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Bridging Global and Local Pharmacovigilance Requirements in Multinational Pharmaceutical Operations.

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Abstract: Multinational drug development and manufacture take place within a pharmacovigilance environment characterised by global safety standards, regional regulatory frameworks, and national legal requirements. The challenge is not merely compliance with distinct rules, but the development of an operating model which can transform diverse local rules into an integrated global safety system while maintaining local accountability. This review evaluates peer-reviewed articles published since 2015 regarding pharmacovigilance system capacity, adverse drug reaction (ADR) reporting, patient and healthcare professional reporting systems, spontaneous reporting databases, electronic monitoring, signal detection, risk mitigation, automation and product traceability. The article highlights ongoing global-local challenges in case intake, quality of individual case safety reports, regulatory reporting timelines, oversight of affiliate operations, risk communication, and local implementation of global signal decisions. The studies report varied local pharmacovigilance readiness, reporting practices, data quality and technological capability. This review concludes that multinational pharmacovigilance needs a nested governance approach incorporating global standardisation, local regulatory awareness, integrated data technology and evidence-based quality assurance. Comparative assessment of affiliate operations, global-local control and transparent evidence of digital automation across regulatory networks remain major evidence gaps.

Keywords: Adverse drug reaction reporting; global regulatory alignment; local pharmacovigilance; multinational pharmaceutical operations; risk minimisation; signal detection.

INTRODUCTION

Pharmacovigilance has changed from a postmarketing reporting discipline into a complex global regulatory and organisational science that concerns itself with the detection, assessment, understanding, and prevention of adverse effects or other medicine-related problems. This is especially relevant for multinational pharmaceutical companies as products are not confined to one regulatory or healthcare market. They may be registered in multiple countries, sold through multiple channels, used in multiple clinical environments and have multiple reporting requirements. Therefore, twenty-first-century pharmacovigilance requires an "operational bridge" between global safety and local regulatory response. The history of pharmacovigilance shows that global co-operation has always been essential for drug safety, but operational competence to turn global adverse event reports into timely and relevant local regulatory actions varies [Fornasier, G. *et al*., 2018]. The operational link between global and local pharmacovigilance needs, therefore, relates to the question of how a pharmaceutical company can gain a coherent view of global safety and achieve regulatory compliance in the countries where medicinal products are marketed.

The relevance of this issue is supported by the burden of adverse drug reactions and the uncertainties of post-marketing safety. European observational studies have demonstrated adverse drug reactions remain a major burden of disease, healthcare burden and preventable harm, and that postmarketing safety monitoring is an essential component of the clinical development process [Bouvy, J. C. *et al*., 2015]. The impact is significant for multinational pharmaceutical companies, as the manifestation of adverse reactions, detection and reporting probabilities may differ across populations due to population characteristics, patterns of prescribing, disease, drug availability and health-care systems. The corporate headquarters may be the site of integrated assessment of signals but the data that trigger safety actions may be local when patients, health professionals, local pharmacovigilance centres, subsidiaries, distributors and regulators interact. So, the solution cannot be achieved through harmonisation alone, or database integration. It requires the co-ordination of the global safety system with the local conditions of visibility of medicine-related harm.

The research frontier includes increasing attention on the assessment of regulatory actions, the quality of safety information and the difficulties in assessing the public health impact of pharmacovigilance measures. Regulatory impact assessment studies have shown that communication, restriction, risk mitigation and other measures used to achieve safety are difficult

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to evaluate as baseline use, prescriber practices, other clinical advice and health system factors may also impact on the outcome [Goedecke, T. *et al*., 2018]. This is more challenging in global operations, where a global risk decision may be communicated in different national documents, languages, times, methods of distribution, educational approaches, compliance monitoring and enforcement. So, the link between global and national standards needs to include monitoring of compliance as well as implementation and measurable consequences. Without this connection, a company may meet documentation requirements without knowing whether risk minimisation measures changed clinical behaviour as intended.

Another incentive to prioritise academic effort is the wide range of safety data sources. The traditional data sources (reports from health care professionals) have been supplemented by those from patients, new media, health care systems and databases, and computerised case management systems. Numerous studies that assessed the value of patient reporting have found that patients provide distinct information about symptoms, effects on quality of life and the effect of treatment, which can complement the information supplied by health professionals in pharmacovigilance systems [Inácio, P. *et al*., 2017]. This poses both a challenge and an opportunity for multinational pharmaceutical companies. Patient reporting may be legally permitted may be legally permitted in one jurisdiction, culturally advanced in another and technology-based through company websites and call centres, market research, patient support programs and social media. The global safety system must determine what to report, how local privacy and consent requirements apply, narrative translation and the encoding of the details of patient experience. Local data are important, but pooling is required to detect signals.

The advent of healthcare databases and other big data has generated an interest in holistic safety governance. Studies on converting big data into safety information for analysis have pointed out that the utility of pharmacovigilance is linked to the quality of data, interpretability of clinical outcomes, transparency of methods and the use of spontaneous reports together with other data sources [Trifirò, G. *et al*., 2018]. This is particularly relevant for meeting global and local needs as multinational corporations want to know when and if local data are suitable for global signal management, when and why it is needed to follow up global signals at local level, and how evidence from a given health system can be used for another. Global standards can support consistency in seriousness assessment, causality assessment, coding, and aggregate reporting. However, local requirements may differ in reporting timelines, electronic submission routes, language, literature monitoring, responsible persons, and risk minimisation programmes. The literature thus suggests a challenge: pharmacovigilance harmonisation is in progress but operational equivalence between affiliates, regions and regulatory agencies still needs to be improved.

