

THE POST-MARKET CLINICAL FOLLOW-UP (PMCF) REQUIREMENTS UNDER THE EUROPEAN MEDICAL DEVICE REGULATION: STEP BY STEP PMCF



The Medical Devices field is a constantly moving area. Several devices are invented or improved every day to benefit patients. More demanding for the manufacturers, the new Regulation (EU) 2017/745 is aiming to increase the safety and supporting innovation of the devices within the European Market. Let's start from the basics and try to understand these two quality processes: Post Market Surveillance (PMS) and Post-market Clinical Follow-up (PMCF) whose plan is an integral part of the PMS plan.

A THE PMS SYSTEM

Until now, under the Medical Device Directives, some MEDDEV documents could help manufacturers to implement a PMS system.

The MEDDEV documents were not legally binding but were summarizing the consensus of various experts, used as guidelines, and created for the MDD. Even though, in general, the MEDDEV 2.7.1 rev. 4 on the clinical evaluation is partly inspired by the Medical device Regulation (MDR), it remains insufficient to presume compliance with the requirements of the MDR.

Additionally, the other MEDDEV specific to the vigilance system and PMCF studies¹ are old (2012 and 2013) and even if the additional guidance on MEDDEV 2.12 rev. 8 (2019) about vigilance and some sections of the guidances are still relevant to the MDR, only the text of the MDR is authentic in law. The compliance to the MDR cannot be claimed through a compliance only with the MEDDEV documents.

The PMS system has now been more defined and fully integrated within the Regulation (EU) 2017/745. The PMS has been introduced in the MDR within the definition 60 of the Article 2:

⁽¹⁾ MEDDEV 2.12-2 rev 2 (Jan 2012) and MEDDEV 2.12/1 rev. 8 (Jan 2013)

*“Post Market surveillance’ means all activities carried out by 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 devices they place on the market**, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions”*

The MDR is explaining that the post-market surveillance shall be **planned, established, documented, implemented, maintained** and **updated** by the manufacturer, **for each device**, taking into account the **risk class** of the device², and, that it shall be an integral part of the manufacturer’s quality management system³.

The objectives of this PMS system are to **actively and systematically** gather, record, analyze the data on the quality, performance and safety of the device **throughout its entire lifetime**. It should be suited to draw the necessary conclusions and linked to the CAPA system of the company.

The data shall be in particular used to update the technical documentation through the following requirements:

- update the benefit-risk determination,
- improve the risk management,
- update the design and manufacturing information, IFU and Labelling, clinical evaluation, summary of safety and clinical performance (article 32),
- identification of need for any CAPA or FSCA (Field Safety Corrective Actions),
- identification of options for improvements (usability, performance and safety of the device),
- detect and report trends⁴.

As part of this Post-Market Surveillance system, the Post Market Clinical Follow-up activities are considered by the MDR as a continuous process that **updates the clinical evaluation**, and, as described above, the PMCF plan is an integral part of the PMS plan.



B THE PMCF WITHIN THE MDR

Even if the definition of the PMCF is not provided within the article 2 of the MDR, there are many instances where an explanation of the Post-Market surveillance follow-up are given.

For example, a mention of it is appearing within the definition of the clinical data:

“clinical data’ means information concerning safety or performance that is generated from the use of a device and is sourced from the following:

- (...)
- *clinically relevant information coming from post-market surveillance, in particular the **post-market clinical follow-up**”⁵*

In the article 10 of the MDR, it is also saying that the manufacturer “shall conduct a clinical evaluation in accordance with the requirements set out in Article 61 and Annex XIV, including a PMCF⁶”. It shall be integrated within the Quality Management System and part of the technical documentation. The article 61 is explaining and reinforcing the clinical data relevance and evaluation process.

Finally, the Annex XIV Part B is entirely dedicated to the PMCF and gives the following definition: “PMCF shall be understood to be a continuous process that updates the clinical evaluation referred to in Article 61 and Part A of this Annex and shall be addressed in the manufacturer’s post-market surveillance plan”.

The goal of the PMCF is to be able to update the clinical evaluation report with new/up to date data; with the same goal safety of the patient and performance of the device.

C PERFORMANCE OF A PMCF PLAN

The realization of a PMCF plan is one of the first step to the implementation of a Post-Market Clinical Follow-Up.

