MDCG 2020-7

Post-market clinical follow-up (PMCF) Plan Template
A guide for manufacturers and notified bodies

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Introduction

The Medical Device Regulation (EU) 2017/745 (MDR) considers the post-market clinical follow-up (PMCF) as a continuous process that updates the clinical evaluation and that shall be addressed in the manufacturer's post-market surveillance (PMS) plan. The MDR reinforces the PMCF process by the manufacturer, devoting part B of Annex XIV to it and providing a set of requirements for developing a plan, necessary to implement PMCF.

A PMCF plan shall specify the methods and procedures set up by the manufacturer, to proactively collect and evaluate clinical data from the use in or on humans of a CE marked medical device, placed on the market or put into service within its intended purpose, as referred to in the relevant conformity assessment procedure.

The aim of the PMCF plan is:

- confirming the safety[1] 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 analysing 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.

The PMCF plan shall be part of the post-market surveillance plan.

The findings of the PMCF shall be analysed by the manufacturer who shall document the results in a PMCF evaluation report. The PMCF evaluation report shall be part of the clinical evaluation report and the technical documentation. The adequateness of the PMCF plan and its application is subject to assessment by the notified body. The notified body's assessment of the clinical evaluation shall also cover the manufacturer's procedures and documentation of the PMCF, as well as the justification in relation to non-performance of PMCF.

The purpose of the present template is to guide manufacturers in complying with the requirements of the MDR with respect to the compilation of the PMCF plan. This would assist manufacturers in a harmonised and complete presentation of post market clinical data and facilitate the activity of notified bodies and competent authorities in finding the information in an organised format.

[1] The confirmation of the safety includes the acceptability of identified risks and particularly residual risks.

Post-market clinical follow-up plan Template

PMCF plan number:			
PMCF plan date:			
PMCF plan version:			
Revision history			
Rev	**Revision date**	**Description of change**	**Revised by**

Section A. Manufacturer contact details
Legal manufacturer name:
Address:
SRN:
Person responsible for regulatory compliance:
E-mail:
Phone:
Fax:
Authorised representative (if applicable):
Address:
Contact person:
E-mail:
Phone:
Fax:

Section B[2]. Medical Device description and specification
Product or trade name:
Model and type:
General description of the device:
Intended purpose[3]:
Intended users
Basic UDI-DI:
Intended patient population:
Medical condition(s)[4]:
Indications:
Contraindications:
Warnings:
List and description of any variants and/or configurations covered by this plan:
List of any accessories covered by this plan:
Certificate number (if available):
CND code(s)[5]:
Class:
Classification rule:

[2] MDR, Annex II, 1,1.
[3] Intended purpose means the use for which a device is intended according to the data supplied by the manufacturer on the label in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation (MDR, Article 2(12)).
[4] It refers to the clinical condition that is to be diagnosed, prevented, monitored, treated, alleviated, compensated for, replaced, modified or controlled by the medical device
[5] Per article 26 of MDR.

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Expected lifetime:[6]
Novel product: ☐ yes ☐ no
Novel related clinical procedure: ☐ yes ☐ no
Explanation of any novel features:

Section C. Activities related to PMCF: general and specific methods and procedures

In this section it is expected to describe the different activities that will be conducted in post-market, including general and specific methods / procedures to conduct in relation to the product covered by the scope of PMCF, also the aim of each activity described and the rational for the appropriateness of the chosen general and specific methods to achieve those objectives as well as the known limitations of the planned activities such as for example incomplete follow up, missing data and so on. The timelines of those activities shall be also defined quarterly or at least yearly.

Here are some examples of different activities related to PMCF:

- A manufacturer **device registry** (specific for the type of device or the group of the medical devices the product belongs to) can be indicated together with a description and a summary of the plan. A pre-specification of what quality and quantity data – based on the risk of the device(s) and the associated accessories – to be collected and analysed shall be included. Any possible evaluation of suitable **national public registries** with clinical data on the manufacturer's own device and/or on similar devices could be specified in this section, identifying the expected quantity and quality of data to be gathered and the search protocols to be adopted.
- **PMCF studies** planned could be indicated in this section, together with a summary of the plan including the design, sample size, the endpoints, the inclusion/exclusion criteria (e.g. extended follow up of patients included in the pre-market clinical investigations, new clinical investigations within the intended use, retrospective studies). In case of implantable devices and class III devices where clinical investigations have not been performed pursuant to Article 61 (4), the PMCF plan shall include post market studies to confirm the safety and performance of the device.
- Planned **Real-world evidence** (RWE) analyses could be indicated in this section, together with a summary of the plan including the design, sample size, the endpoints, and analysis population. The real-world data (RWD) from which these analyses are based on should be of sufficient quality and come from reliable data sources.
- **Surveys** planned to collect information about the use of the concerned medical device could be described.

