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PHARMACOVIGILANCE

Global research output in ‘pharmacovigilance’ during 2010–2020

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Summary The rapid spread of Covid-19 pandemic globally has thrust drugs safety into the spotlight and the public is now more aware of the role of healthcare professionals and health regulators. The present study aimed to measure the global research landscape on pharmacovigilance (PV) indexed in Scopus database for eleven years period spanning from 2010–2020. The study has sought to use quantitative and visualization technologies for data analysis and interpretation. The search strategy accumulated a total of 2052 global publications data on PV. The findings disclose that the global research productivity on PV registered 8.74% average growth rate (AGR) and 7.38% compound average growth rate (CAGR). The mean relative growth rate (RGR) and doubling time (DT) of PV global publications for the 11 years is 0.27 and 3.03, respectively. The average number of authors per paper (AAPP) is 1.52 and average productivity per author (PPA) is 0.68. The authorship patterns in PV research shows collaborative trend as most of the publications have been published by multiple authors (80.75%). The mean values of degree of collaboration (DC), collaboration index (CI), collaboration coefficient (CC) and modified collaboration coefficient (MCC) during the selected period of study are 0.79, 2.74, 0.72, and 0.73, respectively which highly significant and indicates the better authorship collaborations. France is the bellwether in PV related scientific research as produced the highest number of publications.

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Abbreviations

ACP average citations per paper
ADRs adverse drug reactions
AGR average growth rate
Introduction

Pharmacovigilance (PV) is an arm of patient care in making the rational use of medicines for the prevention of disease. In the recent times, the PV is of great importance as it is a key element in the regulation of effective drug use systems for the detection and prevention of adverse drug reactions (ADRs). According to the World Health Organization (WHO), ADRs defines as “a response to a drug which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for the modifications of physiological function” (as cited by Ibrahim et al. [1]). As per the WHO, ADRs are responsible for a significant number of hospital admissions ranging between 0.3 ≥ 11 percent [2,3]). The WHO has defined the PV as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem” [4].

PV is all about the safer and more effective use of medicines for everyone. PV has been regarded as a continuous monitoring of undesired effects and drugs safety related issues. Therefore, the development of PV within a public health programme should be seen as an important opportunity towards the development of PV within the local health service of a comprehensive National PV System and should be seen as an obligatory investment in the future public health of the territory [5,6]. According to WHO, the aims of PV are to:

- encourage the safe, rational and more effective use of medicines; and
- promote understanding, education and clinical training in PV and its effective communication to the public.

The safety monitoring of medicines has been used in national health programs of various countries and with the measures of education, awareness, training and technical assistance, the patients or consumers (the end users of the healthcare products) are now reporting the ADRs [7]. The healthcare professionals are the cornerstone in detection and reporting of ADRs to ensure medications safety [8].

To coordinate, report and monitoring ADR detection at global level, the World Health Organization (WHO), Geneva has established the pharmacovigilance (PV) unit at Uppsala Monitoring Center (UMC), Sweden. The current global network consisting of 145 countries have been reporting ADRs to the UMC, Sweden [6].

Within the pharmaceutical field, PV deserves a special attention, as it monitoring the performance of the pharmaceutical products that already available in the market. Although the pharmaceutical products are formulated to prevent, alleviate and to cure the illnesses but even can produce undesirable harmful effects. This duality of pharmaceutical products has significant for the public health and makes PV as an essential activity for health regulation in the country. Through early detection of the risk and timely intervention, the PV protects population from the damage caused by the pharmaceutical products.

PV importance in COVID-19 pandemic

In the current scenario, the clinical trials in drug therapy or drug discovery against novel coronavirus prove the importance of PV. The global devastating impact of coronavirus disease 2019 (COVID-19) pandemic has been pushed the PV to innovate and develop new and more efficient ways for collecting and utilizing the drug’s safety data. It’s a global concern that sufficient information related to safety of therapies or different treatment alternatives being used for the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections is limited. In light of the rapid drug discovery process (vaccine or drugs) across the globe, it is crucial that countries must share relevant ADRs in a time bound manner towards better understanding the efficacy and safety of the treatment or therapies used against the COVID-19 to manage long-term and pre-existing conditions.

WHO-UMC has provided useful information and issued necessary guidelines to perform the PV work during this COVID-19 pandemic, these include the following:

- medicines safety during COVID-19;
- how to capture adverse event reports (coding guidance) for COVID-19 treatments; and
- how to find adverse event reports linked to COVID-19 in VigilLyze (application used to visualize and analyze the drug safety data in COVID-19).

The rapid spread of COVID-19 pandemic globally has thrust drugs safety into the spotlight and the public is now more aware of the role of health professionals and health regulators. Therefore, the PV experts, clinicians, stakeholders and drug regulators needed to collaborate and assess the
suspected ADRs timely to the success of public health across the globe.

In the scientific scenario, the production of the thematic area of PV has increased significantly over the past years. Therefore, it is essential to evaluate this production. In fact, a limited number of bibliometric studies carried out to measure the quality and impact of PV and ADRs related research activities have concentrated on the traditional bibliometric investigations extricated data from Web of Science, Scopus, and PubMed database. Therefore, the present study has tried to bridge the research gap and studies the collaborative networks using the knowledge mapping techniques.

Statement of the problem

In light of the rapid drug discovery process (vaccine or drugs) across the globe, prove the importance of PV in relation to safety of therapies or different treatment alternatives being used for the COVID-19 infections. Therefore, PV across the world has become the important public health issue concern to regulators, drug manufacturers, and the healthcare professionals. In light of its increasing relevance, the present study is an effort to evaluate the global research productivity in PV and assess the current research trends on a set of quantitative and qualitative metrics to provide some insights into the complex dynamics of research productivity on PV.

Review of related literature

A limited number of bibliometric analyses related to PV, ADRs, and medication errors have been carried out. Huang, Du and Cong [9] analyze the global research trends of PV in China and identified the growth in hospitals, pharmaceutical enterprises, and of the opinion that the collaborations between institutions were tight. Zheng, Cheng and Song [10] in analyzing the current status and shortcomings of PV research in China, revealed that the PV research in China still focuses on traditional adverse drug reactions monitoring. The global research growth and patterns on systemic use of off-label and unlicensed drugs has witnessed a general increase in the past two decades [11].

