MDCG 2025-10

Guidance on post-market surveillance of medical devices and in vitro diagnostic medical devices

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1 Introduction

Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in-vitro diagnostic medical devices (IVDR) establish a regulatory framework to ensure a high level of protection of the health and safety of patients, users and other individuals, whilst supporting innovation. Devices may only be placed on the Union market if they comply with these Regulations.

To ensure that devices remain compliant with the requirements of the Regulations and that real-world experience gained from the use of the devices is taken into account for the product realisation, manufacturers must have a Quality Management System[1] (QMS) comprising a Post-Market Surveillance (PMS) system[2] in place. These systems should be proportionate to the risk posed by the device and appropriate for the type of the device.

According to, respectively, Recitals 74 MDR and 75 IVDR, Article 10(10) of the MDR/IVDR, manufacturers are required to implement and keep up to date a PMS system in accordance with Article 83 MDR/Article 78 IVDR. This obligation reinforces the importance of a structured and proactive PMS approach as an integral part of the manufacturer's QMS[3].

Manufacturers need to play an active role during the post-market phase by:

- Systematically and actively gathering information from post-market experience with their devices.
- Using this information to update their technical documentation.
- Cooperating with national competent authorities responsible for vigilance and market surveillance.

To support this, manufacturers must:

- Establish a comprehensive PMS system, set up under their QMS.
- Base the PMS system on a PMS plan.

Data and insights from PMS activities must be used to:

- Update relevant parts of the technical documentation (e.g., risk assessment, clinical evaluation).
- identify the need for preventive and/or corrective action.
- Enhance transparency (e.g. through the SS(C)P)

PMS is a continuous process. Manufacturers must carry out PMS throughout the lifetime[4] of a device to monitor its safety, quality and performance.

After having established the initial PMS plan, which is part of the technical documentation[5], the first PMS process cycle begins when the first device has been placed on the market/put into service and concludes with a report. However, surveillance activities and data collection must be systematically performed and recorded on a continuous, ongoing basis, throughout the

[1] Article 10(9) MDR/IVDR
[2] Article 10(10) MDR/IVDR
[3] Article 83(1) MDR/Article 78(1) IVDR
[4] For further clarification on the meaning of device lifetime, refer to section Device lifetime of the MDCG 2022-21 Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745 (MDR). https://health.ec.europa.eu/latest-updates/mdcg-2022-21-guidance-periodic-safety-update-report-psur-according-regulation-eu-2017745-december-2022-12-16_en
[5] Article 84 MDR/Article 79 IVDR

entire period between the first placing on the market/putting into service and the end of the intended lifetime of the last device placed on the market/put into service.

2 Scope and Objectives

Unless otherwise stated, this guidance is applicable to all medical devices (MDs) and in vitro diagnostic medical devices (IVDs). The main objectives of this guidance are:

1. To describe the PMS system.
2. To describe the PMS plan.
3. To describe the main activities within the PMS system.
4. To clarify the interactions of the PMS system in accordance with Article 83 MDR/Article 78 IVDR with other key aspects of the QMS as described in Article 10(9) MDR and Article 10(8) IVDR).

Out of scope:

- This guidance does not provide details on how a manufacturer should prepare a periodic safety update report ('PSUR') or a post-market surveillance report. Specific guidance on PSUR is provided in MDCG 2022-21. Although not covering post-market surveillance reports, MDCG 2022-21 may provide useful suggestions on how a manufacturer can present information in a post-market surveillance report.

- This guidance does not cover the requirements for health institution exemption under Article 5(5) MDR/IVDR (in-house devices), though it is expected that health institutions review experience gained from the use of in-house devices and take all necessary corrective actions[6].

Where this guidance references terms defined or aspects clarified in other documents, the relevant sources are cited.

Unless otherwise stated, the definitions provided in Article 2 MDR and IVDR apply for this guidance document. Furthermore, the term 'device' is used as outlined in Article 1(4) MDR and Article 1(2) IVDR.

3 The PMS System required by the MDR/IVDR

Article 10(9)(i) MDR and Article 10(8)(i) IVDR refer to a PMS system in accordance with Article 83 MDR/Article 78 IVDR. Manufacturers are required to 'plan, establish, document, implement, maintain and update' a PMS system which is to be implemented effectively and in a manner 'that is proportionate to the risk class and appropriate for the type of device[7].

3.1 General obligations

The PMS system must be suited to actively and systematically gathering, recording and analysing relevant data on the quality, performance and safety of a device throughout its entire

[6] For further information on requirements for in-house devices, refer to MDCG 2023-1 Guidance on the health institution exemption under Article 5(5) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746. https://health.ec.europa.eu/system/files/2023-01/mdcg_2023-1_en.pdf

[7] Article 83(1) MDR/Article 78(1) IVDR

lifetime. It must also enable the manufacturer to draw the necessary conclusions and support the determination, implementation and monitoring of any preventive or corrective actions.[8]

In addition to this requirement, it is in the manufacturer's interest to use the PMS data to identify options to improve the usability, performance, and safety of the device.

The PMS system interfaces directly with other aspects of the QMS, such as clinical/performance evaluation and risk management (see section 6 for further clarification on the interactions of the PMS system with other key aspects of the QMS).

Figure 1 below provides a general, high-level overview of the PMS system as integral part of the manufacturer's QMS.

