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Pharmacovigilance and Adverse Drug Reactions in Traditional and Herbal Medicine: A Global Bibliometric Analysis (1980–2025)

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Abstract

Traditional and herbal medicines remain integral to global healthcare, yet increasing concerns regarding safety, Adverse Drug Reactions (ADRs), and herb–drug interactions highlight the importance of effective pharmacovigilance systems. Despite a growing body of literature, global research trends in this field have not been comprehensively mapped using bibliometric approaches. This study analyzes the global research landscape on pharmacovigilance and ADRs related to traditional and herbal medicines from 1980 to 2025. A systematic search of PubMed and Scopus retrieved 8,019 unique publications after deduplication. Bibliometric analyses using VOSviewer were performed to examine co-authorship networks, institutional and country collaborations, and keyword co-occurrence patterns. China emerged as the leading contributor with 1,572 publications, followed by the United States, the United Kingdom, and India. The Journal of Ethnopharmacology and Medicine (United States) were among the most prominent publication sources. Collaboration networks revealed strong regional clustering, particularly among Chinese institutions, with comparatively limited cross-regional integration. Keyword and Medical Subject Headings (MeSH) co-occurrence analyses showed a strong clinical orientation, with dominant themes including "humans," "Chinese herbal drugs," "plant extracts," "phytotherapy," and "complementary therapies." Research output increased gradually after 2000, with a marked surge after 2015 and a peak in 2024. This bibliometric overview highlights evolving research patterns and identifies priority areas needed to strengthen safety monitoring and support the safe integration of traditional and herbal medicines into modern healthcare systems.

Major findings: Global research on pharmacovigilance of herbal medicines has expanded rapidly in the last decade, led primarily by China and Western countries. However, gaps persist in herb–drug interaction studies, causality assessment, regulatory harmonization, and the adoption of digital pharmacovigilance tools.

Keywords: Adverse Drug Reactions, Bibliometric Analysis, Herbal Medicine, Pharmacovigilance, Traditional Medicine

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1. Introduction

Traditional and herbal medicines have been an integral part of healthcare systems across cultures for centuries and continue to play a significant role in global health. According to the World Health Organisation (WHO), nearly 80% of the population in some regions relies on herbal remedies as a primary source of healthcare[1]. The growing popularity of complementary and alternative medicine[2], coupled with the perception that "natural" therapies are inherently safe, has led to their increasing use not only in developing countries but also in high-income settings. However, this rising utilisation has also drawn attention to potential safety concerns, particularly adverse drug reactions[3] and herb–drug interactions, which often remain underreported or poorly characterised. Pharmacovigilance, defined as the science and activities related to the detection, assessment, understanding,

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and prevention of adverse effects or other drug-related problems, has traditionally focused on conventional pharmaceuticals[4]. In contrast, pharmacovigilance systems for traditional and herbal medicines are comparatively underdeveloped, fragmented, and inconsistently regulated across regions. Challenges include the complexity of herbal formulations, variability in product quality, lack of standardised nomenclature, and widespread informal use outside formal healthcare systems[5]. These factors complicate causality assessment and hinder the development of reliable safety databases.

In recent years, research on pharmacovigilance and ADRs related to herbal medicines has expanded, reflecting the growing scientific and regulatory interest in ensuring their safe integration into modern healthcare[6]. Bibliometric analysis offers a systematic approach to mapping this evolving research field, identifying publication trends, influential contributors, collaborative networks, and emerging themes. Such analyses provide valuable insights into how the field has progressed, where gaps remain, and what future directions are necessary to strengthen pharmacovigilance practices for herbal medicines[7]. Against this background, the present study undertakes a global bibliometric analysis of pharmacovigilance and ADR research in traditional and herbal medicine from 1980 to 2025. The objectives are to map the research productivity and publication trends, identify key contributors, journals, and collaborative networks, and highlight research gaps and propose future directions for advancing pharmacovigilance in this domain. By addressing these aims, the study seeks to contribute to evidence-based policymaking, improved regulatory frameworks, and enhanced patient safety in the use of traditional and herbal medicines worldwide.

The increasing reliance on traditional and herbal medicines has raised critical questions regarding their safety monitoring and regulatory oversight. Unlike synthetic pharmaceuticals, herbal preparations are often complex mixtures of multiple bioactive compounds, with considerable variability in formulation, dosage, and quality. Factors such as geographical origin, cultivation practices, and methods of extraction further influence their pharmacological profile. These variations make the detection and attribution of ADR more complicated compared to conventional medicines[8]. Pharmacovigilance systems worldwide remain underprepared to capture the full scope of safety issues associated with herbal medicines. Challenges include underreporting of ADRs, limited awareness among healthcare professionals and traditional medicine practitioners, and the absence of harmonised guidelines for evaluating causality in herbal-related adverse events[9]. In addition, herb–drug interactions are often poorly documented, posing risks to patients who combine herbal remedies with prescribed pharmaceuticals. These gaps underscore the need for a comprehensive understanding of research activity in this domain. Bibliometric analysis offers a valuable approach to systematically evaluate publication trends, influential studies, research networks, and thematic evolution in pharmacovigilance and herbal medicine safety[10]. By mapping the existing knowledge landscape, such analysis can identify strengths, weaknesses, and future opportunities for advancing global pharmacovigilance practices in traditional and herbal medicine.

2. Materials and Methods

2.1 Literature Search

To explore global research trends on pharmacovigilance and adverse drug reactions in traditional and herbal medicine, bibliographic data were retrieved from the PubMed and Scopus databases (Elsevier), two of the most comprehensive and widely accepted abstract and citation platforms for scientific literature. We searched PubMed and Scopus to capture biomedical and broad multidisciplinary literature. Scopus provides wide journal coverage and citation data, while PubMed supplies focused biomedical indexing. The search strategy employed database-specific Boolean queries. In PubMed, the query was, ("pharmacovigilance" [Title/Abstract]) OR "adverse drug reactions" [Title/Abstract] AND ("herbal medicine" [Title/Abstract] OR "traditional medicine" [Title/Abstract] OR "complementary medicine" [Title/Abstract] OR "alternative medicine" [Title/Abstract] OR "ethnomedicine" [Title/Abstract]) AND (English [Language]) AND (humans [Filter]) AND ("1980/01/01" [Date - Publication] : "2025/09/15" [Date - Publication]). In Scopus, the query was, TITLE-ABS-KEY ("pharmacovigilance" OR "adverse drug reaction") AND TITLE-ABS-KEY ("traditional medicine" OR "complementary medicine" OR "alternative medicine" OR "ethnomedicine" OR "herbal medicine") AND (LIMIT-TO (DOCTYPE, "ar") OR LIMIT-TO (DOCTYPE, "re")) for January 1980 - September 2025. This query was restricted to articles (ar) and reviews (re) to ensure the inclusion of peer-reviewed literature.

