Post-Market Clinical Follow-Up Report (PMCFR)

This template is used to document the results of all post-market-clinical-follow-up activities conducted for the <name of the medical device>.

> Note:
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> According to the MDR, Annex XIV, Part B (7), the manufacturer shall analyse the findings of the PMCF and document the results in a PMCF evaluation report that shall be part of the clinical evaluation report and the technical documentation.
>
> This means that you can decide to use this template or alternatively you can enter the results of the PMCF activities directly into the CER.

Product information

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

Context

> For your orientation, here is guidance documents that may further help you to fill out the template:
>
> - MDCG 2020-8 Post-market clinical follow-up (PMCF) Report Template: A guide for manufacturers and notified bodies

The post-market clinical follow-up report (PMCFR) is compiled at the end of a surveillance interval as specified in the post-market clinical follow-up plan (PMCFP) and serves as input for the next update of the clinical evaluation. Following Annex XIV MDR, the PMCF is conducted 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

In this section the manufacturer shall report all the activities described in the PMCF plan which have been performed, all the collected clinical data obtained from those completed activities, as well as any justification of deviations from the plan.

The discussion shall include the analysis of the findings, whether positive or negative and also the potential impact on the different documents (clinical evaluation report, risk management file, SSCP, etc. . .) initially reviewed during the conformity assessment.

It is expected for each activity performed, a description in different subsections, related to the type of activities (device registry, PMCF studies, real world evidence, surveys about the use of device, etc. . .), and for each subsection, a description about the quality of data collected

1.1 General methods and procedures

Summarize the PMCF activities that have been described in the PMCF plan in section 1.1

1.2 Specific methods and procedures

Summarize the PMCF activities that have been described in the PMCF plan in section 1.2

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

In this section the manufacturer shall report all the clinical data collected relating to an equivalent device or selected similar device(s), provide an analysis and conclusions, and whether changes of the state of the art, or newly identified hazards would have an impact on the devices benefit-risk determination, the clinical evaluation and/or the PMCF plan.

Product name of equivalent / similardevice	**Results discussed**	**References used to get the results (publications, part of technical documentation from this equivalent / similar device)**

3. Impact of the results on the technical documentation

In this section, the manufacturer shall discuss the aggregate results coming from each PMCF activity planned and performed, described in section C, but also results coming from equivalent and/or similar device, described in section D, which are considered to impact the technical documentation and at least the following documents shall be considered:

3.1 Clinical evaluation report - CER (date and version)

- No relevant information from the clinical evaluation report have been considered.

If applicable, it is expected from the manufacturer to describe why some information that might have an impact on the CER have not been considered.

Relevant information analyzed and monitored:

- Add information here

Analysis of the outcome is to be reported in the updated clinical evaluation report.

3. 2. Risk management file (date and version)

- No relevant information from the risk management file have been considered

If applicable, it is expected from the manufacturer to describe why some information that might have an impact on the risk management file have not been considered.

Relevant information analyzed and monitored:

- Add information here

4. Conclusions

In this section, it is expected that the manufacturer shall provide an overall conclusion of the findings and relate them to the aims of the PMCF plan. The conclusions shall be taken into account in the following clinical evaluation and in the risk management. Finally, this conclusion shall highlight if any need for preventive and/or corrective measures has been identified. The conclusion may also give input to the next PMCF plan.

5. Update of Post-Market Clinical Follow-Up

Describe implications for PMCF activities in the next surveillance interval.