Staying ahead of the curve

Proactive regulatory intelligence for vigilance in pharmaceuticals and medical devices

Clarivate

Abstract

This white paper explores the intersection of regulatory intelligence and vigilance systems, specifically about pharmacovigilance for medicinal products, and materiovigilance for medical devices, underscoring the imperative for organizations to remain aligned with evolving compliance demands.

By examining publication volume, topic focus, and geographic variations, it provides a strategic overview of the global vigilance regulatory landscape and offers insights into both established regulatory authorities and those still developing their frameworks.

To generate these insights, Clarivate Clinical & Regulatory Consulting Services department conducted an analysis of regulatory publications issued over the past five years by health authorities across 50 countries. The focus was placed exclusively on official regulations and guidelines pertaining to pharmacovigilance and materiovigilance frameworks. Using clearly defined search parameters (outlined in the methodology section), the analysis identified 1,328 relevant documents. Less enforceable documents, such as safety alerts, administrative notices, reports or forms, were intentionally excluded to ensure a targeted and actionable perspective on the evolving global vigilance landscape.

In this context, the systematic analysis of regulatory publications becomes an essential practice across all functions within pharmaceutical and medical device organizations. It serves not only as a compliance safeguard but also as a proactive intelligence tool for anticipating regulatory shifts, aligning internal policies, and guiding forward-looking decisions that reinforce both market readiness and patient safety.

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Understanding pharmacovigilance and materiovigilance

Pharmacovigilance and materiovigilance represent two fundamental pillars in the lifecycle oversight of pharmaceutical products and medical devices, respectively. While the underlying goal across these domains is the same, safeguarding public health through the continuous evaluation of benefit-risk profiles, the regulatory approaches and requirements differ substantially based on the risk, intended use, and complexity of each product type.

Pharmacovigilance focuses on the detection, assessment, understanding, and prevention of adverse effects and other drug-related issues throughout the medicinal product lifecycle. In parallel, materiovigilance encompasses the safety surveillance of medical devices, monitoring incidents that may result in harm to patients, users, or others.

A key axis along which vigilance systems are structured is the division between pre-market and post-market requirements. Pre-market activities typically focus on generating sufficient evidence to support the initial authorization of a product regarding safety and efficacy or performance. This includes clinical trials for medicines and performance and safety evaluations for medical devices. However, no pre-market assessment can fully predict a product's behavior under real-world conditions. This reinforces the importance of post-market surveillance, the structured collection and analysis of safety and performance data once a product is available to the public.

Vigilance requirements for pharmaceuticals and medical devices diverge notably in terms of scope, data collection, and regulatory oversight.

Pre-market vigilance for drugs centers on clinical trial safety reporting, with strict protocols for adverse event monitoring and regulatory submission. For medical devices, requirements vary by risk class; high-risk devices undergo clinical investigations, while lower-risk ones often rely on literature or bench data. Device vigilance remains less standardized today, but it has seen notable growth in recent years and is expected to continue expanding gradually, driven by the need to enhance the safety and effectiveness of medical devices.

Post-market drug vigilance involves continuous signal detection, ICSRs, PSURs, and risk management plans under strict regulatory oversight. In contrast, medical device vigilance is event-driven, focusing on incident reporting and corrective actions, with fewer routine submissions. Coordination with notified bodies and health institutions adds complexity, and requirements vary more significantly by region and risk classification.

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Staying ahead in a shifting regulatory landscape

Amid a rapidly evolving pharmaceutical and medical device landscape, developments such as the emergence of gene and cell therapies, the rise of digital health technologies, the integration of real-world data into regulatory decision-making, the expansion of combination products, and the globalization of clinical development highlight the urgent need for vigilant, responsive, and harmonized safety systems.

Regulatory bodies such as the European Medicines Agency (EMA), the U.S. Food and Drug Administration (FDA), and authorities across Latin America, Africa, and Asia-Pacific are continuously refining their vigilance requirements, such as introducing changes in reporting timelines, signal detection processes, risk minimization tools, and data traceability protocols. Each update brings operational and strategic consequences.

Besides, global initiatives such as those led by the International Council for Harmonisation (ICH), Uppsala Monitoring Centre (UMC), and International Medical Device Regulators Forum (IMDRF) play a vital role in aligning safety expectations across jurisdictions.

Considering all of the above, being unaware of, or delayed in adapting to, these regulatory updates can have serious consequences. Non-compliance may lead to warning letters, fines, product recalls, suspension of clinical trials, or even loss of market authorization. More broadly, it can erode stakeholder trust and damage brand credibility, impacting long-term business sustainability.

From a strategic standpoint, remaining informed about regulatory developments is not merely a matter of compliance, it is also a competitive advantage. Proactively adapting systems and processes to regulatory changes enable companies to enhance operational efficiency, ensure continuity of market access, and ultimately support better patient outcomes.

Methodology

Clarivate's Clinical & Regulatory Consulting used Cortellis Regulatory Intelligence (CRI) to review the updates published by each regulatory authority in the last five years. The search strategy is detailed below.

Country: Countries included in CRI. Figure 1 excludes E.U. member states. E.U. member states are analyzed separately in Figure 6.

Topic: 'Pharmacovigilance, technovigilance, risk management' and 'GVP'.

Date: Authority acceptance date: '30 April 2020' to '30 April 2025'.

Document types in scope: Circular, decision, decree, directive, federal register announcement, guideline, instructions, law, opinion, order, ordinance, policy, questions & answers, recommendation, regulation, resolution, rules of procedure, standard operating procedures.

Document types out of scope: Agreement, announcement, checklist, citizen petition, committees and working groups, communication, compliance program manual, consultation, curriculum vitae, EPAR, fact sheet, form, information note, inspection report, letter, meeting, newsletter, notification, other type, pharmacovigilance bulletin, presentation, press release, product information, product miscellaneous, product safety, public comment, safety alert, warning letter, report.

Metrics and results

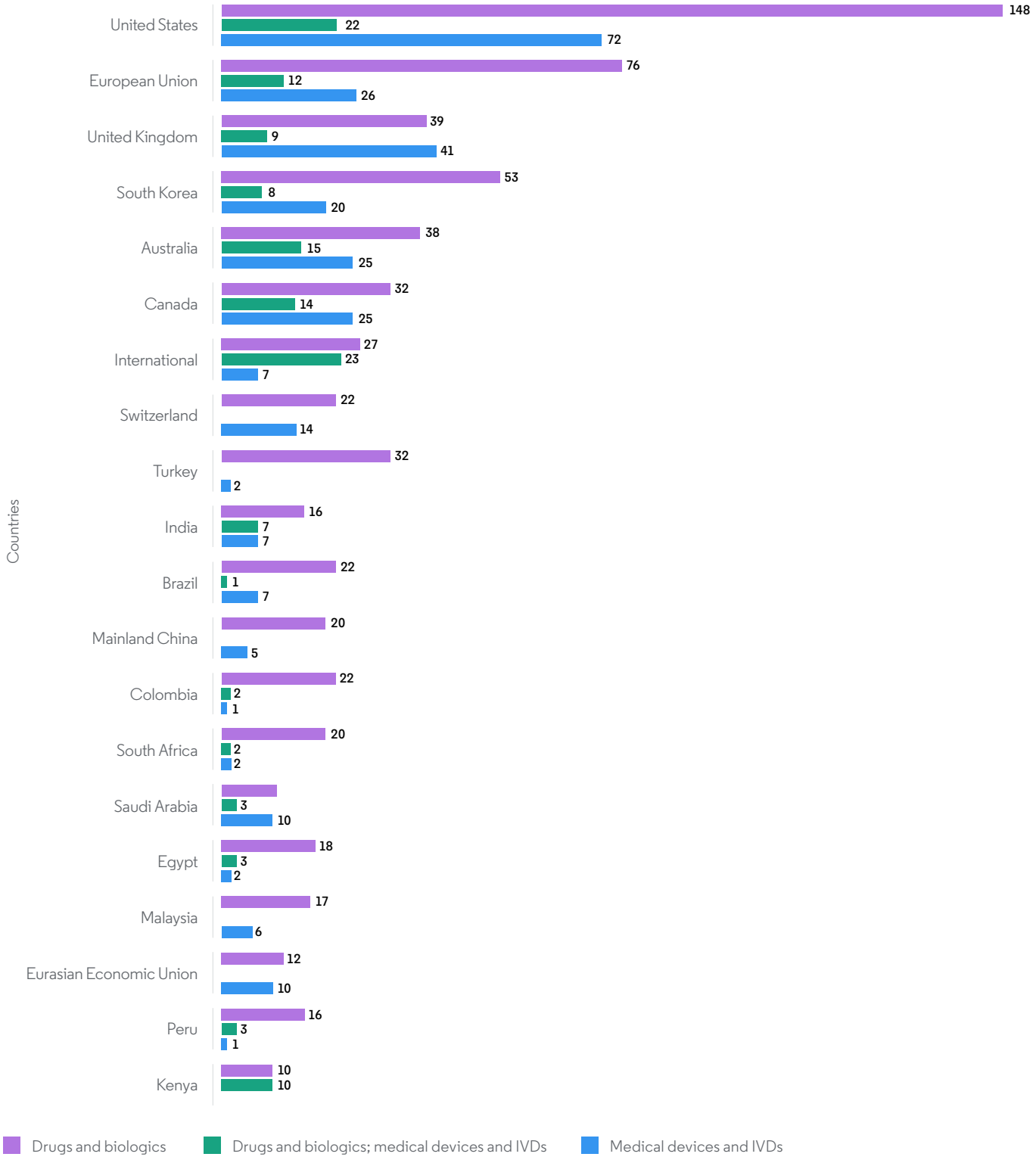
Global vigilance activity: mapping the leaders and laggards

