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Evolving Post-Market Surveillance of Medical Devices: A Deep Dive into FDA 21 CFR 822 and EU MDR PMS–PSUR–PMCF Requirements

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ABSTRACT

Post-market surveillance (PMS) of medical devices has transitioned from being a mere formality after approval to a crucial element of regulatory and public health responsibilities. This shift is evident in both the United States and the European Union, where PMS frameworks have progressively become more proactive, data-centric, and integrated throughout the device lifecycle. This evolution is partly a response to notable device failures and the swift pace of technological advancements, especially in software-driven and high-risk implantable devices. In the United States, PMS obligations are rooted in the Federal Food, Drug, and Cosmetic Act, with an intricate network of regulations outlined in 21 CFR Parts 803, 806, 820, 821, and 822. Notably, Section 522 empowers the Food and Drug Administration (FDA) to mandate specific post-market surveillance studies for certain Class II and III devices that meet particular risk criteria. The Quality System Regulation (QSR) embeds routine PMS, supported by both passive and active mechanisms such as Medical Device Reporting (MDR), the Manufacturer and User Facility Device Experience (MAUDE) database, device recalls, tracking, and registries. On the other side, the European Union's Medical Device Regulation (EU-MDR) 2017/745 on medical devices marks a significant shift from previous directives. It explicitly incorporates PMS into the entire device lifecycle, requiring every manufacturer to establish a documented PMS system and a device-specific PMS plan. The system's outputs include PMS reports for Class I devices, Periodic Safety Update Reports (PSURs) for higher-risk categories, and systematic post-market clinical follow-up (PMCF). These outputs, alongside vigilance obligations and the European Database on Medical Devices (EUDAMED) database, create a structured and transparent evidence base. Recent analyses using 2024 data from sources like MAUDE, EUDAMED, and national databases have revealed both strengths and limitations in current systems. While robust PMS can greatly mitigate the recurrence of hardware-related failures, managing software malfunctions and cybersecurity issues remains a significant challenge. This article offers an in-depth, comparative examination of PMS regulatory requirements in the USA and EU, delving into the legal foundations, planning, documentation, data sources, outputs, and institutional roles. It also synthesizes recent scientific and policy literature (post-2022) to critically assess these systems, identify practical implications for manufacturers, and explore future directions such as real-world evidence, digital registries, and international harmonization initiatives led by the International Medical Device Regulators Forum (IMDRF). The discussion posits that a unified, ISO-aligned, and risk-proportionate PMS strategy can fulfill both US and EU expectations while fostering innovation, enhancing patient safety, and facilitating health system learning.

Keywords: *Post-market surveillance; medical devices; FDA; EU MDR; EMA; Section 522; 21 CFR Part 822; PSUR; PMCF; MAUDE; EUDAMED; vigilance; real-world evidence; IMDRF; ISO 13485; ISO 14971.*

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INTRODUCTION

The swift growth and diversification of medical technologies such as implantable devices, combination products, software as a medical device (SaMD), and connected wearables have significantly increased both the potential advantages and the intricacies of risk management throughout the product lifecycle. While traditional pre-market evaluations are crucial, they are inherently limited by factors such as finite sample sizes, controlled trial environments, selective patient demographics, and short follow-up periods. These constraints make it challenging to identify rare adverse events, issues with device-user interactions, or long-term failure modes [1, 2].

PMS plays a crucial role in bridging the gap in device safety by allowing regulators and manufacturers to assess the safety, performance, and quality of medical devices in real-world conditions. This involves monitoring how these devices perform across various clinical settings and patient subgroups. PMS includes

a range of activities such as gathering complaints and adverse event reports, systematically analyzing trends in incidents, conducting specific post-market studies or maintaining registries, and implementing corrective and preventive actions (CAPA). Additionally, it involves transparently communicating emerging risks and ongoing benefit-risk assessments. The ultimate goal of PMS is to ensure that devices continue to function as intended, promptly identify and address any new risks, and incorporate insights from real-world usage into the development of safer and more effective device designs [3-5].

Recent high-profile device failures have highlighted both the capabilities and limitations inherent in current Post-Market Surveillance (PMS) systems. For example, the worldwide recall of specific metal-on-metal hip implants was prompted by unexpected, elevated failure rates and adverse local tissue reactions. Similarly, the issue of premature battery depletion in cardiac implantable cardioverter defibrillators was initially detected through post-market data rather than during pre-market trials. These incidents illustrate that while devices may meet pre-market standards, they can still present unforeseen issues over time, especially when used in varied patient anatomies, with different comorbidities, and across diverse clinical practices [6].

Regulatory bodies have steadily intensified post-market surveillance (PMS) requirements over recent years. The European Union's shift from the Medical Device Directive (MDD) to Regulation (EU) 2017/745 (MDR) has made PMS a fundamental part of its regulatory framework. This transition mandates the creation of documented PMS plans, Periodic Safety Update Reports (PSURs), and Post-Market Clinical Follow-up (PMCF) studies to consistently demonstrate ongoing safety and performance. In the United States, the Food and Drug Administration (FDA) has traditionally leaned on passive adverse event reporting and Quality System Regulation (QSR) for complaint management. However, it has broadened its 522 post-market surveillance program, invested in active surveillance initiatives like the National Evaluation System for Health Technology (NEST), and encouraged the integration of real-world evidence in its regulatory decisions [3, 7, 8].