Each activity will be developed in a different subsection (e.g. C.1, C.2, …), and for which the manufacturer will:

[6] The expected lifetime is to be defined during the design input phase by considering the current state of the art for a specific intended use and indication of a device.

- Define where the need of conducting the PMCF activity is coming from (requested by notified body, clinical evaluation report, PMS, risk management report, previous PMCF report, etc…)
- Provide the description of activity, and if it is a general or specific procedure / method.
- Define the aim of this activity:
  - confirming the safety of the medical device
  - confirming the performance of the medical device
  - identifying previously unknown side-effects (related to the procedures or to the medical devices).
  - monitoring the identified side-effects and contraindications
  - identifying and analysing emergent risks
  - ensuring the continued acceptability of the benefit-risk ratio
  - identifying possible systematic misuse or off-label use of the device

- Describe the different procedures which will be used as part of PMCF:
  - screening of scientific literature and other sources of clinical data
  - post-market studies
  - collecting data in registries
  - survey from health care professional
  - survey from patients/users
  - review of case reports which may reveal misuse or off-label use

- Describe the rationale for the appropriateness of the chosen methods/procedures, including:
  - the justification for sample size, timescales and endpoints
  - justification for comparator, on the basis of intended purpose and state of the art
  - justification of the study design on the basis of all of the above, and why it is sufficient to ensure representative patient populations and provide for adequate controls on sources of bias (an evaluation of the potential sources of bias should form part of this)
  - a statistical justification for the expected quality of outcomes, and justification for why this is satisfactory in light of the residual risks. This is an important consideration. For example, retrospective surveys with no justification other than “this should demonstrate the expected quality of evidence that we require,” but without showing a statistical rationale, are not acceptable.

- Provide the timelines of the activity. A detailed and adequately justified time schedule for PMCF activities, such as the analysis of PMCF data and reporting, shall be described.

A summary table of the different PMCF activities foreseen by the manufacturer is provided below:

Number of activity	Description of activity	Aim of the activity	Rationale and known limitations of the activity	Timelines of the activity

Section D. Reference to the relevant parts of the technical documentation

In this section the manufacturer is required to include references to the relevant information from the clinical evaluation report and from the risk management file, which need to be analysed, followed up, and evaluated in this plan. As an alternative, the manufacturer is required to state that there is no relevant information from the clinical evaluation report and/or from the risk management file to be considered in this plan.

Clinical Evaluation Report (date and version)

Relevant information to be further analysed and monitored:

-

-

-

Risk Management File (date and version)

Relevant information to be further analysed and monitored:

-
-
-

☐ No relevant information from the clinical evaluation report to be considered in this plan

☐ No relevant information from the risk management file to be considered in this plan

Section E. Evaluation of clinical data relating to equivalent or similar[7] devices

The manufacturer shall gather in this section information regarding equivalent / similar devices for which clinical data will be further evaluated and presented in the PMCF report.

Please note that PMCF data intended to demonstrate continuing safety and performance should be sourced from the device under evaluation.

Data from equivalent or similar devices may be used, for example to update the information relating to the state of the art, to identify and further assess relevant safety outcomes etc.

The selected devices shall be consistent throughout the technical documentation. Indicate whether the selected device is demonstrated to be equivalent or is a similar device. For each device listed, a clear reference to the pertinent parts of the CER can be made.

The following items of each equivalent and/or similar devices would be at least provided, in a table format:

[7] Section 5, MDCG 2020-5 Clinical Evaluation – Equivalence, A guide for manufacturers and notified bodies.

Product name of equivalent / similar device	Intended purpose	Intended users	Intended patient population	Medical condition	Indication	Reference to clinical data evaluation in the CER (date, version and location in the text)

Section F. Reference to any applicable common specification(s), harmonized standard(s) or applicable guidance document(s)

Common specification(s) to comply with, if applicable:

(Title, date and version)

Harmonised standards to apply, if applicable

(Title, date and version)

Guidance on PMCF, if applicable

(Title, date and version)

Section G. – Estimated date of the PMCF evaluation report
When the manufacturer plans to have the first report. The timelines shall be defined quarterly or at least yearly.

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