The interdisciplinary challenges of integrating global and local pharmacovigilance requirements include regulatory science, pharmacoepidemiology, health informatics, quality management, organisational governance, medical affairs, clinical pharmacology and patient safety. Multinational pharmaceutical operations are at the interface of these disciplines because regulatory requirements for safety demand scientific, legal, data engineering, process control and medical affairs expertise. There are important gaps in research around measurement of global-local interfaces, the contribution of affiliate performance to the global detection of safety signals, the role of local regulatory intelligence in corporate strategy and the use of automation to support rather than replace accountability. The purpose of this review is to critically examine peer-reviewed literature since 2015 that informs this interface. In the following sections, we organise the literature, propose a model for global-local pharmacovigilance harmonisation, compare the methods and findings from the literature and identify research opportunities in multinational pharmaceutical operations.

LITERATURE REVIEW

The post-2015 literature pertinent to bridging global and local pharmacovigilance needs can be grouped into four major clusters. The first relates to the performance of national pharmacovigilance systems and the variability of local systems. The second concerns reporting practices, report quality and variability among reporter groups. The third relates to computational and database methods for signal generation. The fourth concerns risk reduction, regulatory response and automation in the corporate environment of pharmaceutical companies. Table 1 presents representative studies from these clusters.

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Table 1. Summary of key findings

Ref	Focus	Key Findings
[Maigetter, K. *et al*., 2015]	National pharmacovigilance system capacity in India, Uganda, and South Africa	The study showed that national systems differed markedly in legal authority, financing, reporting mechanisms, staffing, feedback capacity, and integration with public health programmes, indicating that multinational companies cannot assume equivalent affiliate environments across countries.
[Olsson, S. *et al*., 2015]	Pharmacovigilance in resource-limited countries	The article identified structural barriers such as low reporting rates, limited trained personnel, weak feedback mechanisms, and fragmented infrastructure, making local implementation capacity a decisive constraint for global safety governance.
[Ampadu, H. H. *et al*., 2016]	African individual case safety report characteristics in VigiBase	Reports from African settings differed from reports from other regions in volume, completeness, medicine categories, and reporter patterns, demonstrating that global databases can reflect local surveillance capacity as much as true safety burden.
[Alatawi, Y. M., & Hansen, R. A. 2017]	Under-reporting in the United States Food and Drug Administration Adverse Event Reporting System	Empirical estimation showed substantial under-reporting, reinforcing that spontaneous reporting data require careful interpretation in global signal management and cannot be treated as incidence data.
[Golder, S. *et al*., 2015]	Adverse event information in social media	The review found that social media contains patient-relevant adverse event information but varies in validity, specificity, duplicability, and clinical detail, creating a need for strict triage rules in company monitoring systems.
[Sarker, A. *et al*., 2015]	Social media data for pharmacovigilance	The study described natural language processing and information extraction methods for identifying safety mentions, while also showing that informal language, ambiguity, and verification limits complicate regulatory-grade interpretation.
[Pierce, C. E. *et al*., 2017]	Facebook and Twitter monitoring against recent safety alerts	The analysis found that social media monitoring had limited an uneven performance for detecting known safety alerts, suggesting that digital listening should complement rather than replace established safety systems.
[Candore, G. *et al*., 2015]	Statistical signal detection across spontaneous reporting databases	The comparison showed that signal detection performance differed across methods and databases, indicating that global safety teams require method governance and database-context awareness.
[Wisniewski, A. F. *et al*., 2016]	Good signal detection practices from IMI PROTECT	The article established practice-oriented principles for signal detection, including documentation, clinical review, database understanding, and reproducible decision-making, which are central to global-local safety alignment.
[Vora, P., Artime, E. *et al*., 2018]	Effectiveness of European risk minimisation measures using the EU PAS Register	The review found methodological variability and frequent limitations in studies evaluating risk minimisation, showing that implementation evidence remains weak despite formal regulatory requirements.
[Rolfes, L. *et al*., 2015]	Differences between patient and healthcare professional adverse reaction reports	Patient reports contained distinctive experiential information and differed from professional reports in content and emphasis, supporting the need for local intake pathways that preserve narrative value for global

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		assessment.
[Schmider, J. *et al*., 2019]	Artificial intelligence in adverse event case processing	The article showed that automation can improve case-processing efficiency but requires human oversight, validation, and governance because regulatory accountability remains with the pharmacovigilance system holder.

The first cluster illustrates that the local arm of multinational pharmacovigilance cannot be considered a passive implementation unit. A comparative study of pharmacovigilance systems in India, Uganda and South Africa found variations in the legal basis, minimum elements, reporting pathways and institutional capabilities [Maigetter, K. *et al*., 2015]. The implication of this for multinational operations is that local subsidiaries may be required to comply with corporate requirements while operating within national pharmacovigilance systems that vary in maturity, responsiveness of the regulator, electronic reporting capacity and public awareness. This view is supported by the resource-limited-country literature, which demonstrates that poor reporting culture, lack of training and limited feedback can result in sparse local safety information, even in the context of high product use [Olsson, S. *et al*., 2015]. These investigations question a naive global compliance model where corporate headquarters issues the same procedures and expects them to be followed. A more realistic model acknowledges local system maturity as a variable that demands risk-based affiliate support and quality oversight, and adaptation of reporting channels.