Considering the current regulatory landscape, having a comprehensive grasp of post-market surveillance (PMS) requirements in the United States and European Union is crucial for manufacturers aiming to develop efficient, globally compliant monitoring systems. This article aims to: (1) delineate the regulatory underpinnings of PMS in both regions, (2) provide an in-depth analysis of the structure and content of PMS plans and their outcomes, (3) offer a comparative assessment of the two systems, drawing from recent empirical studies and policy literature, and (4) examine future trends, including the use of registry-based evidence and efforts towards harmonization led by the International Medical Device Regulators Forum (IMDRF).

Detailed regulatory requirements in USA and EU

United States

Legal framework and scope

In the United States, the post-market surveillance (PMS) of medical devices is primarily based on the Federal Food, Drug, and Cosmetic Act (FD&C Act) and a network of interconnected regulations found within Title 21 of the Code of Federal Regulations (CFR). The key sections of these regulations include [3]:

21 CFR Part 803 – Medical Device Reporting (MDR): Manufacturers, importers, and device user facilities are obligated to report specific incidents related to their devices to the FDA, particularly those involving deaths, serious injuries, or malfunctions. The reporting must occur within designated timeframes. Generally, most events should be reported within 30 days. However, in situations where remedial actions are necessary to avert an unreasonable risk of substantial harm, the timeframe is reduced to 5 days [2, 3].

21 CFR Part 806 – Corrections and Removals: The regulation of reporting corrections or removals of medical devices is essential when these actions aim to mitigate health risks or address a violation that could pose such risks. This regulatory framework establishes a direct connection between post-market surveillance (PMS) and the processes involved in recalls and field actions. These elements work together to ensure that any potential threats to health are promptly identified and addressed, maintaining the safety and efficacy of medical devices on the market [2, 3].

21 CFR Part 820 – Quality System Regulation (QSR): Integrating complaint handling, Corrective and Preventive Action (CAPA), nonconformance management, and feedback into the Quality Management System (QMS) is essential. This integration mandates that manufacturers develop and maintain documented procedures specifically for the review, investigation, and analysis of post-market information. Such a comprehensive approach ensures that any issues identified are systematically addressed and that trends are monitored effectively [2, 8].

21 CFR Part 821 – Device Tracking: Mandating traceability for specific devices, particularly certain implants and life-supporting devices utilized beyond health facility settings, is crucial. This measure ensures the ability to conduct patient-level follow-ups and implement targeted recalls when necessary. By

doing so, healthcare providers can more effectively manage device-related issues, thus safeguarding patient health and improving overall device safety [3, 8].

21 CFR Part 822 – Post market Surveillance: This document implements Section 522 of the Federal Food, Drug, and Cosmetic Act, establishing the regulatory framework for FDA-mandated post-market surveillance studies. These studies are specifically required for certain Class II and Class III medical devices. The framework outlines the criteria and procedures necessary for conducting comprehensive surveillance to ensure the ongoing safety and efficacy of these devices once they are available on the market [7, 8, 21].

The FDA has the authority to invoke Section 522 under several specific conditions. This may occur if the failure of a medical device has the potential to result in serious health repercussions. Additionally, this section may be utilized when a device is anticipated to remain implanted for over a year, or if it serves a life-supporting or life-sustaining function outside of user facilities. Furthermore, Section 522 may be applied should new data emerge that prompts concerns regarding the long-term safety or effectiveness of a device. This provision empowers the agency to gather more precise and high-quality evidence than what could be achieved through passive reporting mechanisms alone [7, 21].

522 post-market surveillance studies (21 CFR Part 822)

The 522 Post-market Surveillance Studies Program outlines the procedures the FDA employs to identify candidate devices, issue orders, and oversee the lifecycle of the ordered studies. After a 522 order is issued, the manufacturer is required to submit a surveillance plan, typically within a 30-day timeframe, for the FDA to review. This plan must address several key elements [8, 7, 22]:

Surveillance objectives: It is crucial to clearly define safety and performance-related questions when evaluating medical devices. These questions might include the rates at which devices fail, the frequency of adverse events such as thrombosis or device migration, and the long-term outcomes for specific groups, like pediatric patients. By establishing these parameters, researchers and clinicians can better assess the efficacy and safety of devices across various populations [8, 7].

Study design: Choice of design (prospective cohort, registry-based observational study, case–control, enhanced passive surveillance) justified in relation to the surveillance question and ethical constraints [2, 7, 8].

Population and sample size: Definition of target population, inclusion/exclusion criteria and statistical rationale for sample size and follow-up duration; for rare events, multi-center or registry-based approaches may be necessary to achieve sufficient power [8, 22, 21].

Data sources and collection: The specification of primary and secondary data sources encompasses a diverse array of origins. These may include hospital registries, electronic health records, and payer databases. Additionally, manufacturer warranty records contribute valuable insights. Active follow-up with clinicians or patients further enriches this data collection process. Each of these sources plays a crucial role in compiling a comprehensive dataset for analysis [1, 8, 21].

Endpoints and analyses: Definition of primary and secondary endpoints (e.g., device failure, re-operation, infection, device-related mortality) and planned statistical analyses, including handling of missing data and planned subgroup analyses [7, 8].