Searches in both databases were conducted on September 15, 2025. Only English-language documents from peer-reviewed sources were considered. Data from PubMed were exported in "PubMed.txt" format, preserving citation and MeSH metadata, while Scopus data were downloaded in Comma Separated Values (CSV) format containing citation, author, affiliation, and keyword information. The PubMed file was processed in Mendeley software, whereas the Scopus CSV file was analysed in Microsoft Excel. As PubMed and Scopus export bibliographic data in distinct formats (".txt" and ".csv," respectively) with different metadata structures and column arrangements, the datasets could not be directly merged for analysis. Combining these files may lead to data misalignment or loss of key bibliometric fields such as authors, keywords, and MeSH terms. Therefore, both databases were analysed separately in VOSviewer to maintain data integrity and ensure accurate visualisation of co-authorship, keyword co-occurrence, and citation networks to map the research landscape and thematic evolution of pharmacovigilance and adverse drug reactions in traditional and herbal medicine studies.

2.2 Screening and Deduplication

After data retrieval, both datasets were exported in CSV format with a Digital Object Identifier (DOI), title, and author information. Potential duplicates were identified using the built-in "Check for Duplicates" tool in Mendeley software. DOI matching and title screening were also performed in Microsoft Excel, and overlapping records were excluded from the final analysis. A total of 737 duplicates/partial records were removed, leaving a final dataset of 8019 unique publications as per Figure 1.

2.3 Inclusion Criteria

The bibliometric and visual analysis focused on publications from January 1980 to September 2025 that are indexed in PubMed and Scopus. Eligible studies were required to mention pharmacovigilance, adverse drug reactions, safety, toxicity, or herb–drug interactions in the context of traditional, complementary, or herbal medicine in the title, abstract, or keywords. The dataset included original research articles and reviews that explored safety monitoring, reporting practices, clinical implications, or regulatory aspects of adverse drug reactions in this domain. Only English-language publications or those with English abstracts and sufficient bibliometric metadata (*e.g.*, authors, keywords, publication year) were considered for analysis using VOSviewer.

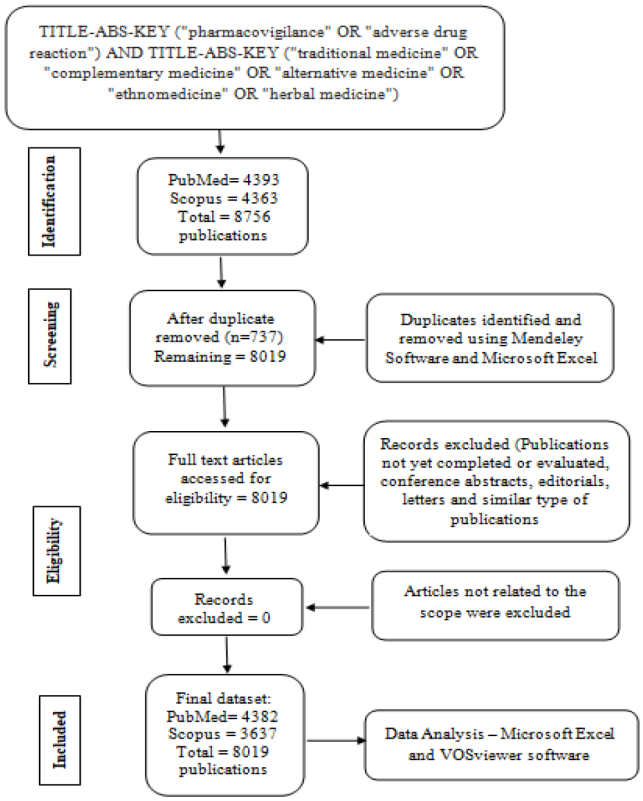


Figure 1. PRISMA flow diagram of study selection for publications on pharmacovigilance and adverse drug reactions in traditional and herbal medicine (1980–2025).

2.4 Exclusion Criteria

An exclusion criterion eliminated studies published outside the 1980–2025 range, non-peer-reviewed content such as blogs or magazines, and articles that reference traditional or herbal medicine without a specific focus on pharmacovigilance, safety, or adverse drug reactions. Non-English works without English metadata, duplicate entries, or publications lacking essential citation information were also excluded. Additionally, articles that did not contribute meaningfully to the thematic or bibliometric analysis, such as those with only passing mentions of safety or pharmacovigilance, were filtered out to maintain analytical relevance and data integrity.

3. PubMed Database

PubMed is a free, publicly accessible database maintained by the U.S. National Library of Medicine. It provides access

to a vast collection of biomedical literature, including research articles, reviews, and clinical studies from trusted scientific journals worldwide[11]. Upon search, a total of 4382 documents related to pharmacovigilance and adverse drug reactions in traditional and herbal medicine research were retrieved from the PubMed database for the period 1980–2024 and analysed using VOSviewer for bibliometric and visual mapping.

3.1 Co-authorship Analysis

To provide an overview of the research landscape, a co-authorship network analysis was conducted using VOSviewer based on PubMed data from 1980 to 2025. Figure 2 illustrates the network of authors contributing to pharmacovigilance and adverse drug reactions in traditional and herbal medicine. Out of 20,571 authors, the prominent contributors identified in the network include Jian-ping Liu, Charlie Changli Xue, Seong-gyu Ko, Seok-jae Ko, Boram Lee, and Eran Ben-Arye. Each node corresponds to an individual researcher, with node size reflecting publication output, while connecting lines indicate co-authorship relations. The visualisation shows that collaborative clusters are relatively small and fragmented, suggesting that while the topic has attracted contributions from multiple scholars, large-scale or international research networks are yet to be firmly established.

3.2 Institutional Collaboration Based on Co-authorship Data

To further map the institutional landscape, a co-authorship network of organisations involved in research on pharmacovigilance and adverse drug reactions in traditional and herbal medicine was generated using VOSviewer (PubMed data, 1980–2025). Figure 3 displays the leading institutions contributing to this field. Out of 11,409 organisations, the prominent clusters include the *Beijing University of Chinese Medicine*, *Department of Clinical Korean Medicine*, *Medicinal Plants Research Centre*, *Hospital of Chengdu University*, and t*he Department of Acupuncture at Guangzhou University*. Each node represents an institution, with node size reflecting publication output, while connecting lines indicate institutional collaborations. The visualisation suggests that although key centres in China and Korea dominate publication activity, inter-institutional linkages remain modest, pointing to the potential for greater global collaboration to strengthen pharmacovigilance research in traditional and herbal medicine.

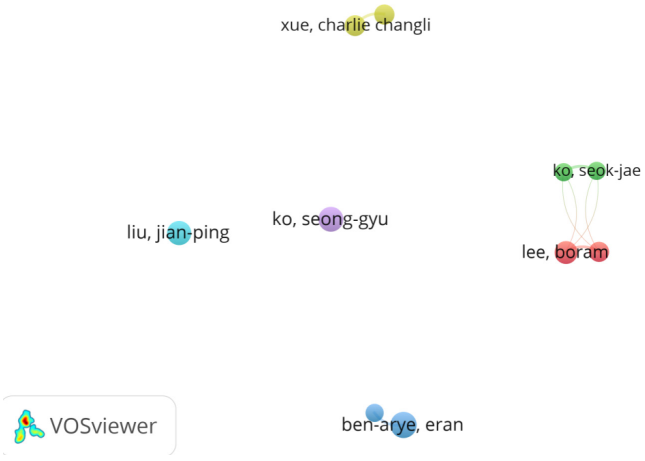


Figure 2. Co-authorship network of authors publishing on pharmacovigilance and adverse drug reactions in traditional and herbal medicine (PubMed, 1980–2025).