The second set of studies relates to the interpretive limitations of spontaneous reporting. Studies of African individual case safety reports (ICSRs) recorded in VigiBase demonstrated that geographical variations in ICSR characteristics may represent surveillance system and reporting practices, not just pharmacological risk [Ampadu, H. H. *et al*., 2016]. In another regulatory setting, the empirical measurement of under-reporting with the US Food and Drug Administration (FDA) Adverse Event Reporting System (FAERS) demonstrated that spontaneous reporting systems capture only a small proportion of adverse events and that they are influenced by report incentives, awareness, media, severity, and drug age [Alatawi, Y. M., & Hansen, R. A. 2017]. These observations are not contradictory but, together, they demonstrate that under-reporting is a global phenomenon while local under-reporting is context-dependent. The message for multinational pharmaceutical manufacturers is that global safety signal review should take into account local denominator uncertainty, reporter mix, product use, and case completeness. A small number of reports from a country does not necessarily reflect low risk, and a spike in local reports may be due to heightened awareness or regulatory activity, rather than a new causal link.

The third cluster explores digital and non-traditional safety data sources. Social media pharmacovigilance reviews found patient reports can include concerns, symptoms and product use that are absent from reports [Golder, S. *et al*., 2015]. Studies on extraction of social media data reported tools to identify mentions of potential adverse events, convert free-form narratives into formal concepts, and remove extraneous messages [Sarker, A. *et al*., 2015]. But empirical testing against known safety issues demonstrated mixed results for Facebook and Twitter monitoring, and low detection value on its own [Pierce, C. E. *et al*., 2017]. Digital pharmacovigilance can be useful if it is part for global operations. Local knowledge may be enhanced through digital listening, particularly where patients share their experiences about medicines outside of health systems, but global safety processes need to be carefully validated, checked for duplicate reporting, protected for privacy, able to identify local languages and have clear criteria for reportable events. Digital pharmacovigilance can be useful if it is part of a governed evidence space, not as a replacement for science.

The fourth cluster relates to detection, mitigation and automation. Signal detection studies have demonstrated disproportionality measures may yield different results, depending on the database, case definitions, control sets, and reporting behaviours [Candore, G. *et al*., 2015]. Good practice in signal detection also recommends that quantitative results be evaluated, documented and interpreted clinically [Wisniewski, A. F. *et al*., 2016]. This is crucial for understanding global and local needs because a global signal may be derived from a multinational database, whereas local action may be dependent on national exposure, practice, other therapeutic options and regulatory

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requirements. A study of European risk minimisation measures found evaluation studies are diverse and often use poor-quality outcomes [Vora, P., Artime, E. *et al*., 2018]. This is relevant to multi-national operations because risk minimisation measures are often executed locally via educational materials, restricted access, pregnancy prevention programs, prescriber messaging or package label changes. Literature on automation adds an operational perspective by revealing that artificial intelligence can assist adverse event case processing but needs to be validated and controlled within responsive pharmacovigilance quality frameworks [Schmider, J. *et al*., 2019]. Across these clusters, we know from the literature that meeting global and local requirements is a control problem involving evidence, interpretation, process, and scientifically valid local adaptation.

METHODOLOGY

The review of the literature supports a conceptual approach to multinational pharmacovigilance that maintains an ongoing connection between global standards, regional systems, national requirements, local operations and safety evidence. This framework is not only a compliance map because the key consideration is the link between local safety information and global evidence, and global risk evaluation and local compliance requirements. Pharmacovigilance national capacity assessments show that local systems differ in their reporting systems, public-sector and regulatory requirements and health-care professional engagement [Maigetter, K. *et al*., 2015]. International signal detection reports show that interpretation of signals is only valid if methods, assessment reports and limitations of databases are standardised [Wisniewski, A. F. *et al*., 2016]. Therefore, the framework proposed in this review is a governance framework that provides clear ownership of local intake, global medical review, regulatory intelligence, signal escalation, risk mitigation and quality management.

Approaches used in studies in this area have their own merits and shortcomings. Comparative health policy analyses examine pharmacovigilance system components across countries, which may demonstrate capacity problems, but may not contain operational data for individual companies [Maigetter, K. *et al*., 2015]. Analyses of spontaneous (voluntary) reports in pharmacovigilance databases allow regional reporting patterns and characteristics to be investigated, but do not determine the incidence and are prone to underreporting and reporting bias [8; 9]. Systematic reviews of patient reports, internet and risk minimisation studies provide insight into the quality of evidence and trends in data sources and methods, but may combine different data sources, outcomes and jurisdictional relevance [4; 10; 15]. Comparative studies of approaches for signal detection provide analytic rigour, but performance evidence is database, reference set and safety issue dependent [Candore, G. *et al*., 2015]. Studies of automation can provide evidence on efficiency of company case processing, but current evidence is more on the feasibility than jurisdictional acceptance [Schmider, J. *et al*., 2019].

