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Artificial intelligence and computational methods in the Asia-Pacific pharmacovigilance landscape: a systematic review

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Objective: To examine the application of artificial intelligence (AI) in pharmacovigilance across the Asia-Pacific and identify reported methodological implementation challenges.

Methods: MEDLINE, Scopus, and Google Scholar were searched using terms related to artificial intelligence, computational signal detection, pharmacovigilance, and Asia-Pacific countries. Peer-reviewed original studies published in English were included. PRISMA 2020 guideline was followed.

Results: We included 64 studies in 14 countries primarily focused on 1) Adverse Drug Reaction (ADR) identification, 2) ADR prediction and risk factor modelling, 3) Drug safety, monitoring, and evaluation, 4) Predictive modelling, and 5) Data information management. Machine Learning (ML) techniques were the most commonly applied AI methods in pharmacovigilance, followed by natural language processing, deep learning, neural networks, and symbolic and explainable AI. Disproportionality analysis methods were also commonly used across studies. Some challenges reported were relevant to data quality issues, generalizability, clinical workflow integration, implementation technicalities, and cultural barriers.

Conclusion: To overcome the challenges of AI application in the Asia-Pacific, a tiered implementation strategy can be employed through establishing a regional collaboration framework and taking into account disparities in technological maturity across countries.

KEYWORDS

AI, artificial intelligence, Asia-Pacific, drug safety, pharmacovigilance

Introduction

The Asia-Pacific region has recently experienced rapid growth in its pharmaceutical market. In 2021, the production output of pharmaceuticals and medical equipment in the Asia-Pacific was ranked the highest globally [1]. Due to its large population, efforts to expand healthcare access, and business improvements, it is expected that the region will experience the fastest growth in pharmaceutical and medical equipment production from 2021 to 2030 [1]. As production and consumption expand across the region, so does the volume of medicines in real-world circulation, making robust post-marketing pharmacovigilance an increasingly essential safeguard. Yet pharmacovigilance systems across the Asia-Pacific remain at a nascent stage and consistently fall short of the World Health Organization (WHO) performance standards [2]. This has urged the immediate implementation of a robust pharmacovigilance system in the region.

Since the 55th World Health Assembly took place in 2002, more attention has been paid to patient safety in the healthcare system [3]. Nonetheless, as important as prioritizing

patient safety through a robust pharmacovigilance system, implementing robust pharmacovigilance is not without any challenges in the Asia-Pacific. While some countries like Japan and Korea have comprehensively established pharmacovigilance ecosystems, some others are still in the stage of developing the system owing to some challenges such as healthcare infrastructure, regulatory, cultural, and linguistic barriers, and economic developments [2]. This diversity has led to remarkable disparities in pharmacovigilance practices, structures, and outcomes across the countries in the region.

In addition to the general challenges in pharmacovigilance—such as underreporting of adverse drug reactions (ADRs), limited numbers of trained healthcare professionals, and inadequate financial resources—[4–6], traditional medicine practices in some countries in the Asia-Pacific add to the complexity of pharmacovigilance implementation in the region [7–10]. Renowned for its traditional medicines, such as Traditional Chinese Medicine (TCM) and Kampo Medicine, Asia-Pacific faces unique, yet complicated, challenges in integrating a modern pharmacovigilance framework into these indigenous medicines [11, 12]. The complex formulation of traditional medicines, compounded with poor quality control and distribution channel regulation, poses further challenges in the incorporation of these medicines in the pharmacovigilance system [13].

To tackle those general and context-specific challenges in pharmacovigilance practice, some countries in the Asia-Pacific have started to integrate artificial intelligence (AI) into their pharmacovigilance systems [14, 15]. Recently, AI adoption in pharmacovigilance practices has been reported in some studies to be effective in supporting data automation and extraction from different sources, improving signal detection and reporting in pharmacovigilance systems [16–18]. Moreover, some studies have highlighted the beneficial outcomes of AI application in pharmacovigilance, including improvements in the accuracy and speed of ADR signal detection, as well as support for real-time data analysis [16, 18, 19].

Despite increasing interest in AI-enabled pharmacovigilance, the extent and maturity of its application across the Asia-Pacific remain unclear. Existing reviews have largely examined global evidence or focused on particular data sources and predictive tasks, with limited attention to regional differences in language, traditional medicine, reporting infrastructure, regulatory capacity, and health-system readiness. This review therefore aimed to: (1) map the pharmacovigilance tasks addressed by AI-based and conventional computational methods in Asia-Pacific countries; (2) examine the methods, data sources, and reported outcomes of the included studies; (3) identify methodological, validation, and implementation challenges; and (4) synthesise recommendations reported by the included studies.

