Congenius

Congenius Whitepaper

A Regulatory Guide to Post-Market Surveillance

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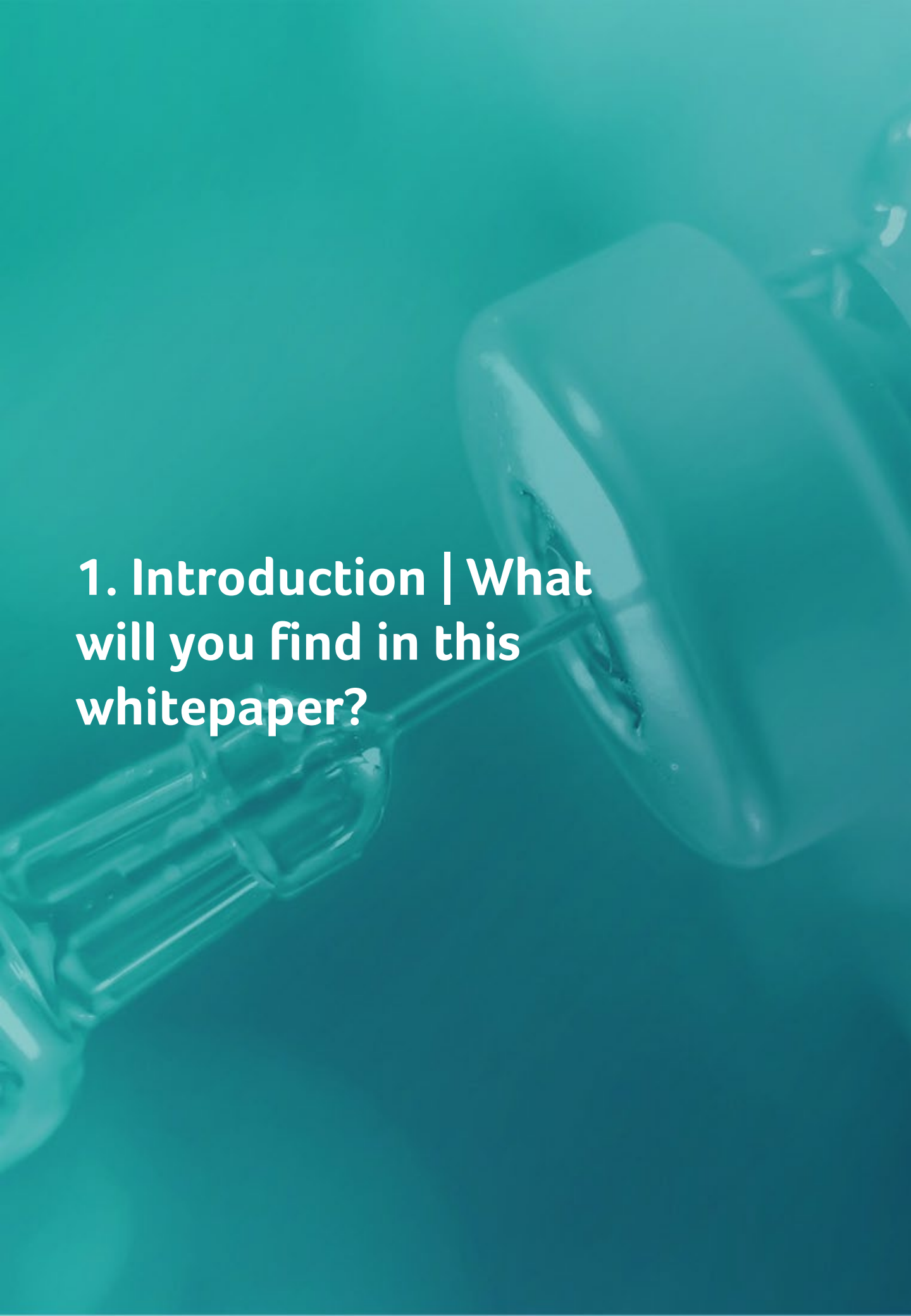

1. Introduction | What will you find in this whitepaper?

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This whitepaper provides an overview of the objectives and procedures of Post-Market Surveillance (PMS) for medical devices, conducted in collaboration between manufacturers and their economic operators.