3.3 Keyword Co-occurrence Network

To identify the thematic structure of research, a keyword co-occurrence analysis was performed. Figure 4 displays the most frequently occurring keywords in publications related to pharmacovigilance and adverse drug reactions in traditional and herbal medicine. Out of 11,837, the central dominance of the term "*humans*" reflects the clinical orientation of much of the literature, with strong linkages to "*male*," "*female*," "*adult*," and "*middle-aged*," indicating frequent demographic categorisations in study reporting. Other prominent terms include "*Chinese herbal drugs*," "*phytotherapy*," "*plant extracts*," "*animals*," and "*complementary therapies*," which highlight the focus on herbal interventions and their safety profiles. The clustering pattern suggests that pharmacovigilance research in this field is mainly oriented toward human clinical studies, while preclinical and mechanistic studies involving plant extracts and animal models form a smaller but interconnected segment.

3.4 MeSH Keyword Co-occurrence Network

A MeSH (Medical Subject Headings) keyword co-occurrence analysis was conducted to map standardised thematic trends in the literature on pharmacovigilance and adverse drug reactions in traditional and herbal medicine. Figure 5 presents the network visualisation generated through VOSviewer (PubMed data, 1980–2025). Out of 5170, the largest

node, "*humans*," reflects the clinical orientation of most indexed studies, frequently linked with demographic descriptors such as "male," "female," "adult," and "middle-aged." Other highly connected MeSH terms include "Chinese herbal drugs," "plant extracts," "phytotherapy," "complementary therapies," and "animals," indicating the breadth of research spanning clinical applications, safety assessments, and preclinical investigations (Table 1). The clustering pattern suggests that pharmacovigilance research in this domain integrates both human-focused clinical studies and experimental work involving herbal products, but demographic indexing continues to dominate the literature's thematic profile.

4. Scopus Database

Scopus is a comprehensive abstract and citation database maintained by Elsevier. It covers a wide range of peer-reviewed literature across science, technology, medicine, social sciences, and the arts and humanities, making it a valuable tool for academic research and literature analysis[12]. Upon search, a total of 3637 documents related to pharmacovigilance and adverse drug reactions in traditional and herbal medicine research were retrieved from the Scopus database for the period 1980–2025 and analysed using VOSviewer for bibliometric and visual mapping.

4.1 Co-authorship Analysis of the Data from Scopus

To complement the PubMed analysis, a co-authorship network was also generated from Scopus data (1980–2025) using VOSviewer. Figure 6 highlights the key authors contributing to research on pharmacovigilance and adverse drug reactions in traditional and herbal medicine. Out of 17,236, the prominent names appearing in the network include Jo Barnes, Yanming Xie, Hongcai Shang, Li Zhang, Wei Wang, Jing Wang, Yi Zhang, Ying Zhang, and Jie Li. Each node represents an individual researcher, with node size indicating publication volume, while connecting lines denote collaborative linkages. The visualisation shows a dispersed pattern with a few small collaborative clusters (*e.g.*, Hongcai Shang–Li Zhang; Ying Zhang–Jie Li), but limited cross-linkages between groups (Table 2). This suggests that, despite the growing body of literature indexed in Scopus, collaborations among leading scholars remain fragmented, reinforcing the need for broader and more interconnected international research networks in this domain.

4.2 Institutional Collaboration Network

Figure 7 illustrates the institutional co-authorship network derived from Scopus data (1980–2025), highlighting the most active research organisations contributing to studies. The map illustrates the major collaborating



Figure 3. Organisational co-authorship network in pharmacovigilance and adverse drug reactions in traditional and herbal medicine-related publications (PubMed, 1980–2025).

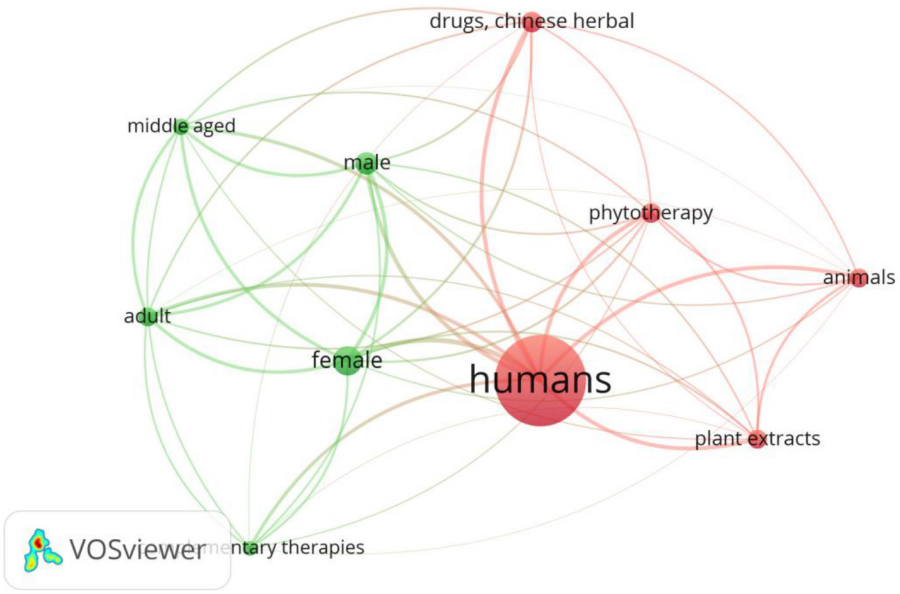


Figure 4. Keyword co-occurrence network in pharmacovigilance and adverse drug reactions in traditional and herbal medicine-related publications (PubMed, 1980–2025).

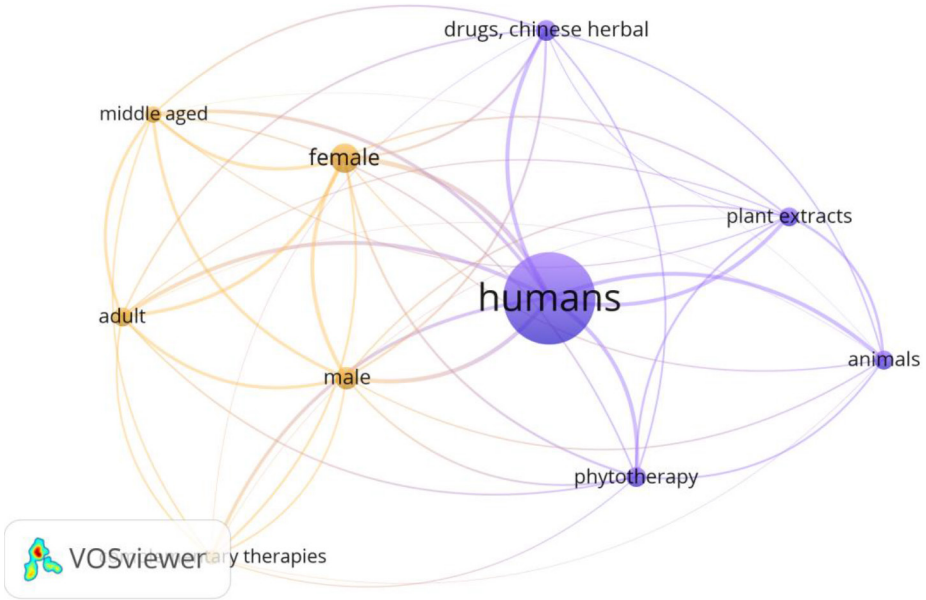


Figure 5. MeSH keyword co-occurrence network in pharmacovigilance and adverse drug reactions in traditional and herbal medicine-related publications (PubMed, 1980–2025).