Methods

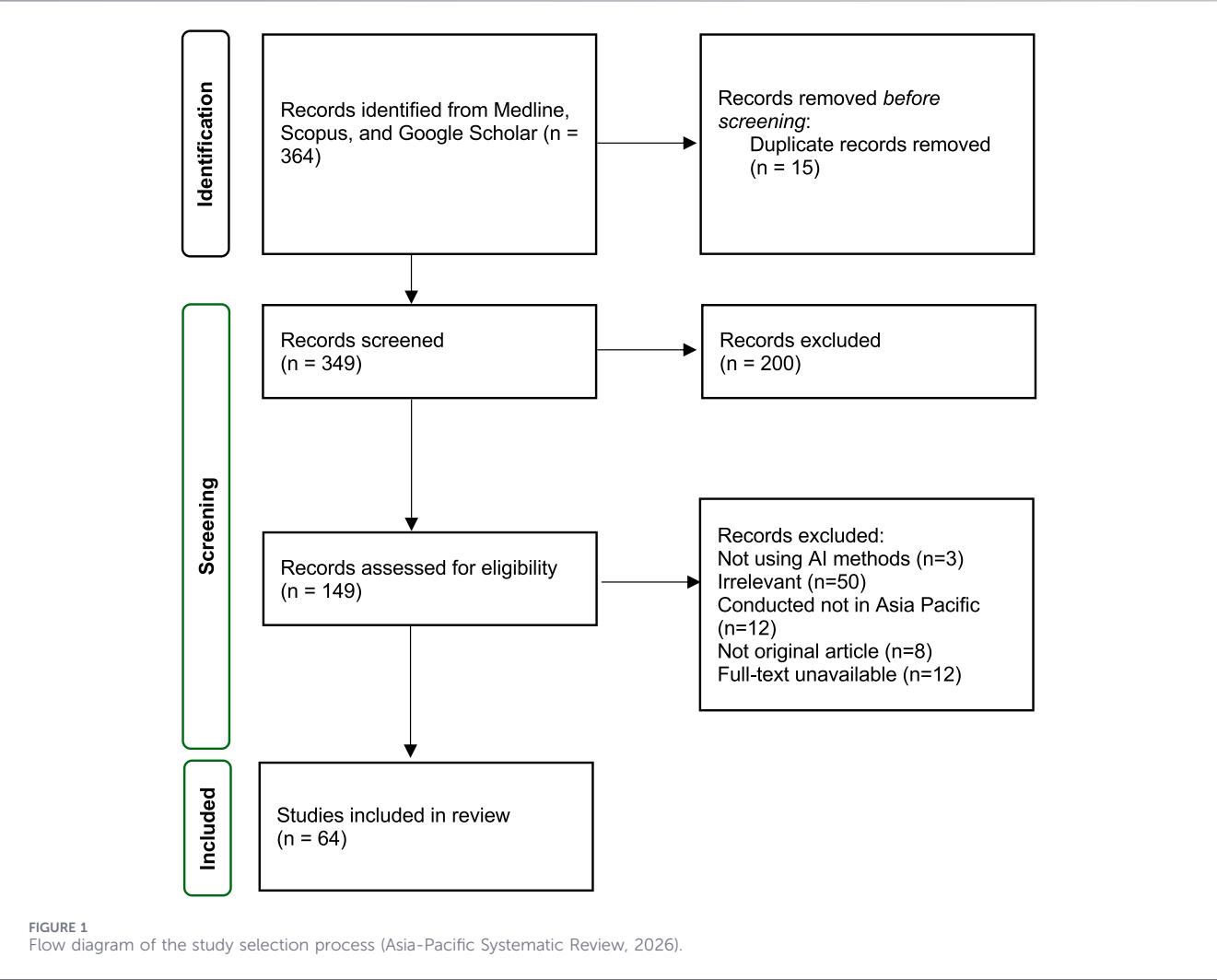
A systematic review of literature was conducted in Medline, Scopus, and Google Scholar (restricted only to the first 100 results for Google Scholar). The database search was conducted from January to March 2025. The selection of the databases was driven by the broad coverage of biomedical, clinical, public health and

interdisciplinary literature discussing pharmacovigilance and artificial intelligence. Google Scholar was additionally searched to enhance the retrieval of multidisciplinary, gray, and rapidly emerging literature, which may enhance the identification of relevant evidence in the rapidly evolving field of artificial intelligence in the region [20]. To ensure that the review captured the most recent evidence, a targeted update search of MEDLINE was conducted in July 2026 (during the publication process of this article). The updated search did not identify any new methodological or conceptual developments that would alter the findings or conclusions of this review.

This systematic review was conducted in accordance with Preferred Reporting Items for Systematic Review and Meta-analyses (PRISMA) guidelines (see Supplementary Material 1) [21]. A keyword combination of “artificial intelligence” AND “pharmacovigilance” AND “Asia-Pacific” along with its synonyms was used to assess the use of artificial intelligence in pharmacovigilance in the Asia-Pacific (Full strategy is presented in Supplementary Material 2). To capture the historical development of computational pharmacovigilance, the review included both conventional statistical signal-detection methods and contemporary AI-based methods. Conventional methods included disproportionality analyses such as reporting odds ratios, proportional reporting ratios, and Bayesian Confidence Propagation Neural Networks. These methods were not classified as AI. AI-based methods included machine learning, deep learning, natural language processing, neural-network models, ontology or knowledge-based systems, and techniques used to explain model outputs. The two groups were analysed separately when describing methodological trends but jointly when synthesising cross-cutting challenges such as data quality, validation, interoperability, and implementation. The Asia-Pacific countries covered in this review were defined by referring to the United Nations Economic and Social Commission for Asia and the Pacific (UN ESCAP) [22].

Studies were eligible if they: (1) reported original, peer-reviewed research; (2) were published in English; (3) used data from at least one UN ESCAP member or associate member; and (4) evaluated an AI-based or conventional computational method for a pharmacovigilance activity concerned with detecting, assessing, understanding, preventing, or managing adverse effects or other medicine-related safety problems. Studies were excluded if they were editorials, opinions, or non-systematic reviews (such as narrative reviews and literature reviews).

Started with comprehensive database research, the review process was then continued with the removal of duplicates and the title and abstract screening. A further comprehensive review was conducted based on the defined eligibility criteria. After all, the following data were extracted from the included studies: authors, year of publication, title, settings or data source, research focus, AI application, type of drugs, main conclusion, challenges of AI use in pharmacovigilance, recommendations, and some specific AI use discussions. Owing to substantial heterogeneity in study objectives, pharmacovigilance tasks, data sources, model types, validation procedures, outcome definitions, and performance measures, quantitative pooling was not considered appropriate. The studies were therefore synthesised narratively and organised according to country, pharmacovigilance task, computational method, data source, validation stage, reported challenge, and



recommendation. Methodological categories were defined before synthesis and were not mutually exclusive because some studies combined multiple computational approaches. Challenges and recommendations were coded inductively from the included studies. GK and GW conducted the extraction and coding, and disagreements were resolved through discussion and consensus with the full author team.