Shrestha et al. [12] emphasized that there is a need to study and evaluate ADR and PV in Nepal to improve PV practice and to promote the quality use of medicines. Zhang et al. [13] stressed that the comprehensive features and the risk factors of cardiac ADRs induced by oral Chinese Materia Medica can be elucidated through the approaches of bibliometric research towards creating awareness of PV. Chen et al. [14] in the field of event detection in social media (ED in SM) identified PV event detection as newly emerged themes among the 14 identified research themes. AlHusaini and AlMubarak [15] emphasized that education on ADRs medical safety are necessary for the population for gaining more awareness of consequences of ADRs and for the healthcare provider to give a clear and accurate information to the patients.

Moore et al. [16] reported that the discovery and quantification of ADRs has long relied on the careful analysis of spontaneously reported cases and the spontaneous reporting remains irreplaceable in signal and alert generation in drug safety. The availability of large databases and computerized automated statistical approaches has modified the assessment of drug safety and of their benefits harms balance [17]. Abou Taam et al. [18] reported that due to paradigm shift in the assessment and management of patient related drug safety, the importance of pharmacoepidemiology and its use in pharmacovigilance has significantly increased.

Lefebvre et al. [19] to enhance the effectiveness of PV programs, clustered the 1244 respondents into 4 segments: not engaged (12%), low-involvement users (29%), careful users (50%) and social information seekers (9%) distinguishing by perceived seeking control, self-appraisal of skill, information insufficiency, self-efficacy, information competency and health literacy towards identifying for prescription drug safety social marketing and communication activities. The result shows significant differences among the segments in their comprehension and perceived utility.

Wilbur, Sahal and Elgaily [20] explore how the pharmacists identify, prioritize, and communicate ADRs to patients in a Doha hospital, Qatar. They found that expert cardiology pharmacists used widely accessible resources during choosing the most commonly reported ADR to communicate during medication counselling. Shang, Chen and Livoti [21] proposed a framework to detect Avandia ADRs using Google Trends to early identify the ADR events and the resultant data proved to have a longer leading time than the traditional drug reaction discovery methods.

The research related to detection methods of cardiotoxicity and preventive drugs is gradually increasing [22]. With the extensive digitalization of medical information globally, the natural language processing is becoming more crucial [23]. Santos et al. [24] highlights the significant increase in the papers from 2009–2018 focusing mostly on infectious, parasitic and communicable diseases, chronic diseases, and risk factors for chronic diseases. The Journal of Medical Internet Research and PLoS ONE published the highest number of papers. Huang et al. [25] retrieved 3343 medication errors and 3352 adverse drug event documents from 1961–2013 through Web of Science database. The study focused 3 key themes namely medication errors in adult inpatients, computerized physician order entry in medication error studies, and medication errors in pediatric inpatients. More research on implementing patient safety improvement initiatives might be needed [26].

Research objectives

The main objective of the study is to measure the global research landscape in the field of PV as reflected in the publication output spanning from 2010–2020. The specific objectives of the study are:

- to identify the growth rates and doubling time of PV research;
- to identify the author productivity and collaborative trends in PV research;
- to identify the contributions of the prolific authors, institutions and countries in PV research;
- to identify the prominent research themes using the keywords analysis.
Table 1 Types of publications.

| Types of Publications | TNP | %TNP | TNC | %TNC | h-index |
|-----------------------|-----|------|-----|------|---------|
| Article               | 1317| 64.18| 10828| 77.14| 47      |
| Review                | 202 | 9.84 | 1909 | 13.61| 25      |
| Letter                | 107 | 5.21 | 350  | 2.49 | 12      |
| Book Chapter          | 99  | 4.83 | 83   | 0.59 | 5       |
| Note                  | 85  | 4.14 | 284  | 2.02 | 12      |
| Editorial             | 79  | 3.85 | 315  | 2.24 | 11      |
| Short Survey          | 75  | 3.66 | 47   | 0.34 | 4       |
| Conference Paper      | 71  | 3.46 | 195  | 1.39 | 8       |
| Book                  | 7   | 0.34 | 18   | 0.13 | 2       |
| Erratum               | 7   | 0.34 | 2    | 0.01 | 1       |
| Undefined             | 3   | 0.15 | 6    | 0.04 | 2       |

TNC: total number of citations; TNP: total number of publications.

Material and methodology

The global research publications data on PV was retrieved and downloaded from Scopus database for the period from 2010-2020 using "date range tag". The Scopus database was used as a tool to retrieve potential publications as Scopus database in terms of wide global coverage of scientific journals, is the largest abstract and citation databases. The search string used for the purpose included "pharmacovigilance" as per the Medical List of Subject Heading. A total of 6789 publications data were retrieved as recall value through the search string "TITLE-ABS-KEY (pharmacovigilance) AND PUBYEAR > 2009 AND PUBYEAR < 2021". Further, to precise the result, the search query was refined as "TITLE (pharmacovigilance) AND PUBYEAR > 2009 AND PUBYEAR < 2021" for retrieving the most refined and potential datasets. As a result, the search strategy accumulated a total of 2052 (TNP = 2052) global publications data on PV. The global data between 2010 and 2020 were downloaded on 27th October, 2021 for analysis based on the preset query sets. The study has sought to use quantitative and visualization technologies for data analysis and interpretation. Network visualization maps including research collaboration of authors, journals, institutions and countries were created by using the VOSviewer program. The study has also made use of analytical provisions as available in the Scopus database [27].

Bibliometrics indicators and scientometric parameters used

Author has used two bibliometric indicators in the present study. These are total number of publications (TNP) and total number of citations (TNC) for measuring the scientific output and impact. Besides these bibliometric indicators, two relative indicators viz average citations per paper (ACP) and relative citation impact (RCI) have also been used. Various scientometric parameters have also been applied such as average growth rate (AGR), compound average growth rate (CAGR), relative growth rate (RGR), doubling time (DT), Pearson correlation, authors’ productivity and explored statistical techniques for the present study. To measure collaboration patterns among authors; degree of collaboration (DC), collaboration index (CI), collaboration coefficient (CC), and modified collaboration coefficient (MCC) methods used.

