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Artificial Intelligence in Pharmacovigilance: Leadership for Ethical AI Integration and Human-AI Collaboration in the Pharmaceutical Industry

1. Nimet Nurdogan Okmen, Pharmacy Advisor, Boots UK.
2. Krishnendu Saha, Graduate School of Management, Birmingham City University, Birmingham, UK. https://orcid.org/0000-0002-7836-2728 (Corresponding author) (krish.saha@bcu.ac.uk)

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Artificial Intelligence in Pharmacovigilance: Leadership for Ethical AI Integration and Human-AI Collaboration in the Pharmaceutical Industry.

Highlights

- A systematic literature review combining bibliometric and content analysis highlights advancements in AI applications in pharmacovigilance.
- Key areas explored include explainable AI, adverse drug reaction detection, and AI's socio-economic impact on pharmaceuticals.
- Addresses critical barriers such as data privacy, regulatory gaps, and ethical concerns in AI adoption.
- Advocates for hybrid systems integrating AI efficiency with human oversight to enhance drug safety processes.
- Highlights AI's potential to streamline pharmacovigilance, reduce costs, and improve patient safety for pharmaceutical companies and regulators.

Abstract:

Purpose

Pharmacovigilance plays a vital role in ensuring medication and vaccine safety, yet it faces persistent challenges, including underreporting, resource-intensive processes, and regulatory complexities. Artificial intelligence has the potential to enhance efficiency, but its adoption requires strategic leadership to navigate automation feasibility, ethical dilemmas, and socio-economic implications.

Design/methodology/approach

This study uses a systematic review with bibliometric and content analysis to address three core questions: the current state of artificial intelligence in pharmacovigilance, the feasibility of full automation, and the ethical dilemmas associated with its adoption. It explores six themes, including explainable AI, effectiveness, predictive applications, social media-based detection, challenges, and models used.

Findings

The findings reveal the growing use of AI, especially machine learning and natural language processing, to improve adverse drug reaction detection and streamline pharmacovigilance. Yet, full automation faces barriers like privacy concerns, regulatory gaps, and data biases. A strategic leadership approach, integrating AI-driven efficiency with human expertise, is essential to maintaining patient safety and public trust. Ethical concerns, including transparency, accountability, and fairness, must be addressed through responsible AI governance frameworks.

Research limitations/implications

The rapid evolution of AI technologies and regulatory frameworks means new insights are increasingly available. Future research should explore leadership strategies, regulatory adaptations, and governance models that ensure ethical and practical AI adoption in pharmacovigilance.

Practical implications

This study offers practical guidance for pharmaceutical companies, regulators, and third-party organisations to integrate artificial intelligence responsibly in pharmacovigilance. It highlights the role of leadership in delivering ethical AI adoption, shaping policy frameworks, and ensuring a balanced approach between technological innovation and human oversight in drug safety management.

Social implications

This study has significant social implications, particularly in enhancing patient safety, improving public trust in drug monitoring systems, and addressing health disparities. Identified challenges such as data privacy concerns, algorithmic biases, and regulatory gaps must be addressed to prevent AI-driven inequities in healthcare.

Originality/value

Unlike existing reviews that primarily focus on technological advancements or regulatory challenges, this research highlights the critical role of leadership in shaping ethical AI adoption and policy frameworks and balancing automation with human oversight. The findings will be valuable for policymakers, industry leaders, and regulators seeking to implement AI responsibly while maintaining trust and compliance in pharmaceutical safety management.

List of abbreviations	
Pharmacovigilance	PV
Artificial Intelligence	AI
Explainable AI	XAI
Adverse Event	AE
Adverse Drug Reaction	ADR
Adverse Drug Event	ADE
Individual Case Safety Reports	ICSR
Food and Drug Administration	FDA
World Health Organisation	WHO
The General Data Protection Regulation	GDPR
The Health Insurance Portability and Accountability Act	HIPAA
Electronic Health Record	EHR
Natural language processing	NLP
Machine Learning	ML
Large Language Model	LLM
Deep Learning	DL
Uppsala Monitoring Centre	UMC
The FDA Adverse Event Reporting System	FAERS

Artificial Intelligence in Pharmacovigilance: Leadership for Ethical AI Integration and Human-AI Collaboration in the Pharmaceutical Industry

1. Introduction

The pharmaceutical industry is rapidly evolving with the integration of artificial intelligence (AI), particularly in drug development, regulatory compliance, and patient safety (McKinsey & Company, 2024). Yet, AI adoption in pharmacovigilance (PV) remains limited due to regulatory complexities, ethical concerns, and data reliability challenges. PV is the science and action that links with the detection, assessment, understanding, and prevention of adverse events related to medications or vaccinations (WHO, 2023). PV, also referred to as drug safety monitoring, primarily focuses on identifying new adverse drug reactions (ADRs) that are unique in their clinical characteristics, severity, or frequency (Alomar et al., 2020). Regulatory authorities such as the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK, and the World Health Organization (WHO) play a significant role in monitoring drug safety and enforcing regulations.

Pharmaceutical companies are legally obligated to conduct PV as an integral part of their post-marketing surveillance, which includes reporting adverse events and maintaining systems that adhere to local and international regulations (Kalaiselvan et al., 2021). It is a critical part of the pharmaceutical industry's operational and strategic framework, as ensuring the safety of marketed and administered drugs is fundamental to maintaining integrity and public trust (Andrews et al., 2014). Managing such complex and critically important surveillance requires effective leadership to navigate evolving regulations, technological advancements, and stakeholder expectations. As AI-driven solutions increasingly reshape PV processes, leaders in the pharmaceutical industry face complex decisions about automation, governance, and human oversight. Although some large companies manage PV in-house, a growing reliance (about one in three drug safety processes, including pre and post-marketing) on third-party organisations (e.g., IQVIA, ICON, Parexel, Covance, and Accenture) (Wasan et al., 2022) reflects an industry-wide shift towards outsourcing, efficiency-driven partnerships, and digital transformation in drug safety monitoring. These changes demand strategic agility, innovation leadership, and ethical foresight to balance technological advancements with regulatory and societal expectations (Marshall et al., 2024).

In 2023, the global PV market was valued at $7.42 billion and is expected to reach $23.45 billion by 2032, with a compound annual growth rate (CAGR) of 13.8% (Fortune Business Insight, 2024). Severe ADRs are associated with substantial costs. For instance, Maity and Longo (2021) conducted a

pharmacoeconomic analysis of Infliximab[1] and Adalimumab[2] using the Canada Vigilance ADR database[3]. They examined the financial impact of ADRs from three perspectives: patients (e.g., loss of productivity and earnings), the health system (e.g., hospital and general healthcare costs), and society. Their findings revealed that severe ADRs caused by Infliximab alone amounted to annual costs of up to $20 million. Therefore, the financial impact of PV positions it as a critical area for both cost control and long-term business strategy.

PV handles vast amounts of data daily on a global scale, encompassing a wide range of reports, from individual case safety reports (ICSRs) to periodic updates (Wadhwa et al., 2020). To illustrate the volume of PV data, VigiBase (https://who-umc.org/vigibase/), managed by the Uppsala Monitoring Centre, contained over 20 million ICSRs for detecting adverse drug reactions (ADRs) as of 2020 (Vogler et al., 2020). Similarly, over the past decade, 21 million adverse events (AEs) have been reported to the FDA's monitoring system (FDA, 2023). The challenge of managing this volume efficiently highlights the strategic opportunity for AI to enhance ADR reporting and management. Digital transformation in PV, therefore, is not only a technological shift but also a strategic imperative for maintaining business competitiveness and ensuring regulatory compliance in the evolving healthcare landscape.