For MedTech companies engaging with the topic for the first time or those with limited experience in managing post-market data, the costs and complexity of comprehensive PMS activities pose a significant challenge. This highlights the necessity for specialised knowledge in the development and execution of effective surveillance strategies.

The purpose of this whitepaper is to highlight the essential steps to ensure continuous compliance with safety, quality, and performance requirements after medical devices have been launched on the market.

The following pages seek to answer:

- What is Post-Market Surveillance?
- What are the related Regulatory requirements in the EU & US?
- What are the fundamentals of Post-Market Surveillance?
- What are the challenges involved in implementing & maintaining an effective PMS system?
- How can companies overcome the challenges arising from PMS requirements?

2. What is Post-Market Surveillance?

What is Post-Market Surveillance?

Let's begin with a little background...

Post-Market Surveillance (PMS) emerged from the now-dissolved Global Harmonization Task Force (GHTF). Their initial concept was further refined through reports aiming to standardise PMS across regulatory bodies. The International Medical Device Regulators Forum (IMDRF) then built upon these efforts.

Today, regulations like the **EU MDR 2017/746** and the **US Code of Federal Regulations (21 CFR)** mandate PMS. Manufacturers are required to proactively gather and analyse data on their marketed devices throughout their lifecycle to ensure ongoing safety and effectiveness.

How is Post-Market Surveillance defined?

In the EU, MDR & IVDR define PMS as:

"all activities carried out by the manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from their devices placed on the market, made available or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions."

Source: MDR Article 2 (60) & IVDR Article 2 (63)

In the US, 21 CFR defines PMS as:

"The active, systematic, scientifically valid collection, analysis, and interpretation of data or other information about a marketed device."

Source: FDA 21 CFR Part 822 (i)

What is Post-Market Surveillance?

What does Post-Market Surveillance involve?

Post-Market Surveillance (PMS) according to MDR 2017/745 and IVDR 2017/746 is a **systematic process to continuously monitor the safety and effectiveness of a medical device after it has been launched on the market.** This is done by collecting information and deriving necessary corrective and preventive actions.

Manufacturers of medical devices are required to minimise any risks associated with their products and ensure user safety before launching them on the market. This obligation is verified through regulatory inspections and evaluations by conformity assessment bodies before approval. **However, some risks become apparent only during regular operation.**

The purpose of Post-Market Surveillance is to systematically identify potential safety issues and address them promptly during the actual use of the devices, evaluate the real-world performance of the devices, identify hidden defects and previously unknown safety risks, constantly reassess the benefit-risk evaluation, and, if necessary, promptly initiate actions such as product recalls.

Among other elements, the regulations impose the following key requirements for Post-Market Surveillance:

- Define, plan, and implement a process for Post-Market Surveillance
- Continuously and systematically collect and assess data
- Decide on actions based on this data, such as:
    - Initiating CAPA measures that may affect both the product and the manufacturer and its procedures
    - Informing authorities and/or users
    - Initiating product recalls
    - Updating the clinical evaluation file and/or risk management file (especially because of PMCF/PMPF activities)
    - Reporting the results (PMS report or Periodic Safety Update Report)

What is Post-Market Surveillance?

Why is Post-Market Surveillance important?

Post-Market Surveillance (PMS) is essential for distinguishing between effective, safe medical devices and those that are defective, ensuring that only products with verified performance are accessible.

Although stricter clinical trial requirements have replaced the 'equivalence rule,' the real challenge lies in the absence of comprehensive long-term data to substantiate the claims made for devices.

PMS tackles this challenge by continuously collecting data to confirm device safety and efficacy, thereby providing a competitive advantage to those devices that are indeed safe and effective, and supporting better decision-making and enhanced quality of treatments for the public and industry alike.

The significance of the MDR's post-market provisions is profound, guaranteeing that medical devices maintain exemplary standards of safety, efficacy, and quality during their lifespan on the market.

The MDR's requirements for detailed PMS, along with post-market clinical follow-up (PMCF), vigilance, and periodic safety update reports, are designed to safeguard public health and patient safety against the backdrop of a dynamic medical field.

These measures also help in the early detection of potential adverse events or device failures, thereby facilitating prompt action to mitigate any risks to patients.

3. What are the related Regulatory requirements in the EU & US?

What are the related Regulatory requirements in the EU & US?