Operational aspects: The comprehensive oversight of a research study involves several critical components. Monitoring plans are essential for ensuring that the study adheres to its intended objectives and protocols. Investigators bear significant responsibilities, which include maintaining the integrity of the research and ensuring compliance with ethical standards. Furthermore, robust data quality assurance procedures must be implemented to guarantee the accuracy and reliability of the collected data. In studies involving human subjects, it is imperative to prioritize their protection, adhering to all relevant ethical guidelines and regulations to safeguard their rights and well-being [9, 10].

Reporting schedule: Timelines and formats for interim progress reports and the final study report, which typically include enrolment status, follow-up completeness, interim safety findings and final conclusions [8, 22]

The FDA generally completes its review of a plan within 60 days, categorizing it as either "approved," "conditionally approved" (pending certain amendments), or "disapproved." Once approved, plans receive tracking identifiers, allowing the FDA to monitor them through periodic reports. These reports, along with progress and final outcomes, are frequently summarized on the FDA's public website. If a required 522 study is not conducted, or if there are substantial delays or deviations, this could be deemed a prohibited act, potentially leading to warning letters or other enforcement measures [8, 22].

Routine PMS activities: MDR, MAUDE, CAPA and recalls

In parallel with formal 522 studies, US manufacturers must operate robust routine PMS systems under the QSR:

Medical Device Reporting (MDR): Manufacturers and importers are required to file Medical Device Reports (MDRs) for any reportable incidents through the electronic MDR (eMDR) system. Meanwhile,

facilities that use medical devices, such as hospitals, are obligated to report any device-related fatalities and serious injuries not only to the manufacturers but also directly to the FDA. These submissions collectively feed into the Manufacturer and User Facility Device Experience (MAUDE) database. This database is publicly accessible and serves as a vital tool for signal detection. It is utilized extensively by the FDA, manufacturers, and researchers alike to monitor and analyze device performance and safety [2, 3, 21].

Complaint handling and trending: Manufacturers are required thoroughly document, and investigate any complaints received. An essential part of this process is determining whether these complaints are reportable under the Medical Device Reporting (MDR) guidelines. Furthermore, identifying trends from these complaints can highlight potential systemic issues. The insights gained from analyzing these trends are crucial, as they inform the Corrective and Preventive Action (CAPA) processes. In some cases, these insights may also necessitate changes in the product design to address the identified issues effectively [3, 8, 17].

Recalls and field corrections (21 CFR 806): When a device poses a health risk or violates the relevant Act, manufacturers are required to assess if corrective or removal actions are warranted. They must determine the appropriate recall classification, which can range from Class I to Class III, and inform the FDA accordingly. Such recall actions are made public and are frequently accompanied by safety communications to inform stakeholders and the general public [3, 16].

Registries and RWE initiatives: In the realm of high-risk medical devices, particularly implants and those used in cardiovascular applications, manufacturers frequently collaborate with clinical societies and the FDA to establish and maintain registries. These registries play a crucial role in both clinical quality improvement and regulatory post-market surveillance (PMS). One prominent example of such an initiative is the National Evaluation System for Health Technology (NEST). This system has been at the forefront of recent discussions by the FDA and the International Medical Device Regulators Forum (IMDRF). NEST exemplifies an active surveillance infrastructure that is effectively built upon real-world data sources, highlighting its importance in the ongoing monitoring and evaluation of medical device safety and efficacy [1, 21, 16].

Recent analyses indicate that although Medical Device Reporting (MDR) and recall processes are effective in identifying and addressing hardware-related failures, they fall short in systematically capturing software anomalies, cybersecurity vulnerabilities, and subtle usability issues. This shortcoming has led to increasing advocacy for the expanded use of registries and more structured Real-World Evidence (RWE) study designs. These methods are considered more adept at providing comprehensive monitoring and evaluation of such complex and nuanced problems [11, 21].

European Union

Legal framework and institutional roles

Regulation (EU) 2017/745, which superseded both the Medical Device Directive (MDD) and the Active Implantable Medical Devices Directive (AIMDD), codifies the Post-Market Surveillance (PMS) framework within the European Union. This regulation, particularly in Chapter VII (Articles 83–92), outlines the protocols for PMS, vigilance, and market surveillance processes. To ensure comprehensive compliance, Annex III and Annex XIV furnish detailed guidelines on the planning and reporting involved in PMS, as well as on Post-Market Clinical Follow-up (PMCF) activities [13, 19, 24].

The post-market surveillance (PMS) framework is managed through a tripartite system involving manufacturers and their authorized representatives, notified bodies, and national competent authorities. Manufacturers, alongside their representatives, play a crucial role in ensuring ongoing compliance with safety and performance standards. Notified bodies are tasked with assessing and periodically reviewing conformity assessments, technical documentation, and Periodic Safety Update Reports (PSURs). Meanwhile, national competent authorities oversee vigilance and market surveillance activities. The European Medicines Agency (EMA) steps in primarily with combination products and cases where there is an interaction between medicinal and device components. Nonetheless, the EMA's expertise in pharmacovigilance significantly shapes broader PMS strategies and methodologies [13, 24, 19, 28].