There is a clear need for AI in PV for several reasons (Chauhan et al., 2024). Firstly, PV processes comprise numerous interconnected actions requiring significant time and human input. Consequently, these processes are both costly and time-consuming. Automation can help accelerate these processes and reduce per-case costs (Medhi et al., 2019). Secondly, the low rate of reporting adverse events poses significant risks to patient safety, as unreported ADRs remain a primary concern. This issue stems from factors such as a lack of awareness (with some believing that only severe ADRs need to be reported), complacency (assuming that only approved drugs are safe), insecurity, reluctance to draw attention, and inadequate training for healthcare professionals on ADR reporting (Costa et al., 2023; García-Abeijon et al., 2023). AI can address these challenges by detecting unreported adverse events from diverse large data sets, such as social media, electronic health records, and medical literature (Abrantes et al., 2018). Beyond detection, it is also transforming routine PV operations by taking on repetitive and entry-level tasks, such as conducting literature reviews, data entry for adverse event cases, and case follow-ups, significantly enhancing both speed and accuracy (Satwika, 2021; Shaik et al., 2024).

[1] Common treatment for people with Crohn's and Colitis diseases.
[2] Treatment for (inflammation) by acting on immune system
[3] *See https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-database.html*

Yet, the potential of AI in PV and wider healthcare industry is held back by limitations such as language ambiguities, contextual (e.g., understanding medical, data context and relevance, domain-specific knowledge, patient-specific variability, cultural and regional variations) (Aronson, 2022), regulatory (for example, data safety, privacy and transparency regulations such as GDPR, HIPAA, and PIPL) (Crisafulli et al., 2024; Salvo et al., 2023), and ethical (i.e., algorithmic data fairness and biases) (Naik et al., 2022) challenges of healthcare. The profound implications for human life and health demand strategic oversight in rigorous standards and a cautious, incremental adoption of AI as the technology continues to evolve and prove its reliability (Sun, 2021).

Building on this cautious progress, the vaccine trials during the COVID-19 pandemic (Hashiguchi et al., 2021; Xu et al., 2023) and the rapid advancement of explainable AI (XAI)technologies (Barredo Arrieta et al., 2020; Ryan et al., 2023) accelerated both the adaptation and awareness of AI within the broader healthcare industry, including PV. An analysis of the Scopus database on 4 November 2024 reveals that there are 247 documents specifically related to “artificial intelligence” AND “pharmacovigilance” while searching these terms individually yields 610,402 and 18,786 results, respectively (Scopus, 2024). Although there are a significant number of reviews in PV (e.g. Hodel et al., 2024; Shafi et al., 2024; Dai et al., 2024) and AI (e.g. Qin et al., 2023; Bojsen et al., 2024; Khare et al., 2024) separately, the number of reviews about combination of these two topics are low (e.g. Kompa et al., 2022; Salas et al., 2022).

The existing literature on these intersections (AI and PV) often falls into two categories: (i) highly technical validation-focused studies, and (ii) those emphasising limitations and outcomes. Given that AI and PV represent two distinct fields, diverse approaches have been employed to address their research questions. Our literature search reveals that despite extensive independent research on AI [for example, Meyer et al.’s (2024) review on AI acute care and Huang et al.’s. (2023) work on consumers' adoption of medical artificial intelligence] and PV, studies on strategic leadership in AI implementation remain fragmented. Therefore, as a systematic literature review (SLR), this study examines AI adoption in PV from a strategic and leadership perspective, identifying key trends, challenges, and opportunities for industry decision-makers through the following research questions (RQs):

RQ1: What is the current state of artificial intelligence implementations in pharmacovigilance, and which methodologies are being followed?
RQ2- Can pharmacovigilance become fully automated?

RQ3- What are the ethical dilemmas regarding artificial intelligence implementation in pharmacovigilance?

To address these research questions, we systematically analyse the literature on PV and AI using a combination of bibliometric and content analysis. This approach goes beyond methodological triangulation as we explore the balance between human and artificial intelligence. In so doing, we also provide a strategic perspective on AI adoption in high-quality PV practices, evaluate the arguments against fully automated PV, and determine which tasks are best suited for human oversight versus AI. This research also provides a unique and comprehensive overview of PV and its automation by examining its economic impact as a business, regulatory challenges in the healthcare sector, and advances in AI technologies. The absence of business and management literature on PV, despite its substantial economic and social importance, further confirms the novelty of this review.

The structure of this paper is as follows: first, the methodological approach is outlined in section 2. Next, the results and analysis are presented in section 3. This is followed by a discussion section that shares thoughts for future research and acknowledges the limitations of this review in section 4 before drawing a conclusion.

2. Methodological approach

This study employed bibliometric analysis and content analysis. The bibliometric analysis was conducted to identify major trends, followed by content analysis to qualitatively extract and analyse the main themes (Saha et al., 2024). Our dual-method analysis effectively addresses the three research questions (RQs) by providing a comprehensive view of the field. The bibliometric analysis identifies key scholars, influential works, and thematic clusters relevant to current AI implementations in PV, addressing RQ1. The content analysis complements this by examining how AI is applied in PV, exploring the balance between human oversight and automation, which directly informs RQ2. Additionally, by coding and categorising articles based on themes such as ethical challenges, our analysis addresses RQ3- the key concerns and regulatory issues in AI implementation.

The study is underpinned by critical realism (Bhasker, 2012) philosophy and supports integrating quantitative and qualitative methods for a deeper understanding. PRISMA has been used during the data collection process of this study (Page et al., 2021) (Figure 1). The literature search was conducted on 29 March 2024 through the Scopus database using keywords: “Pharmacovigilance” AND "artificial intelligence" AND (“adverse event " OR "adverse drug reaction”) OR (“Machine Learning" OR NLP) OR

(" Business Efficiency" OR "Cost-Benefit" OR "Regulatory Compliance"). This yielded an initial sample of 138 articles under the “Article title, Abstract, Keyword” filter. Inclusion and exclusion criteria were rigorously applied. We only selected studies in the English language that were published between 2018 to 2024. This timeframe was chosen to capture the most recent and relevant advancements in AI technologies and their applications in PV, especially considering the surge in AI developments and regulatory responses following the COVID-19 pandemic.