The EU | MDR versus IVDR

Annex III in both the EU MDR and EU IVDR defines the requirements for the PMS plan, including the analysis of sources, evaluation methods, and the implementation of measures.

Specific requirements for the Post-Market Clinical Follow-Up (PMCF) plan and associated activities are laid out in Annex XIV, Part B in the MDR. For IVDs, the requirements for the Post-Market Performance Follow-up (PMPF) plan and the associated activities are laid out in Annex XIII, Part B of the IVDR.

While the overarching framework for PMS under both the **MDR and IVDR share many similarities**, the specific applications, focus areas, and methodologies reflect the unique characteristics and requirements of medical devices and in vitro diagnostics.

Both sets of regulations aim to ensure that devices continue to perform as intended and remain safe for use throughout their lifecycle, but they tailor their approaches to the distinct nature of the devices they regulate.

This whitepaper applies to both regulations unless specifically indicated.

What are the related Regulatory requirements in the EU & US?

The EU | MDR versus IVDR – PMS similarities & differences

The **non-exhaustive** tables below outline some of the key similarities and differences between MDR and IVDR relating to PMS:

	EU MDR | Section 1	EU IVDR | Section 1
PMS Applicability	Medical devices for human use manufactured or sold into the EU • MDR Art 83 (PMS) • MDR Art 15 (PRRC)	In-vitro diagnostic medical devices for human use manufactured or sold into the EU • IVDR Art 78 (PMS) • IVDR Art 15 (PRRC)
Pre-Market Data	Clinical Evaluation Plan based on evaluation of clinical evidence or clinical investigations • MDR Art 84 (Plan) • MDR Annex III (TD on PMS)	Performance Evaluation Plan and performance studies • IVDR Art 79 (Plan) • IVDR Annex III (TD on PMS)
Post-Market Data	Post-Market Clinical Follow-up (PMCF) is required on a regular basis • MDR Art 85 (PMS report) • MDR Art 86 (PSUR incl. PMCF findings) • MDR Annex XIV (Clinical Evaluation and PMCF)	Post-Market Performance Follow-up (PMPF) is required on a regular basis • IVDR Art 80 (PMS report) • IVDR Art 81 (PSUR incl. PMPF findings) • IVDR Annex XIII (PE, PS and PMPF)
Notified Body Involvement	Applicable to all Class IIa, IIb and III medical devices plus Class I sterile, Class I with measuring function and Class I reusable surgical instruments	Applicable to all Class B, C and D IVD medical devices

	EU MDR | Section 2	EU IVDR | Section 2
Vigilance	Reporting & Trend Reporting • MDR Art 87 (serious incidents and FSCA) • MDR Art 88 (Trend Reporting) • MDR Art 89 (serious incidents and FSCA)	Reporting & Trend Reporting • IVDR Art 82 (serious incidents and FSCA) • IVDR Art 83 (Trend Reporting) • IVDR Art 84 (serious incidents and FSCA)

What are the related Regulatory requirements in the EU & US?

The EU | PMS Legal Requirements & Guidelines

Below and on the next page you'll find an overview of the most important EU regulations, guidance documents, and standards that should be considered in the context of Post-Market Surveillance activities.

EU | Legal Requirements

Enacted by the European Union in May 2017, the **Medical Device Regulation (MDR) 2017/745** and the **In Vitro Diagnostics Medical Devices Regulation (IVDR) 2017/746** represent a major overhaul in the regulatory framework for medical devices within the EU.

These regulations supersede earlier directives and introduce a novel approach to the governance of medical devices, **focusing on their full lifecycle, especially after they are released into the market**.

This change is aimed at guaranteeing the ongoing safety, efficacy, and quality of medical devices from the moment they are launched to their ultimate use. The regulations are crafted to uphold stringent public health and safety standards by ensuring that medical devices maintain their expected performance during operation.

A key highlight of MDR 2017/745 is its stringent post-market requirements, which reflect a global movement towards more comprehensive healthcare oversight. By focusing on Post-Market Surveillance (PMS), Post-Market Clinical Follow-up (PMCF), vigilance, and Periodic Safety Update Reporting (PSUR), the regulation promotes a proactive approach to identifying and mitigating risks associated with medical devices after they have been commercialised.

