]. Probabilistic models, such as the Liverpool ADR Causality Assessment tool aim to reduce this subjectivity, especially for paediatrics [32].

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3.4 Risk management plans and periodic safety updates

Modern pharmacovigilance is a proactive science driven by RMPs and PSURs/PBRERs which should incorporate current information on the safety profile of a drug and corresponding risk management measures [16,20]. The introduction of the PBRER format (ICH E2C R2) emphasizes benefit risk interpretation, rather than a simple list of safety information [33].

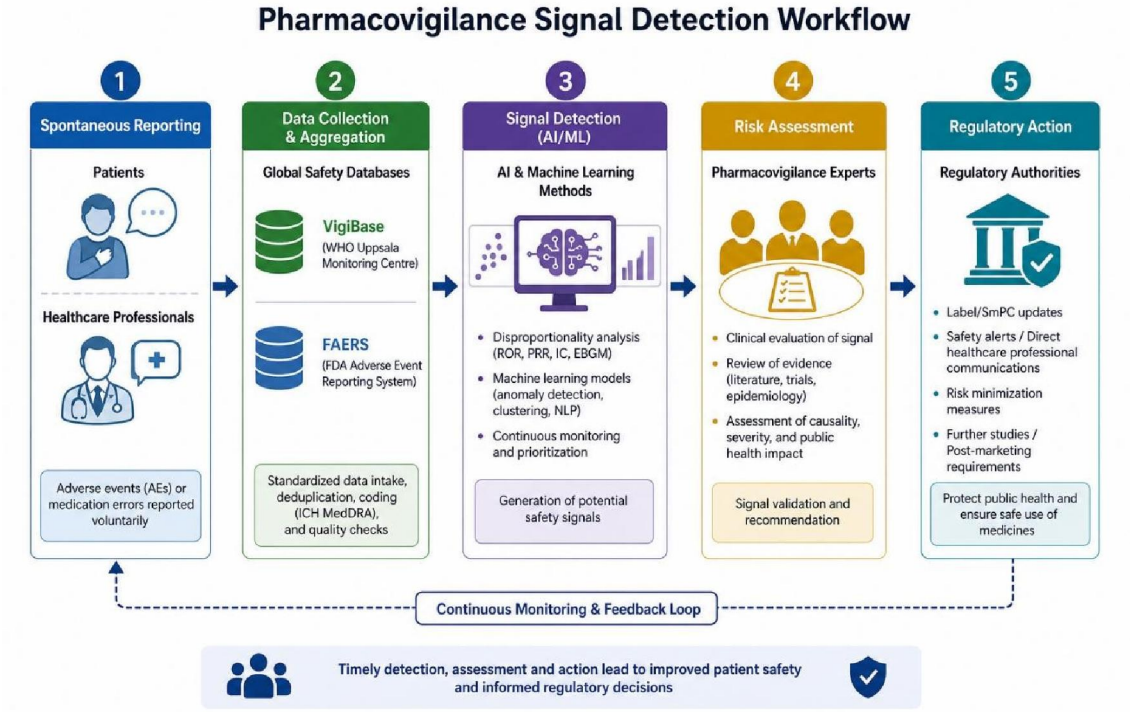

Figure 2. Schematic workflow of modern pharmacovigilance: data acquisition, signal detection, risk assessment, and regulatory action.

IV. RECENT ADVANCES (2019–2024)

4.1 Artificial Intelligence and Machine Learning

AI/ML has permeated all stages of the PV process, from case intake to signal analysis. Ball and Dal Pan outline how AI can enhance the reporting of individual cases to include automated duplicate finding, MedDRA coding and seriousness assessment [12]. ML can triage ICSRs to within 90% sensitivity using classifiers such as Comfort et al [34]. Lee and Yoon have reviewed more than 70 uses of ML in PV during 2018-2022 where a clear trend emerged of using ML primarily for text classification and prediction [35].