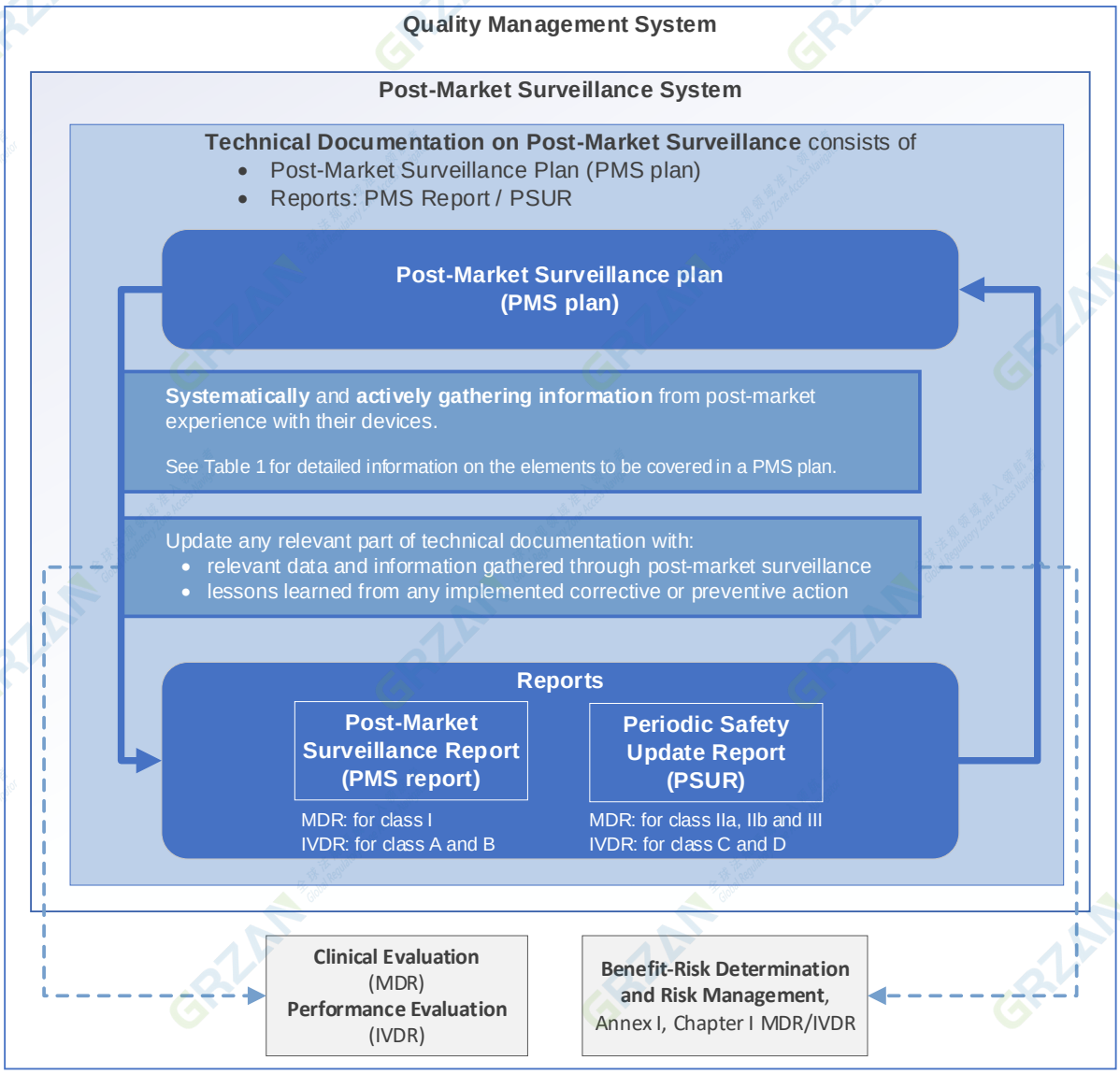


Figure 1: High-level Overview of the PMS system and the Technical Documentation on Post-Market Surveillance. The figure shows hat the PMS system is an integral part of the Quality Management System and the information gathered from post-market experience of the device is not only driving updates to the Technical Documentation on PMS but is also an input to other processes of the Quality Management System, such as clinical/performance evaluation and risk management.
Note: The figure provides is a high-level overview and is not meant to be exhaustive. It does not include all details or account for every possible scenario.

[8] Article 83(2) MDR/Article 78(2) IVDR

For a successful implementation of the PMS system the manufacturer must provide for appropriate structures, procedures, processes and resources. The effectiveness of the PMS system should be reported to top management, e.g., via management review.

An overview of PMS obligations laid down in the MDR and IVDR is provided in Annex 1 of this guidance.

3.2 Specific obligations for manufacturers of custom-made devices under the MDR

The PMS requirements according to Article 83 MDR are applicable to all devices including Custom-Made Devices (CMD). Section 5 of Annex XIII MDR states that "The manufacturer shall review, and document experience gained in the post-production phase, including from PMCF as referred to in Part B of Annex XIV MDR, and implement appropriate means to apply any necessary corrective action. In that context, it is required to report in accordance with Article 87(1) MDR to the competent authorities any serious incidents or field safety corrective actions or both as soon as it learns of them."

Post-market review is mainly focused on the expected performance. A PMCF plan is therefore required. This implies that for a CMD, the manufacturer needs to establish and maintain a PMS system, and to document the experience gained from the post-production phase. Therefore, even though that Article 84 does not clearly state that the PMS plan should be part of the documentation held in accordance with Annex XIII MDR, it doesn't remove the obligation for a PMS plan. It is recommended that the manufacturer plan and document its experience gained in the post-production phase, including from PMCF as referred to in Part B of Annex XIV MDR, and implement appropriate means to apply any necessary corrective action as stated in section 5 of Annex XIII MDR.

For class I devices, the CMD manufacturer must establish a PMS report according to Article 85 MDR whereas, for classes IIa, IIb and III devices, a Periodic Safety Update Report (PSUR) according to Article 86 MDR must be established. Both the PMS report and the PSUR should be part of the CMD documentation according to section 2 of Annex XIII MDR.

To implement a MDR compliant post-market surveillance system, the CMD manufacturer should establish appropriate communication channels with relevant healthcare providers/professionals or patients to receive feedback on the quality, performance and in particular the clinical performance and safety of the devices in the field.

For risk management, post-market surveillance and clinical evaluation life cycle processes as defined by the MDR, CMD manufacturers should apply these obligations to groups of devices with the same intended purpose, materials and processes used, principal design etc. and not to each individual CMD[9]. In the PMS plan, the relevant CMD placed on the market should be part of the scope.

4 The PMS plan

Article 84 MDR/Article 79 IVDR refer to the PMS system being based on a PMS plan, which is part of the technical documentation (except for custom-made devices under the MDR). The requirements for the PMS plan are outlined in section 1 of Annex III of both the MDR and IVDR.

[9] This is clarified in MDCG 2021-3 Questions and Answers on Custom-Made Devices https://health.ec.europa.eu/document/download/385d7e20-d8b5-49d0-abd7-8daf269bf1b8_en?filename=mdcg_2021-3_en.pdf

PMS planning starts already during the development of a device. The manufacturer should think ahead and determine which activities should be carried out to systematically and proactively collect experience gained from devices they place on the market or put into service[10].

Each device must be covered by a PMS plan. A plan can cover a single device or a group of devices. For example, devices with the same manufacturing process, design and intended purpose, or in the same device family can be covered by the same PMS plan. The plan should clearly state which devices are included within its scope.

The PMS plan specifies the aspects of the device or group of devices to be monitored, the frequency of monitoring, and the methods to be applied. The chosen methods should be appropriate and based on the device's risk profile, and the rationale for selecting these methods needs to be documented.

Although the fourth indent of section 1(b) of Annex III MDR/IVDR requires that methods and procedures are covered in the PMS plan, in practical terms, the PMS plan should define what types of methods are to be applied. An explanation of how and by whom these methods are to be applied may instead be covered by procedures that are referenced within the PMS plan.

