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MDR: Product Lifecycle Reporting

The MDR defines new responsibilities for medical device manufacturers such as a regular preparation of plans and reports. Some updates follow a fixed schedule, others need to be integrated in this cycle reasonably. The graphic shows the plans and reports in a logical sequence. This makes it easier to identify interdependencies. The collection of clinical data must be planned already during product development. After approval you are in a continuous process of preparing plans and reports throughout the entire product lifecycle.

To comply with all requirements and be able to provide all documents in a timely manner, the individual stages need to be aligned carefully.

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Explanation of the phases

1 CDP - Clinical Development Plan

The clinical development plan defines how you will collect sufficient clinical data for later clinical evaluation. This may include exploratory investigations, first-in-man studies, feasibility and pilot studies, to confirmatory investigations; an outlook for possible PMCF activities is also possible at this stage.

2 CEP - Clinical Evaluation Plan

The clinical evaluation plan defines the scope of the clinical evidence. Available pre- and clinical data, remaining residual risks, newly identified risks (from PMS/PMCF/complaints) as well as all other claims (also from marketing) are considered. Afterwards, clinically relevant questions as well as open questions from risk management are derived. Finally, the search strategy is defined (sources, search terms, selection and evaluation criteria) that is to be applied for the clinical evaluation.

3 CER - Clinical Evaluation Report

The clinical evaluation report represents the results of the clinical evaluation. At this stage, clinical data is collected, selected, evaluated, and analyzed from the device or devices for which it has been demonstrated that they are equivalent to the device. It is checked whether the device meets the requirements for safety, performance, undesired side effects and the benefit-risk ratio defined by the MDR. Furthermore, currently available alternative treatment options also have to be taken into consideration.

4 PMS Plan / PMCF Plan

In the PMS plan the manufacturer defines how the device will be monitored after the market launch and which data is to be collected. Product-specific planning of activities needs to take into account the findings from the clinical evaluation and the device's risk potential. Furthermore, the methodologies for analyzing the data and the criteria for the analysis are defined. The manufacturer is responsible for collecting the data on the market proactively.

Post-market clinical follow-up (PMCF) is part of PMS. PMCF is to close the gaps that could not be answered in the scope of the clinical evaluation (e.g. long-term behavior, monitoring of side effects and contra indications). The PMCF plan describes methodologies and procedures for the proactive collection and evaluation of clinical data. The extent may vary considerably depending on the PMCF activities. Therefore, a PMCF master plan may well be established at this point that refers to different PMCF plans defining the individual activities.

5 SSCP - Summary of Safety and Clinical Performance

An SSCP report must be prepared only by manufacturers of class III and implantable devices. The report is referenced in the user manual or the label and is made publicly available via EUDAMED. The report must be written in such manner as to be comprehensible for laypersons. The purpose of the short report is to introduce the device in the context of its application and explain alternative therapeutic or diagnostic options as well as residual risks and undesirable effects. Prior to publication, the report is validated by the notified body, which will then upload the report to EUDAMED. Content and format of the representation may be defined by the commission.

6 Proactive PMS: Vigilance Report, PMCF Report, Trends

The proactive PMS phase is where you conduct your PMCF activities and collect and evaluate market data. The strategies you defined in the PMS plan have to ensure that reportable events such as vigilance cases and trends may be identified and reported in a timely manner.

Vigilance: Describes the reporting of serious incidents and field safety corrective actions to the authority. For this purpose, every manufacturer needs an appropriate system in which it is ensured that the evaluation and analysis of such events is enabled and that the deadlines for reporting them may be adhered to. Reporting is carried out via EUDAMED.

PMCF: The results of PMCF activities are documented and analyzed in one or several PMCF reports. The extent of analysis may vary considerably depending on the PMCF activity. The conclusions of the PMCF report must be taken into account for the PSUR/PMS report and furthermore for the clinical evaluation and risk management.

Trends: Statistically significant increases in the frequency or severity of non-serious incidents or expected undesirable side effects must be reported to the responsible authority provided they affect the benefit-risk ratio. By comparing your observations to the expectations from risk analysis, you will arrive at a conclusion whether an increase is significant. The PMS plan must define a methodology how to identify trends reliably. In addition, the observation period has to be defined.

7 PMS Report / PSUR

A PMS Report is created for class I devices and includes a summary of the results from market data collected over the last observation period. Based on these results, a conclusion is derived that is passed on to clinical evaluation. Furthermore, corrective and preventive actions are defined and explained. The purpose of the PMS report is to gain insights into the behavior of the device on the market across the entire product life cycle. These may then be used for further product development as well as for ensuring the device's safety. That way it may be ensured that the device complies with the requirements of the regulation at any time.

A PSUR is prepared for class IIa, IIb, and III products. Like the PMS report, it includes a summary of the results from market data collected over the last observation period. Based on these results, a conclusion is derived that is passed on to clinical evaluation. Furthermore, corrective and preventive actions are defined and explained.
In addition to the topics of the PMS report, the PSUR also includes the conclusions from the benefit-risk assessment, the most important results from PMCF, and the total number of units sold as well as other information on frequencies, e.g. on application.
The purpose of the PSUR is to gain insights into the behavior of the device across the entire product life cycle. These may then be used for further product development as well as for ensuring the device's safety. That way it may be ensured that the device complies with the requirements of the regulation at any time.