Figure 1 shows an approach to co-ordinate global and local pharmacovigilance needs in multinational firms. The figure shows that global safety governance does not supersede local regulatory requirements, but facilitates co-ordination of evidence, decisions and controls through an interface. It also shows that affiliate and local regulatory intelligence are not "back room" functions, but essential for global safety validity.

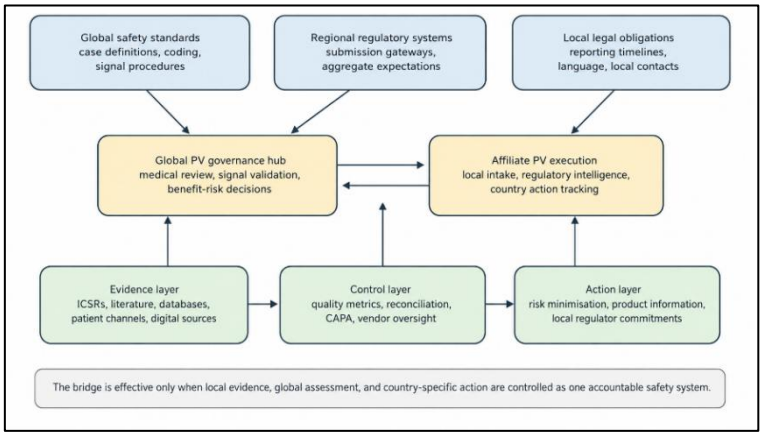


Figure 1. Global-local pharmacovigilance governance interface for multinational operations

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The figure reveals three research implications. First, national regulatory intelligence should be considered as safety infrastructure rather than as a bureaucratic add-on, since national reporting rules and expectations of authority determine if global procedures can be carried out promptly. Second, the evidence layer must be bidirectional; local cases must flow to global assessment, and global decisions must flow back to local settings through product labels, educational materials, and regulator-approved risk minimisation measures. Third, the control layer must assess interface quality, not just case throughput because multinational pharmacovigilance failure often occurs at the interface between global and local sites, vendors, global safety physicians, regulatory affairs and quality assurance.

The model also explains why literature about national capacity, patient reporting, signal detection, and risk minimisation is included in the review. All address a sector of the global-local bridge. Capacity studies show structural bottlenecks in individual countries, patient-report studies show the local context that gets into the safety system, signal detection studies explain the global work of analysis, and risk minimisation shows whether the global decision is operationally meaningful once implemented locally. A multinational company that is strong in just one of these areas could fail as a pharmacovigilance system. Good statistical analyses cannot make up for delays in local intake; high case processing speed cannot make up for poor medical review; local educational materials cannot make up for poor evidence about whether prescribing practices changed.

One conceptual take-home message is that global-local pharmacovigilance system alignment should be reviewed with four control questions. First, is all locally reportable information captured in mandated time frames? The second is whether local case information is sufficiently rich in clinical, product and other information for global analysis. The third asks whether global signal and benefit-risk assessments are communicated in country-specific regulatory commitments without conflicts of information. The fourth asks whether local implementation data are measured to inform global decision-making. The literature does not yet provide an entirely validated set of metrics for these questions, but it does provide sufficient evidence to support performing interface assessment rather than routine quality assurance checks alone.

DISCUSSION

The studies reported above collectively suggest that it is hard to meet global and local pharmacovigilance needs because the evidence is aggregated globally but generated locally. Studies in Table 1 demonstrate that local pharmacovigilance maturity has an impact on the quantity, quality and interpretation of safety data. The country-specific capacity studies found variations in infrastructure and governance elements [Maigetter, K. *et al*., 2015], and the VigiBase study found regional variations in case characteristics [Ampadu, H. H. *et al*., 2016]. This is significant as multinational pharmaceutical companies often assess safety signals using global databases that pool cases from jurisdictions with very different reporting cultures. The signal management team will see one dataset, but that dataset may contain different components from highly developed electronic reporting systems, fledgling national centres, company call centres, literature monitoring, patient support programs and distributors. The consequence of this is an evidence imbalance: international assessment relies on local data, but local data are not produced under the same conditions.

Table 2 lists key methods in the literature. It shows the methods vary not only technically but in their utility to multinational pharmaceutical companies. National system benchmarking is helpful to identify local capability gaps, but not for determining product risk. Spontaneous-report database analysis can identify signal hypotheses, but it can be affected by reporting bias and lacks denominators. Social-media search can detect patient experiences but may be hard to verify and classify. Automation studies may enhance the efficiency of case processing, but the evidence is less advanced for accountability, auditability and local regulatory acceptance. These differences are why a single evidence source cannot fill the gap between global and local needs.