institutions contributing to research in this domain. Out of the 4831 Universities, the large nodes, such as the University of Chinese Medicine, Academy of Chinese Medicine, Shanghai University of Traditional Medicine, and Guangzhou University of Chinese Medicine, indicate high publication output. The connecting lines show active research collaborations, with denser clusters reflecting strong regional partnerships, especially among Chinese institutions (Table 3). Notably, while ADR reporting in herbal and traditional medicine is a global issue, research visibility in Scopus is disproportionately dominated by Chinese universities, whereas contributions from Indian or other traditional medicine research centres appear less represented.

4.3 Country-wise Collaboration Network

The visualisation map generated using VOSviewer illustrates the co-authorship and collaboration patterns among countries (Figure 8). Each node represents a country, with the size of the node proportional to its publication volume, while the thickness of the connecting lines indicates the strength of collaborative linkages. Out of 123 countries, China emerges as the most dominant contributor, forming extensive collaborations with the United States, Japan, Canada, and Australia. The United States also plays a central role, acting as a hub that connects multiple countries across clusters. The United Kingdom, Germany, and Italy show strong inter-European collaborations, whereas India and South Korea appear as important contributors within Asia (Table 4). Overall, the map highlights China and the United States as leading centres of global research, supported by active cross-regional cooperation in the field.

4.4 Keyword Co-occurrence Network

The network visualisation depicts the most frequently co-occurring keywords extracted from the bibliometric dataset. Node size represents the frequency of occurrence of a keyword, while the thickness of connecting lines indicates the strength of association between terms (Figure 9). Out of 33,130, the terms *"human"* and "*humans*" dominate the map, reflecting their central role in research related to safety assessments. Strong associations are observed with keywords such as "*herbaceous agent*", "*unclassified drug*", "*controlled study*", and "*adult*", indicating the clinical and pharmacological focus of published studies. Additionally, terms like "*article*" and "*review*" highlight the methodological context, while gender-related keywords ("*male*" and "*female*") emphasise population-specific considerations (Table 5). The map suggests that research in this field is largely human-centered with significant emphasis on clinical trials and observational studies assessing herbal and traditional medicine safety.

Table 1. Leading MeSH keywords in research on pharmacovigilance and adverse drug reactions in traditional and herbal medicine (1980–2025, PubMed)

Sr. No.	MeSH Keyword	Occurrences	Total Link strength
1.	Humans	4393	8727
2.	Female	1418	5129
3.	Male	1098	4329
4.	Drugs, Chinese Herbal	997	2626
5.	Phytotherapy	951	2730
6.	Animals	941	2089
7.	Plant Extract	915	2360
8.	Adult	906	3672
9.	Middle Aged	782	3439
10.	Complementary Therapies	719	1859

4.5 Citation Analysis

Citation analysis revealed the most frequently cited articles and authors, highlighting influential contributions in pharmacovigilance and adverse drug reactions in traditional and herbal medicine related research. It also helped identify core journals and emerging focus areas within the field.

4.5.1 Top-cited Articles

The visualisation map presents the key articles with the highest citation impact in the field. The analysis highlights *Ekor (2014; 2607 citations)*[1] as the most influential and highly cited work, followed by *Stevens (2024; 1581 citations)*[13], *Meshnick (1996; 671 citations)*[14], *McKay (2006b; 624 citations)*[15], *McKay (2006a; 557 citations)*[16], and *Nosten (2007; 526 citations)*[17]. Earlier contributions such as *Classen (1991; 646 citations)*[18] and *Ernst (1998; 560 citations)*[19] also appear as notable references that shaped the foundation of this research area. More recent studies like *Shaito (2020; 518 citations)*[20] and *Zhang (2020; 493 citations)*[21] demonstrate the growing contemporary interest in safety evaluation of herbal and traditional medicines. Overall, the network underscores a blend of seminal works and emerging studies that form the knowledge base of pharmacovigilance and ADR-related research in this domain.

4.5.2 Journal-wise Publication Trends

The visualisation map identifies the most prominent journals contributing to the field. Each node represents a journal, with node size proportional to its publication output or citation impact in Figure 10. Out of 1248, the *Journal of Ethnopharmacology* and *Medicine (United States)* appear as the leading publication source, followed by

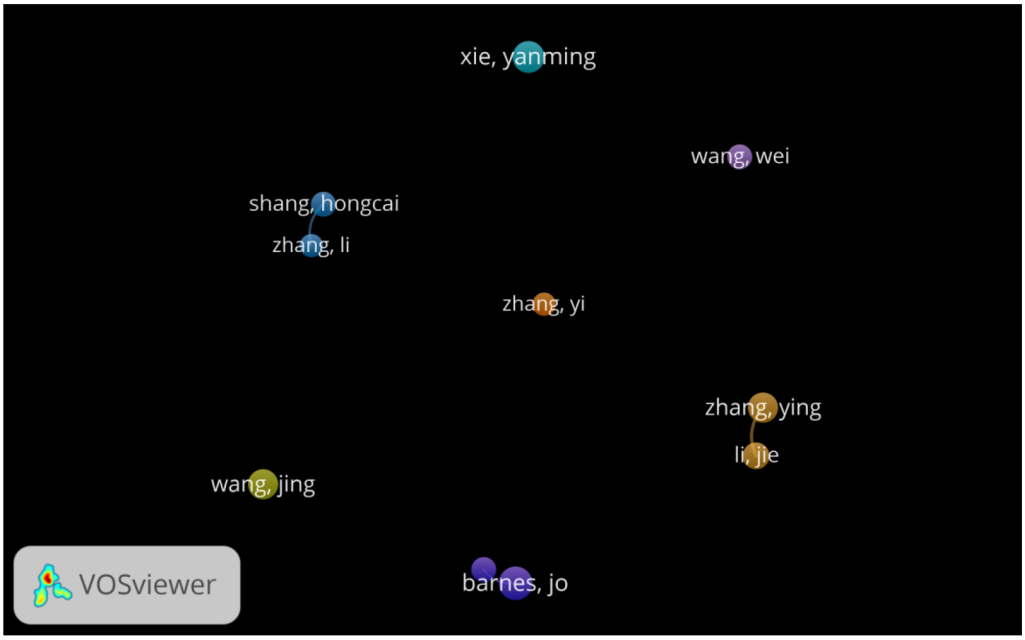


Figure 6. Co-authorship network of researchers in pharmacovigilance and adverse drug reactions in traditional and herbal medicine-related publications (Scopus, 1980–2025).