The regulation's emphasis on the post-market phase represents a paradigm shift from a predominantly pre-market approval process to a lifecycle approach. This approach is predicated on the understanding that the safety and effectiveness of medical devices can only be fully assessed through their performance in real-world settings. Consequently, the MDR mandates rigorous continuous evaluation and monitoring, ensuring that any potential adverse events or device malfunctions are quickly identified and addressed to prevent harm to patients.

What are the related Regulatory requirements in the EU & US?

The EU | PMS Legal Requirements & Guidelines (continued)

EU | Guidance Documents

The Medical Device Coordination Group (MDCG) has issued several guidance documents relevant to Post-Market Surveillance (PMS) for medical devices under the MDR and IVDR. These documents aim to clarify the requirements and provide recommendations on implementing effective PMS systems. Some of the key MDCG documents related to PMS include:

MDCG 2019-9

Guidance on the summary of safety & clinical performance for medical devices

Specifically relevant for Class III and implantable devices under the MDR.

MDCG 2020-1

Guidance on Clinical Evaluation (MDR) / Performance Evaluation (IVDR) of medical device software

While focusing on software, it also touches upon PMS and PMCF aspects.

MDCG 2020-7

Post-Market Clinical Follow-Up (PMCF) plan template

Guide for manufacturers to develop a comprehensive PMCF plan as part of their PMS system.

MDCG 2020-8

Post-Market Clinical Follow-up (PMCF) Evaluation Report Template

Guide for manufacturers on complying with the MDR requirements relating to the compilation of the PMCF evaluation report.

MDCG 2022-21

Guidance on Periodic Safety Update Report (PSUR)

Provides manufacturers with guidance on how to compile, maintain, & submit PSURs for their medical devices.

MDCG 2022-2

Guidance on General Principles of Clinical Evidence for IVDs

MDCG 2022-9

Summary of safety and performance template

These documents are instrumental for manufacturers to understand and comply with the PMS requirements under the new regulations. It's important to regularly check the European Commission's website for the most recent updates and publications.

What are the related Regulatory requirements in the EU & US?

The US | PMS Legal Requirements & Guidelines

US Legal Requirements

Implementing **robust post-market quality processes** is crucial, but they do not encompass the entirety of Post-Market Surveillance (PMS) requirements in the US (nor the EU).

In the US, PMS primarily involves quality processes outlined in your Quality Management System (QMS), such as handling nonconformances, managing complaints, conducting Corrective and Preventive Actions (CAPA), and internal auditing.

However, the FDA may mandate additional PMS activities under 21 CFR Part 822 for Class II and Class III devices, particularly those with potential serious health consequences if they fail, those intended to be implanted for more than a year, or devices used outside of professional healthcare facilities to support or sustain life. These mandated activities, which must follow a formalised plan, are additional to regular QMS activities.

US Guidance Documents

In 2022, the FDA released a guidance document specifically addressing 21 CFR part 522, designed to offer further support to manufacturers.

What are the related Regulatory requirements in the EU & US?

International Standards & Other sources

It is important to understand that the Post-Market Surveillance (PMS) process is closely linked to other quality management processes, especially risk management.

ISO 13485 | Quality Management Systems - Requirements for regulatory purposes requires manufacturers of medical devices to implement a systematic post-market surveillance system as part of their quality management, ensuring ongoing safety and performance of their products after market-launch. This includes collecting and analysing relevant data, conducting evaluations to identify areas for improvement, and implementing corrective and preventive actions. Additionally, all PMS activities must be documented, and results must be retained for continuous risk assessment and regulatory purposes.

ISO 14971 | Application of risk management to medical devices emphasises the need for continuous risk assessment and management for medical devices, supported by PMS. Key requirements include constant monitoring of product safety and performance, updating the risk management file with real-world data, analysing customer feedback, implementing risk control measures, and communicating with stakeholders. The standard highlights that effectively integrating PMS into risk management is essential for maintaining product safety and compliance.

ISO TR 20416 | Medical devices - post-market surveillance for manufacturers provides guidance on the application of post-market surveillance for medical devices, focusing on manufacturers' processes for collecting and analysing information on devices once they are on the market. The document covers the importance of integrating PMS with other quality management processes, particularly risk management, and emphasises the need for manufacturers to continuously monitor, evaluate, and update their PMS processes in response to real-world data.