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Table 2. Method comparison

Ref	Method	Strengths	Limitations
[Maigetter, K. *et al*., 2015]	Comparative assessment of national pharmacovigilance systems against minimum structural requirements	Identifies local system gaps that affect affiliate reporting feasibility, regulator engagement, and country-level implementation planning.	Provides limited company-specific evidence and cannot show how individual multinational safety systems perform inside each national environment.
[Ampadu, H. H. *et al*., 2016]	Analysis of regional individual case safety report characteristics in a global database	Reveals differences in completeness, reporter mix, and regional reporting patterns that affect global signal interpretation.	Cannot separate true safety burden from reporting capacity, reporting culture, medicine access, and public health programme effects.
[Alatawi, Y. M., & Hansen, R. A. 2017]	Empirical estimation of under-reporting in a spontaneous reporting system	Quantifies the scale of missing safety information and supports cautious interpretation of low report volumes.	Estimates remain system-specific and cannot be directly transferred to all countries or products within a multinational portfolio.
[Golder, S. *et al*., 2015]	Systematic review of adverse event data in social media	Shows the potential value of patient-generated safety narratives outside formal reporting channels.	Evidence quality varies because social media posts often lack clinical verification, product certainty, seriousness detail, and follow-up feasibility.
[Sarker, A. *et al*., 2015]	Review of natural language processing and information extraction for social media pharmacovigilance	Describes computational methods for identifying and structuring informal safety mentions across digital channels.	Informal language, multilingual variation, sarcasm, misspellings, and duplicate posts limit direct regulatory interpretation.
[Candore, G. *et al*., 2015]	Comparative statistical signal detection across spontaneous reporting databases	Demonstrates method-dependent signal outputs and supports governance of quantitative screening algorithms.	Performance depends on database structure, reference events, comparator selection, and local reporting patterns embedded in the source data.
[Wisniewski, A. F. *et al*., 2016]	Practice-based development of signal detection principles	Connects statistical detection with clinical review, documentation, and reproducible decision-making.	Provides governance principles rather than empirical measurement of global affiliate performance or local implementation quality.
[Vora, P., Artime, E. *et al*., 2018]	Review of risk minimisation effectiveness studies in a regulatory study register	Identifies weaknesses in evaluation designs and outcome measures for local risk control activities.	Register-based evidence may omit unpublished operational difficulties and may not capture country-level execution differences in detail.
[Schmider, J. *et al*., 2019]	Applied evaluation of artificial intelligence in adverse event case processing	Shows potential efficiency gains in intake, triage, duplicate detection, and case workflow support.	Requires validation, human oversight, data quality control, and jurisdiction-sensitive governance before regulatory reliance is defensible.
[Vermeer, N. S. *et al*., 2015]	Analysis of traceability challenges for biological	Clarifies why product identifiers, batch data, and	Product traceability depends on local prescribing,

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	products	naming conventions are essential for global signal attribution.	dispensing, recording, and reporting practices that are outside direct company control.

Risk minimisation studies highlight a second key problem: international safety decisions do not translate into local risk minimisation. The review of European risk minimisation measure studies revealed considerable variation in design, outcome measures and evidence [Vora, P., Artime, E. *et al*., 2018]. This is particularly relevant for multinational operations, as risk minimisation measures are often site-specific. Education materials need to be tailored to local practice and language. Risk minimisation systems need to adapt to local pharmacy and prescriber practices. Health-care professional letters may require country-specific approvals. Patient cards, pregnancy prevention cards or laboratory monitoring may be possible in one country but not another. A global benefit-risk committee may accept a risk minimisation strategy, but the benefit to public health depends on whether it is implemented and changes behaviour. Table 3 shows the outcomes reported or interpreted in the reviewed literature, and how similar operational categories can generate different strengths of evidence.

Table 3. Results comparison

Ref	**System / Context**	**Metric / Basis of Comparison**	**Outcome**
[Maigetter, K. *et al*., 2015]	India, Uganda, and South Africa national pharmacovigilance systems	Presence of minimum pharmacovigilance requirements, institutional capacity, and system functions	Local system maturity varied substantially, supporting the need for risk-based affiliate support rather than uniform operational assumptions.
[Olsson, S. *et al*., 2015]	Resource-limited pharmacovigilance settings	Reporting capacity, human resources, feedback, and system sustainability	Structural limitations reduced local detection capacity and increased dependence on targeted training, partnerships, and simplified reporting pathways.
[Ampadu, H. H. *et al*., 2016]	African reports in VigiBase compared with reports from other regions	Report volume, completeness, reporter type, and medicine categories	Regional report profiles differed, showing that global databases carry local surveillance signatures that require contextual interpretation.
[Alatawi, Y. M., & Hansen, R. A. 2017]	United States spontaneous reporting system	Estimated degree of under-reporting	Under-reporting was substantial, confirming that spontaneous report counts cannot serve as direct incidence measures in global safety governance.
[Golder, S. *et al*., 2015]	Social media adverse event evidence	Prevalence, frequency, and comparative value of safety posts	Patient-generated posts contained potentially useful safety information but had inconsistent clinical detail and uncertain verification status.
[Pierce, C. E. *et al*., 2017]	Social media monitoring compared with recent safety alerts	Ability of Facebook and Twitter monitoring to detect known safety concerns	Monitoring performance was limited and uneven, supporting a complementary role rather than replacement of established safety systems.
[Candore, G. *et al*., 2015]	Multiple spontaneous reporting databases	Comparative signal detection performance	Signal outputs varied across methods and databases, indicating that global signal

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			governance requires method transparency and local data awareness.
[Vora, P., Artime, E. *et al*., 2018]	European risk minimisation evaluations	Study design, outcome measures, and effectiveness evidence	Many evaluations lacked robust designs or direct behavioural endpoints, limiting confidence in local effectiveness of formal risk controls.
[Schmider, J. *et al*., 2019]	Company adverse event case-processing environment	Automation potential in case intake and workflow	Artificial intelligence tools showed operational promise but required validation, human review, and quality system integration.
[Vermeer, N. S. *et al*., 2015]	Biological product pharmacovigilance	Product and batch traceability for attribution of safety events	Traceability gaps limited accurate product attribution, making local recording practices central to global assessment of biologicals.