Figure 1 highlights the top 20 countries or regions with the highest volume of publications related to pharmacovigilance and materiovigilance. The data reveal a huge difference between top six authorities, each issued more than 70 publications, with the United States leading the list.
In contrast, the bottom nine countries in the ranking released fewer than 30 publications, underscoring significant differences in regulatory activity across countries and regions.

The other 30 countries evaluated have less than 20 publications over the past five years. The countries with less than 2 publications are Morocco, Vietnam, Algeria, Iraq and Costa Rica. You can find the table with the numbers in the annex I.

European Union member states have been excluded from this first analysis depicted in Figure 1 to avoid overlapping with EMA publications. However, these countries will be analyzed in a separate point below.

Figure 1: Top 20 most active countries/regions in publication of legislation and guidance for pharmacovigilance and materio-vigilance



Source: Cortellis Regulatory Intelligence

This graphic displays the number of regulatory publications related to pharmacovigilance and materiovigilance issued by competent authorities, categorized by country or region included in CRI1. The data distinguish between documents related to drugs and biologics, medical devices and IVDs, or both categories combined. It shows the top 20 countries or regions with the highest volume of such publications over the past five years. For clarity, individual E.U. member states have been excluded.

[1] Cortellis Regulatory Intelligence (CRI) is the Clarivate proprietary database comprising more than 270,000 regulatory documents, including publications from health authorities from more than 80 countries.

Over the past five years, the United States (U.S.) has been the most active regulatory authority in the field of pharmacovigilance and materiovigilance, issuing a total of 242 publications. Leading by a wide margin, it has published more than twice as many regulatory updates as the second-ranking entity, the European Union.

The European Union (E.U.) ranks second, with 114 publications. The E.U. shows an unbalanced publication rate, focused predominantly on drugs and biologics (76 publications). The relatively low number on vigilance regulatory updates on medical devices and IVDs within the E.U. might reflect that some aspects of vigilance regulations for these products are set on a national basis instead of an E.U. level (for instance countries such as Belgium, Romania, Poland or Finland have more publications related to medical devices than medicinal products).

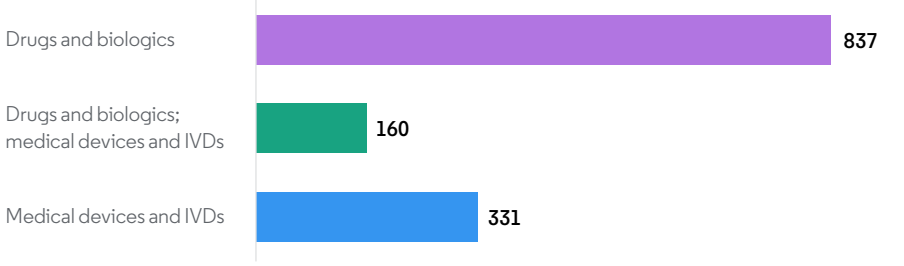
The next tier of countries, with publications counts ranging between 70 and 90, includes United Kingdom (U.K.), South Korea, Australia and Canada, all demonstrating a strong regulatory output around safety.

Notably, the International category ranks seventh in total publication volume, a position that underscores the increasing influence of global organizations in shaping vigilance standards. This category includes contributions from key institutions such as the World Health Organization (WHO), the International Council for Harmonisation (ICH), the International Medical Device Regulators Forum (IMDRF), the European Directorate for the Quality of Medicines & Healthcare (EDQM), and the Pharmaceutical Inspection Co-operation Scheme (PIC/S). The high publication rate from these entities reflects an effort to harmonize regulatory approaches, promote consistency across jurisdictions, and support the development of global best practices in both pharmacovigilance and materiovigilance.

Regulatory imbalance: who's falling behind on device safety?

Figure 2 highlights a notable global disparity between pharmacovigilance and materiovigilance activity worldwide. Some low- and middle-income countries are clear examples like Kenya, Colombia and Lebanon with one or no regulatory updates published solely about materiovigilance. This underscores the investment in regulatory capacity, particularly for medical devices.

Figure 2: Count of updates per product category.



Source: Cortellis Regulatory Intelligence

While most countries show a higher volume of publications focused on drugs and biologics compared to medical devices, some countries like the U.K., Saudi Arabia and Eurasian Economic Union (EAEU) show a more balanced regulatory engagement, maintaining equal activity in both pharmacovigilance and materiovigilance.

In U.K., the need to replace E.U. mechanisms with national systems has driven the MHRA to produce comprehensive materials to guide manufacturers and stake-holders, thereby contributing to the balanced volume of regulatory publications in both pharmacovigilance and materiovigilance. In pharmacovigilance, the MHRA has implemented specific requirements such as the establishment of a U.K.-based Qualified Person for Pharmacovigilance (QPPV) or a national contact person if the QPPV resides in the E.U., the maintenance of a Pharmacovigilance System Master File (PSMF) accessible within the U.K., and the submission of safety reports through MHRA's dedicated portals. Regarding materiovigilance, the MHRA introduced the U.K. Conformity Assessed (UKCA) marking and the establishment of U.K.-specific requirements for device registration and vigilance reporting.

On the contrary, Lebanon focused their efforts on pharmacovigilance with cero publications about materiovigilance in the last five years. This limited number of materiovigilance publications can be attributed to the relatively recent development and implementation of their pharmacovigilance systems, with materiovigilance frameworks still in nascent stages. Lebanon stablished their Lebanese National Pharmacovigilance Program (LNPVP) in 2018, this system became fully operational in 2022 (the 2 publications related to both product types are COVID related). Actually, even when the authority encourages health professionals to report adverse events for medical devices, there is still no specific format or process for reporting.