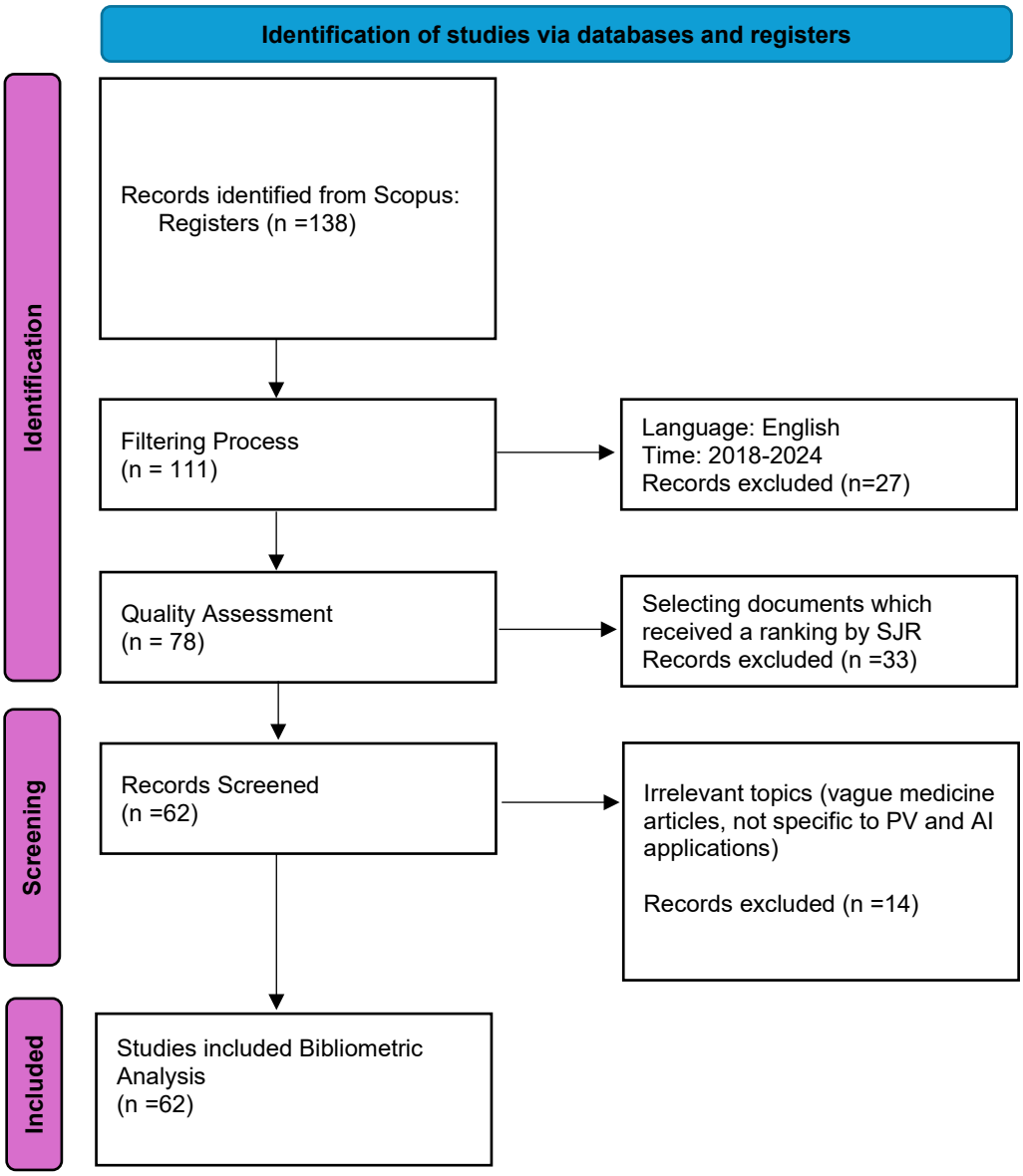

Figure 1: PRISMA METHOD

Source: Authors’ elaboration of the PRISMA model.

2.1. Bibliometric review process

We apply author co-citation analysis, keyword co-occurrence analysis, and bibliographic coupling to uncover citation patterns and group related documents within the field of AI in PV. Author co-citation analysis measures how often authors are cited together, serving three primary purposes: (i) identifying influential scholars within the AI-PV domain, (ii) revealing the connections between these scholars, and (iii) providing insights into the main themes and research directions within the field (Donthu et al., 2021). Keyword co-occurrence analysis determines how frequently specific terms appear together in the literature, uncovering common topics and themes while highlighting key focus areas and emerging trends in AI-PV research. Bibliographic coupling examines the similarity between the reference lists of different academic works, identifying articles that share a conceptual basis and revealing emerging topics and areas in the field (Nwagwu, 2024). We employed the VOSviewer (Van Eck & Waltman, 2017) for the bibliometric reviews.

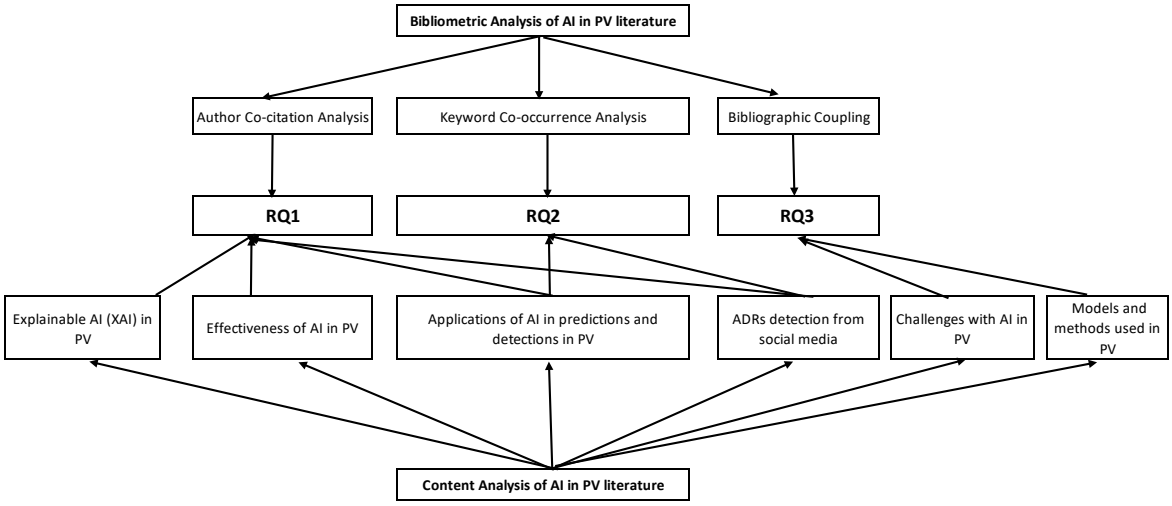

Figure 2: Methodological approaches for artificial intelligence (AI) in pharmacovigilance (PV) review

Source: Authors' elaboration of adopted methodological approaches.

2.2. Content analysis process

In this paper, we conduct content analysis to critically review selected articles, evaluating the impact of AI implementations on different PV-related variables (Gheyle & Jacobs, 2017). To ensure the quality of the selected literature, articles were evaluated using the SCImago Journal Rank (SJR) indicator, which assesses a journal's prestige by considering the quality of its citing sources rather than just citation counts (Mañana-Rodríguez, 2015). The abstracts of 111 papers (identified using our inclusion and exclusion criteria, figure 1) were meticulously reviewed for content analysis. Each journal was assessed for inclusion in the SJR system, and its h-index score was recorded. This quality screening

excluded 33 articles that did not meet the required standards, reducing the pool to 78 articles for further consideration. Articles were then evaluated for relevance to the study's three research questions (RQs). For this, we thoroughly read and coded the eligible articles based on six key themes: (i) XAI in PV; (ii) effectiveness of AI in PV; (iii) applications of AI in predictions and detections in PV; (iv) ADRs detection from social media; (v) challenges with AI in PV, and (vi) different models and methods have been used in PV. Each article's relevance was rated on a scale from 1 (low) to 3 (high) for its connection to the three RQs, resulting in a score out of 9. Articles were categorised as high relevance (score >7), medium relevance (score 4-6), or low relevance (score <4), yielding a refined selection of 62 articles (21 high, 38 medium, and 3 low relevance) from the original sample (Saha et al., 2024), as detailed in Table 1.

Table 1. Selected articles for content analysis

Nos.	Authors	H Index	SJR	RQ1	RQ2	RQ3	Total	Relevance to review scope
1	Al-Azzawi et al. (2023)	140	Q1	2	2	1	5	Medium
2	Alimova and Tutubalina (2018)	71	Q2	2	1	1	4	Medium
3	Aronson (2022)	140	Q1	3	2	1	6	Medium
4	Ball and Dal Pan (2022)	140	Q1	3	3	2	8	High
5	Basile et al. (2019)	244	Q1	3	2	2	7	High
6	Bate and Hobbiger (2021)	140	Q1	3	3	2	8	High
7	Bate and Luo (2022)	140	Q1	3	3	1	7	High
8	Bate and Stegmann (2023)	37	Q1	3	2	2	7	High
9	Beninger P. (2018)	150	Q1	2	1	1	4	Medium
10	Bhardwaj et al. (2023)	43	Q3	3	3	2	8	High
11	Chan et al. (2022)	56	Q1	3	2	2	7	High
12	Danysz et al. (2019)	58	Q1	2	2	1	5	Medium
13	Davidson and Boland (2020)	138	Q2	2	1	1	4	Medium
14	De Pretis et al. (2021)	87	Q2	3	2	1	6	Medium
15	Del Rio-Bermudez et al.(2020)	32	Q1	3	3	2	8	High
16	Destere et al. (2024)	167	Q1	3	3	2	8	High
17	Di Giovanni et al. (2022)	109	Q1	3	2	1	6	Medium
18	Edrees et al.(2022)	140	Q1	2	1	1	4	Medium
19	Haigney (2023)	19	Q1	3	3	2	8	High
20	Hauben (2022)	109	Q1	1	2	2	5	Medium
21	Hauben (2023)	150	Q1	2	2	2	6	Medium
22	Hauben and Hartford (2021)	150	Q1	2	2	1	5	Medium
23	Hussain et al. (2022)	56	Q1	3	2	2	7	High