Table 2. Leading authors in research on pharmacovigilance and adverse drug reactions in traditional and herbal medicine (1980–2025, Scopus)

Sr. No.	Authors	Documents	*Citations*	Total Link Strength
1.	Barnes, Jo	19	1363	1
2.	Xie, Yanming	18	225	0
3.	Zhang, Ying	17	157	3
4.	Wang, Jing	17	291	0
5.	Li, Jie	15	219	3
6.	Shang, Hongcai	14	239	2
7.	Ernst, Edzard w.	14	2059	1
8.	Wang, Wei	14	230	0
9.	Zhang, Li	13	586	2
10.	Zhang, Yi	13	162	0

Frontiers in Pharmacology, *Evidence-Based Complementary and Alternative Medicine*, and *Phytomedicine*. Other contributing journals include *Phytotherapy Research*, *Chinese Journal of Integrative Medicine*, and *PLOS One*, indicating both specialised ethnopharmacology outlets and broader pharmacology/medicine platforms (Table 6). The network demonstrates that research dissemination occurs through a combination of high-impact speciality journals and multidisciplinary biomedical journals, reflecting the growing academic and clinical interest in safety monitoring of herbal and traditional medicines.

4.6 Temporal Trend in Publications

The publication trend on pharmacovigilance and adverse drug reactions in traditional and herbal medicine (Scopus, 1981–2025) reveals a gradual increase in scholarly output over the past four decades. During the 1980s and 1990s, the number of publications remained relatively low, reflecting limited research attention in this area. However, after the early 2000s, a steady rise can be observed, with notable growth from 2010 onwards. A significant surge appears after 2015, reaching its peak in 2024 with 522 publications (Figure 11). This sharp upward trajectory underscores the growing global recognition of safety monitoring, adverse drug reaction reporting, and pharmacovigilance practices in traditional and herbal medicine research.

5. Results and Discussion

The present bibliometric analysis offers one of the most extensive evaluations of global research trends on pharmacovigilance and adverse drug reactions in traditional and herbal medicine, covering a 45-year span

Table 3. Leading institutions in research on pharmacovigilance and adverse drug reactions in traditional and herbal medicine (1980–2025, Scopus)

Sr. No.	Organisation	Documents	*Citations*	Total Link Strength
1.	Beijing University of Chinese Medicine, Beijing, China	182	3038	83
2.	China Academy of Chinese Medical Sciences, Beijing, China	145	2516	78
3.	Guangzhou University of Chinese Medicine, Guangzhou, China	81	999	42
4.	Guangdong Provincial Hospital of Traditional Chinese Medicine, Guangzhou, China	39	459	36
5.	Tianjin University of Traditional Chinese Medicine, Tianjin, China	73	1391	35
6.	Chengdu University of Traditional Chinese Medicine, Chengdu, China	80	1213	23
7.	Shanghai University of Traditional Chinese Medicine, Shanghai, China	99	1515	22
8.	Nanjing University of Chinese Medicine, Nanjing, China	51	756	19
9.	West China School of Medicine/ West China Hospital of Sichuan University, Chengdu, China	40	879	16
10.	Shandong University of Traditional Chinese Medicine, Jinan, China	53	353	12

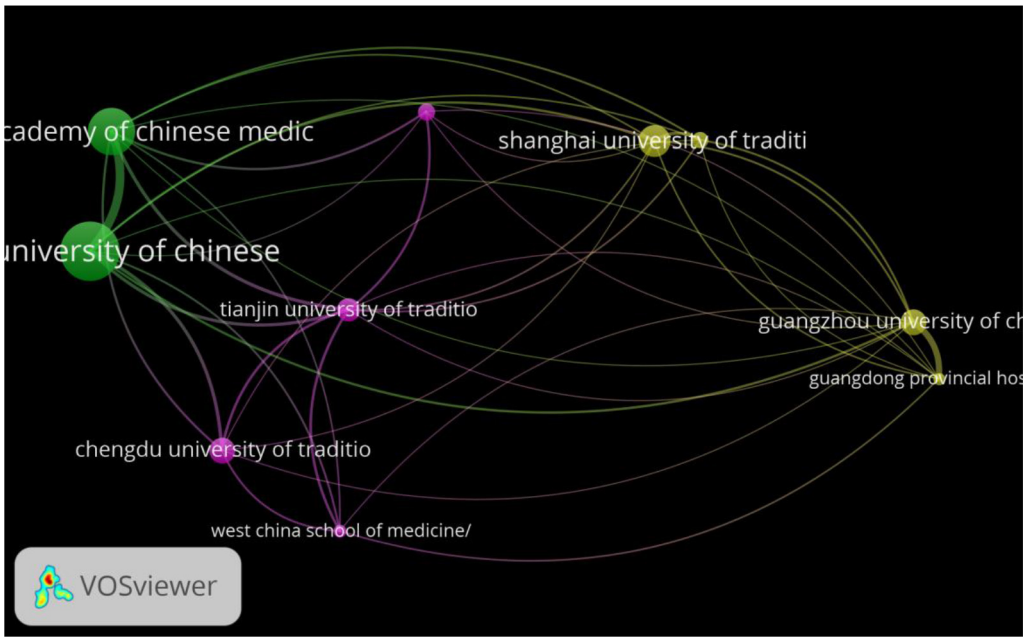


Figure 7. Institutional collaboration network in pharmacovigilance and adverse drug reactions in traditional and herbal medicine-related publications (Scopus, 1980–2025).

from 1980 to 2025. The results demonstrate that scholarly attention to safety, ADR reporting, and regulatory oversight in herbal medicine has increased steadily since the early 2000s, with a sharp acceleration after 2015 and a peak in 2024, reflecting growing international awareness of safety challenges associated with traditional therapies. The thematic landscape is dominated by clinically oriented MeSH and keyword clusters centred around "humans," "adult," "female," "male," and "middle-aged," underscoring that most indexed studies focus on patient-level ADR evaluation rather than mechanistic or product-standardisation research. Strong representation of terms such as "Chinese herbal drugs," "phytotherapy," "plant extracts," and "complementary therapies" highlights the continued reliance on botanical interventions and the