It is also worth noting that in some countries, regulatory frameworks do not clearly differentiate between medical devices and medicinal products. Instead, a single set of regulations may apply to both product types, typically focusing on medicinal products vigilance and extending the application to medical devices or even to other product categories. This approach can be seen in countries such as Kenya and Nigeria. For example, Kenya published guidelines such as 'Guideline HPT/PDS/VMS/GUD/022 Rev. 1: Guidelines on the Safety and Vigilance of Medical Products and Health Technologies, Jan-2023' and 'Guidelines HPT/PDS/VMS/GUD/054 Revision 1: Post-marketing Surveillance of Health Products and Technologies in Kenya, Jan-2024'. Similarly, Nigeria's 'PV- GDL-024-00: Nigerian Guidelines for Detecting & Reporting of Adverse Reactions for Pharmaceutical Products and Medical Devices, 14-Oct-2024' and 'PMS-GDL-016-01: Guidelines for Post-Marketing Surveillance of Medical Products in Nigeria, 27-Sep-2024' reflect a unified approach, combining surveillance protocols for pharmaceuticals and medical devices within the same regulatory documents.

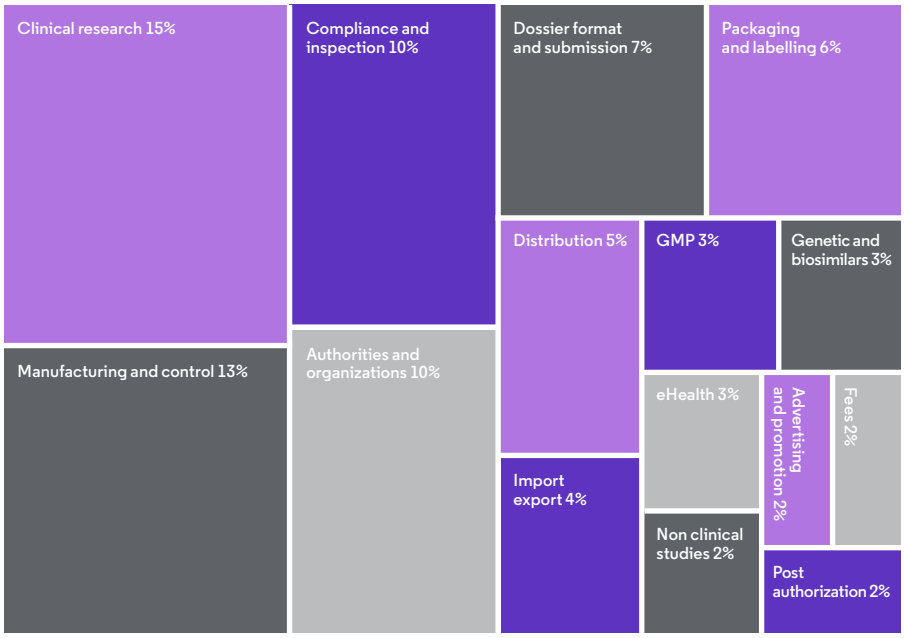
Beyond safety: what related topics say about regulatory intent

Cortellis Regulatory Intelligence (CRI) database labels each update with different topics to ease the identification and classification of regulatory documents. Each of these documents has between 1 and 15 topic tags, with a media of 3 topic tags per document.

It is valuable to examine the relationship between different topics in the same document to understand the regulatory intent and scope of the document.

Figure 3 presents the fifteen most frequently assigned topic tags across the analyzed documents, offering insight into the primary focus areas besides pharmacovigilance and materiovigilance in the analyzed regulatory updates.

Figure 3: Most repeated topics



Source: CRI

Top 15 more mentioned topic tags, excluding the ones selected during the search 'pharmacovigilance technovigilance risk management' and 'GVP' and the ones that describes in general the document types selected 'regulatory procedures' and 'legislative framework'.

The data reveal a strong regulatory emphasis on operational standards and oversight mechanisms based on the prevalence of 'manufacturing and control' and 'compliance and inspection' topics. Besides, the presence of 'clinical research' as the top tag also reflects the connection between new safety regulations and ongoing research.

Overall, the topic distribution highlights the broad regulatory concern with quality assurance, governance, and procedural integrity in both pharmacovigilance and materiovigilance.

The irruption of eHealth across the medical field and corroborated by its presence among the most frequently cited topics, ranked 11th in the analysis of Figure 3, reflects its rising influence across healthcare and regulatory domains, which implies the necessity of increasing the regulation around this field.

In the context of pharmacovigilance and materiovigilance, eHealth plays a pivotal role in two main areas:

- Data collection and signal detection—leveraging electronic health records, mobile apps, and patient-reported outcomes to enhance the speed and accuracy of adverse event monitoring; and

- Regulatory communication and oversight—enabling more efficient submission, review, and dissemination of safety data through digital platforms.

As eHealth evolves, its integration with vigilance systems will be critical for achieving real-time surveillance, improving traceability, and ultimately enhancing patient safety in both drug and device sectors.

Actually, many low- and middle-income countries have adopted mobile app reporting systems like the Med Safety App[2] supported by the World Health Organization (WHO).

eHealth has become a vital partner for pharmaceutical and MedTech companies in different aspects and staying informed on the latest regulatory updates in this field is critical. Regarding pharmacovigilance and materiovigilance landscape, eHealth helps develop efficient and cost-effective strategies to fulfil both pre- and post-commercialization product surveillance requirements.

As eHealth evolves, its integration with vigilance systems will be critical for achieving real-time surveillance, improving traceability, and ultimately enhancing patient safety in both drug and device sectors.

[2] Ndagije, H., Van Geertruyden, J. P., & Boum, Y. (2022). The use of smartphone-based mobile applications for adverse drug reaction reporting: a systematic review. BMC Medical Informatics and Decision Making, 22(1), Article 183. doi.org/10.1186/s12911-022-01832-1

Guidance vs. governance: how document types reflect enforcement and strategy

Document types play a crucial role in regulatory analysis because they indicate the legal weight and enforceability of the information provided. Regulations, laws, and decrees, grouped as regulatory framework, are legally binding, while guidances typically offer interpretative support and best practices.

The next level of document types in Figure 4 are Federal Register Announcements (FRA) and SOPs. Federal Register Announcements are published by the United States and are used to communicate proposed rule changes, final rules, public meetings, draft guidances for comment, and notices of regulatory actions, which encompasses all other document types. Standard Operating Procedures (SOPs), often internal to regulatory agencies, can signal expected operational standards.

Finally, Recommendations are non-binding communications intended to advice companies about best practices.

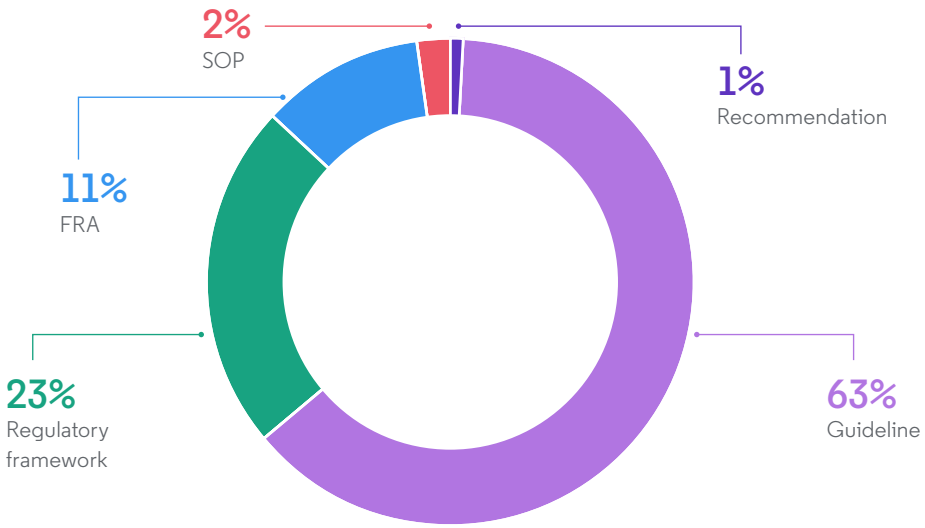
As shown in Figure 4 most of the documents fall under the category of guidances, which account for 63% of the total. This is followed by documents classified as part of the regulatory framework (23%), such as laws, regulations, and decrees. Federal Register Announcements (FRA) make up 11%. A smaller portion—2%—corresponds to Standard Operating Procedures (SOPs) and a negligible percentage consists of other minor document types (recommendations, opinions and rules of procedure).