Quality assessment

The quality of the included studies was appraised using critical appraisal tools selected based on the study design and intended purpose of the AI model. A descriptive reporting assessment was conducted using seven reporting domains adapted from previous systematic reviews evaluating AI-based clinical and diagnostic studies [23, 24]. The assessment criteria included conflict of interest disclosure, study aim, input feature, ground truth, dataset distribution, performance metric, and description of the AI model. These seven items were scored on a two-point scale: 0 (not reported or unclear) or 1 (reported and adequate). For those studies developing or validating individualized multivariable diagnostic or prognostic prediction models (n = 14), a supplementary

appraisal was conducted using the Prediction Model Risk of Bias Assessment Tool (PROBAST). One randomised study [25], meanwhile, was appraised using Joanna Briggs Institute (JBI) critical appraisal tool [26].

Results

Study selection process

We identified 364 articles through the initial comprehensive database search (Figure 1). Upon removing 15 duplicative articles, 349 articles then went through the title and abstract screening process, where 200 of them were excluded and 149 were thoroughly reviewed against the inclusion criteria. During the process, 85 studies were excluded owing to several different reasons, including: the absence of an AI application in their methodology (n = 3), a lack of relevance (n = 50), being conducted in countries outside the Asia-Pacific region (n = 12), not being primary research (n = 8), or unavailable in full-text (n = 12). Finally, 64 eligible studies were analysed narratively in this review.^{25,27–66,67(p019),68–89}

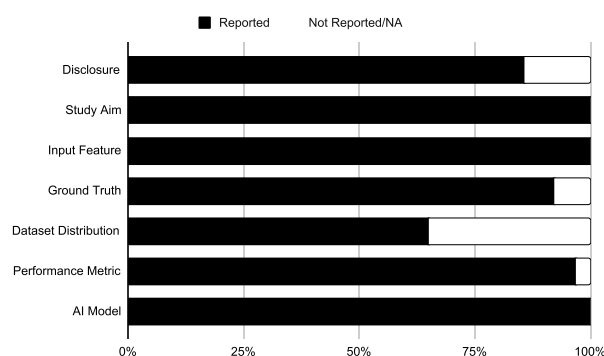


FIGURE 2
Study quality critical appraisal results (Asia-Pacific Systematic Review, 2026).

Quality appraisal

Figure 2 demonstrates the results of the quality appraisal for non-randomised studies. Among all assessment domains, the study aim, input features and AI model were clearly reported across all studies. Additionally, 86% of the studies disclosed conflicts of interest involved in their research. Regarding the ground truth, the assessment domain was adequately addressed by 83% of the studies. Lastly, the assessments of dataset distribution and performance metrics were adequately addressed by 65% and 97% of the studies, respectively. This lack of reporting on data distribution, however, should be interpreted cautiously due to the inapplicability of the assessment question in a few studies. While the tool was technically developed to assess studies focusing on the development and training of predictive AI models in health research, several questions were not relevant to real-world implementation AI studies. These included studies focusing on AI operational implementation, signal detection applicability, or the comparison of different data mining methodologies in pharmacovigilance [27–45]. The critical appraisal of the RCT indicated that the study was of a high quality since it met all the criteria in the assessment tool [25].

As for the PROBAST assessment, the results showed that all the 14 predictive modelling studies have a low risk of bias across the participants, predictors, and outcomes domains [29, 46–58]. Nevertheless, the results in the analysis domain indicated greatest methodological limitations, where 79% of the assessed studies ($n = 11$) were judged to have a high risk of bias primarily due to the unavailability of external validation, inadequate assessment of model optimism, and insufficient reporting of missing-data handling [29, 47, 49, 51–58]. As a result, these 79% studies ($n = 11$) were judged to have an overall high risk of bias. Regarding the applicability assessment, all studies ($n = 14$) were considered to have low concerns of applicability [29, 46–58]. The details of the quality appraisal are presented in the Supplementary Material 3.

Study characteristics

This systematic review summarised the findings of the studies conducted in 14 different countries in the Asia-Pacific, including China, Japan, Australia, South Korea,

Taiwan, Singapore, Malaysia, India, Indonesia, Vietnam, New Zealand, Turkey, Thailand, and Russia (Figure 3). Among these countries, Japan ($n = 17$) and China ($n = 15$) are the leading countries in the Asia-Pacific in terms of the number of publications about AI applications in pharmacovigilance, followed by South Korea ($n = 6$), Taiwan ($n = 5$), Australia ($N = 4$), and other remaining countries. A summary of the study characteristics can be found in Supplementary Material 4.

In terms of study focus, five broad application areas were identified: 1) ADR identification and surveillance, 2) ADR prediction and risk factor modelling, 3) medicine safety, monitoring, and evaluation, 4) prediction of medicine-related safety outcomes, including toxicity and dose-related risk, and 5) pharmacovigilance data extraction, linkage, and information management. As illustrated in Figure 4, ADR detection and surveillance have consistently remained the primary focus of AI applications in pharmacovigilance across the Asia-Pacific region.