The evidence landscape of the pool of reviewed articles across years and themes is shown in Figure 2. This is not a bibliometric comment about the field; instead, it illustrates the themes of the peer-reviewed studies included in this review. The figure helps to support the interpretation that the literature initially focused on system capacity, quality of reporting and digital resources, and more recently automation and data-driven pharmacovigilance.

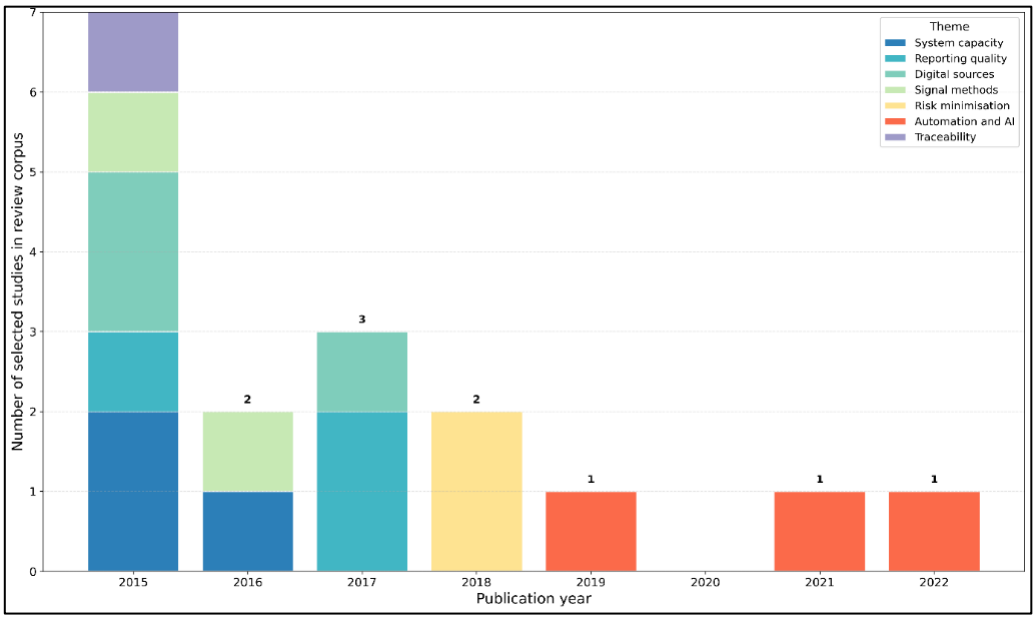


Figure 2. Thematic distribution of reviewed peer-reviewed studies, 2015–2022

The pattern in Figure 2 contributes to the varied maturity of the evidence. The 2015-2016 papers played a crucial role in clarifying the system's gaps, report attributes, and research methods, while more recent work broadened the focus to automation and more effective data use. The lack of a rich cluster of company-level multinational operational studies is notable: the evidence base is populated by many parts needed for global-local bridging, but not many studies assess the bridge as an integrated system.

Figure 3 offers a comparative map of operational friction derived from studies. The x-axis is local variability, and the y-axis is global standardisation. It illustrates how some activities, like ICSR reporting and signal validation, need to be highly standardised globally, whereas other activities such as risk minimisation and patient reporting need to be highly flexible locally, while maintaining global control.

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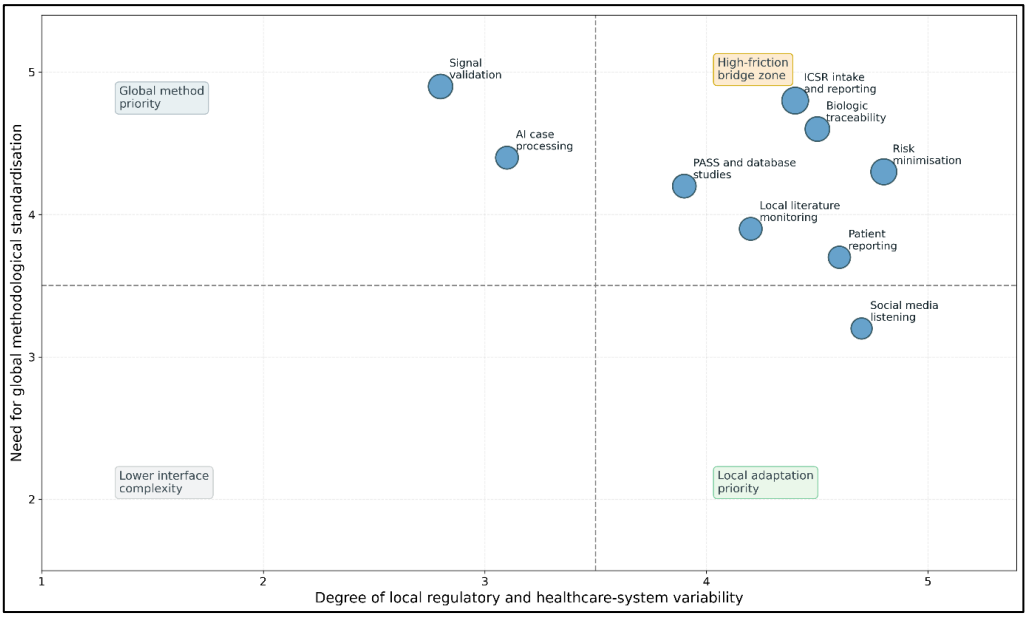


Figure 3. Operational friction map for global-local pharmacovigilance interfaces

The bridge zone in Figure 3 is where the greatest operational challenge occurs for multinational pharmaceutical companies. ICSR, biologic traceability and risk minimisation are all highly localised processes, but need a high degree of global standardisation, making these processes particularly susceptible to delay, interpretation problems, and quality issues. This map also explains why global pharmacovigilance decisions may not be implemented effectively at the local level.