Result and discussion

Types of publications

The study presents the types of publications in PV related global scientific research output during the study period from 2010—2020. Ten (n = 10) types publications excluding undefined category indexed in the Scopus database were found in the total publications (TNP = 2052) retrieved. The researchers of PV preferred to publish work in the form of the journal article with a proportion of 64.18 per cent (n = 1317) of the total publications. At the second place was review accounting for 9.84 per cent (n = 202). Other publication types included letter with proportion of 5.21 per cent (n = 107), book chapter with 4.83 per cent (n = 99), note with 4.14 per cent (n = 85), editorial with 3.85 per cent (n = 79), short survey with 3.66 per cent (n = 75) and conference paper accounting for 3.46 per cent (n = 71) publication share. The table shows that less than 1 per cent of publications appeared as book and erratum. The impact of citation in the terms of research was also noticeable in PV related global research output and journal articles with h-index 47 received the highest number of citations with a proportion of 77.14 per cent (n = 10828) of the total citations (TNC = 14037), followed by review accounting for 13.61 per cent (n = 1909) (Table 1).

Source types

The journals considered as the vital source and main channel of information towards disseminating the research output. Five (n = 5) source types excluding undefined category indexed in the Scopus database were found in the total publications (TNP = 2052) retrieved. The most preferred source type was journal accounting for 90.74 per cent (n = 1862) of the total publications. At the second position was book with a proportion of 4.53 per cent (n = 93). Other source
types included conference proceedings accounting for 1.99 per cent (n = 41), book series with 1.37 per cent (n = 28) and trade journal with a proportion of 1.32 per cent (n = 27). The impact of citation in the terms of research was also noticeable in PV related global research output and journal received the highest number of citations with a proportion of 98.25 per cent (n = 13791) of the total citations (TNC = 14037), followed by conference proceedings accounting for 0.78 per cent (n = 109) (Table 2).

Global research output and citations count

Table 3 demonstrates the chronological global research output (TNP = 2052) and the impact of citations (TNC = 14037) on PV literature during the study period from 2010–2020. The PV has made a remarkable development in terms of scientific principles and effective clinical practices towards establishing itself as a well-recognized research topic. This led to the rapid jump in the number of publications over the past years. The global research output in PV registered an 8.74 per cent AGR and 7.38 per cent CAGR. The research impact of global publications in PV averaged to 6.84 ACP. Of the retrieved publications data, it revealed that the year 2018 has recorded the highest annual output with a proportion of 12.33 per cent (n = 2326) and fetched 16.57 citations (n = 2326) averaged to 9.19 ACP. The lowest output recorded in the year 2010 with a proportion of 5.17 per cent (n = 106) with 0.19 per cent citations. The highest h-index 25 is in the year 2011 (Table 3).

The following equation is used for calculating the AGR:

\[ r = \frac{P_1 - P_0}{P_0} \times 100 \]

Where, \( r \) = Publication growth in percentage 
\( P_0 \) = Number of publication in the base year 
\( P_1 \) = Number of publication in the present year

The formula given by Pandya, Joorel and Solanki [28] is used to calculate the compound average growth rate (CAGR).

\[ CAGR = (V_{final} / V_{begin})^{1/t} - 1 \]

Where, 
\( CAGR \) = compound average growth rate 
\( V_{begin} \) = beginning value 
\( V_{final} \) = final value 
\( t \) = time in years

Relative growth rate and doubling time of publications

Relative growth rate (RGR) is a measure to study the increase in the number of publications per unit of time over the specific period of the interval and is calculated using the following equation (as cited in Mohan and Kumbar [29]):

\[ RGR = \frac{lnN2 - lnN1}{t2 - t1} \]

Where,
The degree of collaboration (DC) defined as “the ratio of the number of collaborative publications to the number of publications in a given field during a particular period of time”. The equation given by Subramanyam [31] is used to calculate the DC:

\[
\text{Degree of collaboration (DC)} = \frac{Nm}{Nm + Ns}
\]

where,

\[
DC = \text{degree of collaboration}
\]

\[
Nm = \text{number of multiple-authored research papers}
\]

\[
Ns = \text{number of single-authored research papers}
\]

Collaboration index (CI) is a measure of mean number of authors and it neither lies between 0 and 1 and nor expressible in terms of percentage. The following equation is used to count the CI:

\[
\text{CI} = \frac{\sum_{j=1}^{A} fj}{N}
\]

where, \( j \) = number authors in an article; \( fj \) = number of \( j \) authored articles

\[
N = \text{total number of articles published in a year}
\]

\[
A = \text{total number of authors per articles}
\]

Collaboration coefficient (CC) vanishes for a collection of single-authored papers and distinguishes between single-authored, two authored, three-authored, etc., papers. However, it fails to yield 1 for maximal collaboration, except when the number of authors infinite [32,33]. The following equation is used to count the CC:

\[
\text{CC} = 1 - \frac{\sum_{j=1}^{A} fj}{N}
\]

Modified collaboration coefficient (MCC) is a measure for quantifying the degree of research collaboration. The following equation is used to count the MCC:

\[
\text{MCC} = \left( \frac{N}{N - 1} \right) \left( 1 - \frac{\sum_{j=1}^{A} fj}{N} \right)
\]
Table 5  Authors’ productivity.

| Time span | TNP | TNA | AAPP | PPA |
|-----------|-----|-----|------|-----|
| 2010      | 106 | 203 | 1.92 | 0.52|
| 2011      | 139 | 250 | 1.79 | 0.56|
| 2012      | 167 | 231 | 1.38 | 0.72|
| 2013      | 156 | 260 | 1.67 | 0.60|
| 2014      | 207 | 266 | 1.29 | 0.78|
| 2015      | 185 | 223 | 1.21 | 0.83|
| 2016      | 190 | 325 | 1.71 | 0.59|
| 2017      | 221 | 281 | 1.27 | 0.79|
| 2018      | 253 | 331 | 1.31 | 0.76|
| 2019      | 196 | 341 | 1.74 | 0.58|
| 2020      | 232 | 327 | 1.41 | 0.71|

AAP: average author per paper; PPA: productivity per author; TNA: total number of authors; TNP: total number of publications.