The regulatory frameworks provide the legal backbone; however, the predominance of guidance documents reflects the regulatory authorities' preference for issuing interpretative and supportive materials to assist stakeholders in complying with pharmacovigilance and materiovigilance requirements.

As the data shows, the relatively lower proportion of SOPs suggests that operational instructions and analytical reviews are less frequently published, and 'recommendations', 'opinions' and 'rules of procedure' are not the preferred way of health authorities to provide guidance on vigilance-related topics.

Overall, the distribution underscores the role of guidance documents as a cornerstone of regulatory communication in the vigilance landscape.

Figure 4: Distribution of document types among the regulatory publications analysed in this report



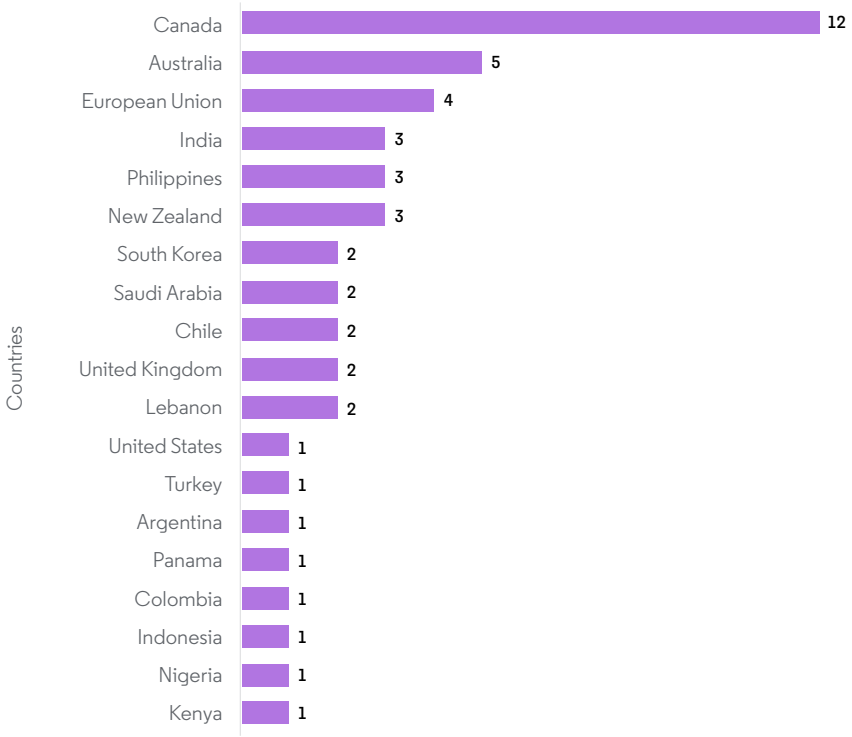
Source: CRI

The document types in this chart have been grouped to show the regulatory binding level. Documents tagged as regulation, resolution, circular, order, decision, decree, law, ordinance, directive and policy have been grouped as regulatory framework. Guideline, questions & answers and instructions have been grouped as guidances.

Understanding the pandemic effect: COVID-related updates and data bias

One potential source of bias in the data could be COVID related pharmacovigilance updates that overestimate the publication activity of the authority regarding pharmacovigilance. Figure 5 shows the number of updates related to COVID included in the results, 48. The majority of COVID Related publications were made in 2021, 18, however, 2024 had a significant number of publications with 12. The count reflects documents with the terms 'COVID', 'SARS-CoV-2' or 'pandemic' in their titles.

Figure 5: Number of COVID-related regulatory updates identified in the CRI search results



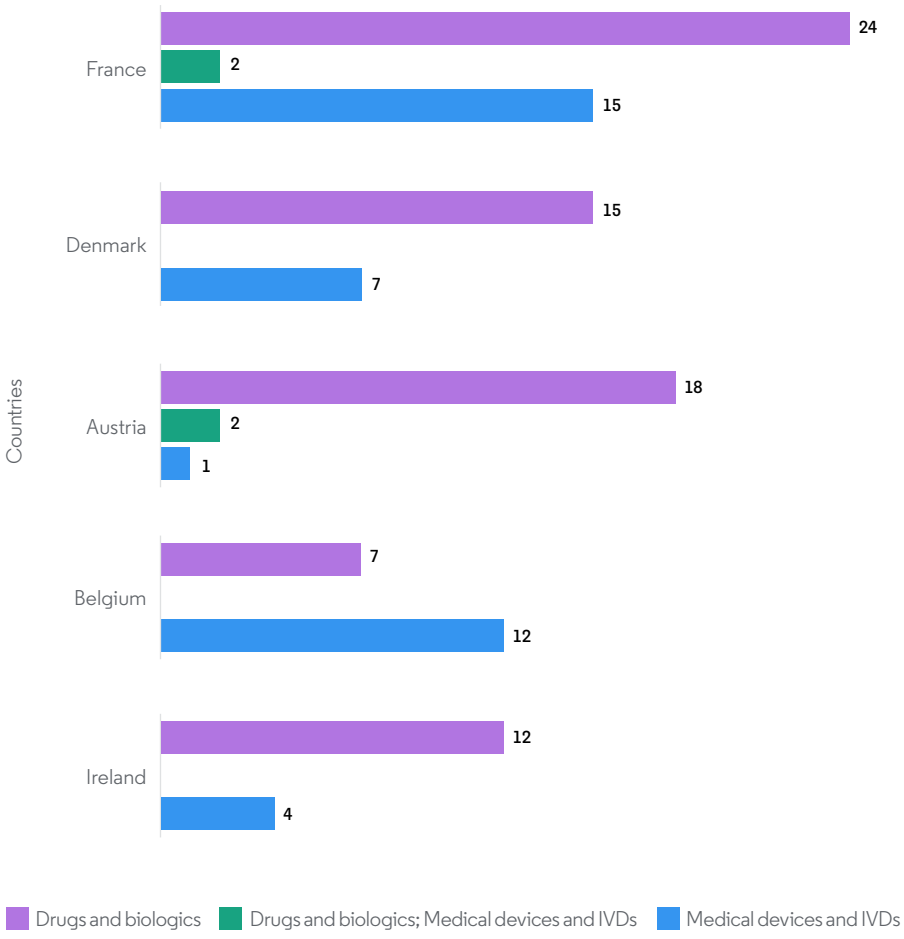
Interestingly, Canada, is the country with more Covid related regulatory publications, indicating that the pandemic prompted a visible regulatory response.

However, these numbers do not modify the Figure 1 results significantly if we eliminate COVID related updates from the results. The only country of the top 20 represented in Figure 1 that lowers in the ranking is Saudi Arabia, that goes from position 15 to position 17, but we consider this as not representative as the difference in between the countries ranked below 15th position only differs on 1 or 2 updates.

E.U. member states in focus: national activity behind the central framework

About E.U. individual member states, they were not included in the previous graphics to avoid overlapping with E.U. central publications. However, some of them like France, Denmark and Austria have a high rate of publications with more than 20 publications in the past five years.

Figure 6: Top 5 most active E.U. member states in publication of legislation and guidance for pharmacovigilance and materiovigilance



Source: CRI

Number of regulatory publications on pharmacovigilance and materiovigilance issued by the top five individual E.U. member states. The data distinguish between documents related to drugs and biologics, medical devices and IVDs, or both categories combined. Cyprus, Luxembourg and Malta are not part of the results because they are not included in CRI.