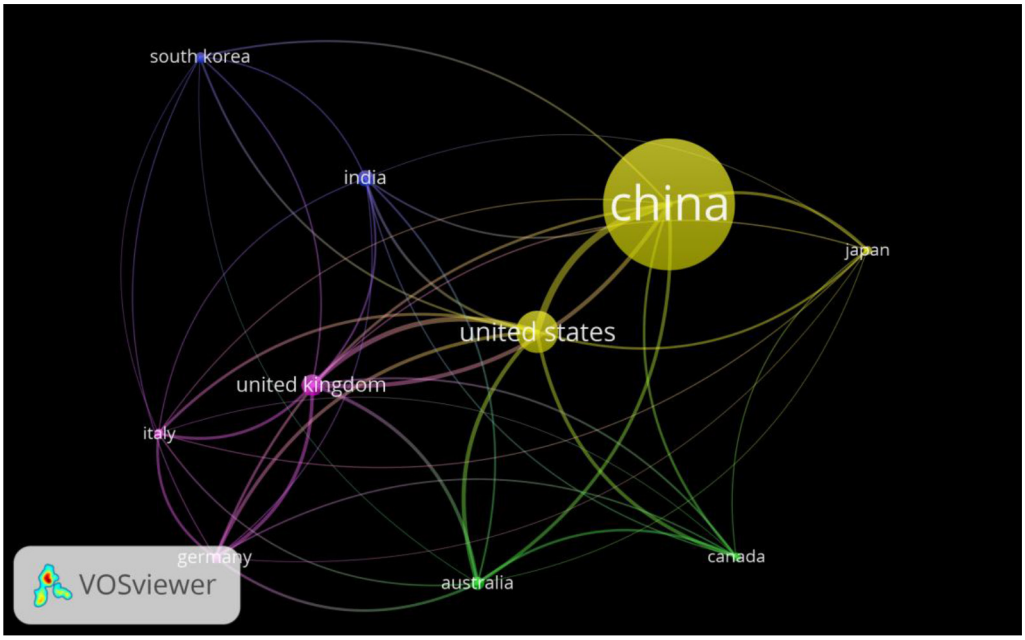


Figure 8. Country-wise collaboration network pharmacovigilance and adverse drug reactions in traditional and herbal medicine related publications (Scopus, 1980–2025).

Table 4. Country-wise distribution of documents, citations and collaboration strength of pharmacovigilance and adverse drug reactions in traditional and herbal medicine-related publications (Scopus, 1980–2025)

Sr. No.	Name of Country	Number of Documents	Number of Citations	Total Link Strength
1	China	1572	27154	167
2	United States	508	19832	219
3	United Kingdom	263	12645	135
4	India	199	4800	39
5	Australia	158	6224	95
6	Germany	133	5645	80
7	South Korea	124	2560	24
8	Italy	122	4533	49
9	Japan	111	2122	33
10	Canada	92	2517	55

pressing need to strengthen safety documentation across both clinical and preclinical domains.

The collaboration networks reveal that although over 20,000 authors and thousands of institutions contribute to this field, global connectivity remains limited. China, the United States, the United Kingdom, and India form the core of research productivity, with Chinese institutions contributing the largest share of publications, yet exhibiting predominantly regional cluster collaboration rather than broad international integration. Similarly, country-level networks show powerful hubs such as China and the United States linked to several secondary collaborators, but with significant fragmentation across Asia, Europe, and Africa. Journals like the *Journal of Ethnopharmacology*, *Medicine (United States)*, *Frontiers in Pharmacology*, and *Phytomedicine* dominate publication output, reflecting a multidisciplinary ecosystem spanning ethnopharmacology, pharmacology, and clinical medicine. Citation analyses further underscore the field's dependence on seminal safety-related works, including

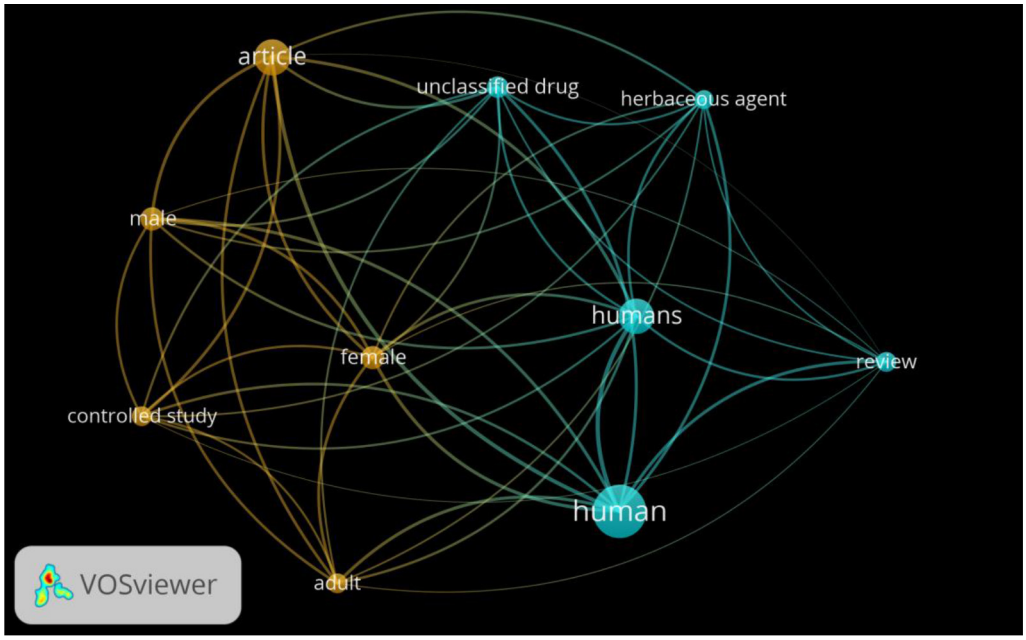


Figure 9. Keyword co-occurrence network in pharmacovigilance and adverse drug reactions in traditional and herbal medicine-related research (Scopus, 1980–2025).

Table 5. Leading keywords in research on pharmacovigilance and adverse drug reactions in traditional and herbal medicine (1980–2025, Scopus)

Sr. No.	Keyword	Occurrences	Total link strength
1.	Human	3084	11448
2.	Article	2094	8820
3.	Humans	2064	8495
4.	Male	1390	7115
5.	Female	1376	7202
6.	Unclassified drug	1284	5819
7.	Review	1173	3173
8.	Adult	1157	6308
9.	Controlled study	1154	5669
10.	Herbaceous agent	1140	5183

major reviews on herbal adverse effects and herb-drug interactions.

Collectively, these patterns reveal a research landscape that is rapidly expanding yet structurally uneven, clinically weighted, geographically imbalanced, and methodologically fragmented. To better understand current progress and future directions, the results were further analysed to identify existing research gaps and to propose research questions. These insights not only highlight the limitations of current pharmacovigilance practices in herbal medicine but also provide strategic directions for enhancing patient safety, strengthening regulatory systems, and fostering multidisciplinary research collaborations.

5.1 Investigation of Research Gap Regarding the Pharmacovigilance and Adverse Drug Reactions in Traditional and Herbal Medicine Research

The bibliometric analysis highlights several underexplored areas in pharmacovigilance and adverse drug reactions in traditional and herbal medicine-related research that impede its broader acceptance in integrative healthcare. These identified gaps, presented in Table 7, provide a foundation for future studies aiming to bridge traditional knowledge with modern scientific frameworks.

The findings summarised in Table 7 reveal persistent gaps that hinder the comprehensive implementation of pharmacovigilance in traditional and herbal medicine research. These deficiencies, including inconsistent reporting systems, limited data on herb–drug interactions and weak international collaboration, highlight the urgent need for harmonised methodologies and stronger regulatory integration. While the bibliometric analysis provides valuable insights into global research patterns

and emerging priorities, certain constraints must be acknowledged to accurately interpret these results.