AI application in the Asia-Pacific pharmacovigilance landscape

Table 1 presents the details of AI applications across a wide range of drugs and medications in the Asia-Pacific and the findings statement reported by the original study authors. Machine-learning methods were reported in 25 of the 64 included studies (39%). Because some studies used more than one computational approach, method categories were non-mutually exclusive and percentages do not sum to 100% [29, 45–49, 51–54, 56, 57, 59–67]. Statistical signal detection, such as Reporting Odds Ratio (ROR), Proportional Reporting Ratio (PRR), and Bayesian Confidence Propagation Neural Network (BCPNN), represented early integration of computational methods in pharmacovigilance system across the Asia-Pacific and laid the foundation for the wider adoption of AI-based methods in the region (Figure 4) [27, 30–32, 37–39, 42, 68, 69]. Most studies reported positive outcomes of applying these disproportionality methods, highlighting their simplicity and efficiency in basic ADR signal detection [27, 32, 37, 38, 42, 68]. However, some other studies had neutral views towards the methods owing to several challenges, such as data variations and sufficiency,



FIGURE 3
Geographical distribution of studies (Asia-Pacific Systematic Review, 2026).

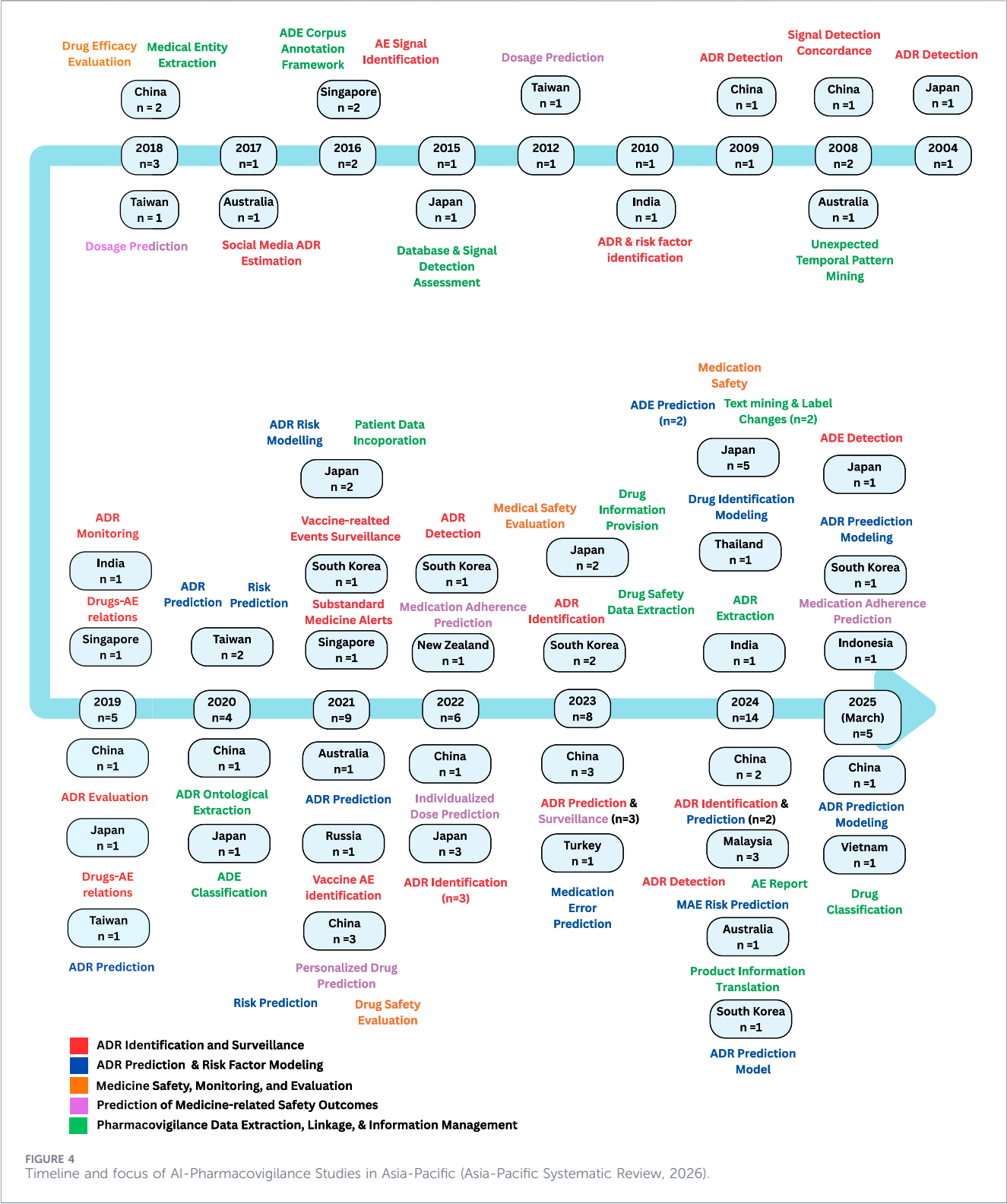
as well as lower sensitivity compared to other methods [30, 31, 39, 69].

After 2015, a shift towards more complex tasks of machine learning techniques emerged [29, 45–49, 51–54, 56, 57, 59–67]. Several supervised learning algorithms, such as XGBoost, Random Forest, and Support Vector Machines (SVM), were progressively utilized to support dose prediction, risk classification, and toxicity assessment [45–49, 51, 53, 54, 57, 59, 61–65]. Studies that adopted machine learning techniques reported positive findings due to its effectiveness and high accuracy in yielding reliable predictive power [29, 45–49, 51–54, 56, 57, 59–67]. These studies concluded that ML is a highly versatile method and is effective, especially in supporting personalized medicine and providing clinical decision support [29, 45–49, 51–54, 56, 57, 59–67].