Table 6  Authorship collaboration.

| Time span | TNP | TNA | Single-authored documents Ns | Multi-authored documents Nm | DC | CI | CC | MCC |
|-----------|-----|-----|------------------------------|----------------------------|----|----|----|-----|
| 2010      | 106 | 203 | 35                           | 71                          | 0.67| 2.65| 0.78| 0.79|
| 2011      | 139 | 250 | 45                           | 94                          | 0.68| 2.48| 0.76| 0.77|
| 2012      | 167 | 231 | 49                           | 118                         | 0.71| 2.62| 0.75| 0.76|
| 2013      | 156 | 260 | 36                           | 120                         | 0.77| 2.58| 0.71| 0.72|
| 2014      | 207 | 266 | 45                           | 162                         | 0.78| 2.64| 0.73| 0.74|
| 2015      | 185 | 223 | 43                           | 142                         | 0.77| 2.56| 0.76| 0.77|
| 2016      | 190 | 325 | 30                           | 160                         | 0.84| 2.51| 0.74| 0.75|
| 2017      | 221 | 281 | 32                           | 189                         | 0.86| 2.84| 0.72| 0.73|
| 2018      | 253 | 331 | 45                           | 208                         | 0.82| 3.17| 0.74| 0.74|
| 2019      | 196 | 341 | 15                           | 181                         | 0.92| 3.16| 0.71| 0.72|
| 2020      | 232 | 327 | 20                           | 212                         | 0.91| 3.19| 0.57| 0.57|

CC: collaboration coefficient; CI: collaboration index; DC: degree of collaboration; MCC: modified collaboration coefficient; TNA: total number of authors; TNP: total number of publications.

The analysis discloses that the authorship patterns in PV research shows collaborative trend as the most of the publications have been published by multiple authors. In all, a total of 80.75 percent (n = 1667) publications have been published in co-authorship, whereas only 19.25 percent (n = 395) published in single-authorship. The resultant data inferred that the magnitude and density of collaborative patterns among the authors are high in PV research. It has been calculated from the data that the DC (0.92) is maximum in the years 2019 and lowest value 0.67 found in the year 2010. The mean value of DC during the selected period of study is 0.79. The calculated values show that the CI is highest in the year 2020 (3.19) and lowest in the year 2011 (2.48). The mean value of CI during the period is 2.74. The analysis demonstrates that the highest value of CC found in the year 2010 (0.78) and lowest in the year 2020 (0.57). The mean value of CC during the study period is 0.72. The figures show that the highest value of MCC found in the year 2010 (0.79) and lowest in the year 2020 (0.57). The mean value of MCC during the selected period is 0.73 (Table 6).

Correlation between number of papers and number of authors

Pearson correlation analysis used to evaluate the correlation between number of papers and the number of authors. The resultant data inferred significant and positive relationship (r = 0.738, n = 11, P = 0.009). As the P-value is < 0.05, therefore, it is highly significant. It means that the higher numbers of co-authors were contributed to the higher number of papers (Table 7).

Most productive authors

It is imperative that contributions by authors in PV related literature have spanned across the globe. A good number of authors (TNA = 3038) had contributed unevenly in global research output in PV. The top ten author’s productivity varied between 21 ≥ 62 publications per author. The top 10 authors dominate research in PV together accounted for 18.37 per cent (n = 377) of global publication share and
Table 7  Correlation between number of papers and number of authors.

|                      | Number of papers | Number of authors |
|----------------------|------------------|-------------------|
| Number of papers     | Pearson correlation | 1                |
|                      | Sig. (2-Tailed)   | 0.738             |
|                      | n                 | 0.009             |
| Number of authors    | Pearson correlation | 0.738            |
|                      | Sig. (2-Tailed)   | 0.009             |
|                      | n                 | 11                |

*Correlation is significant at the 0.05 level.

accounting for 31.69 per cent ($n = 4449$) citations exhibiting with a proportion of citation impact of 11.80 average citations per paper (ACP). It denotes that it is necessary for the authors to collaborate for strengthening the international co-authorship patterns. The resultant data revealed that among the top 10 productive authors; Montastruc, Jean Louis with a proportion of 3.02 per cent ($n = 62$) produced the highest number of publications and most of the publications are in Therapies journal, followed by Thurisch, Boris accounting for 2.63 per cent ($n = 54$) publications and Sickmüller, Barbara with a proportion of 2.39 per cent ($n = 49$) publications ranked at second and third positions, respectively. Other authors with publications ranging between $21 \leq 36$ were actively participated in producing the global research output in PV. The author Lapeyre-Mestre, Maryse has the highest citation impact of 26.88 ACP and exhibit highest 3.92 relative citation impact (RCI). The analysis also discloses that most of the productive authors in the list belong from France (7 authors), followed by Germany (2 authors) and 1 from Sweden. RCI is an indicator (developed by Thomas Reuters erwhile Institute of Scientific Information) used to measure the impact of research production of nations/institutions/authors/journals. The authors having $RCI < 1$ implies that the research output was not commensurate with their impact, whereas, authors having $RCI > 1$ indicates the high impact research (Table 8).

Collaborative network of authors

There were 47 authors meeting the threshold of a minimum of 10 documents per author and grouped into clusters, where cluster indicates group of closely collaborating authorship [34]. The co-authorship network of authors in the field of PV is visually depicted in Fig. 1. Out of the total 3038 authors, 47 meet the criteria; however, only 38 items are seen to be connected in terms of collaboration. The network visualization map demonstrates the strength of collaboration between 38 authors, distributed across 5 clusters, coloured differently, with 142 links and total link strength (TLS) of 572 (Fig. 1).

Most productive countries

In all, a total of one hundred fifty two ($n = 152$) countries contributed unevenly in global PV scientific research. The countries were ranked according to the descending order of their total publications. The top ten countries share ranging between 77 $\geq 373$ publications reflect the major contributions on PV research. France has the highest number of publications with a total of 373 publications accounting for 18.18 per cent of the total publications in this field. It revealed that France is the bellwether in PV related scientific research. United States of America (USA) ranked second with a proportion of 15.11 per cent ($n = 310$) of the total publications, followed by India accounting for 10.09 per cent ($n = 207$) publications share. The top 10 leading countries in a combined manner contributed with a proportion of 85.23 per cent ($n = 1749$) of the total publications denotes increasing in the collaborative research. A large number of publications by the top 10 countries denote that these countries have the greater advantages than the others. The USA has the highest 1.82 RCI followed by Switzerland with 1.54. The countries having $RCI < 1$ implies that the research output was not commensurate with their impact, whereas, countries having $RCI > 1$ indicates the high impact research (Table 9).