The concept of "proactive" is central to understand the requirements set out in section 1(b) of Annex III MDR/IVDR, which describe the PMS plan to ensure a "proactive"[11] information collecting process. Similarly, the term "proactive" appears in sections 5 and 6.1 of Part B of Annex XIV MDR and section 4 and 5.1 of Part B of Annex XIII IVDR in the context of Post-Market Clinical Follow-up (PMCF) and Post-Market Performance Follow-up (PMPF).

"Proactive" emphasizes the manufacturer's obligation to actively seek out available information and not merely wait for it to arrive through channels such as complaints. Manufacturers should play an active role during the post-market phase by systematically and actively gathering information from post-market experience with their devices.

This involves deliberately planning the gathering or generating information from a variety of sources. These may include, but are not limited to, customer surveys, gathering of clinical experience, user feedback, screening of scientific literature, other clinical data sources, meta-analyses of published clinical data, evaluation of suitable registers, and post-market studies.

Manufacturers should determine the appropriate methods, and the choice of methods should be tailored to the specific device or group of devices and reflect the level of innovation and research activity within the relevant field.

The PMS plan should also reference procedures and frequencies related to the output of the plan, such as a PMS report for class I devices per Article 85 MDR and classes A and B devices per Article 80 IVDR and a PSUR for all other classifications per Article 86 MDR/Article 81 IVDR.

Table 1 on the next pages provides a summary of the elements to be covered in the PMS plan as per section 1(b) of Annex III MDR/IVDR. It also details effective and appropriate methods and processes for assessing the collected data, including explanations and examples of these methods.

[10] Article 2(60) MDR / Article 2(63) IVDR
[11] See Annex III, section 1(b), first indent MDR/IVDR

Table 1. Summary of the elements to be covered in the PMS plan per section 1(b) of Annex III MDR/IVDR

Required per section 1(b) of Annex III MDR/IVDR	Explanation	Examples of content in the PMS plan[12]
— a proactive and systematic process to collect any information referred to in point (a). The process shall allow a correct characterisation of the performance of the devices and shall also allow a comparison to be made between the device and similar products[13] available on the market	Manufacturers are expected to collect the information referred to in section 1(a) of Annex III MDR/IVDR and to use it to address understanding of device usage, safety and performance, usability as well as identify areas for improvement. By collecting information on similar products, the manufacturer can compare their device with similar products on the market (in terms of design or intended use). The information is used to demonstrate that the device remains state of the art (SOTA)[14].	- List of activities with references to procedure(s) for collecting the information referred to in section 1(a) of Annex III MDR/IVDR. - Sources of data regarding similar products - Frequency of the activity and the role(s)/function(s) responsible, if not already specified elsewhere.

— effective and appropriate methods and processes to assess the collected data	Methods and processes for assessing the data are expected to be proportionate to the type of device. The methods selected are also dependent upon the type and quality of the collected raw data[15]. It is expected that higher-risk devices will require more specific methods of data analysis.	- Methods to be applied (e.g., qualitative, or quantitative, statistical methods) and processes for assessing the collected data, along with rationale.
		- List of parameters to be analysed for example:
		  ○ side effect or type of incident, device malfunction, hazard, harm, complaint rate, severity, etc.
		- List of the measurable values for example:
		  ○ batch, batch quantity, hours/frequency of use, number of devices in use/sold, number of exposures, etc.

— suitable indicators and threshold values that shall be used in the continuous reassessment of the benefit-risk analysis and of the risk management as referred to in section 3 of Annex I MDR/IVDR	Suitable indicators and threshold values (i.e., limits beyond which action should be taken) are to be established in the pre-market phase. The data obtained through PMS activities is fed back into the risk management process and used to re-evaluate indicators and threshold values.	- Indicators and thresholds relevant for assessing the impact; on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, benefit-risk ratio, and risk acceptability.
— effective and appropriate methods and tools to investigate complaints and analyze market-related experience collected in the field	Methods and tools are expected to be proportionate to the type of device: For higher-risk devices, more rigorous approaches to investigation and analysis of complaints and other market-related experience may be required.	- Methods to be applied (e.g., qualitative, or quantitative, statistical methods) and processes for analysing the collected data, along with rationale, for example. ○ methods described in IMDRF Adverse event Terminology Annex B[16], Cause Investigation -Type of Investigation.

[12] These examples are intended to provide guidance to manufacturers. They should not be understood as mandatory elements. It is up to the manufacturer to select the most appropriate methods, parameters, values, processes, and tools depending on the nature and usage of the device.
[13] In this context the terms “products” and “devices” have the same meaning.
[14] State of the art should be understood as: Developed stage of current technical capability and/or accepted clinical practice in regard to products, processes and patient management, based on the relevant consolidated findings of science, technology and experience. Source: Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices, IMDRF/GRRP WG/N47.
[15] CEN ISO/TR 20146:2020 Medical devices – post-market surveillance for manufacturers (ISO/TR 20416:2020)
https://standards.cencenelec.eu/ords/f?p=CEN:110:::::FSP_PROJECT,FSP_ORG_ID:66261,581003&cs=1614CA9C900CA51B856D1D3B8744BFC3D
[16] IMDRF Adverse event Terminology Annex B
https://www.imdrf.org/working-groups/adverse-event-terminology/annex-b-cause-investigation-type-investigation