Deep learning (DL) models and Natural Language Processing (NLP) have also been increasingly employed in pharmacovigilance recently, especially transformer-based NLP such as Bidirectional Encoder Representations from Transformers (BERT) [28, 33–36, 41, 43–45, 50, 70–81]. Deep learning models like Bidirectional Long

Short-Term Memory (BiLSTM) or Convolutional Neural Networks (CNNs) were more prevalently used in time-series prediction or image-based diagnosis [45, 70, 71, 75]. A growing trend of using deep learning models in multi-source data or complex diseases such as Parkinson's was shown [25]. NLP, meanwhile, is more popular for being widely used for extracting ADRs from unstructured data such as summaries, social media, and package inserts [28, 33–36, 41, 43, 44, 73, 76–81]. It is often combined with ML methods for better classification or signal detection [81]. Several studies reported favourable extraction or classification performance when applying NLP to unstructured text, including spontaneous reports, social-media data, package inserts, and clinical narratives. Evidence that these improvements translated into better post-marketing safety decisions was limited [28, 33–36, 41, 43, 44, 73, 76–79, 81]. Apart from ML-NLP approach combinations, the use of general neural network methods in pharmacovigilance is often in conjunction with ML, DL, or NLP contexts, indicating a trend towards a hybrid approach in pharmacovigilance research [45, 47, 57, 59, 65].

Ontology and knowledge-based approaches were examined in several recent studies. Explanation techniques were also



applied to selected machine-learning models to make individual predictions or feature contributions more interpretable [28, 49, 55, 82]. Symbolic AI was more commonly used in structured data, such as medical products, with emphasis on interpretability and traceability [28]. XAI, meanwhile, appeared to be used in acute coronary syndrome prediction and vaccine risk monitoring [49,

55]. The studies reported that explanation techniques could identify features contributing to model predictions. However, the included evidence did not establish whether these explanations improved clinician understanding, regulatory acceptance, or decision quality. Lastly, other AI methods such as ARM, MUTARC/UTARs, and YOLO were reported to be used

TABLE 1 Characteristics of AI-based and computational methods applied in pharmacovigilance (Asia-Pacific Systematic Review, 2026).

No	Methods*	Specific Techniques	No of Studies	Drugs/Diseases Involved
1	Statistical disproportionality methods	ROR, PRR, MHRA/MCA method, BCPNN, GPS, MGPS, RRR, PRRCI, RORCI	10	General drugs, TCMs, paliperidone palmitate, cardiac therapy drugs, antiretroviral therapyetc.
2	Machine learning (ML)	Random forest, SVM, logistic regression, XGBoost, LightGBM, CatBoost, AdaBoost, TPOT, decision tree, LASSO, ridge regression, GLM, elastic net, extra trees regressor, kNN, SVR, MLP, CART, model tree	25	Antipsychotics, tacrolimus, methotrexate, ICIs, anti-TB drugs, warfarin, digoxin, vaccinesetc.
3	Natural language processing (NLP)	NER, IE, NLC, BERT (tohoku, UTH, ELECTRA, PhoBERT), pretrained NER, NLP + ML	15	General drugs, SLE, chemotherapy, kampo, cancer meds, ADE detection, COVID-19 vaccine, acetaminophen/ibuprofen
4	Deep learning (DL)	Deep neural network (DNN), BiLSTM, BiLSTM-CRF, DCNN, YOLOv8-nano, IMV-LSTM	7	TCM + Parkinson's, SCARs, DILI, general drugs
5	Neural networks (general)	ANN, GAN, Word2Vec, simple RNN, LSTM, MLP, BiLSTM	9	Parkinson's, COVID-19, hepatotoxicity, lipid therapy, TCMs
6	Explainable AI (XAI)	LIME, SHAP	2	Vaccines, cardiovascular/musculoskeletal drugs
7	Symbolic AI/KRR/Ontology-based	Ontology-based side-effect prediction (OSPF), KRR, ontology engineering	2	Quinolone antibiotics, TCMs/COVID-19
8	Other/Unconventional AI methods	Association rule mining (ARM), MUTARC/UTARs, YOLO object detection	3	Drugs affecting cognition in CKD, broad-spectrum drugs, and unanticipated AE patterns

*Methods categorization is not mutually exclusive since several studies employed more than one particular computational or AI-based method. Therefore, the total number of studies reported in this table does not equal the total number of the included studies in this review.

TABLE 2 Challenges and Recommendations on AI integration in Pharmacovigilance in Asia-Pacific (Asia-Pacific Systematic Review, 2026).

Challenge Area	Key Issues	Recommended Solutions
Data quality and generalizability (n = 24)	- Poor data quality and sparsity - Inconsistent datasets - Unstructured narrative reports - Fragmented data silos - Lack of interoperability	Enhance data integration & diversity (n = 9) - Expand multi-center data integration - Include patient-generated and social media data - Incorporate heterogeneous structured/unstructured data
Clinical integration (n = 18)	- Lack of digital maturity - Manual reporting limitations - Legal/procedural data sharing issues - Poor AI output interpretability - Validation gaps with real-world outcomes	Promote clinical validation & regulatory alignment (n = 15) - Deploy models in real-world clinical settings - Integrate into regulatory workflows - Apply AI in early drug development and post-marketing surveillance - Use explainable AI (XAI) models
Technical implementation (n = 15)	- Complex medical terminology handling - Ineffective rare ADR detection - Class imbalance issues - High computational demands - Black-box model explainability problems	Improve AI model robustness & techniques (n = 11) - Implement advanced ML techniques (GANs, SMOTE) - Use specialized deep learning networks - Enhance preprocessing and algorithm tuning - Continuously update dictionaries
Regional & cultural adaptation (=8)	- Regional language nuances - TCM complexity and non-standardized formats - Lack of digital infrastructure - Regulatory fragmentation - Cultural bias in self-reported data	Address cultural & educational gaps (n = 10) - Improve language models with domain-specific data - Tailor AI models for region-specific contexts - Provide education/training for healthcare professionals

in rare signal discovery and complex association mining. The studies highlighted their powerful capability in hypothesis generation or exploratory analysis [32, 40, 83].