5.2 Recommended Research Questions for Scholarly Study

To advance the scientific understanding and translational relevance of pharmacovigilance and adverse drug reactions in traditional and herbal medicine, future research must address specific thematic areas. Table 8 outlines key focus areas along with recommended research questions that can guide robust, multidisciplinary investigations in this field.

The research questions outlined in Table 8 provide a structured framework for advancing pharmacovigilance and ADR-related investigations in traditional and herbal medicine. They emphasise the need for an integrated approach combining clinical, regulatory and technological perspectives. However, despite these proposed directions, current research still

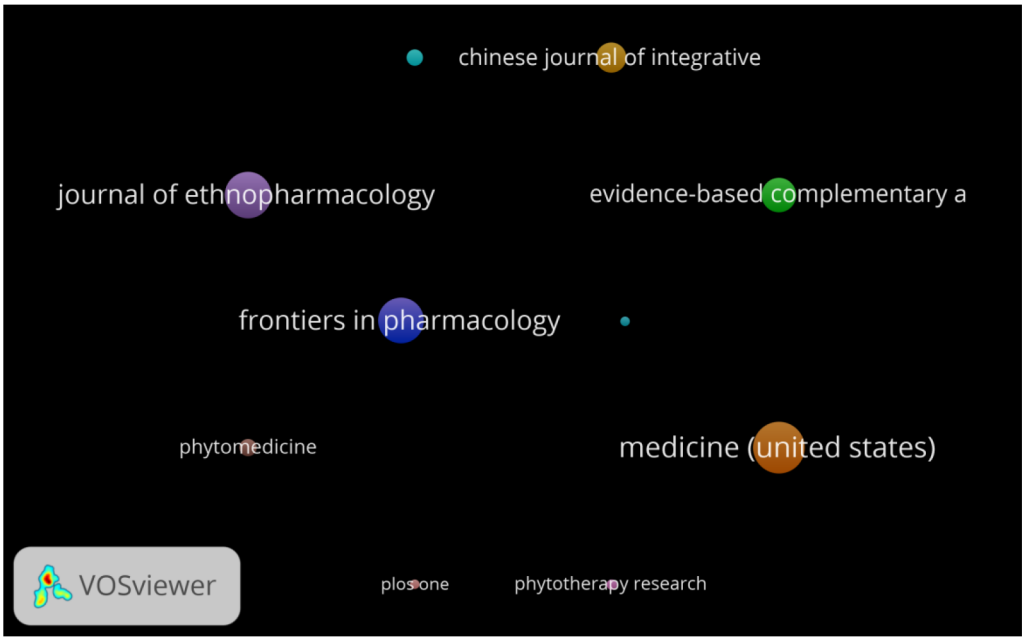


Figure 10. Journal-wise publication trends on pharmacovigilance and adverse drug reactions in traditional and herbal medicine (1980–2025).

Table 6. Leading sources in research on pharmacovigilance and adverse drug reactions in traditional and herbal medicine (1980–2025, Scopus)

Sr. No.	Source	Documents	Citations	Total Link Strength
1.	Chinese Journal of Integrative Medicine	100	1633	0
2.	Drug Safety	56	2879	0
3.	Evidence-based Complementary and Alternative Medicine	114	1987	0
4.	Frontiers in Pharmacology	152	2223	0
5.	Journal of Ethnopharmacology	155	5007	0
6.	Journal of Traditional Chinese Medicine	32	307	0
7.	Medicine (United States)	171	1138	0
8.	Phytomedicine	59	1783	0
9.	Phytotherapy Research	36	2623	0
10.	Plos One	34	723	0

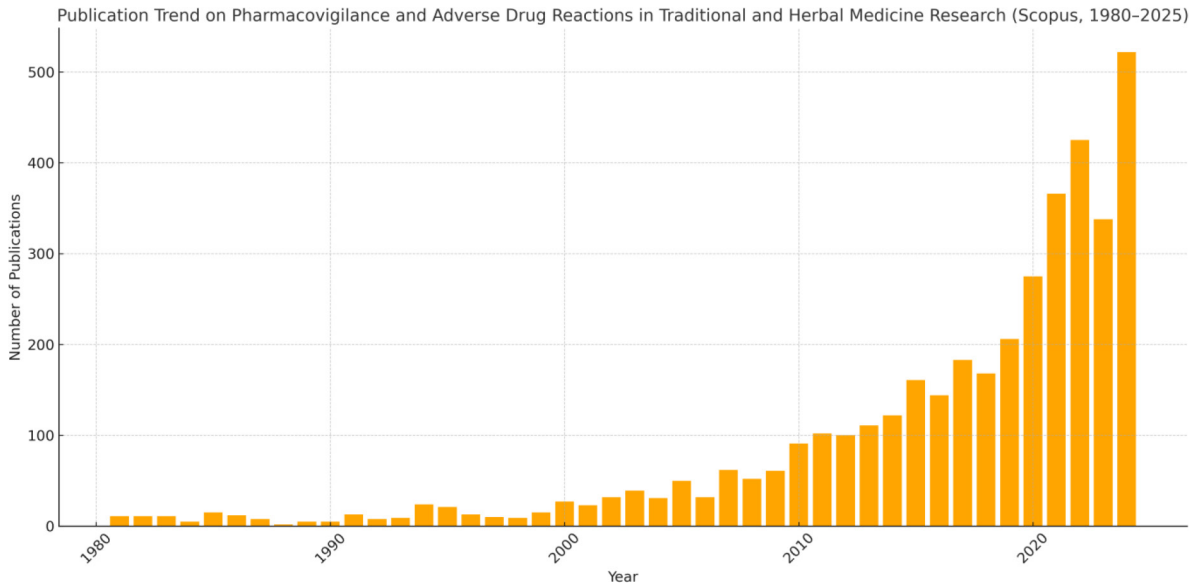


Figure 11 Publication trend on pharmacovigilance and adverse drug reactions in traditional and herbal medicine-related research (Scopus, 1980–2025).

Table 7. Identified research gaps regarding pharmacovigilance and adverse drug reactions in traditional and herbal medicine-related research

Sr. No.	Category	Research Gap
1	Pharmacovigilance Infrastructure	Lack of structured and dedicated pharmacovigilance systems for traditional and herbal medicines in many regions.
2	Adverse Drug Reaction Data	Limited systematic reporting and under-reporting of ADRs related to herbal medicine use.
3	Causality Assessment	Inadequate and non-standardised methods for assessing causal relationships between herbal medicines and reported ADRs.
4	Herb–drug Interactions	Scarcity of comprehensive data on clinically significant herb–drug interactions and their health implications.
5	Product Quality and Standardisation	Variability in formulation, dosage and quality control of herbal products contributes to inconsistent ADR patterns.
6	Regulatory Frameworks	Regulatory gaps and a lack of harmonised global policies for ADR monitoring and reporting in herbal medicine.
7	Awareness and Training	Insufficient knowledge and training among healthcare professionals, traditional medicine practitioners and patients about ADR reporting.
8	Research Methodologies	Limited use of advanced research designs, real-world evidence and technological tools for ADR monitoring.
9	Digital Innovations	Underutilisation of AI, big data and mobile health applications for surveillance of ADRs in herbal medicine.
10	Global Collaboration	Weak international collaboration and data-sharing platforms for monitoring ADRs in traditional and herbal medicine.
11	Population Diversity	Lack of studies covering diverse populations, ethnicities, and age groups limits the generalisability of ADR findings.
12	Long-term Safety Data	Scarcity of longitudinal studies assessing chronic or cumulative adverse effects of traditional and herbal medicines.
13	Integration with Conventional Medicine	Poor integration of traditional medicine ADR data with conventional pharmacovigilance databases reduces overall monitoring efficiency.
14	Standardised Terminology	Absence of universally accepted terminology for ADRs in herbal medicine leads to inconsistent reporting and data interpretation.