PMS system and PMS plan (Articles 83–84, Annex III)

Article 83 mandates that every manufacturer develop, organize, record, execute, sustain, and revise a Post-Market Surveillance (PMS) system tailored to the specific risk class and type of each device. This PMS system is not simply an auxiliary process but must be woven into the fabric of the manufacturer's Quality Management System (QMS) as specified in Article 10(9). It must possess the capacity to actively and systematically collect, document, and scrutinize pertinent data [14, 24].

Article 84 and Annex III require a **PMS plan** as part of the technical documentation for each device or category of devices. Key elements of the PMS plan described in regulatory text and guidance include [13, 24, 12]:

Objectives and strategy: The overarching objectives include verifying safety and performance, uncovering any unknown side effects, monitoring the benefit-risk profile, and identifying as well as reporting emerging trends [12, 13].

PMS activities and methods: Engaging in proactive activities such as Post-Market Clinical Follow-up (PMCF) studies, surveys, comprehensive literature reviews, and participating in registries, forms a crucial part of maintaining a product's efficacy and safety profile. Simultaneously, addressing reactive activities, which include handling complaints and vigilance reports, is equally important. Both proactive and reactive measures necessitate robust methodologies for data collection and thorough evaluation. These methodologies ensure that data is gathered systematically and analyzed effectively, providing accurate insights into product performance and safety. Combining both approaches allows for a holistic understanding of the product, guiding improvements and ensuring compliance with regulatory standards [12, 24, 14].

Data sources: The comprehensive assessment of both internal and external data sources is essential for ensuring the quality and safety of medical devices. Internally, this involves scrutinizing complaints, identifying nonconformities, and reviewing servicing records and product returns. Externally, it requires a thorough examination of scientific literature, databases, registries, and publicly available information on similar devices. Additionally, feedback from users, distributors, and importers provides invaluable insights, contributing to a holistic understanding of the product's performance and potential areas for improvement. This multi-faceted approach helps maintain the highest standards in device management and user safety [12, 13, 24].

Analysis and signal detection: The integration of statistical methods with clinical review processes forms a cornerstone of modern healthcare practice. By employing trend analysis techniques, professionals can discern patterns that might otherwise go unnoticed, offering critical insights into patient outcomes. Additionally, these methods are intricately linked to risk management strategies and clinical evaluation processes. This interconnected approach ensures that potential risks are identified and mitigated effectively, while also enhancing the overall quality of clinical assessments. Such a comprehensive framework not only improves patient care but also solidifies the reliability and efficacy of healthcare interventions [14, 24].

Triggers and CAPA: Criteria for initiating investigation, CAPA, Field Safety and Corrective Actions (FSCA) and communication with notified bodies or competent authorities [13, 24].

PMS outputs: Mechanisms for generating PMS reports, PSURs and updates to technical documentation, including Clinical Evaluation Reports (CERs) and Summary of Safety and Clinical Performance (SSCPs) [5, 13, 24].

Consulting firms offer templates for Post-Market Surveillance (PMS) plans that are consistent with the requirements outlined in Annex III. These templates highlight the importance of ensuring traceability of data streams, clearly defining responsibilities, and establishing timelines. Additionally, they underscore the connections to Post-Market Clinical Follow-up (PMCF) activities [5, 13, 24]..

PMS outputs: PMS report, PSUR and PMCF

The EU MDR introduces a tiered approach to PMS outputs:

PMS report (Article 85): Manufacturers of Class I devices are required to compile a Post-Market Surveillance (PMS) report. This document should encapsulate the findings and conclusions drawn from analyzing PMS data collected in accordance with the established PMS plan. Additionally, the report should offer a rationale and detail any preventive and corrective actions that have been implemented. It is crucial that this report is revised as needed to reflect current information and should be readily accessible to competent authorities if they request it [13, 24].

Periodic Safety Update Report (PSUR, Article 86): For medical devices classified as Class IIa, IIb, and III, it is imperative to prepare a Periodic Safety Update Report (PSUR) for each individual device or for a group of similar devices. This document must be regularly updated—at a minimum, every two years for Class IIa devices. In contrast, for Class IIb and Class III devices, annual updates are required. The PSUR should specifically encompass the following elements [5, 24]:

- conclusions of the benefit–risk determination;
- main findings of the PMCF;
- sales volume of the device and an estimate of the population using the device;
- The justification and description of preventive and corrective actions are essential components of Post-Market Surveillance Reports (PSURs) for Class III and implantable medical devices. These reports must be submitted to the relevant notified body. Additionally, in specific circumstances, they are also required to be uploaded to the EUDAMED database [13, 24].

Post-Market Clinical Follow-Up (PMCF, Annex XIV): Post-Market Clinical Follow-up (PMCF) entails an ongoing process dedicated to gathering and assessing clinical data from devices actively in use. This process aims to ensure continued safety and performance throughout a device's anticipated lifespan and to identify any previously unknown side effects, emerging risks, or contraindications. Within PMCF plans, it is essential to delineate the clinical questions that need addressing, alongside the methodologies employed—such as registries, post-market studies, and analyses of routine clinical data—and the criteria for evaluation. The findings from PMCF evaluation reports are integral to and directly inform updates to Post-Market Surveillance (PMS), Periodic Safety Update Reports (PSUR), and Clinical Evaluation Reports (CER) [5, 13, 24].