24	Kalaiselvan et al. (2021)	32	Q2	2	2	1	5	Medium
25	Kassekert et al. (2022)	140	Q1	3	2	1	6	Medium
26	Khademi Habibabadi et al. (2023)	140	Q2	2	2	1	5	Medium
27	Klang et al. (2023)	108	Q2	2	2	3	7	High
28	Kompa et al. (2022)	435	Q1	3	2	2	7	High
29	Lamberti et al. (2019)	150	Q1	2	1	1	4	Medium
30	Le Louët and Pitts (2023)	41	Q1	3	3	2	8	High
31	Lee et al. (2023)	242	Q1	3	2	1	6	Medium
32	Létinier et al. (2021)	209	Q1	3	2	1	6	Medium
33	Li et al. (2022)	470	Q1	2	2	1	5	Medium
34	Li et al. (2024)	128	Q1	3	1	1	5	Medium
35	Martin et al. (2018)	43	Q1	3	2	2	7	High
36	Martin et al. (2022)	70	Q1	3	2	1	6	Medium
37	Menz et al. (2024)	390	Q1	1	1	3	5	Medium
38	Mockute et al. (2019)	25	Q2	3	3	2	8	High
39	Montastruc et al. (2023)	123	Q2	1	1	1	3	Low
40	Murphy et al. (2023)	25	Q1	2	2	1	5	Medium
41	Ng et al. (2020)	113	Q1	1	1	1	3	Low
42	Pinheiro and Kurz (2022)	109	Q1	3	2	3	8	High
43	Powell et al. (2022)	154	Q1	1	2	1	4	Medium
44	Price (2018)	150	Q1	2	1	1	4	Medium
45	Rifat et al. (2019)	242	Q1	3	2	1	6	Medium
46	Roche et al. (2023)	110	Q1	3	2	1	6	Medium
47	Roosan et al. (2022)	167	Q2	3	2	1	6	Medium
48	Ryan et al. (2024)	140	Q1	2	1	1	4	Medium
49	Salas et al. (2022)	25	Q2	3	2	1	6	Medium
50	Salvo et al. (2023)	90	Q1	2	3	2	7	High
51	Sandeep et al. (2022)	203	Q1	2	2	1	5	Medium
52	Satwika et al. (2021)	42	Q3	3	3	2	8	High
53	Schmider et al. (2019)	140	Q1	3	2	2	7	High
54	Singh et al. (2024)	60	Q1	2	1	2	5	Medium
55	Stergiopoulos et al. (2019)	90	Q2	2	2	1	5	Medium
56	Streefland (2018)	150	Q1	2	2	1	5	Medium
57	Trifirò et al. (2018)	140	Q1	1	1	1	3	Low
58	Vo et al. (2023)	16	Q2	3	1	1	5	Medium
59	Wang et al. (2021)	64	Q4	2	2	1	5	Medium
60	Ward et al. (2021)		Q1	2	2	2	6	Medium
61	Xu et al. (2019)	52	Q2	2	1	1	4	Medium
62	Zheng et al. (2022)	51	Q1	3	3	2	8	High

Source: Authors' analysis of reviewed literature.

Figure 2 illustrates how our bibliometric and content analysis methods collectively address our RQs. In the following section, we present the findings derived from our analysis.

3. Results and Analysis

The results of our bibliometric review and content analysis are presented in this section. We identify the key research patterns through author co-citation, keyword co-occurrence, and bibliometric coupling, in this section. These tools provide a comprehensive mapping of the research landscape, highlighting core themes, influential authors, and emerging trends within the field.

Keywords Co-occurrence Analysis

Pharmacovigilance and artificial intelligence were used as keywords for the research, and as a result, they received the highest number (63 and 58, respectively). Human (53), machine learning (37), and drug surveillance programs (35) followed with high occurrence rate. Looking at the AI domains, machine learning (ML) has the highest occurrence at 40, natural language processing (NLP) second at 23, and data mining at 11 and deep learning at 13. It shows (Figure 3) that ML and NLP have been researched more and are becoming common in pharmacovigilance. However, deep learning and data mining are relatively new and undiscovered in the field.

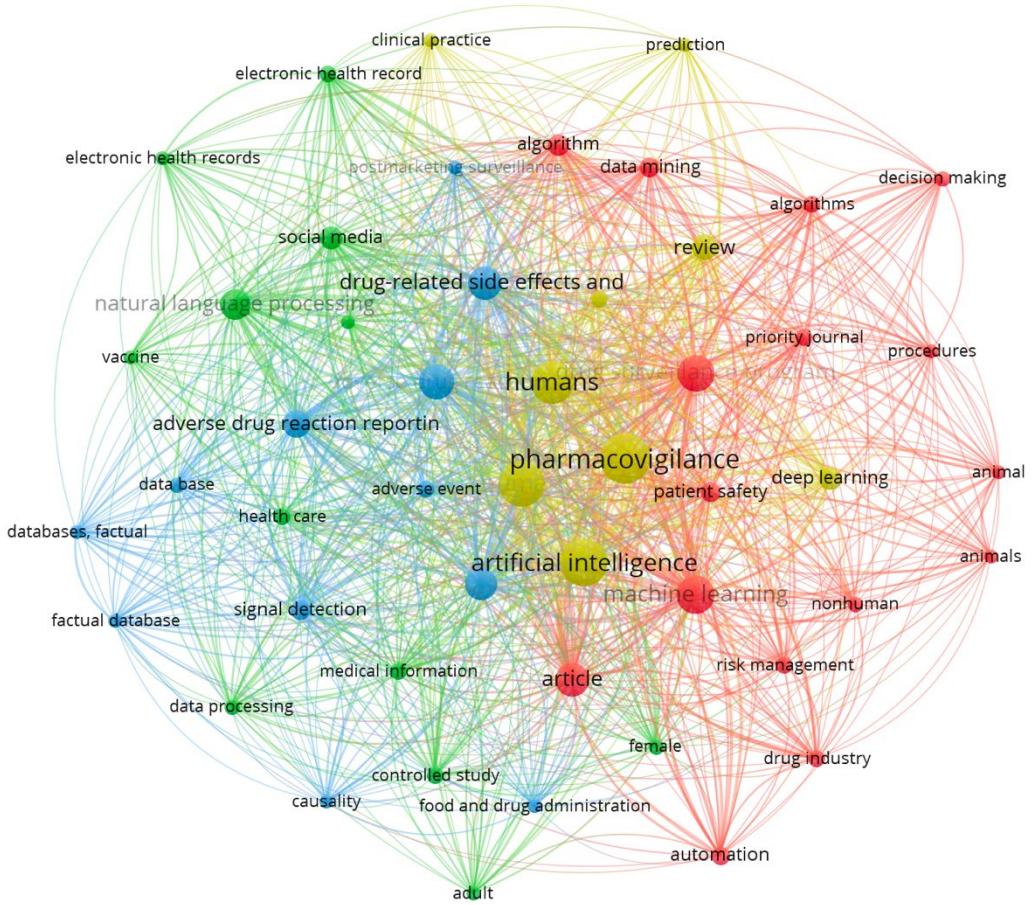

Figure 3. Analysis of Keyword Co-occurrence [Minimum number of occurrences of a keyword is 5]

Source: Authors' elaboration of VOS Viewer analysis.