— methods and protocols to manage the incidents subject to the trend report as provided for in Article 88 MDR/Article 83 IVDR, including the methods and protocols to be used to establish any statistically significant increase in the frequency or severity of incidents as well as the observation period	Non-serious incidents or clearly documented expected undesirable side-effects may be subject to trend reporting. It is expected that the methodology used for determining any statistically significant increase in the frequency or severity of such incidents, as well as the observation period are defined in the PMS plan, or a reference is made to associated procedure(s)) that specify those aspects.	- References to relevant procedures and statistical methods to be applied along with parameters to be monitored, including threshold values and indicators. - Relevant procedures, documentation, and methods/criteria for submitting reports. - Details of the frequency of the activity and the role(s)/function(s) responsible, if not already specified elsewhere.
—methods and protocols to communicate effectively with competent authorities, notified bodies, economic operators, and users	Manufacturers must establish processes to ensure effective communication with competent authorities, notified bodies, other economic operators and users (including patients and customers) with respect to the output of PMS activities.	- References to relevant procedures, i.e., to contact and inform competent authorities, notified bodies, other economic operators, and users – including patients and customers. - Details of, or reference to forms, communication methods and data transfer tools which may be used, and the role(s)/function(s) responsible, if not already specified elsewhere.
— reference to procedures to fulfil the manufacturers obligations laid down in MDR Articles 83, 84 and 86 or IVDR Articles 78, 79 and 81	Procedures must be in place to enable the implementation of the PMS system, as well as for generating PMS-related plans and reports.	- References to relevant procedures, i.e., to generate/update PMS plans, reports, etc. - Details of the frequency of the activity and the role(s)/function(s) responsible, if not already specified elsewhere.
— systematic procedures to identify and initiate appropriate measures including corrective actions	Procedures are expected to describe criteria for corrective actions and the type of measure to be undertaken (such as documenting a nonconformance, initiating a CAPA or FSCA according to the impact or risk posed by the issue identified.	- List of identified criteria which would lead to the initiation of appropriate measures or corrective action. Details of the role(s)/function(s) within the organisation responsible for specific tasks as part of an action plan.
— effective tools to trace and identify devices for which corrective actions might be necessary	Tools used to identify and trace devices for which corrective actions might be necessary must be described. Procedures describing controls for non-conforming devices (e.g., recall and quarantine) and identification of relevant economic operators are expected to be referenced.	- List of methods and/or tools to trace and identify devices affected by an issue requiring corrective action. - References to relevant procedures, i.e., to identify and trace devices using specified tools. - Details of the role(s)/function(s) within the organisation responsible for specific tasks as part of a corrective action plan.
— a PMCF plan as referred to in Part B of Annex XIV, or a justification as to why a PMCF is not applicable (MDR) **— a PMPF plan as referred to in Part B of Annex XIII, or a justification as to why a PMPF is not applicable (IVDR)**	The PMCF/PMPF plan[17] is an integral part of the PMS plan. If the manufacturer determines that no specific PMCF/PMPF activities are required, a justification is required.	- Description of planned PMCF/PMPF activities and justification. - Reference to a detailed PMCF/PMPF plan/protocol, where appropriate. - Reference to relevant procedures. - Details of the frequency of the activity and the role(s)/function(s) responsible, if not already specified elsewhere. - Justification as to why a PMCF/PMPF is not applicable, if appropriate.

[17] See also MDCG 2020-7 Post-market clinical follow-up (PMCF) Plan Template
https://health.ec.europa.eu/document/download/a5cdb303-c782-4010-8723-7d389af678f7_en?filename=md_mdcg_2020_7_guidance_pmcf_plan_template_en.pdf

5 The main activities of the PMS system

The PMS system should be suited to actively and systematically gathering, recording, and analysing relevant data on the quality, performance, and safety of a device throughout its entire lifetime. This chapter explains the different steps in the cycle of PMS, including the collection, assessment and analysis of post-market data and guidance on how to process the outputs.

5.1 Determining appropriate sources of available information for PMS

The manufacturer should decide which sources are relevant and appropriate for the device concerned. When selecting data sources, the different economic operators, users (healthcare professionals, patient, or lay users) and the situation in which the devices are used need to be considered. The examples given in Table 2 are intended to provide guidance to manufacturers. They should not be understood as mandatory elements.

It is up to the manufacturer to select the most appropriate methods, parameters, values, processes, and tools depending on the type of the device. Data quality and integrity should be considered before analysing data to ensure the information is reliable. For example, the use of unverifiable data can lead to over-reaction, as it can be based on non-scientific data sources such as social and public media.

Table 2 on the next pages provides an explanation of each indent of section 1(a) of Annex III MDR/IVDR. It describes the information that should be collected and how this should be utilised.

Table 2. Breakdown of Section 1(a) Annex III MDR/IVDR: Information to be collected and use of that information

Required Information as per section 1(a) of Annex III MDR/IVDR	Examples of information to be collected to fulfill requirements as per section 1(a) of Annex III MDR/IVDR	Use of information obtained through PMS
Information concerning serious incidents, including information from PSURs, and field safety corrective actions	Outputs from procedures to receive, document, investigate and analyze serious incidents received from customers, users, healthcare professionals, patients, or other economic operators. Information/feedback gathered during design, implementation and tracking of progress and effectiveness of field safety corrective actions.	<u>Information may contribute to</u>: - identification of emerging risks, or previously unknown side effects - demonstration of the continued acceptability of the performance and safety of the device - tracking any emerging or developments to practices or benefits associate with device use (SOTA) - the determination of reportability of incidents to the competent authority/notified body - the identification and investigation of trends - comparison of the device with similar products on the market - identification of new benefits of the device - identification of possible systematic misuse or off-label use of the device <u>Information may support identification of need for:</u> - corrective or preventive action (CAPA) - field safety corrective action (FSCA) - options to improve the usability, performance, and safety of the device, if applicable, to contribute to the PMS of other devices. - Information to be notified to Competent Authorities/Notified Body: o report serious incidents and corrective and preventive actions[18] o report field safety corrective actions - improvement of internal processes such as internal PMS, vigilance, CAPA, and design control - reporting of trends in accordance with Article 88 MDR/ Article 83 IVDR - design changes including improving usability, performance and or safety. <u>Information may be used to update the</u>: - indicators and threshold values for continuous reassessment of the benefit-risk analysis - risk management - Benefit-risk determination and to improve the risk management. - design and manufacturing information, the IFU and the labelling - clinical/performance evaluation - SS(C)P - technical documentation - PMS plan and PMCF/PMPF plan - risk management including need for CAPA or FSCA - labelling, IFU or other documentation
Records referring to non-serious incidents and data on any undesirable side-effects	Outputs from procedures to receive, document, investigate and analyze: - incidents determined to be non-serious. - complaints and information. - service and repair records including those received from customers, users, healthcare professionals, patients, other economic operators.	
Information from trend reporting	Outputs from procedures, systems and methodologies established for trending of non-serious incidents, undesirable side effects and expected erroneous results received from customers, users, healthcare professionals, patients, other economic operators	
Relevant specialist or technical literature, databases and/or registers	Literature review/clinical evaluation process/ external database evaluation process regarding the device(s) in question. For example: - Screening literature for reports involving the device(s) in question. - Searching competent authority websites and databases, including EUDAMED. - Searching device registers or registries, where available. Other published information including clinical guidelines, health technology assessments/reports.	
Information, including feedback and complaints, provided by users, distributors, and importers;	For example: - Surveys of users, customers, distributors, importers, and other stakeholders. - Feedback received during user training, education, workshops.	