Since 2023, publications from consultancy firms and notified bodies have highlighted that the expectations surrounding Periodic Safety Update Reports (PSUR) and Post-Market Clinical Follow-up (PMCF) are some of the most challenging components of compliance with the Medical Device Regulation (MDR). This is especially true for legacy devices that were originally CE marked under the Medical Device Directive (MDD) with only a limited amount of clinical data [5, 7].

Vigilance, trend reporting and EUDAMED (Articles 87–92)

Vigilance requirements address serious incidents and field safety corrective actions (FSCAs):

Serious incident reporting: Manufacturers are required to report serious incidents to the competent authority in the Member State where the incident took place. For incidents that pose a serious public health threat, the report must be submitted within two days. In cases where the incident results in death or an unexpected serious deterioration in health, the timeline extends to ten days. For other serious incidents, manufacturers have fifteen days to report [13, 19].

FSCA and field safety notices: Field Safety Corrective Actions (FSCAs) need to be reported and must be accompanied by field safety notices directed to users. These actions can encompass a variety of measures, such as recalling devices, issuing software updates, making changes to product labeling, or implementing enhanced surveillance protocols [13, 24].

Trend reporting: Manufacturers are required to submit periodic trend reports to competent authorities whenever they observe a statistically significant increase in the frequency or severity of non-serious incidents or expected side effects that could significantly impact the benefit-risk profile. This obligation ensures that any potential changes in the risk associated with a product are promptly communicated to regulatory bodies, facilitating timely interventions if necessary [5, 24].

EUDAMED: Articles 33 and 92 characterize EUDAMED as a comprehensive database, designed to serve multiple purposes through its various modules. These modules encompass actor registration, UDI/device registration, notified bodies and certificates, as well as clinical investigations and post-market clinical follow-up (PMCF), vigilance, and market surveillance. The integration of vigilance and post-market surveillance (PMS) data into EUDAMED facilitates cross-border analysis and enhances the coordination of oversight across the European Union. However, it is important to note that not all of the information stored within EUDAMED will be accessible to the public [13, 2].

Recent empirical analyses of the 2024 EUDAMED data reveal that high-risk orthopedic and cardiovascular devices represent a significant share of reported incidents and Field Safety Corrective Actions (FSCAs) across the European Union. Among the most frequently encountered issues are hardware failures, software malfunctions, and calibration problems. These findings also underscore the variability in reporting and coding practices between EUDAMED and various national databases, indicating a need for enhanced harmonization and improvements in data quality. Such efforts could lead to more consistent and reliable reporting across the board. [21].

COMPARATIVE ANALYSIS

Conceptual and structural similarities

At a conceptual level, both the US and EU PMS systems share several features:

Lifecycle perspective: Post-market surveillance (PMS) is conceptualized as an ongoing process that spans the entire lifecycle of a medical device, rather than being limited to a distinct phase following its launch. Both regulatory jurisdictions stress the importance of persistently re-evaluating the benefit-risk profile of the device as new evidence and data become available[8, 21, 24].

Integration with QMS and risk management: The FDA's Quality System Regulation (QSR) and the European Union's Medical Device Regulation (MDR) Article 10(9) mandate that Post-Market Surveillance (PMS) be an integral component of the Quality Management System (QMS). The information gathered from PMS activities must inform Corrective and Preventive Actions (CAPA), as well as drive necessary design modifications, updates to clinical evaluations, and revisions in risk management documentation. These processes are typically aligned with the standards set by ISO 13485 and ISO 14971 [8, 14].

Combination of passive and active mechanisms: In both the United States and the European Union, the monitoring of medical devices post-market involves several critical mechanisms. These include the reporting of adverse events and complaints, known as Medical Device Reporting (MDR) in the US and vigilance in the EU. Additionally, there are more structured approaches, such as post-market studies, registries, and device tracking systems, particularly for high-risk devices. By employing this multifaceted strategy, both jurisdictions aim to ensure that any potential issues with medical devices are identified and addressed promptly [3, 13, 21].

Focus on high-risk devices: Both regulatory systems acknowledge that devices classified as high risk, such as Class III implants and those heavily reliant on software, necessitate more rigorous post-market surveillance. The FDA addresses this need through the implementation of 522 orders and post-approval studies. Meanwhile, the European Union's Medical Device Regulation (EU MDR) requires Post-Market Clinical Follow-up (PMCF) and mandates more frequent submission of Periodic Safety Update Reports (PSURs) for these categories [12, 21, 24, 22].

Growing role of real-world evidence: Recent guidance and policy statements highlight the significant potential of utilizing registries, electronic health records, and claims data to generate evidence about device performance that is both more timely and broadly applicable. By leveraging these data sources, it becomes possible to obtain insights that are not only current but also relevant across diverse populations and settings. This approach promises to enhance the overall understanding of device effectiveness, making it a vital component in the ongoing effort to improve healthcare outcomes [1, 21].

KEY DIFFERENCES

While these parallels exist, there are still significant differences, especially when it comes to formal documentation and transparency [4,26, 28]

Universality of PMS plans:

- In the European Union, it is a requirement for every medical device to have a Post-Market Surveillance (PMS) plan in place. The content and structure of these plans are specifically outlined by the Medical Device Regulation (MDR) and guidance from the Medical Device Coordination Group (MDCG) [5, 13, 24].
- In the United States, the submission and regulatory approval of a Post-Market Surveillance (PMS) plan is mandated only under specific circumstances. These include instances when the FDA issues a 522 order or when the plan is part of a post-approval study. Outside of these situations, the development and implementation of a PMS plan remain an internal matter within the Quality Management System (QMS), allowing for greater flexibility [5, 13, 24].