Additionally, it has been realised that "social media" and "electronic health record/records" are commonly used keywords. These platforms provide a high volume of data (Abrantes et al., 2018), and it may lead researchers and PV professionals to find a way to apply automation on these platforms. "Drug-related side effects and adverse reactions" has been a trend with 28 because PV aims to monitor them, and AI has been found to be an effective tool. Detecting and monitoring ADRs are the fundamental topics of PV, and aiming to increase the pace leads to AI involvement (Edrees et al., 2022). Therefore, future research will continue to put these research topics at the core and expand according to new advancements in AI.

Author co-citation analysis

Author co-citation is a widely used technique to show intellectual framework by showing which authors are cited together (Jeong et al., 2024). In this study, we implemented a minimum of 10

citations, and 42 thresholds were met with 738 links and 7110 total link strengths. This approach reduces the chance of a random co-citation relationship. The most prominent author in the field is Bate A., who is the strongest node with 59 citations and 1227 strengths.

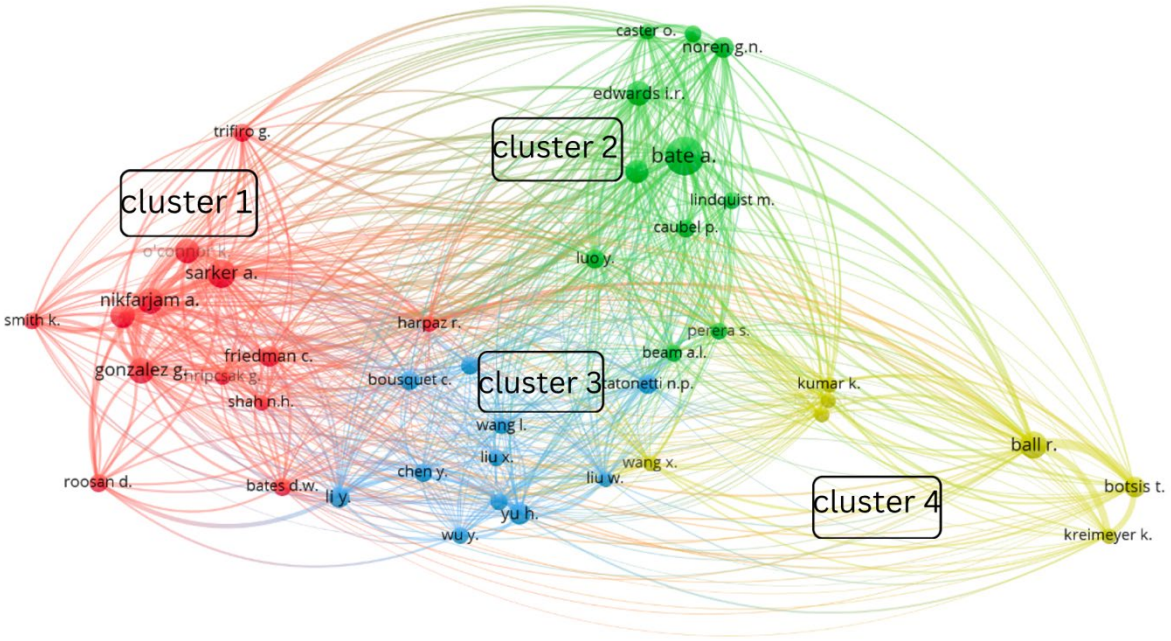

Figure 4: Co-citation analysis [Minimum number of citations is 10]

Source: Authors' elaboration of VOS Viewer analysis.

Authors in cluster 1, which is shown in red colour, focus on how efficient the AI models and domain are in PV processes (Figure 4). The authors in cluster 3, with blue colour, emphasise the potential benefits and challenges of AI in PV and their role in improving patient safety. Cluster 2 is shown with green, and the theme is ADR detections from different social media platforms. Finally, the yellow colour represents cluster 4 and the central theme, classifying and detecting ADRs using AI from such documents as FDAERS and VAERS. Table 2 presents the authors in each cluster.

Table 2. Author Co-citation Analysis Data

Clusters	Paper counts	Total citations	Average citations	Documents in clusters	Highest cited paper
Cluster 1: RED Efficiency and Accuracy of AI models and domains	13	233	17.92	Bates D.W., Friedman C., Ginn R., Gonzalez G., Harpaz R., Hripcsak G., Nikfarjam A., O'connor K., Roosan D., Sarker A., Shah N.H., Smith K., Trifiro G.	Sarker A. (32)

Cluster 2: GREEN ADRs detections from different social media platforms	11	206	18.73	Bate A., Beam A. L., Caster O., Caubel P., Edwards I.R., Hauben M., Lindquist M., Luo Y., Noren G.N., Orre R., Perera S.	Bate A. (59)
Cluster 3: BLUE Potential benefits and challenges	11	148	13.45	Aronson J.K., Bousquet C., Chen Y., Li J., Li Y., Liu W., Liu X., Tatonetti N.P., Wang L., Wu Y., Yu H.	Yu H. (19)
Cluster 4: YELLOW Classifying and detecting of ADRs by using AI from such document	7	96	13.71	Ball R., Botsis T., Kreimeyer K., Kumar K., Laforest C., Schmider J., Wang X.	Ball R. (29)
Total	42	683			

Source: Authors' analysis of reviewed literature.

Bibliometric Coupling (Documents)

Bibliographic coupling is discovering connections between documents based on the references they share. It is a way to determine how ideas in one paper might be linked to another, even if those papers are new and have not been cited many times (Pandey et al., 2024). The minimum number of citations was 5, and 62 documents were used. As a result, 37 thresholds were met, and 153 links were created, with a total strength of 260 (Figure 5).

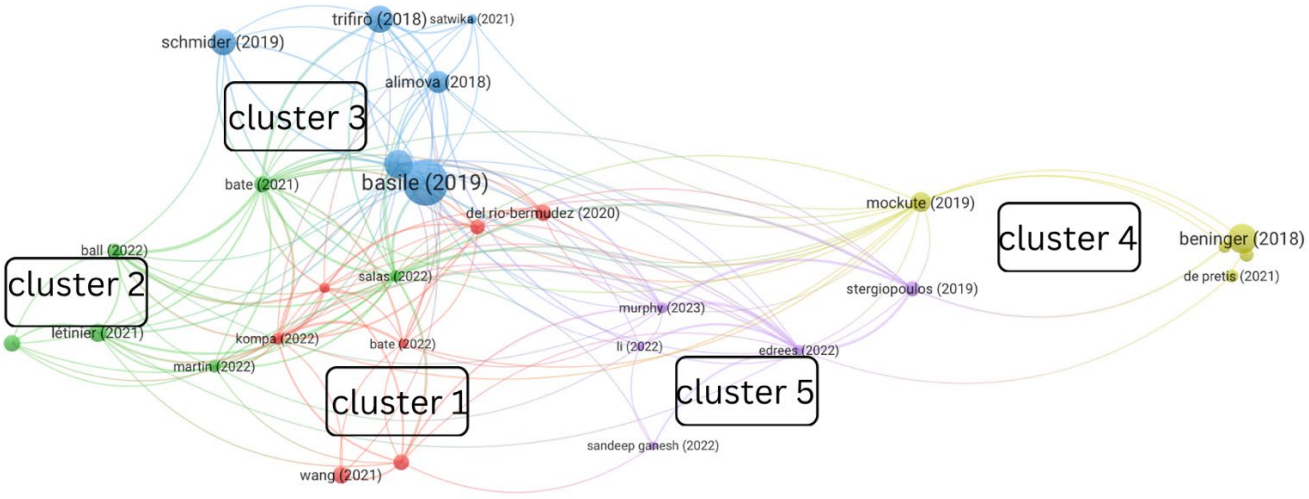

Figure 5: Bibliometric coupling [Minimum number of citations is 5]

Source: Authors' elaboration of VOS Viewer analysis.