France leads among E.U. member states with a total of 41 publications, demonstrating significant activity in both pharmacovigilance and materiovigilance, standing out with nearly twice as many publications as the other countries included in the top five. Denmark and Austria show similar levels of total output, but Austria is largely focused on drugs and biologics.

Belgium's higher number of publications related to materiovigilance, almost double those focused on pharmacovigilance, is a rare exception that reflects its active implementation of the European Union's new regulatory frameworks for medical devices (MDR) and in vitro diagnostic devices (IVDR). The Federal Agency for Medicines and Health Products (FAMHP/AFMPS) has issued multiple guidelines and legal instruments to operationalize national compliance. These include laws, royal orders, and agency-level guidances that define procedures for clinical investigations, performance studies, distributor responsibilities, and materiovigilance point-of-contacts.

Overall, these figures highlight national-level engagement in safety regulation of these countries despite the central role of the European Medicines Agency (EMA). The variation suggests that while E.U. legislation sets the overarching framework, member states continue to develop and communicate national guidances, particularly in areas where local implementation or interpretation of E.U. regulations is required.

In contrast, Bulgaria issued only one regulatory update during the study period. The 2021 publication relates to temporary ICSR reporting requirements, applicable until six months after the EudraVigilance database is declared fully functional.

France leads among E.U. member states with a total of 41 publications, demonstrating significant activity in both pharmacovigilance and materiovigilance, standing out with nearly twice as many publications as the other countries included in the top five.

Conclusion

This global analysis of regulatory publications related to pharmacovigilance and materiovigilance over the past five years highlights not only the volume and geographic distribution of updates, but also the maturity and priorities of health authorities worldwide.

The findings highlight significant variation in global regulatory engagement in both pharmacovigilance and materiovigilance. Entities such as the United States and the European Union lead in publication volume, reflecting strong regulatory activity. In contrast, countries like Morocco, Vietnam, Algeria, Iraq, and Costa Rica reported fewer than two relevant publications over the past five years, indicating minimal public regulatory output in these areas.

Pharmacovigilance continues to be the dominant focus of regulatory activity across most regions. This reflects the historical prioritization of drug safety and the more established nature of pharmacovigilance frameworks. However, materiovigilance is steadily gaining ground as regulatory systems adapt to the growing complexity and use of medical technologies.

A closer examination of document types reveals a strong preference for guidance documents, which accounted for over half of the total publications. Binding legal instruments, like laws, regulations, and decrees, still play a critical role in establishing enforceable frameworks, but the predominance of guidances suggests a regulatory strategy centered on support and interpretation.

The prominent presence of clinical research among the top associated topics reflects the growing emphasis on pre-market vigilance. Authorities are increasingly integrating vigilance requirements into clinical trial oversight, ensuring that adverse events, investigational product performance, and risk-benefit profiles are systematically monitored from early development stages. In parallel, the high frequency of operational topics like 'manufacturing and control' and 'compliance and inspection' points out continued regulatory emphasis on ensuring product quality, traceability, and adherence to operational standards throughout the supply chain. eHealth also appears as a rising theme, signaling the integration of digital technologies into vigilance infrastructures.

The high publication rate of international bodies such as the WHO, ICH, and IMDRF demonstrates a clear effort toward harmonization and global alignment. Their influence provides structure and coherence to help align an evolving regulatory landscape.

At European Union member states level, France demonstrates substantial national-level activity alongside E.U.-wide initiatives and some other E.U. countries show a strong regulatory focus on materiovigilance, driven by the national implementation of the European Medical Device Regulation 2017/745 (MDR) and In Vitro Diagnostic Regulation 2017/746 (IVDR), like Belgium, Romania, Poland or Finland.

In summary, the landscape of pharmacovigilance and materiovigilance regulation is evolving rapidly, not just in volume, but in form, focus, and coordination. For regulatory professionals and industry stakeholders, staying informed of these trends is no longer optional, it is essential for compliance, strategic planning, and the shared mission of protecting patient safety worldwide.

Appendix 1.

Table 1: Volume of pharmacovigilance and materiovigilance updates

Country/region	Drugs and biologics	Medical devices and IVDs	Drugs and biologics; medical devices and IVDs	Total
United States	148	72	22	242
European Union	76	26	12	114
United Kingdom	39	41	9	89
South Korea	53	20	8	81
Australia	38	25	15	78
Canada	32	25	14	71
International	27	7	23	57
Switzerland	22	14	0	36
Turkey	32	2	0	34
Brazil	22	7	1	30
India	16	7	7	30
Mainland China	20	5	0	25
Colombia	22	1	2	25
South Africa	20	2	2	24
Saudi Arabia	11	10	3	24
Egypt	18	2	3	23
Malaysia	17	6	0	23
EAEU	12	10	0	22
Peru	16	1	3	20
Kenya	10	0	10	20
Taiwan	12	7	0	19
Japan	12	0	7	19
Indonesia	13	3	1	17

Country/region	Drugs and biologics	Medical devices and IVDs	Drugs and biologics; medical devices and IVDs	Total
Lebanon	15	0	2	17
Nigeria	9	1	6	16
Mexico	15	1	0	16
Singapore	8	6	0	14
Russian Fed.	4	9	1	14
Chile	9	5	0	14
Serbia	12	0	0	12
Panama	8	2	0	10
Philippines	6	2	2	10
New Zealand	8	0	2	10
Hong Kong	6	3	0	9
Argentina	8	1	0	9
Jordan	7	0	1	8
Norway	3	3	0	6
Thailand	2	4	0	6
Venezuela	5	0	0	5
UAE	2	0	2	4
Tunisia	4	0	0	4
Guatemala	4	0	0	4
Israel	3	0	0	3
Ukraine	2	1	0	3
SICA	2	0	0	2
Morocco	1	0	1	2
Vietnam	1	0	1	2
Algeria	2	0	0	2
Iraq	2	0	0	2
Costa Rica	1	0	0	1
Grand total	**837**	**331**	**160**	**1328**

Appendix 2.

Table 2: Overview of pharmacovigilance and materiovigilance regulation and guidance

Country/ region	Pharmacovigilance	Materiovigilance
Australia	**Pre-Market:** 1) NHMRC Safety Monitoring and Reporting in Clinical Trials involving Therapeutic Goods **Post-Market:** 1) Therapeutic Goods Act 1989 2) Therapeutic Goods Regulations 1990 3) Guideline: Pharmacovigilance Responsibilities of Medicine 4) Guideline Therapeutic Product Vigilance 5) Guideline: Pharmacovigilance Inspection Program 6) Guideline: Risk Management Plans for Medicines and 7) Biovigilance responsibilities of sponsors of biological 8) International scientific guidelines adopted in Australia	1) Therapeutic Goods Act 1989 2) Regulations: Therapeutic Goods (Medical Devices) Regulations 2002 3) Guideline: Understanding your Post-Market Responsibilities for Medical Devices
Brazil	**Pre-Market:** 1) Resolution CNS 251: Approving the Regulations for the Conduct of Clinical Trials with New Medicinal Products, Vaccines and Kits for Diagnosis 2) Resolution 346: Approval Procedure for Multicenter Clinical Research Protocols by the CEP and by the CONEP 3) Resolution CNS 466: Approving Guidelines and Regulations for the Conduct of Clinical Trials 4) Resolution RDC 945: On the Guidelines and Procedures for Conducting Clinical Trials in the Country Aimed at the Future Grant of the Marketing Authorization 5) Circular Letter 13/2020-CONEP/SECNS/MS: Establishes the Procedure for Reporting Adverse Events in the CEP / Conep System 6) Guide: Notification of Adverse Events and Monitoring of Safety in Clinical Trials (Version 7) Guideline: How to Use VigiMed for Notifying Adverse Events for Marketing Authorization Holders **Post-Market:** 1) Order 696: Establishment of the Centro Nacional de Monitorização de Medicamentos-CNMM (Brazilian Medicinal Products Monitoring Center) 2) Resolution RDC 339: On the Establishment of the National Biovigilance System 3) Instructions for Submitting the Periodic Benefit-Risk Evaluation Report (PBRER) 4) Normative Instruction 63: On Periodic Benefit-Risk Evaluation Report (PBRER) to be submitted to Anvisa by Marketing Authorisation Holders for Medicinal Products of Human Use 5) Resolution RDC 406: On the Good Pharmacovigilance Practices for Marketing Authorisation Holders of Medicinal Products and Other Measures, 22-Jul-2020 6) Instructions for Submitting the Periodic Benefit-Risk Evaluation Report (PBRER) 7) Resolution RDC 339: On the Establishment of the National Biovigilance System 8) Normative Instruction 63: On Periodic Benefit-Risk Evaluation Report (PBRER) to be submitted to Anvisa by Marketing Authorisation Holders for Medicinal Products of Human Use	1) Resolution RDC 67: Technovigilance Requirements Applicable to Registration Holders of Medical Devices 2) Resolution RDC 551: On the Registration Holder's Obligation to Implement and Notify Field Safety Corrective Actions