[18] For further explanation see MDCG 2023-3 Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices. https://health.ec.europa.eu/document/download/af1433fd-ed64-4c53-abc7-612a7f16f976_en?filename=mdcg_2023-3_en.pdf

	- Reported complaints other than serious incidents. Feedback obtained through sales channels including internet or digital sales, and customer service departments or marketing activities.	- processes to determine reportability of incidents <u>Information may be used to prepare the</u>: - PMS report as per Article 85 MDR/ Article 80 IVDR - PSUR as per Article 86 MDR/Article 81 IVDR - PMCF/PMPF evaluation report - Clinical/Performance Evaluation report
Publicly available information about similar devices	Information presented in this section needs to be publicly available and relates to similar devices. For example: - Screening the literature for reports involving similar devices. - Searching competent authority websites and databases, including EUDAMED. - Searching device registers or registries, where available. - Other published information including manufacturer website, Instructions for use (IFU) and labelling, SS(C)P. - Information available from third countries (worldwide). - Information on safety and performance gained from conferences, congresses, and commercial exhibitions.	

5.2 Collecting necessary data

The MDR and IVDR require a manufacturer to develop a robust PMS system that enables them to gather, record and analyse relevant data on the quality, performance, and safety of a device throughout its entire lifetime actively and systematically. In this way, information is sought to gain insight into the real-world performance of the device.

The data collection for PMS typically starts once a manufacturer declares the device's conformity with the requirements of the applicable Regulation and places it on the market or puts it into service.

When gathering PMS data, manufacturers should establish the processes for receiving, reviewing, and evaluating information, including the screening of scientific literature, feedback and complaints provided by users, distributors, importers or other third parties.

In some instances, manufacturers may be required to generate data relating to real-world use of the device. This is especially applicable in the case of higher risk devices and/or devices with novel features or applications, in most cases through specific methods and procedures of PMCF/PMPF.

5.3 Assessment and analysis of data

The PMS system should include the manufacturer's processes and methods that are used to effectively assess and analyse the data collected under the PMS plan. In assessing the data, the manufacturer should refer to the objectives of their PMS (and PMCF/PMPF) plan to evaluate whether those objectives have been achieved.

Data is assessed to analyse and characterise the performance of the device and to enable comparisons with similar devices, thus allowing the manufacturer to confirm the continued acceptability of the benefit-risk ratio. If the analysis reveals previously unknown side effects or device deficiencies, the manufacturer should ensure that the processes linked to their risk management are followed.

The manufacturer should also reflect on the performance of their device versus the generally accepted State of the Art (SOTA)[19], taking into consideration datasets relating to different patient populations, device combinations and/or models and variants.

Furthermore, when assessing the data, it is important that data from different sources is compared, and conflicting data identified and evaluated. Data quality and validity should be evaluated to enable the drawing of appropriate conclusions and where necessary to identify suitable actions.

5.4 Drawing conclusions and determining the need to take action(s)

As outlined in Article 83(2) MDR/Article 78(2) IVDR, drawing the necessary conclusions and determining the need to take any preventive and corrective actions[20] are central aspects of the manufacturer´s assessment of the overall device safety and performance.

[19] Annex I, Chapter 1, Section 1 MDR/IVDR

[20] As explained in the MDCG 2022-21, Corrective or Preventive Action(s) (CAPA) which are covered by Article 83(4) MDR, Article 78(4) IVDR first sentence, can be made available to the competent authorities either through the PSUR or PMS report. All relevant information can be found in the section 2.1.2. of MDCG 2022-21.

The drawing of conclusions should be based on the analysis of the data collected. Furthermore, those conclusions and the actions taken subsequently need to be documented in (an update of) a summary report, either in the PMS report or in the PSUR[21].

Following the outcome of that report, a review of the current PMS plan may be necessary. This will drive the level of PMS activity required for the next cycle of PMS (based on the device class, historical data, similar products and including the need for PMCF/ PMPF for example).

6 The interactions of the PMS system with other key aspects of the QMS

Article 83(3) MDR/Article 78(3) IVDR specifically request that information generated from PMS activities should be used as input, on a continuous basis, to other processes within the QMS.

Table 3 on the next page provides an overview of potential activities to be considered to fulfill the requirements listed in Article 83(3) MDR/Article 78(3) IVDR.

Annex 2 of this guidance provides examples demonstrating the various elements and interactions of a post-market surveillance system with other key aspects of the quality management system.

[21] MDCG 2022-21 Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745.

Table 3. Interactions of the PMS system with other key aspects of the QMS

Required Information per Article 83(3) MDR/78(3) IVDR	General	Activity
Update the benefit-risk determination and the risk management (Art. 83(3)(a) MDR/Art. 78(3)(a) IVDR)	Information obtained through PMS activities should be used in the benefit-risk determination process and in the continuous assessment of the overall benefit-risk profile of the device to ensure that the benefit-risk profile remains acceptable. Furthermore, the data should be utilised to update the risk management documentation. The suitable indicators and threshold values used in the continuous reassessment of the benefit-risk analysis of the device should be covered in the PMS plan and be linked to the risk management documentation (as referred to Annex I, section 3 MDR/ IVDR). Changes to the benefit-risk profile of the device as a result of PMS information should be identified, documented, and evaluated for acceptability. The need to initiate appropriate measures, including corrective and preventive action should be considered.	• Establish procedures to adequately address the interface between PMS and the risk management process • Analyse and appraise the data collected by the planned and established PMS activities • Assess the impact of collected data on the probability and the severity ratings of existing risks or if new risks were identified • Evaluate the impact of the collected information on the overall risk, benefit-risk ratio and risk acceptability.
Update the design and manufacturing information, instructions for use and labelling (Art. 83(3)(b) MDR/Art. 78(3)(b) IVDR)	Information obtained through the PMS process should be used to evaluate the need for updating the design and manufacturing information, the instructions for use and the labelling. Therefore, a manufacturer should ensure that its design and development process consider PMS data as an input.	• Take appropriate action when evidence of new or increased risks is identified (for example, through identifying previously unknown side-effects and monitoring of identified side-effects and contraindications, or through identifying possible systematic misuse or off-label use of the device. This could include but is not limited to updates or changes to the design of the device itself or to the labelling and IFU.
Update clinical evaluation / performance evaluation (Art. 61 and Art. 83(3)(c) MDR/ Art. 56 and Art. 78(3)(c) IVDR	PMCF/PMPF should be addressed in the manufacturer's PMS plan and should be performed pursuant to a documented method laid down in a PMCF/PMPF plan that specifies the general and specific methods and procedures for proactively collecting and evaluating the collected clinical/performance data. The linkage of the PMS plan to the PMCF/PMPF plan is also described in indent 10, section 1(b) of Annex III MDR/IVDR.[22] Under the MDR, clinically relevant information coming from PMS, in particular the PMCF data, is considered “clinical data”. Annex XIV Part B	• Consider the outputs of any relevant data associated with PMS in the process of updating the manufacturer’s clinical evaluation or performance evaluation. • Analyse the findings of the PMCF/PMPF and document the results in a PMCF/PMPF evaluation report that should be used to update the clinical evaluation/performance evaluation and the technical documentation. The