There were 5 clusters, the first 2 clusters involved 13 documents and are represented by red and green colours in Figure 4. Blue presented cluster 3 with 6 documents, and Basile (2019) has the highest number of citations with 137. Cluster 4, represented by a yellow colour on the table, concludes five papers and cluster 5 is shown by purple colour with five items on figure 4. Basile (2019) is the most cited paper among all the papers. This is because it provides a comprehensive review of how AI models affect current drug safety with practical examples in real-life tools. The paper covers a wide range of topics, such as the limitations of traditional drug safety practices and the innovative uses of AI in pre-clinical drug safety and post-marketing surveillance. We think these are the reasons that the paper has been cited by the high volume of other papers.

3.2. Content Analysis: Key Thematic Areas within AI in PV

Our content analysis, guided by findings from the bibliometric analysis, maps out the key thematic areas within the field of study. The analysis focused on six primary themes (figure 2). The key areas (PV, AI, ML, and NLP) identified from the keyword co-occurrence analysis influenced our focus on the effectiveness of AI in PV and applications of AI in predictions and detections. Keywords like “social media” and “electronic health records” lead to the inclusion of ADR detection from social media as a distinct theme in our content analysis. The author's co-citation analysis revealed clusters aligned with specific themes in our content analysis. For example, cluster 1 informed our exploration of how AI models improve data extraction and processing in PV, and Cluster 3 emphasised potential benefits and challenges, reinforcing the importance of including ethical dilemmas transparency issues, and data biases in our analysis. Bibliometric coupling further supported our content analysis by identifying influential documents that link shared ideas. The high citation count of Basile (2019) establishes the importance of classifying and detecting ADRs and reinforces our focus on models and methods used in PV.

Explainable AI (XAI) in PV

Explainable AI (XAI) plays an essential role in increasing transparency within AI-driven PV processes. This transparency builds trust among healthcare practitioners by clarifying the reasoning behind AI decisions, which is crucial for informed decision-making (Lee et al., 2023; Martin et al., 2022). Ward et al. (2021) demonstrated the use of XAI models such as LIME and SHAP[4] to identify key elements and

[4] LIME (Local Interpretable Model-Agnostic Explanations) and SHAP (SHapley Additive exPlanations) are tools that help explain how AI models make decisions. LIME works by tweaking input data to see how predictions change. SHAP assigns importance scores to different features to show how much each one contributed to the outcome. These tools

specific drugs influencing AI predictions. Using data from the Western Australian health databases, their study showed that nonsteroidal anti-inflammatory drugs, like Rofecoxib and Celecoxib, significantly impacted the risk of acute coronary syndrome. Hauben (2022) highlighted the utility of XAI for monitoring, developing, and managing drug safety signals, noting that understanding AI model behaviour and robustness enhances the safety assessment process. However, Hauben also argued that the need for XAI depends on specific use cases in PV, as some processes may require less explainability when focusing on routine safety monitoring rather than critical safety issues. Ethical discussions on balancing the need for transparency with the complexity of AI models continue, as making all models explainable is not always practical (Cheng et al., 2021; Pinheiro & Kurz, 2022).

Effectiveness of AI in PV

AI has proven to significantly enhance the efficiency and effectiveness of PV processes. This improvement is particularly evident in data extraction and analysis tasks, such as detecting duplicate reports and anomalies, which optimises overall workflow (Bate & Stegmann, 2023). The use of ML and NLP for analysing unstructured data from sources like EHRs enables faster identification of adverse reactions and medication errors (Del Rio-Bermudez et al., 2020; Edrees et al., 2022). Studies (i.e., Li et al., 2024; Wong et al., 2018) evidenced the substantial time savings of these technologies, as one hour of NLP development can replace up to 20 hours of manual EHR review. Furthermore, a survey indicated that 61% of biopharmaceutical companies plan to implement ML in their full ICSR processes-a testament to AI's growing role in handling safety data and augmenting human expertise (Stergiopoulos et al., 2019). While full automation is not yet achievable, current AI applications provide critical support by improving efficiency and enabling PV experts to focus on more complex tasks (Kassekert et al., 2022).

Applications of AI in Predictions and Detections in PV

AI applications in PV are diverse-for example, predicting and detecting adverse drug events (ADEs) from various data sources such as EHRs, social media, and insurance claims (Del Rio-Bermudez et al., 2020; Edrees et al., 2022). AI technologies can effectively process unstructured data, facilitating the identification of potential ADEs and medication errors, ML models have shown the potential to improve prediction accuracy and expand the scope of ADR surveillance beyond traditional data sources, enhancing the capability of PV systems (Kassekert et al., 2022). Despite these advancements,

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are particularly useful in pharmacovigilance, where understanding AI's reasoning is crucial for transparency, trust, and meeting regulatory requirements.

AI is primarily used to augment human analysis rather than fully automate the process, reinforcing the importance of collaborative human-AI systems.

Models and Methods Used in PV

A variety of AI models and methods are used in PV, from basic ML algorithms to more complex neural networks. The process typically begins with meticulous data collection and pre-processing, followed by dividing the data into training and testing sets. Cross-validation and benchmarking are conducted to ensure the robustness of the model, with performance assessed using metrics such as the F1 score. The F1 score, which balances precision and recall, provides an average measure of these two metrics. It is commonly used to assess the performance of ML models in identifying adverse drug reactions (ADRs) from patient reports (Létinier et al., 2021; Montastruc et al., 2023). An AI model can work well on average; however, it may give errors on subgroups of rare diseases and adverse events. To address these challenges and enhance automation efficiency, PV professionals apply the no-free-lunch theorem (which suggests no single model is universally optimal) by leveraging multiple tools and comparing models and parameters to identify the most effective solutions for specific pharmacovigilance tasks (Davidson & Boland, 2020; Kassekert et al., 2022). To this end, Ball and Dal Pan (2022) and Edrees et al. (2022) emphasised that performance metrics should encompass validity, generalisability, non-bias, and transparency to ensure that models function effectively in real-world PV settings.

ADRs Detection from social media

Social media has emerged as a significant data source for ADR detection due to the high volume of health-related information users share. Research (e.g., Wong et al., 2018) shows that approximately 60% of Americans use social media platforms to seek and share health information. Platforms such as Twitter, which generates around 500 million tweets per day, provide an expansive dataset that is challenging to process manually. Therefore, NLP tools are commonly used to extract and analyse ADR data from these platforms (Alimova & Tutubalin, 2018; Khademi et al., 2023). Studies (e.g., Rifat et al., 2019) have demonstrated that AI can effectively extract ADRs from social media and identify misuse patterns, making social media a valuable addition to traditional PV data sources. Consider the study by Rifat et al., who used AI to analyse opioid-related events on Twitter, demonstrating that AI can detect not only ADRs but also patterns of drug misuse. This capability allows for real-time monitoring and early detection of potential safety concerns, although it requires sophisticated AI tools to handle the informal and varied nature of social media language (Powell et al., 2022).

Challenges with AI in PV

Implementing AI in PV comes with three major challenges, (i) language limitations, (ii) data privacy concerns, and (iii) bias in training data. One of the primary issues is the limited support for languages other than English, which restricts the global applicability of many AI tools (Murphy et al., 2023). Language ambiguities, such as lexical and grammatical complexities, can also affect data interpretation, as Aronson (2022) has seen with terms that have multiple meanings in medical literature.

Data security and patient privacy remain significant concerns, mainly when extracting information from EHRs. Although tools for anonymising data exist, the effectiveness of these solutions varies, especially when data is combined from different sources (Del Rio-Bermudez et al., 2020). Bias in training data is the third major limitation; models trained on incomplete or skewed datasets can produce inaccurate results, as seen in algorithms that underperform for minority populations (Ryan et al., 2023). The black-box nature of many AI models, which makes their decision-making processes difficult to interpret, poses further challenges to transparency and accountability (Hauben, 2022).