Recent work on automation adds to this. Automation has been suggested for adverse event ingestion, de-duplication, narrative classification, seriousness determination and prioritisation [Schmider, J. *et al*., 2019]. Subsequent analysis of automation and medicine safety suggested artificial intelligence can enhance pharmacovigilance efficiency but should not become a scientific black box separated from quality-system governance [Bate, A., & Hobbiger, S. F. 2021]. A scoping review of machine learning in pharmacovigilance also found that the literature is growing in methods for signal detection, case triage, and literature screening, but varied in validation, reproducibility and interpretability [Kompa, B. *et al*., 2022]. For multinational pharmaceutical companies, the implications of these studies are that automation should be managed globally but tested locally. A natural language model trained on English narratives from established reporting systems may not work as well for translated reports or local patient language, translated narratives, or country-specific product names. So, automation provides efficiency, but also a new challenge of global-local fit.

Biological traceability demonstrates how local documentation practices affect global safety assessment. Biological traceability studies have demonstrated that attribution is dependent on the documentation of product name, manufacturer and batch number, among other things [Vermeer, N. S. *et al*., 2015]. This is important in multinational systems as the use of biosimilars, parallel distribution, hospital formularies, tendering and substitution policies may vary. An adverse event for a biological medicine might be entered into a global database, but absence of information in the local record may mean that the event cannot be traced to a particular product or batch. This impacts signal detection, regulatory communications and quality-defect communications. It also illustrates how closing the gap between global and local requirements sometimes depends on actions beyond company control in the health-care system. Multinational companies can provide forms, training and request further information, but local prescribing and dispensing evidence determines the quality of traceability evidence.

Figure 4 offers an integrated control-layer model of multinational pharmacovigilance. It does not represent a process but layers of control from local evidence capture to global quality assurance. The approach underpins the argument by revealing local capture, case processing, signal and risk assessment, regulatory communication and quality

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assurance are not discrete steps but control layers around patient and product safety.

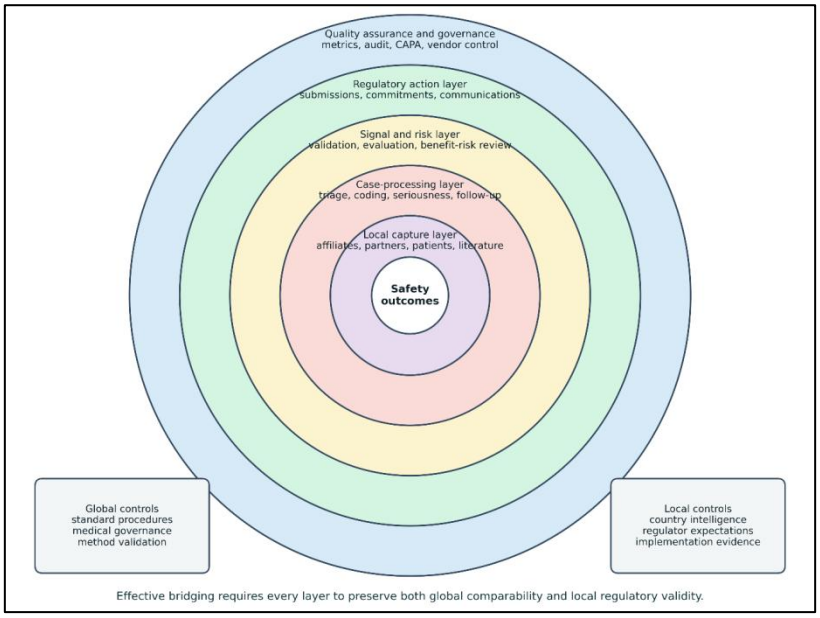


Figure 4. Control-layer architecture for multinational pharmacovigilance operations

The model in Figure 4 synthesises the insights of all studies. Local capture is important because poor-quality or incomplete data cannot be fully compensated for by centralised analytics. The outer governance layer is also critical because global businesses need formal oversight of subsidiaries, partners, suppliers, automation technologies and regulatory commitments. The model also demonstrates that global-local bridging is not a harmonisation project. It is an ongoing quality process in which data, decisions and actions must be harmonised regardless of evolving product portfolios, local laws and regulatory requirements, technology and models of care.