Structured safety update reports:

- The European Union Medical Device Regulation (EU MDR) stipulates that Post-Market Surveillance (PMS) reports for Class I medical devices, as well as Periodic Safety Update Reports (PSURs) for Class IIa to Class III devices, must be submitted at predetermined intervals. These reports must include specific content, such as the outcomes of Post-Market Clinical Follow-up (PMCF) studies, conclusions on benefit–risk assessments, and data on sales and usage. Additionally, these documents are subject to review by a notified body to ensure compliance with regulatory standards [5, 24].
- In the United States, there is no mandate for periodic safety update reports for the majority of medical devices. Instead, the country depends on a system of ongoing medical device reporting (MDR), recalls, and device-specific study reports, such as those arising from Section 522 post-market surveillance studies or post-approval studies required under the premarket approval (PMA) process. These alternative mechanisms, while serving their purpose, often lack a standardized format, which can introduce variability in how data is reported and analyzed [3, 7].

Clinical follow-up as a formal PMS instrument:

- The EU Medical Device Regulation (MDR) formally establishes Post-Market Clinical Follow-up (PMCF) as a standard component of Post-Market Surveillance (PMS) for numerous devices. It integrates PMCF activities directly with the updates to Periodic Safety Update Reports (PSURs) and Clinical Evaluation Reports (CERs). This linkage ensures a comprehensive and continuous assessment of device performance and safety throughout its lifecycle [12, 13, 24].
- In the United States, the process of ongoing clinical follow-up is typically tailored to specific medical devices and is largely influenced by conditions set forth in Premarket Approval (PMA) or 522 post-market surveillance orders. Unlike in some other regulatory environments, there is no universal mandate for this follow-up, and the term "Post-Market Clinical Follow- up" (PMCF) does not hold formal recognition within U.S. regulatory frameworks [3, 8, 27].

Regulatory governance:

- Oversight of post-market surveillance (PMS) within the European Union is a shared responsibility between notified bodies and national competent authorities. This system is further coordinated by the European Commission and its committees. However, this structure can lead to variations in both the expectations placed on manufacturers and the intensity of enforcement. As a result, companies operating across different EU member states may encounter differing regulatory demands and scrutiny levels [24, 27].
- The oversight of post-market surveillance (PMS) in the United States is primarily managed by the Center for Devices and Radiological Health (CDRH) within the Food and Drug Administration (FDA). This centralization can lead to more consistent interpretations of regulations and guidelines. However, it also means that decision-making authority is concentrated within a single entity, which might limit diverse perspectives in the process [3, 27].

Transparency of PMS outputs:

- Clinicians and researchers frequently rely on the publicly accessible MAUDE and FDA recall databases. These resources provide essential information for their work, supporting a wide range of medical and scientific inquiries [4, 21].
- EUDAMED is currently being rolled out, featuring some modules that are accessible to the public. However, certain elements, such as the detailed content of Periodic Safety Update Reports (PSURs) and specific vigilance data, might still be restricted to regulators and notified bodies [15, 24].

Practical implications for manufacturers

When viewed from a manufacturer's perspective, these differences lead to a variety of practical considerations [8, 20, 25]:

Designing a "global" PMS system: The more prescriptive requirements of the EU Medical Device Regulation (MDR) can serve as a foundational baseline. For instance, one can develop a single Post-Market Surveillance (PMS) plan for each device family. This plan should distinctly outline both PMS and Post-Market Clinical Follow-up (PMCF) activities. Furthermore, this structured approach can be harmonized with the Quality System Regulation (QSR) processes in the United States. It is also adaptable to accommodate the demands of 522 studies when such studies are mandated[8, 24].

Documentation and evidence burden: The EU MDR mandates the preparation of formal Periodic Safety Update Reports (PSURs) and Post-Market Clinical Follow-up (PMCF) reports at specified intervals. This requirement significantly increases the documentation workload for manufacturers. However, it also leads to the development of a structured and comprehensive knowledge base. On the other hand, the regulatory requirements in the United States might initially appear less burdensome in routine circumstances. Nonetheless, they can become quite demanding when situations such as 522 studies, product recalls, or enforcement actions arise [5, 13].

Resource allocation: Smaller manufacturers frequently experience significant strain on their resources when trying to meet the expectations for Periodic Safety Update Reports (PSUR) and Post-Market Clinical Follow-up (PMCF). This strain is particularly acute when notified bodies demand extensive detail and require frequent updates. In contrast, the post-market surveillance (PMS) efforts in the United States tend to be more variable over time. However, it is worth noting that these efforts become heavily intensified initially when safety issues are identified. This front-loading of resources can create a different set of challenges for manufacturers operating within the US regulatory framework [5, 12, 25].