Country/ region	Pharmacovigilance	Materiovigilance
Canada	**Pre-Market:** 1) Notice: Implementation of International Council for Harmonisation (ICH) Integrated Addendum to ICH E6(R1) - Guideline for Good Clinical Practice E6(R2) 2) Guidance for Clinical Trial Sponsors: Clinical Trial Applications **Post-Market:** 1) Food and Drugs Act 2) Food and Drug Regulations (C.R.C., c. 870) 3) Guideline: Health Product Vigilance Framework 4) Canada Vigilance Program — Collecting and Assessing Adverse Reaction Reports	1) Regulations: Medical Devices Regulations (SOR/98-282) 2) Guidance Document: Incident Reporting for Medical Devices 3) Guidance document: Foreign Risk Notification for Medical Devices
Mainland China	**Pre-Market:** 1) CDE Notification: Standards and Procedures for Expedited Reporting of Safety Data During Clinical Trial of Drugs 2) NMPA Order No.27: Drug Registration Regulation 3) NMPA & NHC Announcement No.2020/57: Good Clinical Practice (GCP) Guidelines 4) Law: Drug Administration Law, P.R.China 5) NMPA Notification No.2020/37: Issuance of Guidelines on Preservation of Necessary Documents for Drug Clinical Trials 6) CDE Notification No.2020/07: Issuance of Provisions on Safety Update Report during R&D Period (Interim) 7) NMPA Announcement No.2021/65: Good Pharmacovigilance Practice (GVP) of Drugs 8) NMPA Notification No.2022/17: Issuance of Technical Guidelines for Pharmacovigilance Inspection 9) CDE Notification No.2023/59: Technical Guidelines for Clinical Safety Evaluation of New Drugs **Post-Market:** 1) Drug Administration Law, P.R.China 2) NMPA Announcement No. 2018/66: Direct Reporting of Adverse Reactions by Marketing Authorization Holders of Drug Products 3) Provisions on Adverse Drug Reaction Reporting and Monitoring [MOH Order No. 81: May 4, 2011] 4) CFDA Notification on Issuance of Guideline for PSUR Writing, GuoShiYaoJianAn [2012]/264 5) Notification on Issuance of Check Points for Periodic Safety Update Report (PSUR) (Trial run),JianCeYuPingJiaZhong [2012]/27 6) Notification of Explanatory Notes for Regular ADR Summary Reporting and Reporting of ADR Occurring outside of China for Import Drugs Marketed Within China [SFDA notification no.:GuoShiYaoJianAn [2005] 89 7)]NMPA Notification No.2022/17: Issuance of Technical Guidelines for Pharmacovigilance Inspection	1) CFDA Order No. 29: Administration Provision on Medical Device Recall, 25-Jan-2017 2) CMDE Notification No.2022/07: Technical Guidelines for Cybersecurity in Medical Devices (2022 Revision) 3) Notification: GuoShiYaoJianXie 2008/766: Notification on the Issuance of Regulations for Adverse Events (AE) Surveillance and Re-evaluation of Medical Devices (Trial), 29-Dec-2008 4) Notification: ShiYaoJianBanXieJian 2014/107: Notification on Recall Information Disclosure for Medical Devices 5) NMPA Notification No.2020/25: Guidance on Adverse Event (AE) Surveillance for Medical Device Registration Applicants 6) CMDE Notification No.2022/07: Technical Guidelines for Cybersecurity in Medical Devices (2022 Revision)

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Colombia	**Pre-Market:** 1) Resolution 2024015321: Regulates the Content and Periodicity of Adverse Event Reports and Pharmacovigilance Programs for Marketing Authorization Holders and Manufacturers 2) Resolution 2378: Good Clinical Practices for Establishments Conducting Research with Medicinal Products for Human Use 3) Resolution 1403: Determines the Administrative Criteria of the Pharmaceutical Service Management Model and Adopts the Manual on the Pharmaceutical Services Essential Conditions and Procedures 4) Resolution 2011020764: Regulates the Periodicity of Adverse Event Reports During Clinical Trials 5) INVIMA Guideline: Evaluation of Clinical Research Protocols (Code ASS-RSA-GU039) (Version 5) 6) INVIMA Guideline: Investigational Medicinal Products and Medicinal Products Used for Clinical Trial Purposes ASS-RSA-GU045 (Version 1) **Post-Market:** 1) Decree 677: Regulates the Process of Registration, the Granting of Licences, Quality Control and Sanitary Surveillance of Medicinal Products, Cosmetics, Herbal Medicinal Products, Personal Hygiene Products and Other Products for Domestic Use 2) Decree 1782: Establishes Requirements and Procedures for the Pharmacological and Pharmaceutical Evaluation of Biological Medicinal Products within the Framework of Registration Applications 3) Resolution 213: Approves the Guidelines on Risk Management Plans for Medicinal Products of Chemical Synthesis with New Chemical Entities and Biologicals 4) Circular 048: Instructions for Post-Marketing Surveillance of Medicinal Products, Medical Devices and IVD defined as Vital and Non-Available 5) Circular 3000-0526-2021: National Pharmacovigilance Program Guidelines for Reporting of Adverse Events through the VigiFlow WebPortal 6) Guide: Follow-up Visits/Inspections to Establishments Belonging to the National Pharmacovigilance Network (Code: IVC-VIG-GU009)	1) Resolution 4816: Regulates the National Technovigilance Program 2) Circular 048: Instructions for Post-Marketing Surveillance of Medicinal Products, Medical Devices and IVD defined as Vital and Non-Available
Eurasian Economic Union (EAEU)	**Pre-Market:** 1) Decision of the Eurasian Economic Commission Council N 87: On Approval of Good Pharmacovigilance Practice 2) Decision of the Eurasian Economic Commission Council N 79: On Approval of Good Clinical Practice 3) Decision of the Eurasian Economic Commission Council N 78: On the Rules of Marketing Authorization and Assessment of Medicinal Products **Post-Market:** 1) Decision of the Eurasian Economic Commission Council N 87: On Approval of Good Pharmacovigilance Practice 2) Decision of the Eurasian Economic Commission Council N 84: On the Procedures for Establishing and Operating the Eurasian Economic Union Common Register of Authorized Medicinal Products and Pharmaceutical Information Databases	1) Decision of the Eurasian Economic Commission N 141: On Approval of the Procedure for Measures to be Used by the Authorized Bodies of the State Members of the Eurasian Economic Union Aimed to Suspend or Prohibit the Use of the Medical Devices Constituting Danger to Human Life and (or) Health, as well as Poor-quality, Counterfeit or Falsified Medical Devices and to Withdraw them from the Address in the Territories of State Members of the Eurasian Economic Union 2) Decision of the Eurasian Economic Commission Council N 174: On Approval of the Rules for Monitoring Safety, Quality and Efficacy of Medical Devices 3) Decision of the Eurasian Economic Commission Council N 47: On Classifier of Adverse Events in Medical Devices