Other sources

Team NB (The European Association of Medical Devices Notified Bodies) creates position papers to standardise approaches and best practices. These documents offer manufacturers crucial guidance on submission expectations, especially concerning post-market data, as detailed in the Best Practice Guidance for Technical Documentation under Annex II of the Medical Device Regulation (EU) 2017/745 and In-vitro Diagnostic Medical Devices Regulation (EU) 2017/746.

4. What are the fundamentals of Post-Market Surveillance?

What are the fundamentals of Post-Market Surveillance?

The relationship between the Clinical Evaluation Report & PMS

While the Clinical Evaluation Report (CER) isn't typically a focal point of PMS discussions, we've chosen to emphasise its connection to the process in this chapter because **the Clinical Evaluation Report (CER) and the Post-Market Surveillance (PMS) process are closely linked, informing each other throughout the lifecycle of a medical device.**

The CER informs PMS

Initial Risk Assessment

The CER provides a foundation for the PMS process by summarising the initial risk assessment conducted during pre-market development. This assessment identifies potential risks associated with the device and their likelihood of occurrence.

Clinical Data Baseline

The CER establishes a baseline of clinical data on the device's safety and performance based on pre-market clinical investigations. This data serves as a benchmark for comparison with data collected during PMS activities.

PMS informs the CER

Real-World Data

PMS activities like collecting and analysing data on adverse events, complaints, and device performance in real-world use provide valuable insights that can be used to update the CER. This "real-world" data can reveal previously unidentified risks or confirm the effectiveness of the device in actual clinical practice.

Continuous Improvement

Information from PMS can be used to refine the risk-benefit analysis within the CER. This ongoing evaluation allows manufacturers to identify areas for improvement in the device design or user instructions, ultimately enhancing its overall safety and effectiveness.

Think of the CER as the script for a play. It presents the initial dialogue and scenes based on thoughtful planning and expected interactions. PMS activities, like watching the play performed across different stages and audiences, reveal how the script holds up under live conditions (e.g., audience reactions, actor interpretations). This real-world feedback can be used to identify any unexpected plot issues and enhance future scripts (CERs) for similar productions.

Overall, the CER and PMS form a continuous feedback loop. The CER provides a starting point for the PMS process, and the data collected during PMS activities are used to update and refine the CER. This ongoing cycle ensures that the CER remains current and accurately reflects the device's safety and performance throughout its lifecycle.

What are the fundamentals of Post-Market Surveillance?

The components of PMS according to MDR

The MDR outlines several key components that constitute a robust PMS system for medical devices:

Post Market Surveillance Plan

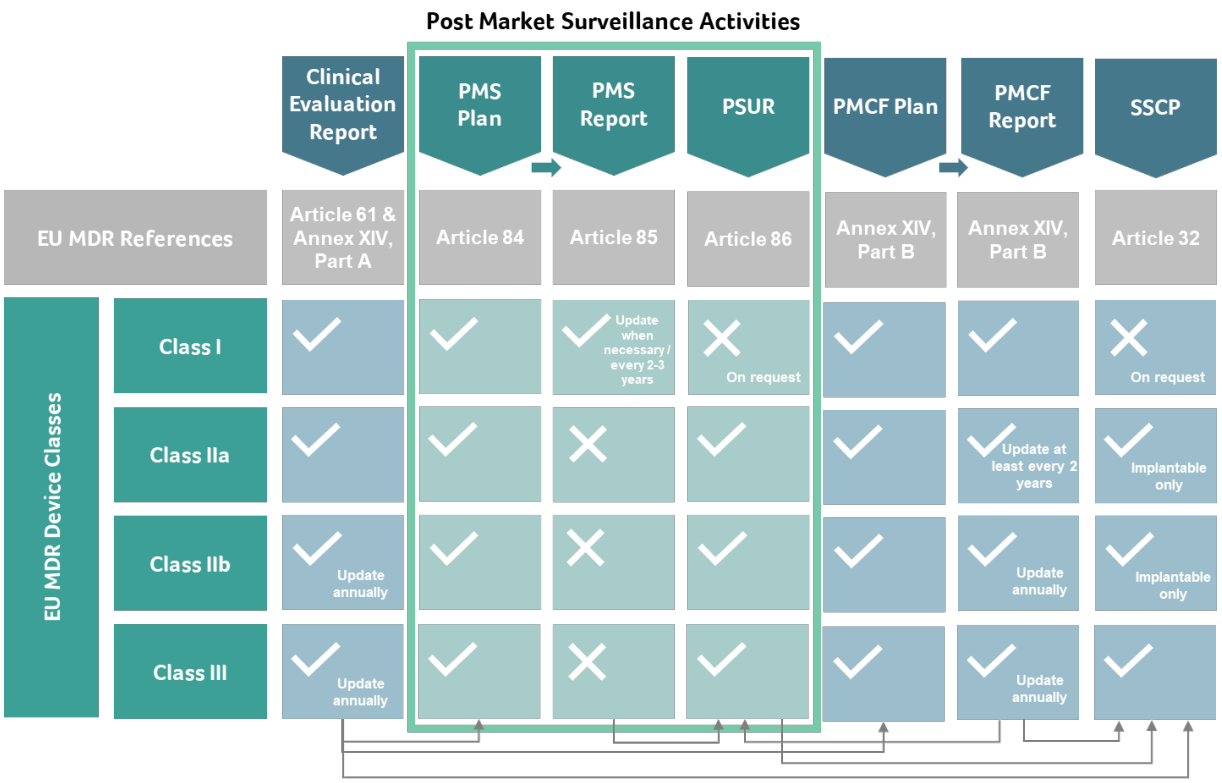
Manufacturers are required to develop a comprehensive plan that outlines the strategies and methodologies for gathering and evaluating data on their medical devices post-market.

Post Market Surveillance Report (PMSR)

The PMSR is required exclusively for Class I medical devices, distinguishing it from the Periodic Safety Update Report (PSUR) needed for higher-risk device classes.

Periodic Safety Update Report (PSUR)

For Class IIa, IIb, and III medical devices, manufacturers are required to create a PSUR that includes a summary of post-market surveillance data analysis, any preventive or corrective actions taken, findings from Post Market Clinical Follow-up (PMCF) activities, a reassessment of the benefit-risk determination, and data on sales volumes, estimated user population, and frequency of use.



What are the fundamentals of Post-Market Surveillance?

The components of PMS according to MDR (continued)

Although the Post Market Clinical Follow-up (PMCF) plan and report are not explicitly mentioned as part of Post-Market Surveillance (PMS) in Article 86 of the MDR, there is a requirement to present the key results of your post-market clinical follow-up in a regularly updated safety report (PSUR).

For this reason, PMCF activities are outlined in this chapter to comprehensively present the key elements of PMS and related activities. More detail on the PMCF plan and PMCF report can be found at the links below:

- **Post Market Clinical Follow-up Plan**
- **Post Market Clinical Follow-up Report**

Related activities

Feedback System

This is a mechanism for collecting and reviewing feedback from users, healthcare professionals, and patients. It includes reports of adverse events, product quality complaints, and any other relevant safety information.

Data Analysis and Reporting

Manufacturers must analyse the collected data to identify any trends or safety concerns. Significant findings must be reported to the relevant regulatory authorities.

Corrective Actions

If potential risks are identified, manufacturers must take appropriate corrective actions to mitigate these risks. This may involve product modifications, recalls, or issuing safety notices to users.

What are the fundamentals of Post-Market Surveillance?

Trend reporting

The EU MDR positions trend reporting within the "Vigilance" section of Article 88. However, this doesn't diminish its significance as a cornerstone of Post-Market Surveillance (PMS) (refer to Article 83). PMS relies on continuous monitoring of a device's performance and safety in real-world use.

Trend reporting plays a vital role within this framework through:

Proactive Risk Detection

Analysing data from adverse events, complaints, and other safety reports allows for identifying statistically significant increases in incident frequency or severity. This proactive approach helps unearth potential new risks associated with the device that may have been missed during pre-market testing.

Early Intervention

Early detection of trends in safety data empowers both manufacturers and regulatory bodies to take timely action to mitigate potential risks before they escalate and cause patient harm. This could involve issuing safety warnings, implementing design changes, or even recalling the device.

