Post-Market Clinical Follow-Up Plan (PMCFP)

This document is used to plan all post-market clinical follow-up activities for the <name of the medical device].

Product information

Parameter	Description
Product or trade name:	
Model and type:	
Intended purpose:	

Context

> Check out this guidance document which may further help you to fill out the template: MDCG 2020-7 Post-market clinical follow-up (PMCF) Plan Template: A guide for manufacturers and notified bodies

The post-market clinical follow-up plan is compiled along with concluding the clinical evaluation and is based on the clinical evaluation report. Following Annex XIV MDR, it specifies the methods used to collect and evaluate clinical data with the aim of:

- confirming the safety and performance of the device throughout its product life cycle,
- identifying previously unknown side-effects and monitoring 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 sections 1 and 9 of annex I MDR, and
- identifying possible systematic misuse or off-label use of the device, with a view to verifying that the intended purpose is correct.

1. Activities related to PMCF: general and specific methods and procedures

> This section outlines post-market activities for PMCF, detailing general and specific methods/procedures related to the product's scope. It also covers the purpose of each activity, the rationale behind chosen methods, and anticipated limitations. Activity timelines are to be defined quarterly or yearly.
>
> Examples of PMCF activities include:

1. **Manufacturer Device Registry:** Specific to the device type or medical device group, include a brief plan description, specifying quality and quantity data based on device risk.
2. **PMCF Studies:** Details study plans, encompassing design, sample size, endpoints, and inclusion/exclusion criteria.
3. **Surveys:** Describes planned surveys for collecting information on the use of the medical device.

The overarching aim is to streamline post-market activities, ensuring comprehensive data collection, analysis, and validation.

1.1 General methods and procedures

According to the MDR, Annex XIV, 6.2 The PMCF plan shall include at least:

(a) the general methods and procedures of the PMCF to be applied, such as gathering of clinical experience gained, feedback from users, screening of scientific literature and of other sources of clinical data;

Below are two examples provided:

Method 1	<Literature Review>
Description:	<Literature search as defined in the search protocol of the CER>
Search period:	<Beginning from last update of CER until Month/Year>
Objective:	<Confirming the findings of the initial Clinical Evaluation Report and identifying new potential benefits and risks>
Search Strategy:	<Copy paste your search strategy from the CER here>
Rationale and known limitations of the activity:	<Address device risk, the novelty of the product and/or of the clinical procedure, the sufficiency of clinical data in the CER & the objective of this method>

Method 2	<Feedback from users or patients>
Description:	<Describe the survey>
Search period:	<State the survey periode here>
Objective:	<Describe the objective of your survey>
Additional information	<Countries, sponsor, survey sides. . . >
Rationale and known limitations of the activity:	<Address device risk, the novelty of the product and/or of the clinical procedure, the sufficiency of clinical data in the CER & the objective of this method>

1.2 Specific methods and procedures

> According to the MDR, Annex XIV, 6.2 The PMCF plan shall include at least: (b) the specific methods and procedures of PMCF to be applied, such as evaluation of suitable registers or PMCF studies;

Method 3	<PMCF Study>
Description:	<Describe the study>
Search period:	<State the study periode here>
Objective:	<Describe the objective of your study>
Additional information	<Countries, sponsor, survey sides. . . >
Rationale and known limitations of the activity:	<Address device risk, the novelty of the product and/or of the clinical procedure, the sufficiency of clinical data in the CER & the objective of this method>

Method 4	<Device registry>
Description:	<Database search as defined in the CER>
Search period:	<Beginning from last update of CER until Month/Year>
Objective:	<Confirming the findings of the initial Clinical Evaluation Report and identifying new potential benefits and risks>
Search Strategy:	<Copy paste your search strategy from the CER here>
Rationale and known limitations of the activity:	<Address device risk, the novelty of the product and/or of the clinical procedure, the sufficiency of clinical data in the CER & the objective of this method>

2. Reference to the relevant parts of the technical documentation

> In this segment, the manufacturer must incorporate citations to pertinent details from both the clinical evaluation report and the risk management file. These references are subject to analysis, follow-up, and assessment within this plan. Alternatively, the manufacturer must explicitly declare if there is no relevant information from the clinical evaluation report and/or the risk management file that requires consideration in this plan.

2.1 Clinical Evaluation Report (date and version)

Relevant information to be further analysed and monitored:

- <Describe what needs to be analysed>

Example: The clinical data gathered and evaluated as a result of this PMCF plan will be used to update and verify the chapters 11.6 (literature summary and conclusion), 12 (clinical experience data), 13 (risk-benefit assessment) and the conclusion of the CER. The literature will furthermore be searched for similar devices with a focus on associated risks and the state of the art.

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

2.2 Risk Management File (date and version)

Relevant information to be further analysed and monitored:

- <Describe what needs to be analysed>

  Example: Clinical data will be used to ensure the ongoing appropriateness of identified hazards, hazardous situations, harms, their frequency and severity estimations in the risk assessment & risk control. Furthermore, the data including information on similar devices shall be evaluated to identify potential emerging risks in the risk assessment & risk control.

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

3. Evaluation of clinical data relating to equivalent or similar devices

In this section, the manufacturer is required to compile information on equivalent or similar devices, the clinical data of which will be subsequently assessed and presented in the PMCF report. It is important to highlight that PMCF data, aimed at demonstrating ongoing safety and performance, should primarily originate from the specific device under evaluation. While data from equivalent or similar devices may be utilized—for instance, to update information on the state of the art or to identify and further evaluate relevant safety outcomes—the selected devices must remain consistent throughout the technical documentation. It is essential to specify whether the chosen device is confirmed to be equivalent or is categorized as a similar device. Each listed device should include a clear reference to the relevant sections of the Clinical Evaluation Report (CER).

The following equivalent or similar devices have been chosen and the clinical data will subsequently assessed:

Parameter	Equivalent / similar device 1	Equivalent / similar device 2
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)		

4. PMCF evaluation report

The findings of the PMCF will be summarized in the PMCF Evaluation Report that is part of the clinical evaluation report and the technical documentation.