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Egypt	**Pre-Market:** 1) EDA President's Decision 111 of 2022: Adoption of the Egyptian Good Clinical Practice (GCP) Guidelines 2) Guideline EDREX.GL.Bioinn.006: Guideline for Good Regulatory Oversight of Clinical Trials by Egyptian Drug Authority (Year 2024), Version 3 **Post-Market:** 1) Minister of Health Assistant Decree No. 2 of 2010: beginning of Pharmacovigilance monitoring in Egypt. 2) Guidelines on Good Pharmacovigilance Practice (GVP) in Egypt For Pharmaceutical Products, Version 2.1, 2023 3) Guideline EDREX:GL.CAP.Care.014: Egyptian Guidelines for Detecting and Reporting of Adverse Reactions for Pharmaceutical Products and Medical Devices, Version 4, 2024 4) EDA Chairman' Decision No. 184 of 2023: Application of the Reliance Practices to Reference Health Authorities Regarding Pharmacovigilance Decisions, Reports and Information 5) Guideline EDREX:NP.CAP.Care.012: Procedural Guide to Good Vigilance Practice for Medical and Biological Products - Year 2023, Version 2	1) Guideline: Medical Supplies' Safety Requirements Updated As Part of Registration, Renewal, Variation and Post-Marketing Procedures, Version 1.1 2) The Egyptian Guideline for Medical Device Vigilance System, 2013 3) Guideline EDREX:GL.CAP.Care.014: Egyptian Guidelines for Detecting and Reporting of Adverse Reactions for Pharmaceutical Products and Medical Devices, Version 4, 2024 4) Guideline EDREX:GL.CAP.Care.014: Egyptian Guidelines for Detecting and Reporting of Adverse Reactions for Pharmaceutical Products and Medical Devices, Version 4, 2024
European Union (E.U.)	**Pre-Market:** 1) Regulation (E.U.) No 536/2014 of the European Parliament and of the Council on Clinical Trials on Medicinal Products for Human use, and Repealing Directive 2001/20/EC 2) Commission Implementing Regulation (E.U.) 2022/20 Laying Down Rules for the Application of Regulation (EU) No 536/2014 of the European Parliament and of the Council as regards Setting Up the Rules and Procedures for the Cooperation of the Member States in Safety Assessment of Clinical Trials **Post-Market:** 1) European Parliament and Council Regulation 726/2004/EC of 31-Mar-2004: Laying down Union Procedures for the Authorisation and Supervision of Medicinal Products for Human and Establishing a European Medicines Agency (as Last Amended by European Parliament and Council Regulation (EU) 2019/5 of 11-Dec-2018) 2) European Parliament and Council Directive 2001/83/EC of 06-Nov-2001: The Community Code Relating to Medicinal Products for Human Use (as Last Amended by European Parliament and Council Regulation (E.U.) 2023/1182 of 14-Jun-2023)	1) Regulation (E.U.) 2017/745 of the European Parliament and of the Council on Medical Devices, Amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and Repealing Council Directives 90/385/EEC and 93/42/EEC 2) MEDDEV 2.12-1 rev 8: Guidelines on a Medical Devices Vigilance System
India	**Pre-Market:** 1) The New Drugs and Clinical Trials Rules, 2019, 19-Mar-2019 2) Guideline: Good Clinical Practice Guidelines 3) Guideline: National Ethical Guidelines for Biomedical and Health Research Involving Human Participants **Post-Market:** 1) Act 23: Drugs and Cosmetics Act, 10-Apr-1940 2) The Drug Rules, 1945, 21-Dec-1945 3) Pharmacovigilance Guidance Document for the Marketing Authorization Holders (MAHs) of Pharmaceutical Products 4) Guidance for Industry on Pharmacovigilance requirements for Human Vaccines 5) Guidance Document: National Pharmacovigilance Protocol	1) G.S.R 78(E): Medical Device Rules 2017, 31-Jan-2017 2) Guidance Document: Materiovigilance Programme of India (MvPI)

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International (ICH, WHO)	**Pre-Market:** 1) ICH Guideline Topic E2A Step 4: Clinical Safety Data Management: Definitions and Standards for Expedited Reporting 2) ICH E2B: Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports 3) ICH E6 (R2 – R3): Good Clinical Practice (GCP) 4) ICH E8: General Considerations for Clinical Trials 5) WHO: Good Manufacturing Practices for Investigational Products (Annex 7 to WHO Technical Report Series, No 1044, Dec-2022) **Post-Market:** 1) ICH E2E: Pharmacovigilance Planning 2) ICH E2C(R2): Periodic Benefit-Risk Evaluation Report (PBRER) 3) ICH E2D: Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting 4) WHO Handbook for Good Pharmacovigilance Practices (GVP) 5) WHO Pharmacovigilance Guidelines	1) IMDRF/AEWG/N63 FINAL: 'Principles and Practices for Medical Device Vigilance' (2015) 2) IMDRF/AEWG/N68 FINAL: 'Medical Device Adverse Event Terminology' (2017) 3) IMDRF/AEWG/N47 FINAL: 'Post-Market Surveillance: Manufacturer's Responsibilities' 4) IMDRF/AEWG/N44 FINAL: 'Medical Device Reporting: Summary of Key Regulatory Elements' 5) IMDRF/AEWG/N41 FINAL: 'Manufacturer Reporting to Regulatory Authorities: Core Elements'
Kenya	**Pre-Market:** 1) Guidelines HPT/PDS/CTR/GUD/003: Conduct of Clinical Trials in Kenya, Rev. 4, Sep-2022 2) Guideline HPT/PDS/VMS/GUD/084: Guideline on Benefit-Risk Assessment of Health Products and Technologies, Jan-2023 3) Guideline: Monitoring, Reporting and Managing Adverse Events Following Immunization (AEFI) in Kenya **Post-Market:** 1) The Pharmacy and Poisons Rules, 2022 2) Guideline HPT/PDS/VMS/GUD/006 Revision No. 1: Guidelines for Establishment of the Qualified Persons for Pharmacovigilance 3) Guideline HPT/PDS/VMS/GUD/022 Rev. 2: Guidelines on the Safety and Vigilance of Health Products and Technologies, Jan-2024	1) Guidelines HPT/PER/HTR/GUD/011: Registration of Medical Devices Including In-Vitro Diagnostics, Version 2.0 2) Guideline HPT/PDS/VMS/GUD/022 Rev. 2: Guidelines on the Safety and Vigilance of Health Products and Technologies, Jan-2024 3) Guidelines HPT/PDS/VMS/GUD/030: Recall and Withdrawal of Health Products and Technologies, Revision 2, Jan-2024
Malaysia	**Pre-Market:** 1) Malaysian Guideline for Application of Clinical Trial Import Licence and Clinical Trial Exemption, 8.1 Edition, Mar-2025 2) Guideline: Malaysian Guideline for Good Clinical Practice (GCP), Fourth Edition, 2018 **Post-Market:** 1) Regulation: P.U. (A) 223/1984 - Control of Drugs and Cosmetics Regulations 1984 2) Malaysian Guidelines On Good Pharmacovigilance (GVP) For Product Registration Holders, First Edition, Aug-2021	1) Laws of Malaysia, Act 737, Medical Device Act 2012 2) Good Distribution Practice for Medical Device (GDPMD) 3) Medical Device Guidance Document Mandatory Problem Reporting 4) Guideline: MDA/GD/0015 - Medical Device Recall, 1st Edition, June-2020 5) Guideline: MDA/GD/0013 - Field Corrective Action (FCA), 1st Edition, June-2020 6) Regulation P.U. (A) 318: Medical Device (Duties and Obligations of Establishments Regulations2019, 03-Sep-2019