Collaborative network of countries

Wang and Chang [35] opined that collaboration network of countries reflect the collaboration relationship in the research. The network visualization map has been created with a threshold of 10 documents per country and out of the total 152 countries participated in the PV research, 39 meet the criteria. These 39 countries have been distributed among 7 clusters, coloured differently, having a total of 254 links and a total link strength (TLS) of 862. As depicted in Fig. 2, clusters of various colours represent the diversification of PV research conducted by authors in collaborative manners. The big nodes represent the dominant countries. The links between the nodes represent the cooperative relationship in PV research. The distance between the nodes and thickness of the links symbolize the cooperative level among the countries (Fig. 2).

Most productive organizations

The total number of PV focused publications was produced by 5322 organizations. The organizations were ranked according to the descending order of their total publications. The top 10 organizations dominate research in PV together accounted for 30.51 per cent ($n = 626$) of global publication share and Exhibit 54.72 per cent ($n = 7682$) citations. The global publication share of top 10 organizations ranging between 36 $\geq 130$ publications reflect the contributions on PV research. The highest share in publication was
Table 8  Most productive authors.

| Most productive authors | Affiliation                                                                 | PC  | %PC  | CR   | %CR  | ACP  | RCI  | h-index | TLS |
|-------------------------|------------------------------------------------------------------------------|-----|------|------|------|------|------|---------|------|
| Montastruc, Jean Louis  | Université Paul Sabatier Toulouse III, France                               | 62  | 3.02 | 1109 | 7.90 | 17.89| 2.62 | 63      | 107  |
| Thurisch, Boris         | Bundesverband der Pharmazeutischen Industrie (BPI) e. V., Germany           | 54  | 2.63 | 4    | 0.03 | 0.07 | 0.01 | 5       | 49   |
| Sickmüller, Barbara    | Bundesverband der Pharmazeutischen Industrie (BPI) e. V., Germany           | 49  | 2.39 | 3    | 0.02 | 0.06 | 0.01 | 4       | 49   |
| Bagheri, Haleh          | Centre Hospitalier Universitaire De Toulouse, France                         | 36  | 1.75 | 648  | 4.62 | 18   | 2.64 | 27      | 65   |
| Montastruc, Francois    | Centre Hospitalier Universitaire De Toulouse, France                         | 32  | 1.56 | 337  | 2.40 | 10.53| 1.54 | 19      | 61   |
| Durrieu, Geneviève      | INSERM, France                                                               | 29  | 1.41 | 267  | 1.90 | 9.21 | 1.35 | 18      | 66   |
| Lebrun-Vignes, Bénédicte| Sorbonne Université, France                                                  | 26  | 1.27 | 612  | 4.36 | 23.54| 3.43 | 27      | 5    |
| Lapeyre-Mestre, Maryse  | Université Fédérale de France                                                | 24  | 1.17 | 645  | 4.59 | 26.88| 3.92 | 43      | 42   |
| Edwards, Ivor           | Uppsala Monitoring Centre, Sweden                                            | 23  | 1.12 | 282  | 2.01 | 12.26| 1.79 | 37      | 0    |
| Bondon-Guitton, Emmanuelle| Centre Hospitalier Universitaire De Toulouse, France                       | 21  | 1.02 | 339  | 2.42 | 16.14| 2.38 | 16      | 49   |
| Gautier, Sophie         | CHU Lille, France                                                            | 21  | 1.02 | 203  | 1.45 | 9.67 | 1.42 | 20      | 7    |

ACP: average citations per paper; CR: citations received; PC: publication count; RCI: relative citation impact; TLS: total link strength

Figure 1. Collaborative network of authors.

reported by *Institut national de la santé et de la recherche médicale* (INSERM), France with a proportion of 6.36 percent (*n* = 130) publications and fetched a citations accounting for 10.08 percent (*n* = 1415) with citation impact of 10.88 ACP and having 1.59 RCI followed by *Centre hospitalier universitaire* de Toulouse, France with a proportion of 4.29 percent (*n* = 88) publications, 8.69 percent (*n* = 1221) citations, ACP of 13.88 and 2.03 RCI. The data also exposes that
Table 9  Most productive countries.

| Most productive countries | TNP  | TNC  | ACP  | RCI  | TLS |
|---------------------------|------|------|------|------|-----|
| France                    | 373  | 4461 | 11.95| 1.28 | 92  |
| United States of America  | 310  | 5265 | 16.98| 1.82 | 138 |
| India                     | 207  | 996  | 4.81 | 0.51 | 60  |
| United Kingdom            | 205  | 2080 | 11.14| 0.51 | 138 |
| Germany                   | 179  | 894  | 4.99 | 0.53 | 60  |
| Italy                     | 145  | 1378 | 9.50 | 1.01 | 64  |
| Sweden                    | 86   | 1095 | 12.73| 1.36 | 88  |
| Netherlands               | 85   | 972  | 11.43| 1.22 | 83  |
| Switzerland               | 82   | 1176 | 14.34| 1.54 | 87  |
| Spain                     | 77   | 810  | 10.51| 1.12 | 44  |

ACP: average citations per paper; RCI: relative citation impact; TNC: total number of citations; TLS: total link strength; TNP: total number of publications. Scopus data may not have been harmonized inflates the output citations counts.

most of the organizations in the list belong from France; therefore, it revealed that France is the bellwether in PV related scientific research and indicating the significant efforts of these organizations. Except one, all the organizations exhibit RCI > 1, indicates the high impact research (Table 10).

