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 medical device.

Product

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Version</th>
</tr>
</thead>
<tbody>
<tr>
<td>(your product name)</td>
<td>(version)</td>
</tr>
</tbody>
</table>

Context

For your orientation, here is some guidance documents that may further help you to fill out the template: MEDDEV Guidance 2.7/1 Rev. 4 on Clinical Evaluation MEDDEV Guidance 2.12/2 Rev. 2 on Post-Market Clinical Follow-Up

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.

PMCF Objectives

In this section, basically copy/paste the objectives from your PMCFP.

PMCF Methods

In this section, basically copy/paste the methods from your PMFCP.

Analysis of Clinical Data

Provide a list of your PMCF activity results. Ideally, divide it into sub-sections per actions taken and conclude if your objectives have been met.
Implications for Clinical Evaluation

Discuss if, based on the clinical data you gathered, your device delivered the anticipated benefits and fulfills the performance characteristics you claimed. For orientation: this refers to the ‘References’ section in your PMCFP.

Implications for Risk Management

Discuss if any new risks were identified or if deviations were observed regarding the assumed probability and severity of existing risks. Outline any risk mitigation measures that should be taken or revised.

<table>
<thead>
<tr>
<th>Risk Measures</th>
<th>Responsible Role</th>
<th>Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

PMCF Summary

Highlight the most relevant results and conclusions from your PMCF activities. For example: does the clinical data suggest that the overall benefit-risk-profile of your product should be updated? If things look worse than before, why can it be assumed that your product is still safe?

Update of Post-Market Clinical Follow-Up

Describe implications for PMCF activities in the next surveillance interval.

Template Copyright openregulatory.com. See template license.

Please don’t remove this notice even if you’ve modified contents of this template.