Continuous Improvement

Insights from trend reporting inform the ongoing improvement of medical devices. This could involve refining the device's design, user instructions, or risk management plan to address identified safety concerns.

By fostering proactive risk detection, early intervention, and continuous improvement, trend reporting strengthens the overall PMS framework. This ensures the ongoing safety and effectiveness of medical devices throughout their lifecycle.

What are the fundamentals of Post-Market Surveillance?

Trend analysis

Article 83 requires manufacturers to systematically collect and analyse data to identify trends that could indicate a possible deterioration in product performance or increased risks to patients. This trend analysis plays a crucial role, as it enables proactive measures before an incident occurs or becomes known.

Article 88 establishes a framework for reporting safety-related incidents to the competent authorities. These vigilance requirements ensure that manufacturers and authorities can respond to incidents that may affect the safety or health of patients.

The essential connection is that trend analysis under Article 83 serves to recognise patterns or changes in the data that could represent potential safety risks. These insights can then, if necessary, be reported within the vigilance system under Article 88 to take corrective actions.

Thus, PMS and the vigilance system work hand in hand to ensure continuous assessment of the safety and effectiveness of medical devices.

Trend analysis supports the early detection of risks, while the vigilance system enables a rapid response to identified risks and incidents. Both processes, therefore, contribute to comprehensive patient protection.

5. What are the challenges involved in the PMS process?

What are the challenges involved in the PMS process?

The volume of data

Many manufacturers can understandably feel overwhelmed by requirements relating to data analysis. The number of information sources is continuously growing, and auditors expect manufacturers to collect and analyse ALL available data. Relying solely on data from a single source or a few sources such as FDA MAUDE or BfArM is no longer considered sufficient.

In addition to well-known regulatory databases like FDA MAUDE, future Swissmedic or EUDAMED databases, manufacturers must also incorporate databases of IT vulnerabilities, such as those from NIST, into their search. Social media channels such as X, LinkedIn, Facebook, as well as websites of SOUP manufacturers and other suppliers, must also be considered as potential sources.

Data access

Manufacturers face a nearly inflationary increase in the amount of information and publications from a variety of sources, and although most of the information is publicly available, direct access is often not possible.

Excessive variability of data sources

Each identified data source uses different formats and interfaces, complicating the evaluation of collected data and making the task difficult and resource intensive.

Experts within the company responsible for PMS activities must constantly adapt and revise their search strategies because using search terms alone is often not effective - for example when product codes must be entered. It can be assumed that a multitude of information will be overlooked.

Increased regulatory expectations

Put simply, regulatory expectations are higher than ever. For example, known and published IT vulnerabilities must now be fixed within two weeks (see FDA-recognised standard UL 2900-2-1). For many companies, the continuous capture of PMS data will soon reach a critical level, posing significant challenges in terms of resources, time, and finances.

What are the challenges involved in the PMS process?

Stringent requirements for trend analysis & risk management

The trend analysis requirements as mentioned earlier can also present challenges for manufacturers, who must proactively engage with these topics early to identify any issues, ensuring patient safety and avoiding reputation damage or penalties.

Accompanying trend analysis, the EU's MDR and IVDR regulations strictly require manufacturers to report any statistical increases that could lead to unacceptable risks. This includes non-serious incidents that could negatively affect the risk-benefit assessment (e.g., frequently occurring mild side effects). Consequently, the regulations compel manufacturers to verify whether the assumptions in their risk management are still valid. If not, they might even have to report non-serious incidents.

The planning of post-market surveillance includes defining suitable indicators and thresholds to continuously re-evaluate the risk-benefit analysis and risk management. In short, manufacturers must constantly review their risk assumptions, set thresholds, and take action if these are exceeded. If the benefit-risk ratio is no longer acceptable, the identified trend must be reported to the authorities. This reporting obligation applies regardless of other mandatory reports and requires a multi-level decision-making process to assess the identified trends.

The volume of available post-market data is increasing exponentially, making it progressively more challenging to find, analyse, and evaluate all relevant information in a timely manner with reasonable effort. This is compounded by requirements related to trend analysis, which are closely linked to PMS activities.

6. How can companies overcome the challenges arising from PMS requirements?

How can companies overcome the challenges arising from PMS requirements?