The PMCF is not to be confused with PMCF study or investigations, which are a type of activities that can be part of the PMCF.

⁽²⁾ Article 83 (1) of the MDR

⁽³⁾ Article 10 (9) of the MDR

⁽⁴⁾ Article 88 of the MDR

⁽⁵⁾ Article 2 (48) of the MDR

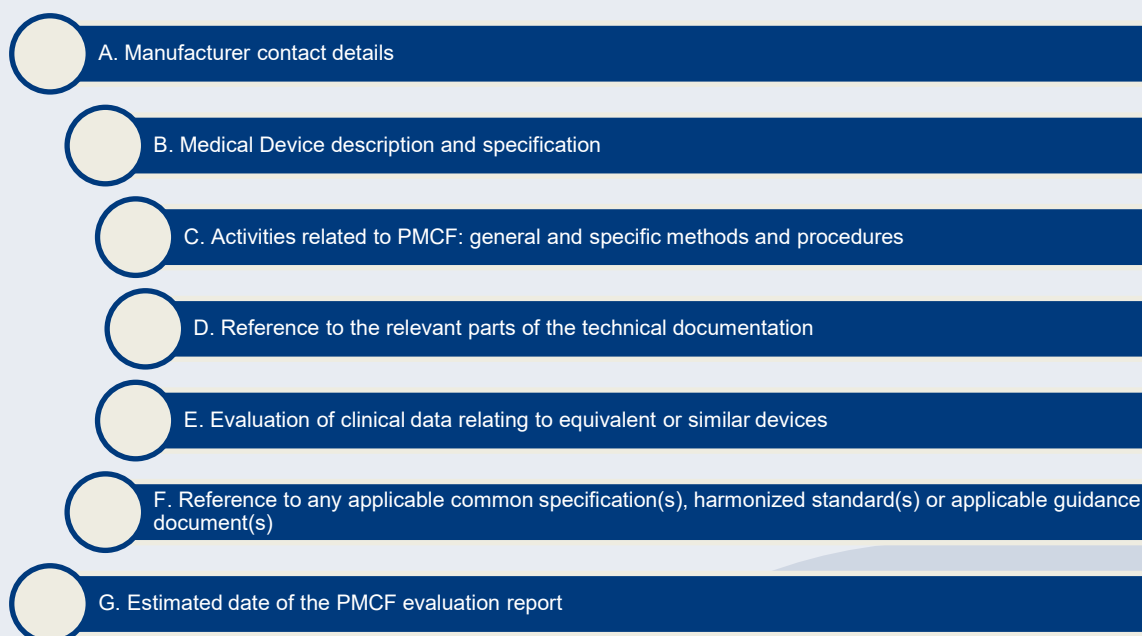
⁽⁶⁾ Article 10 (3) of the MDR

The aim of the PMCF plan is as follows:

- “Confirming the **safety and performance**, including the clinical benefit if applicable, of the device throughout its expected lifetime;
- Identifying previously **unknown side-effects** and monitor the identified side-effects and contraindications;
- Identifying and **analyzing emergent risks** on the basis of factual evidence;
- Ensuring the continued acceptability of the **benefit-risk ratio**, referred to in section 1 and 9 of annex I in the MDR;
- Identifying possible systematic **misuse or off-label use** of the device, with a view to verifying that the intended purpose is correct.”

Within the MDCG 2020-7, the Medical Device Coordination Group described a template to perform a PMCF plan, which could be used as a guidance to comply with the MDR requirements. Below, you can find the proposed plan for the PMCF plan of the MDCG Guide.

Figure 1: Post-market clinical follow-up (PMCF) Plan



The MDCG Guidance is helpful for manufacturers, notified bodies and competent authorities as it is harmonizing and organizing the information. You can find below some useful information related to the PMCF plan:

Part C: “Activities related to PMCF: general and specific methods and procedures”

In the figure below, you can find examples of procedures that may be used as part of the PMCF⁷.