Collaborative network of organizations

The network visualization mapping among the organizations in the field of PV research has been visually depicted in Fig. 3. The map has been created with a threshold of 2 documents per organizations and out of the total 5322 organizations, 384 meet the criteria. However, only 49 items are seen to be connected in terms of collaboration. The map demonstrates the strength of collaboration between 49 organizations, distributed across 11 clusters, coloured differently, with 85 links and TLS of 96. The organizations have shown the weak collaboration (Fig. 3).

Most productive journals

The PV focused research publications were produced in 1862 journals and the top 10 productive journals depicted in Table 11. According to the Bradford’s Law, the journals were ranked in terms of the decreasing order of their
Table 10  Most productive organizations.

| Most productive organizations                                      | TNP  | %TNP | TNC  | %TNC | ACP  | RCI  |
|-------------------------------------------------------------------|------|------|------|------|------|------|
| Institut national de la santé et de la recherche médicale (INSERM), France | 130  | 6.34 | 1415 | 10.08| 10.88| 1.59 |
| Centre hospitalier universitaire de Toulouse, France              | 88   | 4.29 | 1221 | 8.69 | 13.88| 2.03 |
| Université Paul Sabatier Toulouse III, France                     | 78   | 3.8  | 986  | 7.02 | 12.64| 1.85 |
| Uppsala Monitoring Centre, Sweden                                  | 65   | 3.17 | 701  | 4.99 | 10.79| 1.57 |
| AP—HP Assistance publique—Hôpitaux de Paris, France              | 62   | 3.02 | 741  | 5.28 | 11.95| 1.75 |
| Université de Bordeaux, France                                     | 49   | 2.39 | 762  | 5.43 | 15.55| 2.27 |
| CERPOP - Centre d’épidémiologie et de recherche en santé des populations, France | 42   | 2.05 | 732  | 5.22 | 17.43| 2.55 |
| Bundesverband der Pharmazeutischen Industrie (BPI) e. V., Germany | 38   | 1.85 | 3    | 0.02 | 0.08 | 0.01 |
| Université fédérale Toulouse Midi-Pyrénées, France                | 38   | 1.85 | 661  | 4.71 | 17.39| 2.55 |
| Sorbonne Université, France                                       | 36   | 1.75 | 460  | 3.28 | 12.78| 1.87 |

ACP: average citations per paper; RCI: relative citation impact; TNC: total number of citations; TNP: total number of publications.

Figure 3. Collaborative network of organizations.

Table 11  Most productive journals.

| Most productive journals                                      | Publisher                     | PC  | TC    | ACP  | RCI  | CiteScore (2020) | SJR  |
|----------------------------------------------------------------|-------------------------------|-----|-------|------|------|------------------|------|
| Drug Safety                                                    | Springer Nature                | 136 | 1891  | 13.90| 2.03 | 6.7              | 1.377|
| Pharmazeutische Industrie                                     | Editio Cantor Verlag          | 83  | 8     | 0.09 | 0.02 | 0.1              | 0.102|
| Therapies                                                     | Elsevier                      | 71  | 621   | 8.75 | 1.28 | 2.5              | 0.387|
| European Journal of Clinical Pharmacology                     | Springer Nature                | 41  | 534   | 13.02| 1.91 | 4.8              | 0.845|
| Pharmacoepidemiology and Drug Safety                          | Wiley-Blackwell                | 41  | 541   | 13.19| 1.94 | 4.4              | 1.023|
| Expert Opinion on Drug Safety                                 | Taylor & Francis               | 32  | 264   | 8.25 | 1.21 | 6.1              | 1.086|
| Mann’s Pharmacovigilance: Third Edition                       | NA                            | 29  | 54    | 1.86 | 0.28 | NA               | NA   |
| Pharmaceutical Medicine                                       | Springer Nature                | 26  | 123   | 4.73 | 0.69 | 2                | 0.403|
| British Journal of Clinical Pharmacology                      | Wiley-Blackwell                | 25  | 700   | 28   | 4.09 | 6.9              | 1.216|
| International Journal of Clinical Pharmacy                    | Springer Nature                | 24  | 197   | 8.21 | 1.19 | 2.7              | 0.538|

ACP: average citations per paper; PC: publication count; RCI: relative citation impact; SJR: SCImago journal rank (Scopus); TC: total citations.
productivity. The resultant data inferred that the most productivity journal was *Drug Safety* with a proportion of 6.63 per cent (*n* = 136) papers and fetched highest citations accounting for 13.47 per cent (*n* = 1891) with exhibiting 13.90 ACP and 2.03 RCI, followed by *Pharmazeutische Industrie* with 4.05 per cent (*n* = 83) papers. At the third position was *Therapies* with a proportion of 3.46 per cent (*n* = 71) papers and accounting for 4.42 per cent (*n* = 621) citation and exhibiting 8.75 ACP with 1.28 RCI. The top 10 leading journals in a combined manner contributed with a proportion of 24.76 per cent (*n* = 508) papers of the total publications. The number of citations fetched for the publications reflect the quality of a paper [36]. According to the analysis of the data, the top 10 journals fetched citations with a proportion for 35.14 per cent (*n* = 4933) of the total citations with an average citation impact of 9.71 ACP. In terms of RCI, the *British Journal of Clinical Pharmacology* exhibit highest with 4.09. The journals having RCI < 1 implies that the research output was not proportional with their impact, whereas, RCI > 1 indicates the high impact research (Table 11).

Co-citation of source

The journal co-citation analysis was performed using citation as the unit of analysis in the counting method in order to identify the core journals by using the minimum threshold number of 100 citations per source and it revealed 32 sources meet the criteria. The network visualization map of 32 sources yielded 5 clusters with 447 links and TLS of 69,943. The link demonstrates the interrelatedness of the journal with other journals. The distance between two journals represents the relatedness in terms of their co-citations. The larger size of label and circle indicates more influence of the journals in pharmacopoeia research. The *Drug Safety* in cluster 2 tops with 30 links 30 and TLS of 24,539 exhibiting 2267 citations (Fig. 4).