4. Discussion

This systematic review addresses three critical research questions: current state and methodologies of AI implementations (RQ1), assess the feasibility of full automation (RQ2), and explore the ethical dilemmas related to AI in PV (RQ3).

Our findings highlight that AI is increasingly integrated into PV processes, primarily leveraging ML and NLP (RQ1). These technologies are widely applied to extract, organise, and analyse unstructured data from electronic health records (EHRs) and social media. This capability significantly improves the detection and analysis of ADRs (Rifat et al., 2019). The bibliometric analysis showed that "pharmacovigilance," "artificial intelligence," "machine learning," and "natural language processing" are dominant research focuses, supported by the work of key contributors like Bate et al. (2020; 2022; 2023). Influential studies, such as Basile (2019), confirm that while AI is used across different PV steps, its integration varies by organisation size, regional regulations, and resource availability. This variability reflects the different levels of AI adoption and highlights a partial but significant reliance on AI to augment human-led PV processes.

Balancing Innovation, Ethics, and Regulatory Alignment: A Strategic Leadership Approach

The review indicates that, despite AI's substantial potential for automating high-volume tasks, full automation of PV is not currently feasible (RQ2). AI functions best as an augmentation tool, enabling PV professionals to concentrate on complex tasks requiring clinical judgment, ethical decision-making, and contextual interpretation. Strategic leadership is essential in guiding AI integration and supporting professionals in complex decision-making areas such as clinical judgment, ethical considerations, and regulatory compliance.

The COVID-19 pandemic demonstrated the importance of AI for managing increased workloads (new vaccine reports) and leading regulatory bodies to issue updates. However, these have not kept pace with AI's rapid evolution, and updated guidelines are needed. While some companies have begun integrating AI into their PV systems, these implementations remain in the early stages. The human-in-the-loop model, where humans oversee and guide AI outputs, ensures transparency and reliability. This structure enables AI to handle routine tasks while human expertise addresses patient safety and complex assessments. Barriers such as data security, privacy concerns, and biases in training data further limit full automation. Consequently, fully automated PV is neither practical nor desirable at this stage. These challenges and ethical and regulatory alignment issues highlight the need for dynamic leadership to develop a hybrid system that combines AI-driven efficiency with human oversight to mitigate risks and maintain trust in PV operations.

The ethical dilemmas surrounding AI in PV are significant and multifaceted (RQ3), as data privacy and security remain the primary concerns. Using personal health data to train AI models introduces risks related to patient confidentiality and the potential for data breaches. Moreover, biases in training datasets can lead to skewed outcomes, adversely impacting patient safety and undermining trust in AI systems. For instance, biases in data collection can lead to models that perform less accurately for underrepresented groups and exacerbate existing disparities in healthcare outcomes. The black-box nature of many AI models compounds these challenges, as it limits the transparency needed for stakeholders to understand how decisions are made. Our findings suggest that explainable AI (XAI) can make AI decision-making processes more transparent and enhance confidence among healthcare professionals and patients. Regulatory authorities are attempting to bridge the gap between existing frameworks and rapid technological advancements; however, this gap poses ongoing challenges for ethical and compliant AI implementation.

Our findings are broadly convergent with existing reviews such as Kompa (2022) and Salas (2022), reinforcing key themes surrounding the integration of AI in PV. Specifically, our results, akin to those in Salas and Kompa, illustrate how AI technologies such as ML and NLP contribute to managing large

volumes of data, detecting ADRs, and improving signal detection processes. For instance, using NLP to extract unstructured data from electronic health records (EHRs) and social media was highlighted as a standard practice across these reviews. Beyond these similarities, our findings converge on recognising challenges in AI implementation.

We reveal significant ethical and regulatory challenges, such as the risk of biases within training data, concerns over data privacy (for example, algorithmic biases can undermine the accuracy of ADR detection, notably when training data lacks representation of diverse populations), and compliance with international regulations like the GDPR and HIPAA (here, we refer to the complexities of integrating AI models with evolving regulatory standards). From a strategic leadership perspective, PV requires proactive governance, adaptive decision-making, and responsible innovation in such circumstances (Marshall et al., 2024). Pharmaceutical and health leaders must address biases within training data, ensuring diverse representation to improve the accuracy of adverse drug reaction detection.

While these points of agreement exist, our study presents a unique contribution in several key areas. Unlike existing reviews, which mainly focus on AI's current technological capabilities and limitations, our paper incorporates a broader methodological approach that includes bibliometric analysis alongside content analysis. This combined method provides a comprehensive overview of publication trends, co-citation relationships, and the evolution of critical topics in AI and PV. Moreover, our work distinguishes itself by exploring the socio-economic implications of AI in PV, an emerging topic that has largely been ignored in the current technology-focused research. We probe into how adopting AI can alleviate the financial burden on pharmaceutical companies by streamlining processes and reducing manual workload, potentially leading to cost savings and increased operational efficiency. This economic perspective is essential for PV leaders who must balance investment in new technologies with expected returns and compliance with regulatory mandates.

Contradicting evidence also emerged in our study, particularly concerning the feasibility of full automation in PV. While existing reviews (i.e., Kompa, 2022; Salas. 2022) acknowledge that AI can significantly automate various aspects of PV, we emphasise the necessity of human expertise to oversee complex decision-making processes. This is supported by studies (e.g., Ball and Dal Pan, 2022) that indicate that fully automated systems struggle with nuanced assessments such as causality determination, which requires human judgment. Therefore, AI should be viewed as a supportive tool parallel to automation in the aviation industry, where human oversight is essential for final decision-making. Accordingly, our position resonates with broader leadership challenges in digital

transformation, where balancing automation with human judgment is essential for maintaining trust, accountability, and adaptability in evolving regulatory landscapes. Nevertheless, our paper expands on this by assessing how different levels of automation impact PV practices and safety outcomes.

Future research should recognise the dynamic nature of the field, necessitating ongoing systematic reviews to provide updates as the research evolves. The current state of PV is continually influenced by regulatory updates, making it essential for future studies to track new announcements and guidance from global authorities such as the FDA, MHRA, EMEA, HC, and other international regulators. The challenges and limitations related to AI applications in PV will evolve alongside advancements in AI technology. Therefore, examining pilot studies and assessing their methodologies and validity will offer practical insights. Research based on real-world data from PV and pharmaceutical companies will be valuable for understanding the current limitations from multiple perspectives.

Ethical concerns, especially those around patient confidentiality, data privacy, and unbiased decision-making, are also crucial areas for exploration. Future research should aim to develop ethical frameworks to address these issues while proposing solutions to improve transparency in AI-driven decision-making for PV professionals. Moreover, the economic impact of AI implementation in PV warrants further investigation, as AI has the potential to reduce costs for pharmaceutical companies by streamlining PV processes. Research into the financial benefits of AI in PV can provide a clear roadmap to guide future investments and collaborations among interdisciplinary teams.

Early detection of ADRs can significantly decrease hospitalisations, patient fatalities, and the economic impact of lawsuits and costly drug withdrawals. Due to its capability to handle high-volume data efficiently, AI presents a practical solution for pharmaceuticals, third-party research organisations, and regulators to enhance early detection efforts. For PV professionals—especially those operating at the strategic level—this research serves as a practical guide to understanding the evolving PV landscape and preparing for AI's increasing role. Pharmaceutical industry stakeholders can also use this study as a guideline to address emerging safety concerns, adopt AI responsibly, and maintain regulatory compliance.