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Peru	**Pre-Market:** 1) Decree 021-2017-SA: Approves the Regulation on Clinical Trials **Post-Market:** 1) Law 29459: Law on Medical Devices, Pharmaceutical and Sanitary Products 2) Decree 016-2011-SA: Adopts the Regulation on the Registration, Control and Sanitary Surveillance of Pharmaceutical Products, Medical Devices and Sanitary Products 3) Decree 013-2014-SA: Regulates the Peruvian Pharmacovigilance System 4) Resolution 813-2000-DG-DIGEMID: Approves Algorithms to Assess Adverse Drug Reactions' Severity 5) Resolution 539-2016/MINSA: Approves Technical Norm Regulating the Activities of Pharmacovigilance and Technovigilance of Pharmaceutical Products, Medical Devices and Sanitary Products 6) Resolution 1053-2020/MINSA: Approves Technical Document: Manual of Good Pharmacovigilance Practices 7) Resolution 328-2022/MINSA: Approves Timetables for Submission of Applications for Good Pharmacovigilance Practices by Pharmaceutical Companies	1) Decree 016-2011-SA: Adopts the Regulation on the Registration, Control and Sanitary Surveillance of Pharmaceutical Products, Medical Devices and Sanitary Products 2) Resolution 539-2016/MINSA: Approves Technical Norm Regulating the Activities of Pharmacovigilance and Technovigilance of Pharmaceutical Products, Medical Devices and Sanitary Products 3) Law 29459: Law on Medical Devices, Pharmaceutical and Sanitary Products, 17-Nov-2009
Saudi Arabia	**Pre-Market:** 1) Guideline: Regulations and Requirements for Conducting Clinical Trials on Drugs, Version 3.0 2) Guideline for Good Clinical Practice (GCP), Version 3.0 3) Guideline: Investigational New Drugs (IND) Requirements, Version 1.1 **Post-Market:** 1) Executive Rules of the Pharmaceutical Establishments and Products, 2019 2) Guideline: Guideline on Good Pharmacovigilance Practices 3) Guideline on Good Pharmacovigilance Practices (GVP) 4) Circular No. 23253: Qualified Saudi Citizen for QPPV in Saudi Arabia 5) SFDA Announcement: Temporary Suspension of Global ICSRs Reporting	1) MDS-REQ11: Post-Marketing Surveillance Requirements for Medical Devices and Supplies, Version 2.0

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South Africa	**Pre-Market:** 1) Guideline SAHPGL-CEM-CT-10: Safety Reporting During Clinical Trials in South Africa 2) Medicines and Related Substances Act (Act No. 101 of 1965) 3) Guideline SAHPGL-CEM-CT-04: Oversight and Monitoring in Clinical Trials 4) Guideline: South African Good Clinical Practice: Clinical Trial Guidelines, Third Edition 5) Guideline SAHPGL-CEM-CT-01: Electronic Submission of Clinical Trial Documents (Amendments, Bioequivalence Studies, Responses, Notifications, and Serious Adverse Events, Version 3.0 6) Guideline: Emergency Procedures for Clinical Trial Sites, Version 3 **Post-Market:** 1) Medicines and Related Substances Act (Act No. 101 of 1965) 2) Regulation: General Regulations Made in Terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), No. R. 859 3) Regulation: General Regulations Made in Terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) 4) Guideline SAHPGL-INSP-RC-01: Post Marketing Surveillance of Medicines andHealth Products, Version 3 5) Guideline SAHPGL-CEM-PV-01: Pharmacovigilance Inspections for Human Medicinal Products, Version 1.0 6) Guideline SAHPGL-CEM-PV-02: Pharmacovigilance Systems, Version 2.0 7) Guideline SAHPGL-CEM-PV-03: Risk Management Plans for Medicines for Human Use, Version 1.0 8) Guideline SAHPGL-CEM-PV-04: Post-Marketing Reporting of Adverse Drug Reactions to Human Medicines in South Africa, Version 9.1 9) Guideline SAHPGL-CEM-PV-05: Handling Dear Healthcare Professional Letters Relating to Medicine Safety, Version 6 10) Communication: Pharmacovigilance Process Of Issuing Safety Recommendations To Applicants/HCRS For Implementation 11) GuidelineSAHPGL-CEM-PV-06: Adverse Drug Reactions (ADRS) Reporting for Healthcare Professionals, Version 2 12) Communication to Industry: Electronic Submission of Adverse Drug Reaction (ADR) Reports - E2B Reporting	1) MDS-REQ11: Post-Marketing Surveillance Requirements for Medical Devices and Supplies, Version 2.0
South Korea	**Pre-Market:** 1) Specifications for Clinical Trial Control (KGCP) of Pharmaceutical Drugs **Post-Market:** 1) MFDS Notification No. 2021-42: Regulation on Execution of Re-evaluation of Pharmaceutical Drugs 2) Provision on Approval and Review of Biological Preparations 3) MFDS Notification No. 2025-10: Regulations on the Operation of Risk Management Plans	1) Law No. 20220: Medical Devices Act 2) MFDS Notification No. 2022-34: Provision on Management of Safety Information Including Adverse Events of Medical Devices
Switzerland	**Pre-Market:** 1) Ordinance of 20-Sep-2013 on Clinical Trials in Human Research (810.305) (ClinO) **Post-Market:** 1) Federal Law of 15-Dec-2000 on Therapeutic Products and Medical Devices (TPA) (812.21) 2) Ordinance of 21-Sep-2018 on Medicinal Products (812.212.21) (TPO)	1) Ordinance of 01-Jul-2020 on Medical Devices (812.213) (MedDO) 2) Swissmedic Guidance Document: Incident Report User (MU680_20_008_WL) 3) Swissmedic Guidance Document: Vigilance Contact Person for MD (MU680_10_007_WL)

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Turkey	**Pre-Market:** 1) TITCK Guideline KAD-KLVZ-08: Development Safety Update Report in Clinical Trials 2) TITCK Guideline KAD-KLVZ-07: Safety Reporting in Clinical Trial **Post-Market:** 1) TITCK Guideline: Pharmacovigilance System 2) ITCK Guideline: Good Pharmacovigilance Practices (GVP) 3) Crisis Management in Pharmacovigilance Activities	1) TITCK Circular 2024/2 on Medical Device Regulations 2) Guideline: UTS - Tracking and Surveillance Web Service Definitions 3) TITCK: EUDAMED User Guide 4) TITCK Guideline: Withdrawal and Recall of Medical Devices and In-Vitro Diagnostic Medical Devices
United Kingdom	**Pre-Market:** 1) SI 2004 No. 1031: The Medicines for Human Use (Clinical Trials) Regulations 2004 **Post-Market:** 1) SI 2012 No. 1916: The Human Medicines Regulations 2012, 19-Jul-2012 2) MHRA Guidance: Pharmacovigilance Following Agreement of the Windsor Framework	1) Act: Medicines and Medical Devices Act 2021 2) MHRA: Guidance for Manufacturers on Vigilance of Medical Devices
United States	**Pre-Market:** 1) 21 CFR Part 312: Investigational New Drug Application (IND) 2) Guidance for Industry and Investigators: Safety Reporting Requirements for INDs and BA/BE Studies (Final) **Post-Market:** 1) 21 CFR Part 314: Applications 2) Guidance for Industry: Providing Postmarketing Periodic Safety Reports in the ICH E2C(R2) Format (Periodic Benefit-Risk Evaluation Report)(Final)	1) 21 CFR Part 803: Medical Device Reporting 2) Guidance for Industry and Food and Drug Administration Staff: Public Notification of Emerging Postmarket Medical Device Signals ('Emerging Signals')(Final) 3) Federal Register: Medical Devices and Device-Led Combination Products; Voluntary Malfunction Summary Reporting Program for Manufacturers - 21 CFR Part 803 (Notification; order granting alternative)

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