Explore optimal strategies for Post-Market Surveillance

PMS activities for each manufacturer possess unique characteristics. Nonetheless, there are recurring challenges and, unfortunately, errors that occur across various companies. Whether you are implementing a PMS program or refining an existing one, applying best practices and learning from the mistakes of others can save time and money, ultimately ensuring patient safety.

Initiate Post-Market Surveillance activities early

A proactive approach involves focusing on patient safety and conducting fault tree analyses to identify potential risks. It is crucial to collect and analyse relevant data early to make informed decisions. Initiating the planning of post-market monitoring activities from the start of the development process can provide significant advantages regarding your subsequent PMS efforts. This also includes considering recommendations for clinical evaluations to gather the necessary data for monitoring and follow-up.

These data should not only be considered once the devices are on the market. Instead, early and continuous evaluation is beneficial, and also required by ISO 13485 - for example, as part of process validation and monitoring.

Instigate effective collaboration between related teams

Instigate timely collaboration between Post-Market Surveillance, Quality Management, Medical Affairs / Clinical Affairs, and Risk Management teams to plan and execute the following steps:

- **Collect data beyond customer feedback |** Determine what data should be collected (e.g. date, device ID), and gather at appropriate frequencies
- **Set evaluation goals |** Review risk assumptions, identify unrecognised hazards, ensure risk criteria are up to date, analyse causes, and monitor off-label use
- **Choose the right statistical methods |** Choose the appropriate method (e.g. regression analysis) based on your question
- **Execute effective trend reporting |** Identify significant increases in potential harms and report them if they could lead to unacceptable risks
- **Consider special cases |** Consider options for devices with limited data and apply qualitative methods (e.g. observations, surveys) as per ISO 20416

How can companies overcome the challenges arising from PMS requirements?

Understand & master processes

Analysis of data from FDA inspections has shown that many manufacturers have deficiencies in the areas of the CAPA process, and the procedures for managing complaints and non-conformities are insufficient. Addressing these fundamental PMS processes from the outset and mastering them is crucial for sustainable success.

Establish effective communication channels

Establishing effective communication channels for handling complaints and feedback from your customers, your economic operators, or your employees is crucial. This will help you avoid a cascade of potential problems from the start and streamline the procedures for submitting, processing, and resolving complaints to maintain control and oversight and ensure compliance.

Ensure visibility & awareness

Targeted and comprehensive training of all employees, especially those in close contact with customers, promotes and sharpens collective responsibility throughout the company and fosters an awareness of a culture of responsiveness.

Embrace automation

Automate as many activities as possible and relieve your team from repetitive tasks such as data collection, processing, and evaluation, or the calculation of statistics and the creation of reports. Automated quality processes for example, help eliminate the error-proneness of manual repetitions, whilst removing inefficiencies.

How can companies overcome the challenges arising from PMS requirements?

Utilise customised tools

Based on the experiences and feedback from our customers, as well as industry reports, a significant number of individuals manage the challenges of PMS tasks using general-purpose tools. This approach may work for smaller companies with a manageable product portfolio, experienced professionals, and well-trained staff. However, reality shows that PMS is a significant challenge even for smaller companies. Medium and large companies quickly reach the limits of feasibility and require customised solutions tailored to the specific needs of the MedTech industry.

There are specialised companies that have developed tools and platforms for the MedTech industry to enable optimised workflows that support compliance with legal regulations. In turn, there are providers that offer targeted solutions for PMS activities, ensuring comprehensive and timely resolution of PMS challenges.

By using customised tools, you can increase transparency within your company, simplify reporting, and ensure efficiency in various PMS functions, including non-conformity, complaints, CAPA, and audit management.

Beyond the core PMS tasks, utilising customised solutions aids in the coordination of investigations, the efficient addressing of tasks, and the tracking of progress according to guidelines. Many of the available tools are comprehensive solutions that can effectively support with all tasks and challenges faced by a manufacturer of medical devices.

As is often the case, the right combination of tools and know-how tends to facilitate the most sustainable solutions. Our Regulatory experts here at Congenius have the insight, knowledge, and experience to help you formulate your post-market surveillance strategy, select the appropriate tools, and implement the necessary action. You can find out more about our Regulatory services here.

Congenius

Should you have a Post-Market Surveillance challenge, please do get in touch – our Regulatory team is ready and happy to help.

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