MDCG 2020-8

Post-market clinical follow-up (PMCF) Evaluation Report Template

A guide for manufacturers and notified bodies

April 2020

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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 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 PMCF plan and its evaluation report, necessary to its implementation.

The manufacturer shall analyse the findings coming from the activities foreseen in the PMCF plan and document the results in this PMCF evaluation report that shall be part of the clinical evaluation report and the technical documentation.

The conclusions of the PMCF evaluation report shall be taken into account to update eventually the clinical evaluation, the risk management documentation, the post market surveillance plan and the SSCP, if applicable.

The purpose of the present templates is to guide manufacturers in complying with the requirements of the MDR with respect to the compilation of the PMCF evaluation report. 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 organized format.

Post-market clinical follow-up evaluation report Template

Post-market clinical follow- up (PMCF) plan corresponding to the present evaluation report
PMCF plan number and version:

Post-market clinical follow- up (PMCF) Evaluation Report			
PMCF report number:			
PMCF report date:			
PMCF report 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. Medical Device description and specification
Refer to section B from PMCF plan, if there are no changes. **If there are changes from PMCF plan, please fill in the different requested fields highlighting those changes.**
Product or trade name:
Model and type:
General description of the device:

Intended purpose[1]
Intended users
Basic UDI-DI:
Intended patient population:
Medical condition(s)[2]:
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)[3]:
Class:
Classification rule:
Expected lifetime[4]
Novel product ☐ yes ☐ no
Novel related clinical procedure: ☐ yes ☐ no
Explanation of any novel features:

[1] 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)).
[2] 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.

[4] 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.

Section C. Activities undertaken related to PMCF: results

In this section the manufacturer shall report all the activities described in section C of 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.[5]

Section D. 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 / similar device	Results discussed	References used to get the results (publications, part of technical documentation from this equivalent / similar device)

Section E. Impact of the results on the technical documentation

[5] For the analysis and assessment of the clinical data collected, some parts of section 9.3.1 from Meddev 2.7/1 rev.4 could be used to assess the quality of data.

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:

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 manufacturer to describe why some information that might have an impact on the CER have not been considered.

Relevant information analyzed and monitored:
-
-

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

2. Risk management file (date and version)

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

If applicable, it is expected from 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:

-
-
-

Analysis outcome to be reported in the risk management file updated:
-
-

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

In this section the manufacturer should point out whether the collected clinical data related the device in question still confirm adherence to applied common specifications and/or applied harmonized standards, and/or guidances listed in the PMCF plan.

Common Specification(s) applied
(Title, date and version)

Harmonised standard(s) applied
(Title, date and version)

Guidance(s) followed
(Title, date and version)

Section G. 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.