Table 8. Proposed research questions for advancing the pharmacovigilance and adverse drug reactions in traditional and herbal medicine-related research

Sr. No.	Research Focus Area	Recommended Research Questions
1	Pharmacovigilance Systems	a) How can existing pharmacovigilance frameworks be adapted to effectively monitor traditional and herbal medicines? b) What mechanisms can be developed for integrating ADR reporting in traditional medicine practice?
2	Adverse Drug Reactions (ADRs)	a) What are the most frequently reported ADRs associated with commonly used herbal medicines? b) How can causality assessment methods be refined for herbal medicine–related ADRs?
3	Methodological Approaches	a) Which study designs are best suited to capture ADRs in traditional and herbal medicine use? b) How can real-world evidence and observational data be systematically incorporated into safety monitoring?
4	Herb–Drug Interactions	a) What types of interactions occur between herbal medicines and conventional drugs, and how can these be predicted or prevented? b) Which high-risk patient groups are most vulnerable to herb–drug interactions?
5	Quality and Standardisation	a) How do variations in preparation, dosage and quality of herbal products influence ADRs? b) What standards can be implemented to reduce risks related to adulteration and contamination?
6	Regulatory and Policy Aspects	a) What are the regulatory gaps in ADR reporting for herbal medicine across different regions? b) How can harmonised global pharmacovigilance policies for herbal medicines be developed?
7	Awareness and Education	a) What strategies can enhance awareness among healthcare professionals and traditional medicine practitioners regarding ADR reporting? b) How can public health campaigns improve patient knowledge on the safe use of herbal medicines?
8	Digital and Technological Tools	a) How can digital platforms, AI and big data analytics be applied for ADR detection in herbal medicine use? b) What role can mobile applications play in improving community-based pharmacovigilance reporting?
9	Global Research Collaborations	a) How can international collaborations strengthen data sharing and standardisation in herbal medicine pharmacovigilance? b) Which collaborative networks can help map global trends and gaps in herbal ADR reporting?
10	Patient-Reported Outcomes	a) How can patient-reported data be integrated into pharmacovigilance frameworks for herbal medicines? b) What tools or surveys can accurately capture adverse events from self-administered herbal therapies?
11	Economic and Health Impact	a) What is the economic burden of herbal medicine-related ADRs on healthcare systems? b) How can cost-effectiveness analyses inform policy decisions regarding herbal pharmacovigilance?
12	Emerging and Novel Therapies	a) How should pharmacovigilance frameworks adapt to new herbal formulations, nutraceuticals, and combination therapies? b) What predictive models can assess safety profiles of newly introduced herbal medicines?

shows uneven progress across regions and thematic areas. To better contextualise these challenges, a detailed examination of the existing research gaps was undertaken, highlighting the critical areas where evidence remains limited and where focused scientific attention is required to strengthen pharmacovigilance systems globally. The following section outlines the key limitations of the present study, which should be considered when evaluating its findings and implications.

6. Limitations

This study has some limitations. First, the bibliometric analysis relied exclusively on two major databases (PubMed and Scopus), which may have resulted in the exclusion of relevant studies indexed in other sources such as Web of Science or regional repositories. Secondly, the analysis was restricted to English-language publications, potentially omitting important contributions in local languages, particularly from regions where traditional medicine is widely practised. Thirdly, the bibliometric tools employed (*e.g.*, VOSviewer) were limited to quantitative mapping and cannot capture qualitative dimensions such as the depth of pharmacovigilance reporting or the clinical relevance of adverse drug reactions. Fourth, although the time frame of 1980–2025 provides a long-term perspective, it may still exclude earlier foundational work or historical safety reports that could add further context to the evolution of this field. Finally, citation counts, author collaborations, and country-level outputs are influenced by indexing practices, publication delays, and varying visibility of journals, which may lead to underrepresentation of emerging research or regional scholarship. Despite these limitations, the study's strengths lie in its systematic approach, robust visualisation methods, and comprehensive mapping of global research trends in safety and pharmacovigilance related to traditional and herbal medicine. It offers valuable insights into collaborative patterns, thematic hotspots, and research gaps, serving as a roadmap for future investigations in this critical area of healthcare.

7. Conclusion

This four-decade bibliometric analysis (1980–2025) offers a comprehensive overview of global research on pharmacovigilance and ADRs in traditional and herbal medicine. A total of 8019 publications (4382 from PubMed and 3637 from Scopus) were identified, reflecting a steady rise in scholarly attention, particularly over the past decade. China, the United States, and India emerged as major contributors, with strong publication outputs but limited cross-regional integration, underscoring the need for broader international collaborations. Key journals such as the *Journal of Ethnopharmacology*, *Frontiers in Pharmacology*, and *Phytomedicine* serve as influential platforms for disseminating research in this field. Keyword and MeSH co-occurrence mapping revealed dominant clinical and safety-related themes, with frequent associations to "*herbal drugs*," "*phytotherapy*," and "*humans*," highlighting the growing emphasis on human-centred safety evaluations. Despite this progress, significant gaps persist, including weak pharmacovigilance infrastructure for herbal medicines, underreporting of ADRs, limited causality assessment tools, insufficient documentation of herb–drug interactions, and lack of harmonised global regulatory frameworks. Furthermore, underutilisation of advanced methodologies, digital surveillance tools, and interdisciplinary approaches continues to restrict the robustness of safety monitoring systems. To strengthen the evidence base and ensure safer integration of herbal medicines into global healthcare, it is crucial to foster structured pharmacovigilance systems, enhance international data-sharing, and integrate real-world evidence with modern analytical technologies. Future research must also prioritise capacity building, practitioner awareness, and policy development to bridge existing regulatory and methodological divides. By identifying research hotspots and critical gaps, this study provides a roadmap for advancing pharmacovigilance practices and ensuring patient safety in the era of increasing reliance on traditional and herbal medicine.

8. Conflict of Interest

The author is an Associate Editor of Toxicology International. The author had no involvement in the editorial handling or peer-review of this manuscript. An independent editor will manage all stages of the review process to ensure transparency and eliminate any potential bias.

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Author Contributions

Conceptualisation: AG; Methodology: AG, MS; Formal analysis and investigation: AG, SB, RP, MS; Data curation: AG, MS; Writing – original draft preparation: AG; Writing – review and editing: SB, RP, MS; Supervision: SB; Validation: AG, SB; Visualisation: AG, MS; Software: AG, MS; All authors reviewed the manuscript.

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