[22] The general and specific methods and procedures of PMCF/PMPF are described in MDCG 2019-9 Summary of safety and clinical performance https://health.ec.europa.eu/document/download/5f082b2f-8d51-495c-9ab9-985a9f39ece4_en?filename=md_mdcg_2019_9_sscp_en.pdf and in MDCG 2022-9 Summary of safety and performance template https://health.ec.europa.eu/document/download/b7cf356f-733f-4dce-9800-0933ff73622a_en?filename=mdcg_2022-9_en.pdf

	MDR specifies that PMCF must be understood as a continuous process that updates the clinical evaluation. Specifically, data obtained by conducting PMCF is aiming to: • confirm the safety and performance of the device throughout its expected lifetime. • identify previously unknown side-effects and monitor the identified side-effects and contraindications. • identify and analyze emergent risks on the basis of factual evidence. • ensure the continued acceptability of benefit-risk ratio. • identify possible systematic misuse or off-label use of the device, with a view to verify that the intended purpose is correct. Under the IVDR, performance relevant information coming from PMS, in particular the PMPF data, is considered "relevant scientific data" and "performance evaluation results". Annex XIII, Part B specifies that PMPF must be understood as a continuous process that updates the performance evaluation. Specifically, data obtained by conducting PMPF is aiming to: • confirm the safety and performance of the device throughout its expected lifetime, • identify previously unknown risks or limits to performance and contra-indications, • identify and analyse emergent risks on the basis of factual evidence, • ensure the continued acceptability of the clinical evidence and of the benefit-risk ratio. • Identify possible systematic misuse.	conclusions of the PMCF/PMPF evaluation report must be taken into account in the clinical evaluation/performance evaluation and the risk management (referred to in section 3 of Annex I MDR/IVDR). • Consider this data from the perspective of the overall benefit-risk assessment of the device and in context with existing clinical data or performance data from the device's previous clinical/performance evaluation. If the need for corrective or preventive measures has been identified, the manufacturer should implement them.
Update the summary of safety and (clinical) performance (SS(C)P) (Art. 32 and Art. 83(3)(d) MDR/Art. 29 and Art. 78(3)(d) IVDR)	The SS(C)P is applicable to class III and implantable devices (MDR) and class C and class D devices (IVDR). The purpose of the SS(C)P is to provide transparency of the clinical data held on the device including aspects of safety and performance to the health care professional and, where applicable, patients.	• Within the PMS System, describe how the PMS data is used to update the SS(C)P, when applicable[23]. • Assess any new information generated from the PMS system for impact on the benefit-risk-profile (safety/performance profile) for update to the SS(C)P. Such updates should be aligned with the information presented in the

[23] For more information see MDCG 2019-9 Summary of safety and clinical performance and MDCG 2022-9 Summary of safety and performance template.

		clinical/performance evaluation report and Periodic Safety Update Report (PSUR).
Identify needs for preventive, corrective, or field safety corrective actions (Art. 83(3)(e) MDR/Art. 78(3)(e) IVDR)	Manufacturers should set up their PMS system not only to actively collect but also analyse and utilise relevant data on the quality, performance, and safety of a device throughout its entire lifetime. The manufacturer should draw the necessary conclusions as to whether implementation of corrective or preventive actions is required.	• Set up processes and procedures to integrate the data obtained by the PMS system into the QMS, in order to initiate and document corrective and preventive actions[24] as well as field safety corrective actions to reduce the risk posed by devices already placed on the market.
Identify options to improve usability, performance and safety of the device (Art. 83(3)(f) MDR/Art. 78(3)(f) IVDR)	Information obtained through the PMS process should be used to identify options to improve the usability, safety, or performance of the device through linkage to the design and development process. These actions can be more proactive and strategic and are not necessarily tied to identified risks. They aim to enhance user experience, clinical outcomes, or operational efficiency rather than specifically addressing hazards.	• Ensure design and development process defines PMS as input to usability, safety, or performance of the device.
Contribute to PMS of other devices (Art. 83(3)(g) MDR/Art. 78(3)(g) IVDR)	PMS data regarding the usability, performance, and safety of one device can contain useful information for the manufacturer's other devices. Any new or increased risk identified should be considered by the manufacturer as to whether it is likely that other devices that share the same or similar intended purpose, design or processing characteristics could be impacted by this new information.	• When relevant, use the collected information, analysis, and conclusions as input to the PMS of other devices. The PMS system can utilize PMS data systematically across other devices.
Detect and report trends (Art. 83(3)(h) MDR and Art. 88 MDR/Art. 78(3)(h) and Art. 83 IVDR)	Information gathered on non-serious incidents, expected undesirable side-effects (MDR), or expected erroneous results (IVDR) should be analysed for any statistically significant increase in the frequency or severity of those events.	• Review any statistically significant increase in the frequency or severity that could have a significant impact on the benefit-risk profile, and which has led or may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits. These are subject to trend reporting, according to MDR and IVDR requirements.

[24]Article 2(67) MDR/ Article 2(70) IVDR, and EN ISO 13485:2016.

7 References

This guidance has been developed taking into consideration the following documents, either in their entirety or partially:

- EN ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes (ISO 13485:2016) + AC:2018 + A11:2021[25]
- EN ISO 14971:2019 Medical devices – Application of risk management to medical devices (ISO 14971:2019) + A11:2021[26]
- EN ISO 14155:2020 Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2020) + A11:2024[27]
- EN ISO 20916:2024 In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice (ISO 20916:2019)[28]
- EN 62366-1:2015 Medical devices — Part 1: Application of usability engineering to medical devices[29]
- CEN ISO/TR 20416:2020 - Medical devices - Post-market surveillance for manufacturers (ISO/TR 20416:2020)[30]
- Commission Implementing Decision (EU) 2021/1182 of 16 July 2021 on the harmonised standards for medical devices drafted in support of Regulation (EU) 2017/745 of the European Parliament and of the Council[31] (consolidated version)
- Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics, World Health Organization[32]

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[25]EN ISO 13485:2016 https://standards.cencenelec.eu/ords/f?p=CEN:110:::FSP_PROJECT,FSP_ORG_ID:37957,581003&cs=15C284A8BCE79EE9233A08DD6ECF0271E (harmonized and cited in the OJEU in support of the MDR and IVDR with the corrigendum AC:2018 and the amendment A11:2021), see https://health.ec.europa.eu/medical-devices-topics-interest/harmonised-standards_en

[26]EN ISO 14971:2019 https://standards.cencenelec.eu/ords/f?p=CEN:110:::FSP_PROJECT,FSP_ORG_ID:63920,581003&cs=106EB5B4C6029ECDFA9802360A2C340E9 (harmonized and cited in the OJEU in support of the MDR and IVDR with the amendment A11:2021).