Close reading of the literature identifies contradictions and limitations. Digital pharmacovigilance is often claimed as a means for better patient insight, but reported reviews demonstrate that social media monitoring has unknown sensitivity and specificity for regulatory safety assessment [Golder, S. *et al*., 2015; Pierce, C. E. *et al*., 2017]. Pharmacovigilance is increasingly based on the detection of statistical signals, but these differ depending on the data source and method used, and require local reporting context for interpretation [Candore, G *et al*., 2015; Wisniewski, A. F. *et al*., 2016]. Risk minimisation is a regulatory priority, but few studies have strong behavioural or clinical outcomes, making it difficult to assess public health effects [Vora, P., Artime, E. *et al*., 2018]. Automation offers efficiency but validation across language, affiliate, product and jurisdiction is still nascent [Bate, A., & Hobbiger, S. F 2021; Kompa, B. *et al*., 2022]. These challenges provide evidence for integration, not substitution: digital data complement reports, algorithms complement judgement, global standards shape local practice, while local data inform global assessment.

The critical gap is a lack of empirical work on operating models of multinational companies. Numerous studies focus on national systems, global databases, reporter groups, risk minimisation studies, social media or automation. Very few studies examine how multinational pharmaceutical companies design subsidiary oversight, align local and global databases, assess compliance of local reporting, validate automation across local languages, or assess implementation quality across geographies. This is significant because the title problem is about the bridge. Existing evidence provides robust components, but the bridge is still partly inferred from other sources. The next generation of research should therefore not only focus on individual pharmacovigilance factors, but also interface controls that determine the congruence of global safety knowledge and local regulatory action.

FUTURE DIRECTIONS

The global-local interface should be a prime focus of future pharmacovigilance research. While prior research has provided considerable evidence on the reporting system, database limitations, patient reports, social media, signal detection, risk minimisation, automation and traceability, there is

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limited direct research on multinational models. There is a need to develop validated metrics for the affiliate-level interface. They should capture local intake timeliness and completeness, follow-up success, local literature coverage, regulatory submission accuracy, deviation management, quality of local regulatory intelligence, and local support for global signal decisions and global support for local signal implementation. Such metrics should not just serve as compliance measures; metrics should help explain if local evidence can inform global scientific judgement.

The second research gap is comparisons of local implementation of global risk decisions. Risk minimisation research has demonstrated that formal measures are often not evaluated using rigorous designs [Vora, P., Artime, E. *et al*., 2018]. Studies should compare the same global safety action across jurisdictions, noting how the approval process, language, prescribing practices, professional societies, pharmacy regulations and access to patients affect its implementation. Such work would be most beneficial for controlled distribution measures, pregnancy prevention measures, direct health care professional communications, and biologic traceability measures. The aim should be to determine which local variations do not compromise the global safety action and which variations reduce efficacy.

A third area relates to technology governance. Automation and machine learning will continue to play a role in case intake, literature screening, duplicate detection, narrative coding and signal triage [Bate, A., & Hobbiger, S. F 2021; Kompa, B. *et al*., 2022]. The next step is to assess these tools on multinational, multilingual and multi-product datasets rather than on pure proof-of-concept data sets. Testing should not only consider accuracy, but also auditability, bias in different reporter subgroups, accuracy for translated narratives, sensitivity to different product names, missing data, and congruence with regulatory inspection practice. A global pharmacovigilance system cannot be automated without confidence that tools will perform well across local jurisdictions which feed the global system.

A fourth need is a greater emphasis on implementation science research in pharmacovigilance. Meeting global and local needs is an implementation challenge as well as a data challenge. The literature needs more studies of affiliate interpretations of global procedures, local escalations of uncertain events, vendor management of country-specific requirements, the role of quality systems in detecting handoff problems across borders, and the impact of safety communications on prescriber and patient behaviour. Multidisciplinary research with regulatory science, organisational science, health informatics, clinical pharmacology and patient safety could lead to models that capture multinational reality. Future research should prioritise testing the controls that make harmonisation work, rather than further conceptualising harmonisation.

CONCLUSION

Pharmacovigilance in multinational pharmaceutical operations is a key challenge for contemporary medicine safety, and multinational pharmaceutical companies must ensure global and local requirements are met. The evidence reviewed demonstrates that global safety governance is dependent on local evidence, and local regulatory measures are dependent on scientifically valid global assessment. This is a symbiotic rather than a hierarchical relationship. Global pharmacovigilance cannot make up for deficient local safety reporting and traceability, poor management of local affiliates, or inadequate risk minimisation in the country.

According to the literature, spontaneous reporting, patient reporting, digital listening, health-care data, signal detection, risk minimisation, and automation all contribute to the global-local pharmacovigilance interface but are not solutions in and of themselves. Local pharmacovigilance, reporting culture, language, regulatory requirements, product traceability and healthcare system design can affect the interpretation and completeness of safety data. Global approaches are needed for harmonisation, but local approaches are needed for understanding and action.

The academic importance of this field lies in moving beyond harmonisation as an abstract concept. It is not whether global and local needs can be harmonised because legal and health care diversity will remain. Rather, it is how multinational organisations can retain one accountable system of safety while honouring country obligations and maintaining local evidence value. This question involves governance, data quality, quality assurance, regulatory intelligence and implementation evidence.

Research gaps remain in empirical studies of performance at the affiliate level, implementation

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across countries of global safety decisions, automation in the face of multiple languages, and the effectiveness of locally implemented risk minimisation controls. The next step will be studies addressing the operational interface rather than individual parts of pharmacovigilance. A robust field will need to produce evidence that not only safety data are gathered, but that global and local knowledge and action are linked to protect patients across borders.

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