The use of deep learning in PV literature screening has also grown significantly; the review by Bhatt et al indicates the use of convolutional neural networks could automate literature review, reducing the workload by 50-70% with no loss in recall [36]. Improved disproportionality analysis, using gradient-boosting, has demonstrated increased ability to identify emerging signals within FAERS, such as immune-checkpoint inhibitor signals [37].

4.2 Natural Language Processing of Unstructured Data

A large portion of data that is relevant to safety resides in unstructured format (clinical notes, discharge summaries, adverse event narratives). NLP techniques utilizing transformer models (BERT, BioBERT and PubMedBERT) can

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extract mentions of ADRs from EMRs with F1 scores of > 0.85 [38,39]. Hospital-level PV use of MedEx and cTAKES has also been implemented to automate the detection of opioid-related events [40].

4.3 Real-World Data and Real-World Evidence

The concept of RWD, supported by RWE, is also well-established within regulatory agencies such as the FDA, where RWE is accepted as supportive evidence under the 21st Century Cures Act [41], and the EMA (DARWIN EU, 2022) which federates EHR and claims data from across the European member states [42]. RWE has influenced the re-evaluation of SGLT2 inhibitors and the characterization of CAR-T cell therapy safety [43,44].

4.4 Social Media and Patient-Reported Outcomes

Patients are now reporting ADRs using social media (twitter/x, reddit) and patient forums. Web-RADR (IMI consortium) was a project investigating the ability of social media listening to identify events, which is particularly useful for certain medications and conditions that might not be publicly discussed [45]. While Sloane et al noted a moderate correlation between Twitter-derived safety signals and FAERS data, there was an insufficient level of specificity [46]. Consumer access to PV reporting through the MHRA Yellow Card App and the EMA's ADR reporter app has been a significant facilitator of reporting [22].

4.5 Pharmacovigilance during the COVID-19 Pandemic

The COVID-19 pandemic presented the most comprehensive stress test for PV to date. The FDA's v-safe platform included more than 10 million vaccinated U.S. Citizens and the EMA provided near real-time monitoring of COVID-19 vaccine data within EudraVigilance, including supportive observational studies like ACCESS and CONSIGN [48]. The identification of vaccine-induced immune thrombotic thrombocytopenia (VITT) following administration of adenovirus-vector vaccines within weeks of its widespread rollout highlighted how modern PV processes can detect rare safety signals rapidly [49,50], as did the detection of myocarditis following vaccination with mRNA-based vaccines in young males, with data shared across spontaneous reporting, EHR and international sources [51].

4.6 Pharmacogenomics and Personalized Pharmacovigilance

Dimension	Traditional PV	Modern PV (2019–2024)
Primary data source	Spontaneous reports (HCP)	ICSRs + EHRs + claims + social media + wearables
Reporter	Healthcare professionals	HCPs, patients, automated systems
Signal detection	Manual review; basic disproportionality	AI/ML, NLP, Bayesian models, deep learning
Timeliness	Months to years	Near real-time
Geographic scope	National / regional	Federated global networks (DARWIN, Sentinel, VigiBase)
Causality assessment	WHO–UMC, Naranjo	Probabilistic + algorithm-assisted
Regulatory output	Periodic reports	Continuous benefit–risk monitoring; dynamic labelling
Patient engagement	Minimal	Apps, social media, PROs
Key limitation	Underreporting	Data heterogeneity, AI explainability, privacy

The integration of pharmacogenomics with PV has opened up avenues for personalized safety monitoring. Pre-emptive HLA-B57:01 testing with abacavir andHLA-B15:02 with carbamazepine, as well as TPMT/NUDT15 testing with thiopurines, have allowed for the prediction and prevention of specific serious adverse events [52,53]. Clinical Pharmacogenetics Implementation Consortium guidelines have now been published for over 25 gene-drug pairs and are increasingly integrated into clinical decision support systems [54].