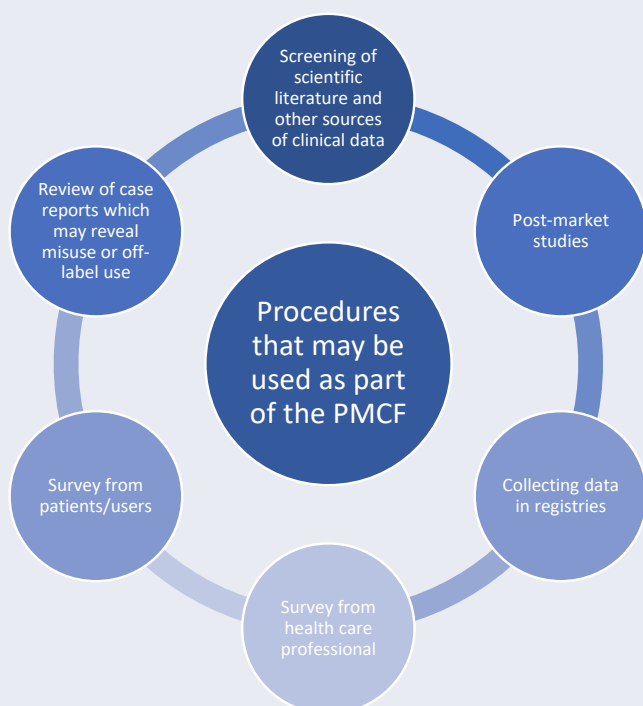


Figure 2: Procedures that may be used as part of the PMCF

Part D: “Reference to the relevant parts of the technical documentation”

The main aim of a PMCF plan is to follow-up and update the Clinical Evaluation report and the Risk Management file. In many cases, the risk management file and the clinical evaluation report are a gold mine of information to know which data need to be analyzed, monitored, followed up and evaluated in the PMCF plan.

Part E: “Evaluation of clinical data relating to equivalent or similar devices”

In the section E, the main goal is to gather all information related to equivalent/similar devices “for which clinical data will be further evaluated and presented in the PMCF evaluation report.” to update the information relating to the state of the art, to identify and further assess relevant safety outcomes etc.

The term ‘similar devices’ may be understood as devices belonging to the same generic device group⁸. The MDR defines the term “generic group” as a set of devices having the same or similar intended purposes or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics⁹.

The MDR requires that technical, biological and clinical characteristics are considered when demonstrating **equivalence** to another device. The following **technical, biological** and **clinical characteristics** shall be taken into consideration for the demonstration of equivalence:

- **Technical:** the device is of similar design; is used under similar conditions of use; has similar specifications and properties including physicochemical properties such as intensity of energy, tensile strength, viscosity, surface characteristics, wavelength and software algorithms; uses similar deployment methods, where relevant; has similar principles of operation and critical performance requirements;
- **Biological:** the device uses the same materials or substances in contact with the same human tissues or body fluids for a similar kind and duration of contact and similar release characteristics of substances, including degradation products and leachables;
- **Clinical:** the device is used for the same clinical condition or purpose, including similar severity and stage of disease, at the same site in the body, in a similar population, including as regards age, anatomy and physiology; has the same kind of user; has similar relevant critical performance in view of the expected clinical effect for a specific intended purpose.

It is important to take into account that the PMCF data intended to demonstrate continuing safety and performance should be sourced from the device under evaluation¹⁰.

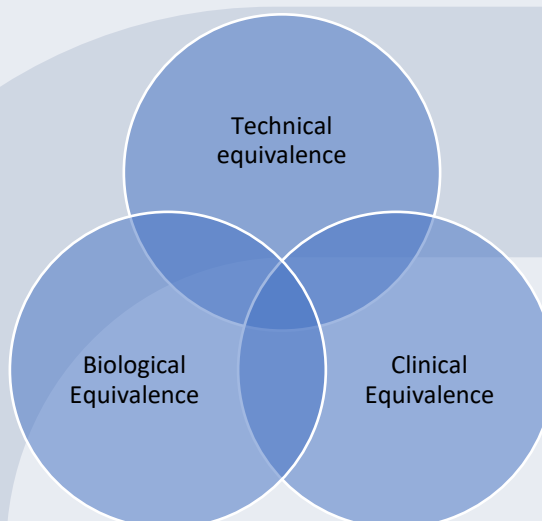


Figure 3: Determining the Equivalence of devices criteria

⁽⁷⁾ [MDCG Guidance 2020-8: Post-market clinical follow-up \(PMCF\) Evaluation Report Template](#)

⁽⁸⁾ [MDCG 2020-5: Clinical Evaluation - Equivalence](#)

⁽⁹⁾ Article 2 (7) of the MDR

⁽¹⁰⁾ [MDCG 2020-7: Post-market clinical follow-up \(PMCF\) Plan Template - A guide for manufacturers and notified bodies - \(April 2020\)](#)

D THE PCMF EVALUATION REPORT

The PMCF evaluation report is a tool which is helping the manufacturer to analyze the findings which are coming from the activities that were foreseen in the PMCF Plan as described above.