Challenges in AI application in pharmacovigilance

Notwithstanding the positive outcomes of AI applications in pharmacovigilance, the reviewed studies also highlighted several key challenges (Table 2) of AI use in pharmacovigilance systems below:

Data quality and standardization challenges

Several studies recorded inadequacy of data quality, sparsity, and inconsistent or incomplete datasets hindering the performance of AI algorithms during the model training process [28, 44, 45, 48, 58]. Two studies reported difficulties during the learning process due to limited dataset annotation and low inter-annotator agreement [76, 78]. In addition to this, the use of unstructured and informal language in narrative reports further added complexity in the accuracy of the data extraction process as well as data standardization [33, 34, 43, 79]. These studies identified poor semantic consistency in datasets sourced from social media or spontaneous reports [43, 80, 84]. Furthermore, other studies [51, 55, 67] highlight challenges in the harmonization and integration of heterogeneous data sources due to fragmented data silos, a lack of interoperability between reporting systems, and discrepancies in relevant regulations.

Limited generalizability

Lack of geographic diversity and pharmacogenetic variation were reported by some studies as restricting model generalizability to broader populations or clinical contexts [29, 53, 54, 57, 77]. This issue is particularly prevalent in single-center studies [49, 52, 65], where model transferability to broader demographic scopes and healthcare practices was restricted due to the nature of the narrowed scope of the data. Additionally, the use of AI models in traditional medicines such as TCM and Kampo poses more challenges since language and cultural differences exist to add difficulties in cross-contextual generalization.

Integration with clinical workflows and health systems

Several studies identified barriers that could hinder the future deployment or operational use of AI-based methods, including limited digital infrastructure, poor interoperability, and the absence of standardised implementation protocols [32, 48, 56, 64, 69, 75, 82, 83]. The reliance on manual or semi-structured reporting limits the incorporation of AI methods in clinical settings, as reported by studies conducted in Japan and Singapore [66, 73]. Additionally, Kittisorayut et al [83] and Noguchi [32] noted that non-uniform data formats and limited integration planning were

identified as barriers to translating model performance into clinical or pharmacovigilance workflows. Some other studies also find barriers in the interpretability of AI outputs, where AI-generated analytics face scrutiny from clinicians due to a lack of rationale or clinical context [32, 42, 82]. Lastly, another challenge is relevant to validation gaps between AI predictions and clinical outcomes in real-world settings [29, 85], especially in AI models developed with single-center data [52, 53], excluding key variables such as pharmacogenetics, comorbidities, and co-medications [48, 86]. This failure to account for those clinical factors in pharmacovigilance may limit the study's generalizability to wider patient populations [46, 60].

Technical implementation barriers

Numerous studies in this review cited substantial issues related to design, training, and computational efficiency. The process of automated information extraction, for example, was noted in two studies as being hindered by the issues with handling complex medical terminology and out-of-vocabulary terms [35] as well as the dependence on manual feature engineering [70]. In addition to this, ineffectiveness in detecting rare ADRs was reported in some studies [40, 74], often particularly due to class imbalance and limited data variability [47, 50, 59]. Other studies [27, 32, 48] also underline the model complexity of computational demands, particularly in integrating temporal and clinical variables or modeling multifactorial ADRs [58]. In traditional signal detection models such as BCPNN, a lack of sensitivity in low-report scenarios was identified with the possibility of missing rare but critical ADRs [30, 39]. Lastly, the application of black-box model designs in pharmacovigilance, such as deep learning models, remains an issue since explainability and transparency are critical in safety assessments and regulatory validation [42, 50, 82].

Regional and cultural adaptation challenges

The nuances of regional languages, such as Chinese semantics and Korean narrative structures, were reported in two studies as introducing distinctive challenges to the application of NLP models [77, 86]. Some other linguistically relevant issues, such as inaccurate translation and dependence on human verification, were also noted as adding further barriers to applying AI models in multilingual settings [41]. In terms of cultural context, the distinct data structures and pharmacological profiles of TCM introduce unique challenges in AI applications. One study suggests that ingredient complexity and non-standardized reporting formats in TCM lead to ineffective ADR signal detection, especially in those AI models trained with Western pharmacovigilance data [72]. Furthermore, the lack of digital infrastructure in certain countries [69], along with regulatory fragmentation, constrains region-wide deployment of unified AI frameworks. Finally, concerns have been raised regarding data representativeness, fairness, and trust in AI-based pharmacovigilance since cultural variability and demographic

bias may influence ADR data recorded through social media or other self-reported platforms [66, 80, 84].

Recommendations for AI application in pharmacovigilance

In response to those barriers, the included studies in this review suggested the following recommendations to optimize AI applications in pharmacovigilance systems (Table 2):

Enhance data integration and diversity

To improve the applicability and accuracy of AI models used in pharmacovigilance systems, several studies highlighted the importance of expanding data integration across diverse datasets [46, 51, 52, 84, 87]. These studies advocated incorporating data across multiple pharmacovigilance centers, variables, and real-world sources such as patient-generated data and social media to broaden representation and generalizability beyond a single institution or population. Additionally, some other studies also emphasized the significance of including heterogeneous data, such as structured and unstructured data, to improve ADR identification and surveillance capabilities [33, 36, 43, 55].

Improve AI model robustness and techniques

Several studies recommended improving model robustness through methods suited to the specific data limitation or pharmacovigilance task. Suggested approaches included temporal modelling, semi-supervised learning, and resampling or synthetic-data techniques such as SMOTE and generative adversarial networks. These approaches may address particular data limitations but require careful validation because synthetic or resampled data can also introduce artefacts, amplify bias, or produce overoptimistic performance estimates [58, 59, 64, 71]. The implementation of specialized models, such as deep learning networks, and the refinement of the existing algorithms were mentioned in some studies as key recommendations for better signal detection and entity recognition [61, 70, 72, 88]. Other technique-related recommendations for building high-performing AI systems to support critical pharmacovigilance functions included enhancing preprocessing systems, tuning algorithms, and continuously updating dictionaries to ensure performance consistency [45, 76, 79].