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4.7 Wearables, Mobile Health and Active Surveillance

Wearable devices provide continuous objective measurements of physiology and could have a role in PV. Pilot studies are ongoing into the ability of wearable ECG sensors to detect drug-induced QT prolongation and glucose monitors for drug- induced hyperglycaemia in oncology populations [55]; however, integration with PV has yet to fully materialize.

V. PHARMACOVIGILANCE FOR NOVEL THERAPEUTIC MODALITIES

5.1 Biologics and Biosimilars. Small molecule drugs do not have any of these safety concerns, as it doesn't cause any immunogenicity issues. As biologic drugs manufacture at different facilities they have differences from batch-to-batch, so the EMA specifies unique identifier (Brand Name and Batch number) which helps for the tracking of biologics and biosimilars [56]. So far, real-world data concerning biosimilar TNF inhibitors indicated they are as safe as originator drugs but nocebo effect related with non-medical switching should be cautiously observed [57].

5.2 Advanced Therapy Medicinal Products (ATMPs). Gene and cell therapy are known to take time for its clinical effect, it will be permanently affect body even in long period of time, the EMA GVP Module about ATMPs suggests to continue long- term safety monitoring up to 15 years [58]. CAR-T cells therapy already proved that; the common critical issues that have to be taken care of, were cytokine release syndrome and ICANS [44].

5.3 mRNA vaccines and therapies. Using the knowledge gained from the COVID-19 mRNA vaccines, the mRNA technology has expanded to the field of oncology and rare-disease therapies. Continuous monitoring for infrequent cardiovascular and neurological events remains a key PV priority, Global Vaccine Safety Initiative (GVSI) among others has played a major role on Global data sharing for vaccines safety surveillance [59].

5.4 Herbal, traditional and complementary medicines. Traditional medicines PV are considerably weak, though it is widely used. Skalli and Bencheikh, had mentioned the need for specialized reporting pathways for herb-drug interactions and contamination-related toxicities [60]. According to WHO strategy of traditional medicine 2014-2023, integrated PV systems are essential [3].

VI. CHALLENGES AND LIMITATIONS

6.1 Underreporting and Data Quality

As stated, technology notwithstanding, underreporting is PV's Achilles heel.Lopez- Gonzalez et al identified lack of time, uncertainty regarding causality and insufficient training as the major barriers in the medical world [61] and education on reportinig yields only marginal, transient improvement [62].

6.2 Data heterogeneity and interoperability

Lack of common terminologies and structures hinders combination of data collected by EHR, claims databases, registries and patient reports. While it is promising that common data models like OMOP and FHIR are more broadly used, application of such models has been inconsistent [63].

6.3 Ethical, privacy and regulatory concerns of AI

Algorithmic bias, explainability and accountability have become major concerns with the increasing application of AI in PV. The EU's AI Act (2024) designates certain AI systems for healthcare as 'high-risk' and therefore subject to rules regarding transparency and human oversight [64]. Regulatory bodies such as FDA and EMA have presented reflection papers detailing requirement for validated, reproducible and explainable AI for use in PV [65].

6.4 Disparities between HIC and LIC

Over half of low and middle income countries (LMIC) do not have any functioning national PV centers to date [66] and, as noted by Olsson et al., substantial gaps in the reporting infrastructure, training and regulatory authority persist in parts of Sub- Saharan Africa and South-East Asia [67]. The WHO's Smart Safety Surveillance (3S) project was developed to tackle this challenge, especially as new vaccines and anti- malarials become available [68].

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6.5 Polypharmacy and specific patient populations

The trials have traditionally omitted older adults, pregnant and pediatric patients and the challenge of defining the causal relationship becomes even more complex when polypharmacy is considered, in particular for the geriatric patient, who has as many as 20-30% of hospital admissions attributed to medication [69]. In Europe, the ConcePTION project is building the infrastructure to improve tracking of medication usage during pregnancy and lactation [70].