Aspect	United States (FDA)	European Union (EU MDR)
Legal basis	FD&C Act; 21 CFR 803, 806, 820, 821, 822	Regulation (EU) 2017/745, Chapter VII, Annex III, Annex XIV
Applicability	Focused on Class II–III and certain high-risk/implantable devices; PMS embedded in QSR	Applies to all device classes (I–III); PMS system mandatory for each device
PMS plan	Formal plan only when ordered (Section 522, 21 CFR 822) or as part of internal QMS	Device-specific PMS plan mandated for all devices (Article 84)
Routine clinical evidence	No general requirement for ongoing post-market clinical studies; 522 studies are targeted	PMCF expected for many devices, especially higher-risk or where residual clinical uncertainties remain
PMS outputs	MDRs, corrections/removals, device tracking, 522 study reports, recall classifications	PMS report (Class I), PSUR (IIa–III), PMCF evaluation, vigilance reports, trend reports
Databases	MAUDE (adverse events), FDA recall database, device registries	EUDAMED modules (device registration, vigilance, clinical investigations, market surveillance)

Oversight bodies	FDA (CDRH) centrally	Notified bodies plus national competent authorities; EU-level coordination via Commission
Emphasis	Strong on adverse-event reporting and targeted surveillance for high-risk devices	Strong on systematic, proactive PMS and lifecycle clinical evidence for all devices

Regulatory risk vs operational burden: Implementing a robust Post-Market Surveillance (PMS) system that aligns closely with European Union standards can significantly mitigate the risk of unexpected regulatory issues in any jurisdiction. By establishing clear data flows, governance structures, and comprehensive documentation, such a system enhances the ability to detect early warning signals. Furthermore, it ensures transparent management practices, which are crucial for maintaining regulatory compliance and preemptively addressing potential crises [8, 20, 25].

Insights from recent empirical and policy literature

Recent analyses and policy papers, both peer-reviewed, offer valuable context for comparing the performance of PMS. These documents not only present the latest findings but also delve into policy implications, enriching our understanding of how PMS operates in various contexts. By examining these sources, researchers and policymakers can gain a nuanced perspective on performance metrics, ensuring a more informed approach to decision-making [20, 17, 18, 21]:

A study conducted in 2025, which analyzed data from 2024 sourced from EUDAMED, MAUDE, and national databases, revealed that high-risk implants, particularly those used in orthopedic and cardiovascular applications, were responsible for a significant proportion of serious incidents and Field Safety Corrective Actions (FSCAs). The primary causes identified were hardware failures and software malfunctions. The study's findings indicated that FSCAs were generally successful in decreasing the recurrence of hardware-related failures. However, the same level of effectiveness was not observed for issues related to software, which typically necessitated iterative corrections and extended periods of monitoring to address effectively [21].

In a 2025 commentary examining European cardiovascular and orthopedic registries, significant discrepancies were noted in areas such as governance, data quality, endpoint definitions, and auditing processes. These variations hinder the effectiveness of registries as tools for regulatory post-market surveillance (PMS) despite of their considerable potential. The authors advocated for the development of standardized reporting frameworks. Furthermore, they emphasized the importance of fostering closer collaboration among regulators, registry owners, and manufacturers to enhance the utility of these registries [23].

The updated guidance from the International Medical Device Regulators Forum (IMDRF) and the National Competent Authority Report (NCAR) exchange criteria for 2023–2025 places a significant emphasis on the prompt dissemination of post-market safety information among regulatory bodies. This is especially crucial in the context of serious public health threats. The updated guidelines advocate for a more harmonized approach to safety communications and the coordination of Field Safety Corrective Actions (FSCAs). By fostering these improvements, the intention is to enhance the overall efficiency and effectiveness of regulatory responses to emerging safety concerns in the medical device sector [10, 12].

The findings underscore that neither system can be deemed superior. Instead, both systems exhibit distinct strengths and weaknesses. The EU Medical Device Regulation (MDR) offers a more formalized structure for post-market surveillance (PMS) documentation and ongoing clinical evidence throughout the product lifecycle. In contrast, the U.S. framework provides a flexible, centralized model capable of harnessing advanced data science initiatives. However, it continues to face challenges related to the limitations of passive reporting.

Case Studies:

Real-world recalls serve as a compelling testament to the efficacy of post-market surveillance (PMS) in safeguarding patient well-being. For instance, the recall by St. Jude Medical of specific implantable cardioverter-defibrillators and cardiac resynchronization therapy devices. This action was prompted by post-market data that identified premature battery depletion as an issue. As a result, global corrective measures were implemented, and monitoring protocols were revised. The prompt detection through PMS likely averted serious adverse events, highlighting the critical role of swift corrective and preventive action (CAPA) once a potential risk is identified [7].

A notable instance in the realm of medical devices is the DePuy ASR metal-on-metal hip systems. Post-market surveillance data for these systems indicated failure rates and adverse tissue reactions that exceeded expectations, primarily due to metal debris. This discovery prompted the recall of the devices and necessitated significant revisions in the surveillance expectations for orthopedic implants. These events have played a crucial role in shaping the current stringent requirements for long-term monitoring of

implants. Furthermore, they underscore the increasing significance of device registries, particularly concerning high-risk, long-duration implants in both the United States and the European Union [7].

CONCLUSION

Post-market surveillance (PMS) has evolved significantly, shifting from a predominantly reactive and complaint-driven approach to a fundamental aspect of medical device regulation in both the United States and the European Union. In the U.S., the framework emphasizes adverse event reporting, the management of recalls, and the implementation of Quality System Regulation (QSR) based complaint and Corrective and Preventive Action (CAPA) systems. Additionally, the FDA has the authority to mandate targeted 522 post-market surveillance studies to address specific safety concerns that may arise.