The PMCF evaluation report shall be part of the clinical evaluation report and may lead to its update along with the update of the risk management documentation or also the Post-Market Surveillance report/PSUR and the SSCP (Summary of Safety and Clinical Performance). The PMCF evaluation report shall be fully integrated as part of the technical documentation and more specifically, its outcome included in the clinical evaluation report (Annex XIV section 8).

Several information is necessary to be within the PMCF evaluation report such as¹¹:

C. Activities undertaken related to PMCF: results	Detail of the activities performed within the PMCF Plan (For each activity, a different subsection and a description of the type of activities and the quality of the data collected is expected)
	All collected clinical data obtained from the completion of the activities
	Justification of the deviation from the plan
	Analysis of the findings
D. Evaluation of clinical data relating to equivalent or similar devices	Potential impact on the different documents
	Reporting of all the data collected relating to an equivalent device of selected similar device
	Provide an analysis and conclusion
E. Impact of the results on the technical documentation	If any data identified and analyzed have an impact on the devices benefit-risk determination, clinical evaluation and/or PMCF plan
	Analysis of the impact on the Clinical Evaluation Report
	Analysis of the impact on the Risk management file
	(Analysis of the impact on the Post Market Surveillance Plan)
F. Reference to any common specification(s), harmonized standard(s) or guidance document(s) applied	(Analysis of the impact on the Summary of Safety and Clinical Performance - SSCP)
	The clinical data that have been collected must be analyzed to confirm adherence to applied common specifications and/or applied harmonized standards, and/or guidances listed in the PMCF plan

Figure 4: PMCF evaluation report: key information to be found

The detailed information can be found within the “MDCG 2020-8 Post-market clinical follow-up (PMCF) Evaluation Report Template”.

⁽¹¹⁾ [MDCG 2020-7 - Post-market clinical follow-up \(PMCF\) Plan Template - A guide for manufacturers and notified bodies \(April 2020\)](#)

Conclusion

The Post-Market Clinical Follow-Up within the Post-Market Surveillance, even if they are not new concepts, have been more explicitly explained with the new MDR. There are more requirements for the Manufacturer and a greater involvement of the Notified Body.

As a conclusion, the PMS and PMCF plan are “product specific”⁽¹²⁾ and any decision not to conduct clinical follow-up as part of the PMS plan should be duly justified and documented.

This is one of the major topics to take into account for the manufacturer, as the Post-Market Surveillance is one of the items that are to be implemented from May 26, 2021⁽¹³⁾ for legacy devices⁽¹⁴⁾ or from the placing on the market for the new devices.

⁽¹²⁾ Article 83 (1) of the MDR

⁽¹³⁾ Article 120 of the MDR

⁽¹⁴⁾ ‘legacy devices’: this is considered to include all devices previously CE marked under the European Medical Devices Directive 93/42/EEC (MDD) or Active Implantable Medical Devices Directive 90/385/EEC (AIMDD) - [MDCG: 2020-6 Regulation \(EU\) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC A guide for manufacturers and notified bodies \(April 2020\)](#)

To go further

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GMED SAS

1 rue Gaston Boissier
75015 PARIS • FRANCE
+33 (0)1 40 43 37 00
info@lne-gmed.com

→ FRENCH REGIONAL OFFICE

GMED SAS

19 D rue de la Télématicque
42000 SAINT-ETIENNE • FRANCE
+33 (0)4 77 10 11 11

→ NORTH AMERICAN SUBSIDIARY

GMED NORTH AMERICA, INC

6550 Rock Spring Drive - Suite # 280
BETHESDA, MD 20817 • USA
+1 (301) 495 0477
request@lne-gmed.com