VII. FUTURE PERSPECTIVES

7.1 Predictive and Precision Pharmacovigilance

The next decade will see PV move from descriptive surveillance towards predictive risk modelling. Combining genomic, proteomic and clinical data could lead to individualised ADR-risk scores integrated into the prescribing workflow [52-54]. This "precision pharmacovigilance" will need validation before early clinical adoption [53].

7.2 Blockchain and Data Provenance

Blockchain has been proposed as a tool to ensure data integrity, provenance, and consent for PV workflows [70]. Pilot projects like MediLedger and the EU's eSafety initiatives demonstrated the viability for ICSR exchange and supply-chain integrity, especially against the risk of falsified medicines [71].

7.3 Federated Learning and Privacy-Preserving Analytics

Training models across decentralized data-sources while keeping raw data local (federated learning) offers a path to private multi-national signal detection [63]. The DARWIN EU and OHDSI networks are already using federated analytics, however further standardization will be necessary [42,63].

7.4 Integration with Digital Therapeutics and the Internet of Medical Things

As the use of DTx and internet-connected medical devices grow, PV will also need to address safety issues in software, such as algorithmic errors and cybersecurity [72]. The FDA's Digital Health Center of Excellence are outlining best practices for SaMD monitoring [72].

7.5 PV in LMICs

To ensure long-term capacity in LMICs investment will be needed in training, infrastructure, and cooperation between regions [73]. The establishment of the AMA in 2023 is an important milestone towards continent-wide PV standards [73], and South-South cooperation has been found effective [67,68].

7.6 Patient Empowerment and Health Literacy

Effective PV is inherently tied to patients. Improving health literacy, designing easier to use reporting systems and transparent communication about drug risks could increase the number and quality of ADR reports [13,45]. Collaborative design where patients work together with developers of PV tools is also gaining ground [74].

VIII. CRITICAL ANALYSIS

While technological progress is transforming PV, several points of caution warrant inclusion: First, AI has not solved the problem of data bias, but may be expected to exacerbate it. Training an AI on FAERS requires it to learn, and transmit, FAERS' own geographical, socio-demographic, and reporting biases [12, 37]. Second, RWE alone is not a panacea, confounding by indication and missing data remain problematic for causality, and regulatory bodies' acceptance of RWE for safety conclusions is a case-by-case matter [41, 43]. Third, the expansion of sources to multiple datasets may create signal saturation-the alert fatigue associated with so many notifications-making it difficult for human reviewers to distinguish meaningful findings from false positives [12, 29].

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A related conflict is the speed vs rigor trade-off. The COVID-19 pandemic revealed the feasibility of real-time and even near-real-time detection systems, but also that signals, whether ultimately proven true (e.g., VITT, myocarditis) or false, have significant public and vaccine hesitancy ramifications when prematurely or carelessly communicated [49-51]. Therefore, investment in rigorous risk communication frameworks is as critical as investment in detection technologies.

The third key point is equity. As data infrastructures continue to be largely concentrated in North America, Europe, and some parts of Asia, a science of safety derived from them is less likely to be relevant for global populations [66-68]. Future advancements in PV will depend as much on more equitable, inclusive data as on smarter algorithms.

IX. CONCLUSION

Pharmacovigilance has come a long way from its post-thalidomide, data entry system roots to today's globally integrated, AI-enabled science. Over the past five years, three simultaneous, and simultaneous, forces – the COVID-19 pandemic, maturing AI/ML capabilities and the integration of real world evidence into decision- making – have pushed PV from a reactive reporting process to a pro-active, predictive, and patient-centric undertaking. Challenges still persist, however – underreporting, data variability, AI regulation ambiguity and a fundamental disconnect between low and high-income systems. Precision medicine technologies, federated and private data analysis, blockchain provenance and patient activation will likely shape the future evolution of PV, but these technological and scientific advancements must be accompanied by robust capacity building within the resource-constrained settings where many patients will be beneficiaries of this transformation, continued education and robust ethical frameworks and sustained global investment and partnership. The true measure of success in modern pharmacovigilance, however, will remain the same as it has always been- preventable harm reduction and sustained trust.

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