Promote clinical validation and practical implementation

To ensure translational impacts of AI models in pharmacovigilance systems, many studies recommended deploying the models into the real-world settings through integration into clinical practice and regulatory workflows [48, 49, 56, 65, 89]. Several studies that used real-world data to monitor drug induced liver injury (DILI), methotrexate toxicity, or individualized tacrolimus dosing have revealed the potential effectiveness of AI models in improving risk prediction which may support therapeutic safety if the models were well integrated into clinical judgment [29, 47, 50, 60]. Furthermore,

employing AI models in the early stage of drug development and post-marketing surveillance was suggested to improve ADR detection [74].

Facilitate interpretability and regulatory alignment

Several studies emphasised the need for interpretable and auditable outputs to support clinical review and regulatory scrutiny. Explanation techniques may assist users in examining model predictions, but they should be accompanied by documentation of data provenance, intended use, model limitations, validation populations, decision thresholds, and model updates [54, 55, 67]. Explainability should not be treated as equivalent to transparency or accountability. Responsibility for reviewing, rejecting, escalating, and acting on AI-generated safety signals must remain identifiable. This transparency process was discussed as a critical element in successful AI applications within pharmacovigilance systems. Some other studies recommended the incorporation of domain-specific ontologies, such as MedDRA, and alignment of AI models with regulatory agencies such as Pharmaceuticals and Medical Devices Agency (PMDA) to identify safety monitoring and compliance [59, 66, 89]. These recommendations are critical for both supporting end-user trust and ensuring that AI systems in pharmacovigilance align well with ethical and legal standards.

Addressing cultural, language, and educational gap

Owing to the contextual challenges found in each country, some studies recognized the pivotal roles of improving linguistic and cultural influence in AI applications [25, 35, 41, 43, 44, 57]. In addition to improving language models with annotated domain-specific data, these studies suggested human validation while applying machine translation systems to ensure systemic accuracy [25]. With regards to AI application in traditional medicines, such as Kampo and TCM, some studies recommended tailoring AI models by taking into account the region-specific narratives and medications [33, 72, 73, 86]. Lastly, in order to address the implementation gaps and promote system adoption, three studies highlighted the roles of education and training about ADRs, hepatotoxicity, and AI tools among healthcare professionals [35, 44, 57].

Discussion

Our review found that published evidence on AI-based and computational pharmacovigilance methods was concentrated in a small number of Asia-Pacific countries. Japan and China accounted for half of the included studies, while only 14 of the 53 UN ESCAP members and associate members were represented. This concentration may reflect differences in pharmacovigilance infrastructure, digital-health capacity, research funding, English-language publication, and database indexing in the region. Countries with well-established pharmacovigilance systems and regulatory agencies, such as Japan through the Pharmaceuticals and Medical Devices Agency (PMDA), may have enabling environments for the development and evaluation of computational and AI-based methods [90]. In contrast, many

other countries with more limited resources may still be strengthening their core fundamental pharmacovigilance functions, including regulatory governance, spontaneous reporting systems and workforce capacity, before the large-scale implementation of AI-based approaches becomes feasible. This result suggests the need for tailored implementation strategies aligned with countries' pharmacovigilance readiness and regulatory capacities rather than assuming a uniform pathway for AI adoption.

This review complements earlier global reviews of AI in pharmacovigilance. Salas et al. [16] primarily examined the types of AI methods used, their performance, and technical barriers across an international literature base. The present review identifies several issues that are especially salient in the Asia-Pacific evidence, including multilingual text processing, pharmacovigilance for traditional medicines, heterogeneous reporting systems, uneven digital infrastructure, and the concentration of research in a limited number of countries. However, these regional observations should be interpreted cautiously because the search was restricted to English-language publications and did not capture evidence from most Asia-Pacific countries.

The apparent technical promise of the reviewed models should be interpreted in light of their validation limitations. Although many studies reported favourable discrimination, classification, or information-extraction results, 11 of the 14 prediction-model studies assessed with PROBAST had a high overall risk of bias. Common limitations included absent external validation, inadequate assessment of model optimism, and insufficient reporting of missing-data handling. Consequently, the available evidence supports the feasibility of model development more strongly than it supports model transportability, clinical utility, or improvement in patient-safety outcomes.

Our study identified substantial challenges of AI integration in the Asia-Pacific landscape. Lack of standardized annotation and other data quality issues keep hindering the process of model learning and evaluation, especially in unstructured ADR reports with minimal inter-annotator agreement. Those models developed in single-center studies often face issues in generalizability and transferability owing to genetic, geographic, and cultural heterogeneity. This result corroborates the previous study conducted by Biswas [91], which found that the diversity of geographical, cultural and medical practices consistently hinders proactive pharmacovigilance practices in Asia. Moreover, this review also found that poor digital infrastructures, fragmented data formats, and limited interpretability add to the complexity of AI system adoption and integration in the healthcare system in the Asia-Pacific. Technical medical language, limited data variability, and heavy computational demands were highlighted as key technical barriers hampering AI performance in pharmacovigilance systems. Lastly, several unique challenges in the Asia-Pacific, such as linguistic diversity, socio-economic levels and traditional medicine complexity, emerge and impede an integrated AI framework in the region. Collectively, these challenges -ranging from healthcare infrastructure to technical barriers and culture complexities-reflect both systemic and technological limitations that vary across the countries in the Asia-Pacific region, suggesting the need for harmonized, context-specific efforts to achieve successful AI-PV implementation.