In contrast, the European Union's Medical Device Regulation (MDR) requires more comprehensive and device-specific PMS systems and plans. This includes the routine preparation of Periodic Safety Update Reports (PSURs) and Post-Market Clinical Follow-up (PMCF). Furthermore, the EU MDR prescribes a more integrated approach, linking PMS closely with clinical evaluation, vigilance activities, and the EUDAMED database.

For manufacturers operating within both frameworks, the most effective approach is to develop post-market surveillance (PMS) as a strategic, data-driven, and cross-functional process. This approach should go beyond viewing it as a mere obligation focused on documentation. By establishing a framework aligned with ISO 13485 and ISO 14971 that can produce MDR-compliant reports, periodic safety update reports (PSURs), post-market clinical follow-up (PMCF) evidence, and 522 study data when necessary, companies can simultaneously ensure regulatory compliance, enhance patient safety, and foster innovation.

Recent empirical studies highlight that a robust PMS significantly reduces the recurrence of certain high-risk failures. However, challenges persist, particularly with software-driven and AI-enabled devices, where fault modes and performance drift can be complex and dynamic.

The alignment of post-market surveillance (PMS) expectations concerning real-world evidence, registries, and improved international data sharing presents a significant opportunity. PMS can transcend its role as a mere regulatory requirement and evolve into a dynamic force for continuous learning and enhancement within healthcare systems. This potential transformation hinges on the effective harnessing of these converging expectations, which could ultimately drive substantial improvements and innovations across the sector.

FUTURE SCOPE AND OUTCOME

The trajectory of post-market surveillance (PMS) in the United States and the European Union is anticipated to be influenced by three main factors: digitalization, international harmonization, and the evolving nature of device technologies.

To begin with, the integration of digital tools and real-world data is expected to grow significantly. Both regulatory bodies and manufacturers aim to transition from traditional, narrative-focused reporting to a more automated, structured approach. This new method emphasizes near real-time signal detection, utilizing electronic health records, claims data, device registries, and even data generated by patients through wearables and home-use devices. Advanced analytics, particularly machine learning, play a crucial role by identifying subtle patterns. These patterns might include unexpected combinations of alerts, device parameters, or clinical events, which can indicate potential safety issues before they become evident through clusters of adverse event reports. Nevertheless, these innovative strategies demand thorough validation, clear methodologies, and strong governance frameworks to prevent false signals and ensure the maintenance of public trust.

Second, efforts towards international harmonization and improved information sharing are anticipated to intensify. The IMDRF's strategic plan underscores post-market surveillance as a key focus area, while its NCAR exchange program offers the necessary criteria and infrastructure for regulators to communicate about serious safety concerns related to medical devices. Recent guidelines outline the appropriate timing for exchanging post-market reports, the recommended structure for benefit-risk assessments, and strategies for coordinating risk reduction activities across different jurisdictions, especially pertinent when devices are distributed globally. Ultimately, this could lead to more uniform reporting formats, standardized terminology, and possibly the development of shared registries or analytical platforms. Such advancements would minimize redundancy and enable more prompt, globally coordinated responses.

Third, the evolving landscape of device innovation—particularly regarding software as a medical device, AI-driven algorithms, and interconnected systems—will necessitate adaptations in post-market surveillance (PMS) frameworks. Challenges like algorithm drift, performance discrepancies due to data bias, cybersecurity vulnerabilities, and the need for cloud-based updates do not easily fit into conventional failure categories, and may require ongoing performance monitoring rather than intermittent incident

reporting. There is an increasing acknowledgment that PMS for certain digital devices will likely integrate elements of pharmacovigilance, software observability, and cybersecurity monitoring. This will demand close collaboration between clinical, IT, and regulatory teams to ensure comprehensive oversight.

When regulators, manufacturers, and clinical stakeholders effectively combine their efforts by developing high-quality registries, standardizing data, implementing validated analytics, and ensuring robust governance, post-market surveillance (PMS) systems could achieve several significant outcomes. These include the earlier detection and resolution of safety concerns, a reduction in large-scale product recalls, the generation of reliable real-world evidence to inform reimbursement decisions and clinical guidelines, and enhanced public trust in the safety of medical devices. For manufacturers, investing in these PMS frameworks should be perceived not just as a compliance expense but as a strategic advantage. Such systems enhance global market access, drive innovation, and safeguard the company's reputation.

ABBREVIATIONS

Abbreviation	Full Term
CAPA	Corrective and Preventive Action
CDRH	Center for Devices and Radiological Health (FDA)
CFR	Code of Federal Regulations
EMA	European Medicines Agency
EUDAMED	European Database on Medical Devices
EU MDR	European Union Medical Device Regulation
FSCA	Field Safety Corrective Action
IMDRF	International Medical Device Regulators Forum
MAUDE	Manufacturer and User Facility Device Experience
MDR	Medical Device Reporting
NEST	National Evaluation System for health Technology
PMCF	Post-Market Clinical Follow-Up
PMS	Post-Market Surveillance
PSUR	Periodic Safety Update Report
QMS	Quality Management System
QSR	Quality System Regulation
SSCP	Summary of Safety and Clinical Performance
UDI	Unique Device Identification

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