6. Conclusion

This study provides a comprehensive overview of the current state of AI applications in PV, outlining the methodologies, benefits, and ongoing challenges. Nonetheless, central to our conclusion is the question: can machines truly replace the nuanced judgment and empathy of human experts, or does

the complexity of patient safety require a balance between algorithmic precision and human insight? Full automation offers the promise of seamless efficiency, yet human involvement, with its empathy and interpretative skill, remains essential. Ethical concerns related to data privacy, bias, and the black-box nature of AI decision-making raise profound questions about trust and fairness. The challenge is not whether PV can be fully automated, as we find, but how business leaders balance technological progress with ethical and responsible healthcare practices. This balance is essential to maintaining trust, ensuring transparency, and safeguarding the foundational values of patient safety.

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Appendices

Appendix 1

Nos.	Authors	Source Title	H Index	SJR	RQ1	RQ2	RQ3	Total	Relevance to review scope
1	Li et al. (2024)	Journal of Biomedical Informatics	128	Q1	3	1	1	5	Medium
2	Lee et al. (2023)	IEEE Access	242	Q1	3	2	1	6	Medium
3	Del Rio-Bermudez et al.(2020)	Journal of Pharmaceutical Policy and Practice	32	Q1	3	3	2	8	High
4	Bate and Luo (2022)	Drug Safety	140	Q1	3	3	1	7	High
5	Létinier et al. (2021)	Clinical Pharmacology and Therapeutics	209	Q1	3	2	1	6	Medium
6	Beninger P. (2018)	Clinical Therapeutics	150	Q1	2	1	1	4	Medium

Nos.	Authors	Source Title	H Index	SJR	RQ1	RQ2	RQ3	Total	Relevance to review scope
7	Al-Azzawi et al. (2023)	Drug Safety	140	Q1	2	2	1	5	Medium
8	Price (2018)	Clinical Therapeutics	150	Q1	2	1	1	4	Medium
9	Montastruc et al. (2023)	European Journal of Clinical Pharmacology	123	Q2	1	1	1	3	Low
10	Hauben (2023)	Clinical Therapeutics	150	Q1	2	2	2	6	Medium
11	Wang et al. (2021)	Frontiers in Artificial Intelligence	64	Q4	2	2	1	5	Medium
12	Basile et al. (2019)	Trends in Pharmacological Sciences	244	Q1	3	2	2	7	High
13	Hauben (2022)	Pharmacoepidemiology and Drug Safety	109	Q1	1	2	2	5	Medium
14	Singh et al. (2024)	Expert Review of Clinical Pharmacology	60	Q1	2	1	2	5	Medium
15	Menz et al. (2024)	JAMA Internal Medicine	390	Q1	1	1	3	5	Medium
16	Ball and Dal Pan (2022)	Drug Safety	140	Q1	3	3	2	8	High
17	Edrees et al.(2022)	Drug Safety	140	Q1	2	1	1	4	Medium
18	Xu et al. (2019)	Topics in Companion Animal Medicine	52	Q2	2	1	1	4	Medium
19	Rifat et al. (2019)	IEEE	242	Q1	3	2	1	6	Medium
20	Lamberti et al. (2019)	Clinical Therapeutics	150	Q1	2	1	1	4	Medium
21	Ward et al. (2021)	Computer Methods and Programs in Biomedicine		Q1	2	2	2	6	Medium
22	Davidson and Boland (2020)	Journal of Pharmacokinetics and Pharmacodynamics	138	Q2	2	1	1	4	Medium
23	Martin et al. (2022)	Drug Safety	70	Q1	3	2	1	6	Medium
24	Ryan et al. (2024)	British Journal of Clinical Pharmacology	140	Q1	2	1	1	4	Medium
25	Roosan et al. (2022)	Journal of Medical Toxicology	167	Q2	3	2	1	6	Medium
26	Danysz et al. (2019)	Drug Safety	58	Q1	2	2	1	5	Medium
27	Khademi Habibabadi et al. (2023)	Applied clinical informatics	140	Q2	2	2	1	5	Medium
28	Martin et al. (2018)	International Journal of Clinical Pharmacy	43	Q1	3	2	2	7	High
29	Alimova and Tutubalina (2018)	Lecture Notes in Computer Science	71	Q2	2	1	1	4	Medium
30	Li et al. (2022)	Expert Opinion on Drug Safety	470	Q1	2	2	1	5	Medium
31	Stergiopoulos et al. (2019)	Pharmaceutical Medicine	90	Q2	2	2	1	5	Medium
32	Murphy et al. (2023)	PLOS ONE	25	Q1	2	2	1	5	Medium
33	Kompa et al. (2022)	Drug Safety	435	Q1	3	2	2	7	High
34	Trifirò et al. (2018)	Drug Safety	140	Q1	1	1	1	3	Low
35	Schmider et al. (2019)	Clinical Pharmacology and Therapeutics	140	Q1	3	2	2	7	High
36	Abrantes and Cordeiro (2018)	Proceedings of the IEEE Symposium on Computer-Based Medical Systems	209		3	2	1	6	Medium
37	Bhardwaj et al. (2023)	Current Drug Safety	43	Q3	3	3	2	8	High
38	Le Louët and Pitts (2023)	Therapeutic Innovation and Regulatory Science	41	Q1	3	3	2	8	High
39	Zheng et al. (2022)	JMIR Public Health and Surveillance	51	Q1	3	3	2	8	High
40	Chan et al. (2022)	Health Policy and	56	Q1	3	2	2	7	High

Nos.	Authors	Source Title	H Index	SJR	RQ1	RQ2	RQ3	Total	Relevance to review scope
41	Hussain et al. (2022)	JMIR Public Health and Surveillance	56	Q1	3	2	2	7	High
42	Destere et al. (2024)	British Journal of Clinical Pharmacology	167	Q1	3	3	2	8	High
43	Satwika et al. (2021)	Recent Patents on Biotechnology	42	Q3	3	3	2	8	High
44	Wong et al. (2018)	The Journal of Human Pharmacology and Drug Therapy	41	??	3	3	2	8	High
45	Hauben and Hartford (2021)	Clinical Therapeutics	150	Q1	2	2	1	5	Medium
46	Vo et al. (2023)	Medicine in Drug Discovery	16	Q2	3	1	1	5	Medium
47	Aronson (2022)	Drug Safety	140	Q1	3	2	1	6	Medium
48	Haigney (2023)	Pharmaceutical Technology Europe	19	Q1	3	3	2	8	High
49	Salvo et al. (2023)	Expert Opinion on Drug Safety	90	Q1	2	3	2	7	High
50	Powell et al. (2022)	Frontiers in Pharmacology	154	Q1	1	2	1	4	Medium
51	Di Giovanni et al. (2022)	Pharmacoepidemiology and Drug Safety	109	Q1	3	2	1	6	Medium
52	Bate and Hobbiger (2021)	Drug Safety	140	Q1	3	3	2	8	High
53	Sandeep et al. (2022)	European Journal of Pharmacology	203	Q1	2	2	1	5	Medium
54	De Pretis et al. (2021)	Journal of Evaluation in Clinical Practice	87	Q2	3	2	1	6	Medium
55	Ng et al. (2020)	BMC Complementary Medicine and Therapies	113	Q1	1	1	1	3	Low
56	Streefland (2018)	Clinical Therapeutics	150	Q1	2	2	1	5	Medium
57	Bate and Stegmann (2023)	Health Policy and Technology	37	Q1	3	2	2	7	High
58	Roche et al. (2023)	Artificial Intelligence In Medicine	110	Q1	3	2	1	6	Medium
59	Pinheiro and Kurz (2022)	Pharmacoepidemiology and Drug Safety	109	Q1	3	2	3	8	High
60	Mockute et al. (2019)	Pharmaceutical Medicine	25	Q2	3	3	2	8	High
61	Klang et al. (2023)	International Journal for Quality in Health Care	108	Q2	2	2	3	7	High
62	Kalaiselvan et al. (2021)	Health and Technology	32	Q2	2	2	1	5	Medium
63	Kassekert et al. (2022)	Drug Safety	140	Q1	3	2	1	6	Medium
64	Salas et al. (2022)	Pharmaceutical Medicine	25	Q2	3	2	1	6	Medium