[27]EN ISO 14155:2020 https://standards.cencenelec.eu/ords/f?p=CEN:110:::FSP_PROJECT,FSP_ORG_ID:62983,6187&cs=102F2E9B41968B33AA15E88BA07B87ECF (harmonized and cited in the OJEU in support of the MDR with the amendment A11:2024).

[28]EN ISO 20916:2024 https://standards.cencenelec.eu/ords/f?p=CEN:110:::FSP_PROJECT,FSP_ORG_ID:71064,6122&cs=194A987D41DF05904FABE8BA5CB8BA30C (harmonized and cited in the OJEU in support of the IVDR).

[29] EN 62366-1:2015 https://standards.cencenelec.eu/ords/f?p=CENELEC:110:::FSP_PROJECT,FSP_ORG_ID:44040,1257161&cs=19242C77366C169B0ED9D4F230B8778FE, (to be harmonised and cited in the OJEU in support of the MDR and IVDR).

[30]CEN ISO/TR 20416:2020 https://standards.cencenelec.eu/ords/f?p=CEN:110:::FSP_PROJECT,FSP_ORG_ID:66261,581003&cs=1614CA9C900CA51B856D1D3B8744BFC3D, (technical report).

[31]COMMISSION IMPLEMENTING DECISION (EU) 2021/1182 of 16 July 2021 on the harmonised standards for medical devices drafted in support of Regulation (EU) 2017/745 of the European Parliament and of the Council https://eur-lex.europa.eu/eli/dec_impl/2021/1182/

[32] Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics (WHO) https://www.who.int/publications/i/item/9789240015319

- IMDRF/GRRP WG/N47 Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices[33]

[33] https://www.imdrf.org/documents/essential-principles-safety-and-performance-medical-devices-and-ivd-medical-devices

Annex 1 Overview of PMS obligations in MDR and IVDR

PMS System - Article 83 MDR/Article 78 IVDR	
Description	**Obligations**
Comprehensive system to collect experience from use of the devices.	**MDR/IVDR: Applicable for all device classes.** • Proactive and systematic approach to collect data. • Analyse relevant data on the quality, performance, and safety of a device throughout its entire lifetime. • Draw the necessary conclusion. • Connect with other internal processes like CAPA, vigilance, design, and labeling processes. • Has to be used to update the technical documentation, (except for custom-made devices). • Integral part of the manufacturer QMS.
PMS Plan - Article 84 & Annex III MDR/Article 79 & Annex III IVDR	
Description	**Obligations**
Describes the implementation of the PMS system to collect data assess the safety and the performance of the devices and the methodology used for collecting and analysing the data.	**MDR/IVDR: Applicable for all device classes.** • Part of the QMS and the technical documentation. • Defines the data to be collected based on the PMS inputs of the manufacturer. • Describes: ○ the methods and protocols to monitor trends, to identify significant increase in frequency or severity of incidents. ○ the methods and tools to investigate complaints and analyse market-related experience collected in the field. ○ the indicators and thresholds to be used to reassess the benefit-risk ratio. ○ the tools to be used to trace and identify any devices in case corrective actions are needed. ○ the PMCF/PMPF plan or a justification why PMCF/PMPF is not applicable. • Describes the references to the documented procedures for: ○ PMS system ○ Creation of PMS plan ○ Generation of PMS report or PSUR as applicable. ○ Corrective actions ○ Risk management
PMS Report, Article 85 MDR/Article 80 IVDR	
Description	**Obligations**
A summary of the results and conclusions of analysis of the PMS data collected	**MDR: applicable to class I devices** **IVDR: applicable to class A and B devices** <u>What information a PMS report contain at a minimum?</u> • A summary of the results and the conclusions of the analyses/assessment of the post-market surveillance data resulting from the execution of the PMS plan. • A rationale and description of any corrective or preventive actions taken during the period covered by the report.

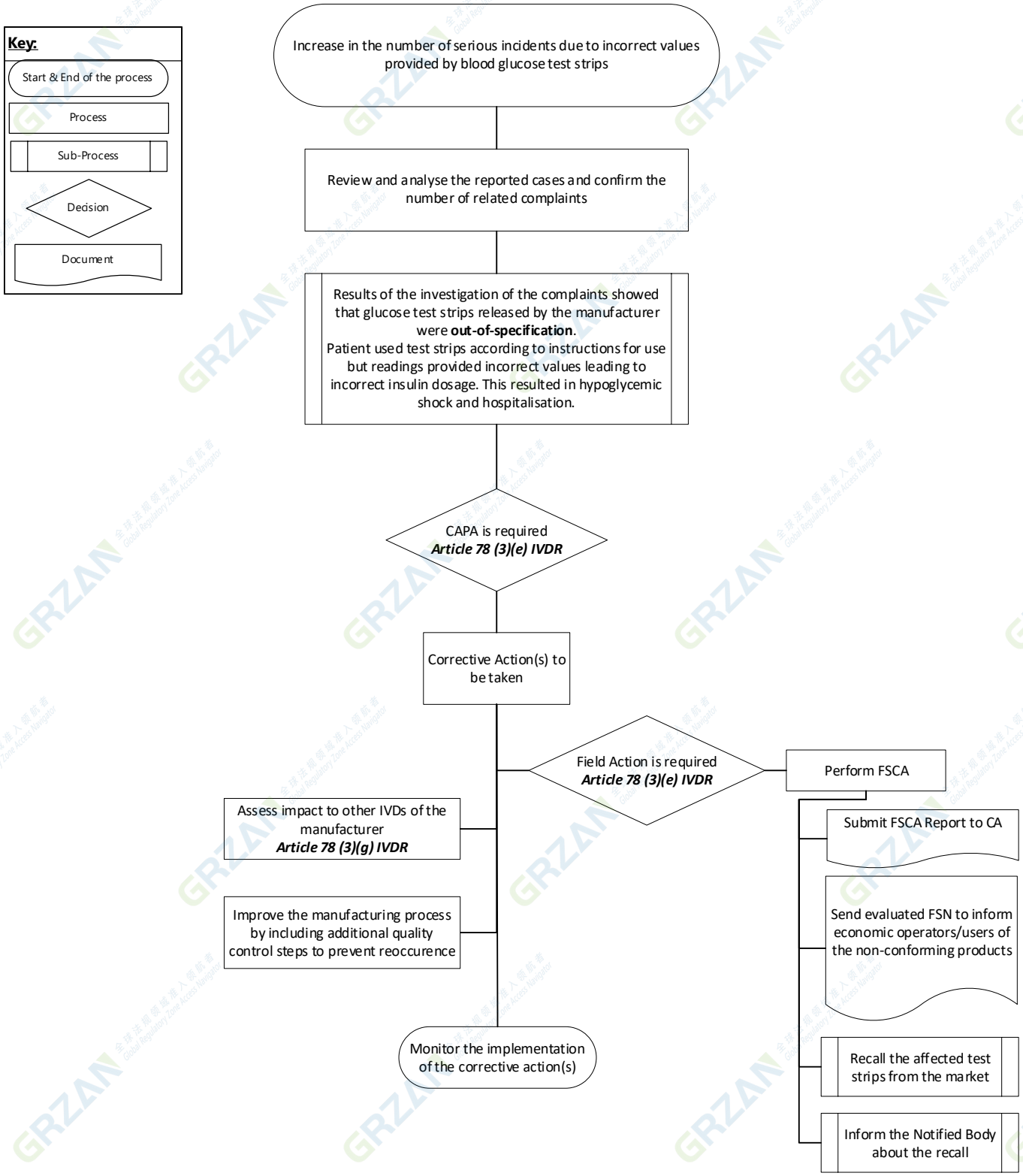
	The guidance MDCG 2022-21[34] although not covering the PMS report, may provide useful suggestions on how information can be presented. <u>When does a PMS report need to be updated?</u> • Update according to the PMS plan or earlier when deemed necessary by the manufacturer. <u>To whom does a PMS report need to be made available?</u> • To competent authority upon request.
PSUR - Article 86 MDR/Article 81 IVDR	
Description	**Obligations**
A summary of the results and conclusions of analysis of the PMS data collected.	MDR: applicable to class IIa, IIb and III devices IVDR: applicable to class C and D devices Detailed guidance on PSUR can be found in MDCG 2022-21