The included studies discussed interpretability, representativeness, and validation, but provided limited direct analysis of broader

governance issues. Drawing on these findings and international guidance on AI for health, several additional considerations concerning accountability, bias, transparency, and human oversight warrant discussion. The WHO report highlights several ethical issues that should become our primary attention regarding AI use in healthcare, including accountability, contextual bias and transparency [92]. Accountability and liability present complex challenges that are further magnified in the Asia-Pacific region, where many low- and middle-income countries lack robust, specific regulatory frameworks for AI in healthcare. Without clear legal and regulatory oversight, there is a significant risk that liability will be unfairly shifted onto local clinicians or health systems, while international developers may evade accountability. Addressing these ethical dimensions requires not only the technical refinement of AI models but also the urgent establishment of clear, region-if not-country-specific governance and liability frameworks that are aligned with global standards. The issue of bias from the current AI data sources is also prominent for the region as current AI models trained on geographically, ethnically, or socioeconomically unrepresentative datasets—risking unequal ADR detection performance for populations in the Asia Pacific. This bias will directly contravene the WHO principle of ensuring inclusiveness and equity in AI deployment. Transparency is equally critical, particularly regarding the integration of AI into clinical workflows and health systems. High-performing deep learning models often operate as “black boxes,” obscuring the rationale behind generated safety signals. In the Asia-Pacific context, as this is compounded by contextual bias—Asia-Pacific clinicians are presented with unexplainable safety signals derived from foreign populations that do not reflect local genetic, epidemiological, or prescribing realities, their trust in the AI system's clinical relevance may further erode. Consequently, healthcare providers may dismiss these AI-generated recommendations as contextually inappropriate or irrelevant to their patients [93]. To maintain trust and ensure human autonomy, AI tools must not only be intelligible—allowing clinicians to interrogate and override recommendations—but they must also be transparently validated using representative Asia Pacific data to prove their precision in the real world clinical setting. Human oversight should be specified as an operational process rather than stated only as a general principle. AI-generated signals require defined procedures for review, escalation, rejection, documentation, and override. Post-deployment monitoring should assess model drift, false-positive burden, subgroup performance, automation bias, and alert fatigue. The responsible human decision-maker should remain identifiable throughout the signal-management process.

We also want to outline several recommendations proposed by the included studies. To improve generalizability and representation, several studies suggested improving data integration through the involvement of diverse, multi-institutional, and real-world data sources [46, 51, 52, 84, 87]. Certain advanced techniques, such as temporal modeling, semi-supervised learning, and continual algorithm adjustment, were recommended to improve model robustness. In terms of practical utility, many studies highlighted the significance of real-world clinical validation, integration into regulatory workflows, and deployment across drug development stages [48, 49, 56, 65, 89]. The application of explainable AI (XAI) models and system alignment with standards like MedDRA were noted as essential for facilitating interpretability and fostering clinical trust. This growing recognition of

XAI models and MedDRA standards reflects on the importance of balancing sophistication with transparency to achieve wider adoption, as also supported by the WHO report in ethics and governance of artificial intelligence for health [92]. In addition to that, addressing linguistic, cultural, and educational gaps were deemed as crucial approaches to support region-wide adoption of AI frameworks in the Asia-Pacific. This educational approach has been highlighted in some studies conducted in low- and middle-income countries [94, 95], which found that enhancing healthcare professionals' knowledge and skills in pharmacovigilance is a key strategy for strengthening pharmacovigilance systems.

Translating these recommendations into practice may require a capability-based rather than algorithm-based approach. Countries or institutions with limited digital infrastructure may initially prioritise standardised adverse-event reporting, data quality, interoperable terminologies, workforce development, and basic analytic capacity. Settings with stronger data and governance capabilities may additionally evaluate externally validated machine-learning or natural-language-processing systems, provided that appropriate human oversight, auditability, and post-deployment monitoring are in place. The appropriate method should be determined by the pharmacovigilance task, available data, validation evidence, and regulatory requirements rather than by an assumption that more complex algorithms represent a more mature system. This proposed approach is an interpretation derived from the review and requires prospective evaluation.

Limitations

First, search and temporal constraints may limit our review comprehensiveness. Restricting searches to MEDLINE, Scopus, and the top 100 English-language Google Scholar results may have excluded regional, non-English, or engineering-focused literature.

Second, geographic and contextual factors restrict generalizability. The evidence is heavily concentrated in Japan and China (representing only 14 of 53 UN ESCAP members). Furthermore, because some studies addressed broader clinical prediction rather than routine pharmacovigilance, the findings reflect computational method development more than operational implementation. Consequently, publications analyzed in our review indicate regional research activity rather than direct evidence of each country's AI readiness or regulatory maturity.

Third, methodological heterogeneity precluded quantitative synthesis and standardized quality appraisal. Diverse study designs necessitated a descriptive, non-validated risk-of-bias assessment, which the current available tools might not be able to quantify correctly.

Conclusion

This review identified the use of AI-based and conventional computational methods for pharmacovigilance analysis in the

Asia-Pacific. To support the effective implementation of AI-based pharmacovigilance in the region, a tiered implementation strategy can be employed through establishing a regional collaboration framework and taking into account disparities in technological maturity across countries in the region.

Author contributions

Conception or design of the work: GK, GW, and AP. Data collection: GK and GW. Data analysis and interpretation: GK, GW, and AP. Drafting the article: GK, GW, and AP. Critical revision of the article: GK, GW, and AP. Final approval of the version to be submitted- GK, GW, and AP.

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Conflict of interest

The authors declare that they do not have any conflicts of interest.

Generative AI statement

The author(s) declared that generative AI was not used in the creation of this manuscript.

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Supplementary material

The Supplementary Material for this article can be found online at: <https://www.ssph-journal.org/articles/10.3389/ijph.2026.1610026/full#supplementary-material>

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