Mapping of co-occurrence of keywords

Co-occurrence of keywords provides the secondary support to understand the scientific research trends by highlighting the research hotspots in research field. A total of 2804 author keywords have been used in PV research during the period 2010—2020. Out of the 2804 keywords, 49 meet the thresholds with minimum of 10 occurrences considered for analysis. A total of 49 keywords yielded 7 clusters represented by different colours and found 308 links and TLS of 1547. According to the frequency and strength of the links, the clusters are sorted. The size of bubble reveals nature of link strength and occurrence relationship. The node’s size indicates dense keywords network and different colours represent distinct cluster. The most frequently used author keywords were pharmacovigilance (frequency = 812), Adverse drug reactions (frequency = 207), adverse drug reaction (frequency = 151), and pharmacoepidemiology (frequency = 104) (Table 12; Fig. 5).

Subject-wise breakup of research output

Table 13 demonstrated the top 10 most crucial research areas in PV. The broad ranging scope of PV remains a dynamic medical discipline to prevent ADRs in human beings, to promote patient safety and also in promoting rational use of quality medicines. The findings revealed that there is a considerable research output in the area of medicine with a proportion of 48.33 per cent (*n* = 1563) papers of the total publications, followed by pharmacology, toxicology and pharmaceutics accounting for 30.30 per cent (*n* = 980) publications share. Other subject areas appearances ranging between 3 ≥ 138 publications share. The figures revealed that PV research in the areas of medicines is in full bloom and in pursuant to this, the researchers and scientists are constantly carrying out the research for better mechanism towards safeguard of the public health (Table 13).

Highly cited papers

Table-14 recorded the top 10 most cited research papers in PV that registered citations between 130 ≥ 330 citations. The citation per year (CPY) is also calculated to overcome the problem encountered during variation of citations (Garg and Tripathi, 2017 [37]). Highly cited papers accumulated a sum of 2033 (14.46%) citations during the time span 2010—2020. All these highly cited papers were collaborative papers. The table shows that the research paper entitled “Pharmacovigilance from social media: Mining adverse drug reaction mentions using sequence labeling with word embedding cluster features” by Nikfarjam et al. [38] was the most cited publication with 308 citations, followed by “Cardiovascular toxicities associated with immune checkpoint inhibitors: an observational, retrospective, pharmacovigilance study” by Salem et al. with 300 citations [39] (Table 14).

Funding agencies

Of the retrieved total 2052 documents, 27.63 per cent (*n* = 567) publications were the funded projects. The National Institute of Health (NIH) with a proportion of 1.90 per cent (*n* = 39) publications was the most active funding agency in PV research at global level.

Recommendations

The recommendations for improving ADR reporting system working under the umbrella of PV mechanism of country are as under:

- Every governmental and the private hospital should establish a PV centre for ADRs reporting;
- PV workshops/seminars/conferences/webinars should be conducted time to time to create awareness and to guide healthcare professionals;
- Patient should be encouraged for self-reporting alongside reporting by healthcare professionals;
- Comprehensive national PV programs should be initiated;
- PV specialists should guide healthcare professionals;
- New modern technology should be incorporated to facilitate ADRs reporting;
- Education on PV should be introduced in pharmacy curricula;
- ADRs reporting should be made compulsory for all the pharmaceutical companies and healthcare professionals.
Summary and conclusion

The research and analytical development across the globe have become a focal point in the national policy of all the countries, which results into the enhancement in research productivity in the scientific field. The present study provides a quantitative and qualitative analysis of global research productivity in PV. The study is based on the 11 years’ global research data (TNP = 2052) on the research theme PV sourced from Scopus database for the time span 2010–2020. Results of this scientometric assessment found that the global research productivity in PV registered 8.74% AGR and 7.38% CAGR. The research impact of global publications in PV averaged to ACP of 6.84. The RGR for the PV global publications decreased gradually from the rate of 0.84 to 0.12. On the other hand, DT of PV global publications displays an increasing trend from the rate of 0.82 to 5.78. The mean RGR and DT of PV publication for 11 years is 0.27 and 3.03, respectively. It was found that the AAPP is 1.52 and PPA is 0.68. The analysis discloses that the
Table 12  Important keywords.

| Important keywords                                      | Frequency | TLS |
|--------------------------------------------------------|-----------|-----|
| Pharmacovigilance                                      | 812       | 918 |
| Adverse drug reactions                                 | 207       | 316 |
| Adverse drug reaction                                  | 151       | 226 |
| Drug safety                                            | 104       | 195 |
| Pharmacoepidemiology                                   | 68        | 109 |
| Safety                                                 | 49        | 75  |
| Knowledge                                              | 39        | 102 |
| Signal detection                                       | 37        | 82  |
| Adverse events                                         | 33        | 41  |
| Spontaneous reporting                                  | 31        | 67  |
| Social media                                           | 24        | 46  |
| Adverse drug reaction reporting systems                | 22        | 29  |
| Data mining                                            | 21        | 40  |
| Adverse effects                                        | 19        | 17  |
| Patient safety                                         | 19        | 41  |
| Attitude                                               | 18        | 60  |
| Children                                               | 18        | 40  |
| Adverse reactions                                      | 17        | 21  |
| Pharmacists                                            | 16        | 30  |
| Spontaneous reporting system                           | 16        | 20  |
| Awareness                                              | 15        | 33  |
| Biosimilars                                            | 15        | 26  |
| Drug                                                    | 14        | 22  |
| Practice                                                | 14        | 46  |
| Pregnancy                                               | 14        | 15  |
| Risk management                                        | 14        | 28  |
| ADR                                                     | 13        | 26  |
| Adverse drug events                                    | 13        | 19  |
| Adverse event                                          | 13        | 29  |
| Drugs                                                   | 13        | 19  |
| Multiple sclerosis                                      | 13        | 9   |
| Natural language processing                            | 13        | 33  |
| Adverse-reaction-monitoring                            | 12        | 10  |
| Drug-related side effects and adverse reactions         | 12        | 20  |
| Eudravigilance                                         | 12        | 12  |
| Machine learning                                       | 12        | 17  |
| Biologics                                               | 11        | 20  |
| Legislation                                            | 11        | 16  |
| Reporting                                              | 11        | 21  |
| Surveillance                                           | 11        | 27  |
| Adverse drug event                                     | 10        | 22  |
| Adverse reaction                                       | 10        | 20  |
| Big data                                                | 10        | 27  |
| Database                                                | 10        | 24  |
| Disproportionality analysis                            | 10        | 16  |
| Drug monitoring                                        | 10        | 16  |
| Faers                                                   | 10        | 13  |
| Product surveillance                                    | 10        | 13  |