[34] MDCG 2022-21 Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745.

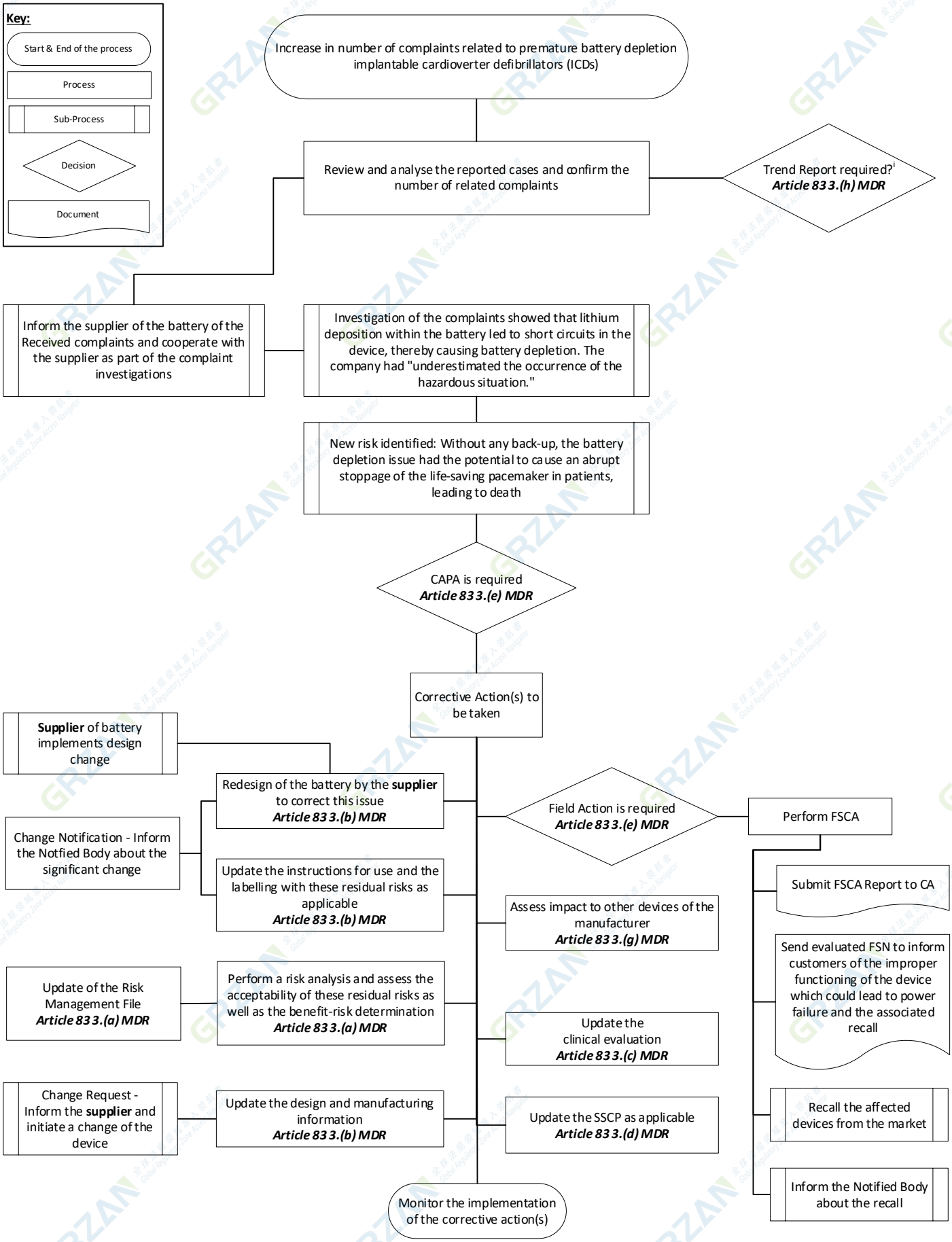
Annex 2 Scenarios IVD and medical devices: how to use PMS data to update other processes

Figure Note: The examples presented in the following figures are entirely fictitious and provided solely for illustrative purposes. These examples should not be interpreted as real-world scenarios or recommendations. They are intended to demonstrate the various elements and interactions of a post-market surveillance (PMS) system within the broader framework of a quality management system (QMS).

IVDs:



Medical Devices:



i: Although in this example trend reporting is not applicable, following DSVG MDCG 2024-1-3, it has been added to indicate the relevant processes, in a highly theoretical situation.