TC: total link strength.

authorship patterns in PV research shows collaborative trend as the most of the publications have been published by multiple authors. In all, a total of 80.75% publications have been published in co-authorship, whereas only 19.25% published in single-authorship. The resultant data inferred that the magnitude and density of collaborative patterns among the authors are high in PV research. The DC (0.92) is maximum in the years 2019 and lowest value 0.67 found in the year 2010. The mean value of DC during the selected period of study is 0.79. The CI is highest in the year 2020 (3.19) and lowest in the year 2011 (2.48). The mean value of CI during the period is 2.74. The analysis demonstrates that the
The rapid spread of COVID-19 pandemic globally has thrust drugs safety into the spotlight and the public is now more aware of the role of healthcare professionals and health regulators. Amid new drugs discovery process against COVID-19, it needs to be ensuring the efficacy and safety of the drugs during clinical trials of the drugs and even in the post-marketing period for the safeguard of the public health. The monitoring of safety of therapies or treatment being given to corona patient is crucial and facing challenges. Monitoring of the safety of medicinal products is an ongoing process and enormous safety related data gathered during clinical trials from different patient population at global level, therefore, a systematic approach to PV should be implemented to identify the ADRs for taking appropriate action to reduce risk and increase benefits associated with the medicines. Therefore, it is needed that the PV experts, clinicians, stakeholders and drug regulators collaborate in the assessment of suspected ADRs timely to reduce risks and increasing benefits associated with the medicinal products towards success of public health across the globe. Further, to generate substantial amount of data, electronic means of reporting must be enhanced in the present time.

The global phenomenon of PV is attracting the scientists of similar interest for collaborative research across the globe towards safeguard of the public health. Although, due to advancement in measuring safety use of medicines or due to ‘publish or perish’ scientific community’s keen interest, the PV research productivity enhancing with every passing day. The study exposes that the PV research is in full bloom and recommended that the scientometric assessment will have to examine the research progress at regular intervals focussing on quantitative and qualitative indicators of publications. The present scientometric assessment is based solely on the literature indexed in the core collection of Scopus database and although the literature available in other databases like Web of Science (WoS) and PubMed as well may be harvested in future research. Overall, this study has led us to grasp the current trends of PV research. The outcome of the study may help drug manufacturers, medical scientists, drug regulators and health-care professionals to identify current research progress in PV at global level.

| Subject areas                                | TNP  | %TNP  |
|----------------------------------------------|------|-------|
| Medicine                                    | 1563 | 48.33 |
| Pharmacology, toxicology and pharmaceutics   | 980  | 30.30 |
| Biochemistry, genetics and molecular biology | 138  | 4.27  |
| Health professions                           | 115  | 3.56  |
| Immunology and microbiology                  | 71   | 2.19  |
| Computer science                             | 56   | 1.73  |
| Social sciences                              | 40   | 1.24  |
| Engineering                                  | 36   | 1.11  |
| Nursing                                      | 35   | 1.08  |
| Neuroscience                                 | 28   | 0.87  |

TNP: total number of publications. Scopus data may not have been harmonized inflates the output counts.
| Table 14 | Highly cited papers. |
| --- | --- |
| Top 10 highly cited papers | Authors | Source journal | Year | TNC | TNC per year |
| Pharmacovigilance from social media: Mining adverse drug reaction mentions using sequence labeling with word embedding cluster features | Nikfarjam, A., Sarker, A., O’Connor, K., Ginn, R., Gonzalez, G. | Journal of the American Medical Informatics Association | 2015 | 308 | 51.33 |
| Cardiovascular toxicities associated with immune checkpoint inhibitors: an observational, retrospective, pharmacovigilance study | Salem, J.-E., Manouchehri, A., Moey, M., Johnson, D.B., Moslehi, J.J. | The Lancet Oncology | 2018 | 300 | 100 |
| Utilizing social media data for pharmacovigilance: A review | Sarker, A., Ginn, R., Nikfarjam, A., Upadhaya, T., Gonzalez, G. | Journal of Biomedical Informatics | 2015 | 277 | 46.17 |
| Once-daily opioids for chronic dyspnea: A dose increment and pharmacovigilance study | Currow, D.C., McDonald, C., Oaten, S., Johnson, M.J., Abernethy, A.P. | Journal of Pain and Symptom Management | 2011 | 203 | 20.30 |
| Benefits and strengths of the disproportionality analysis for identification of adverse drug reactions in a pharmacovigilance database | Montastruc, J.-L., Sommet, A., Bagheri, H., Lapeyre-Mestre, M. | British Journal of Clinical Pharmacology | 2011 | 195 | 19.50 |
| Performance of pharmacovigilance signal-detection algorithms for the FDA adverse event reporting system | Harpaz, R., Dumouchel, W., Lepeule, P., Ryan, P., Shah, N.H. | Clinical Pharmacology and Therapeutics | 2013 | 162 | 20.25 |
| Causality assessment in pharmacovigilance: The French method and its successive updates | Miremont-Salamé, G., Théophile, H., Haramburu, F., Bégaud, B. | Therapies | 2016 | 160 | 32 |
| Web-scale pharmacovigilance: Listening to signals from the crowd | White, R.W., Tattonetti, N.P., Shah, N.H., Altman, R.B., Horvitz, E. | Journal of the American Medical Informatics Association | 2013 | 154 | 19.25 |
| Characterizing major bleeding in patients with nonvalvular atrial fibrillation: A pharmacovigilance study of 27,467 patients taking Rivaroxaban | Tamayo, S., Peacock, W.F., Patel, M., Yannicelli, D., Yuan, Z. | Clinical Cardiology | 2015 | 142 | 23.67 |
| Pharmacovigilance of herbal medicine | Shaw, D., Graeme, L., Pierre, D., Elizabeth, W., Kelvin, C. | Journal of Ethnopharmacology | 2012 | 132 | 14.67 |

TNC: total number of citations.
In addition, it will also help to identify the most prolific authors, institutions, countries and channels of communication in the development of research. PV is a global developing field with significant future research.

**Disclosure of interest**

The author declares that he has no competing interest.

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