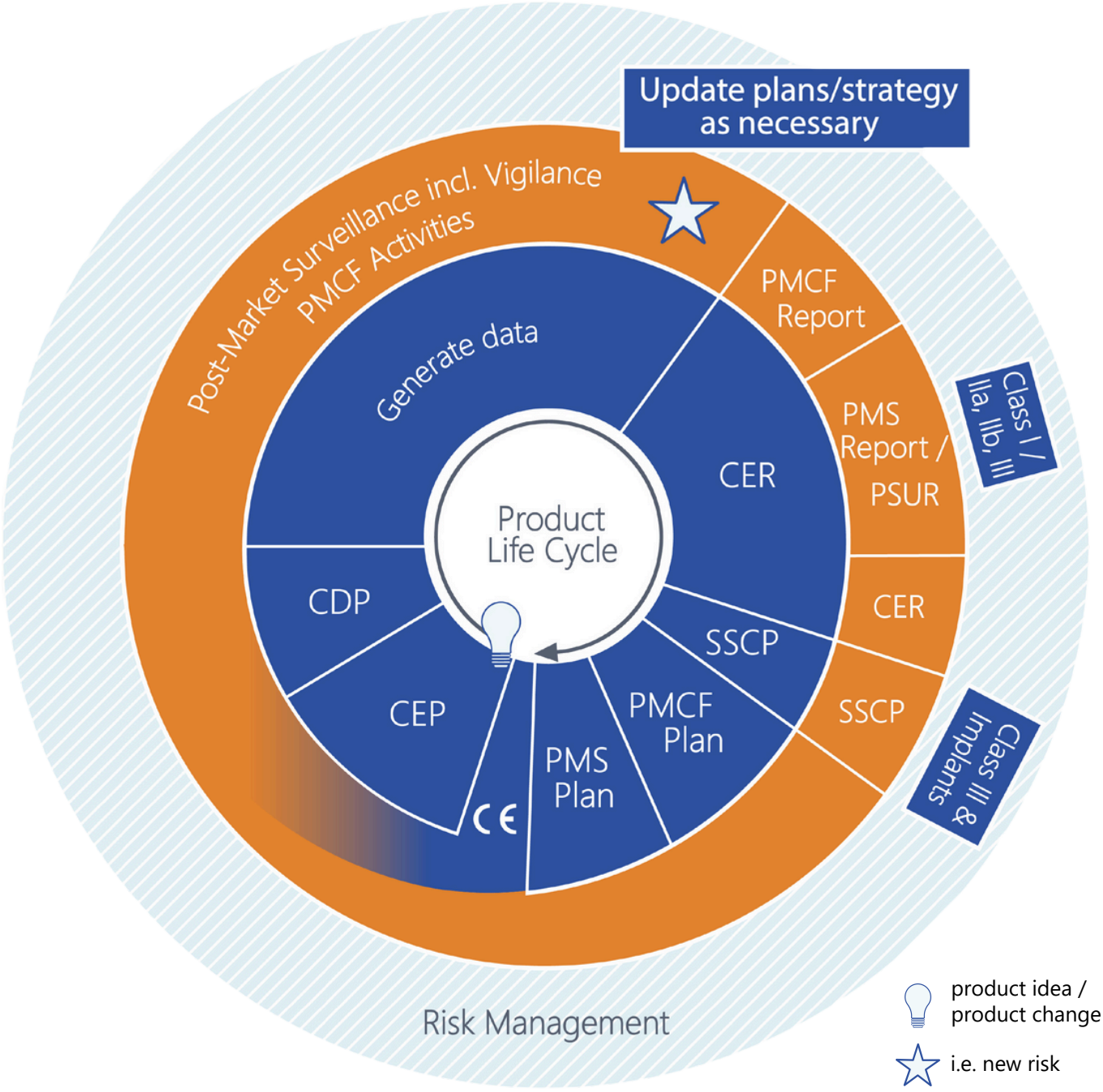
MDR: Product Lifecycle Reporting

The MDR defines a multitude of responsibilities for medical device manufacturers, such as the regular preparation of plans and reports throughout the entire product life cycle. Some updates follow a fixed schedule, while others must be sensibly integrated into this cycle. The diagram shows the plans and reports in a logical sequence. This makes it easier to identify interdependencies. The collection of clinical data must already be planned during product development. After obtaining CE marking, you are in a continuous process of writing reports and adapting plans throughout the product life cycle.

In order to meet all requirements and prepare all documents on time, every step must be carefully coordinated. Metecon supports you in both strategic planning and effective implementation.



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Explanations of the plans and reports

CEP - Clinical Evaluation Plan

The CEP defines the scope of the clinical evidence. It defines the aspects of the intended purpose (and thus intended clinical performance and clinical benefit) and residual risks. The parameters required to assess the benefit-risk ratio are identified and all marketing claims must also be substantiated by appropriate data. The strategy (route) of the clinical evaluation is determined taking into account these aspects and parameters, preclinical and clinical data already availabe, the risk class, and possible equivalent products. Finally, the search strategy is defined, including at least a literature search (planning of sources, search terms, selection and appraisal criteria) and, where necessary, a clinical study. The CEP is updated if the necessary scope or route changes.

CDP - Clinical Development Plan

The CDP defines how you will generate the required clinical data. This may include exploratory studies, first-in-man studies, feasibility studies, and pilot studies up to proof-of-concept studies. An outlook on possible PMCF activities is also possible at this point. The CDP is updated when study objectives are changed or additional studies are added.

CER - Clinical Evaluation Report

The CER presents the results of the evaluation of all clinical data. Data from the product or from proven equivalent products are collected, selected, evaluated, and analyzed. It is examined if and to what extent the requirements for performance/benefit and safety (risks and undesirable side effects) are met and the acceptability of the resulting benefit-risk ratio is assessed. The CER also identifies the need for the collection of futher clinical data as part of PMCF. It is continuously updated with PMCF data to asses continued conformity with the GSPRs.

PMCF Plan - Post-market clinical follow-up Plan

PMCF is formally part of PMS and is intended to extend the clinical evidence on the product over its entire life cycle. PMCF also answers open questions that could previously only be estimated as part of the clinical evaluation (e.g. long-term behavior, monitoring of side effects and contraindications). The PMCF plan describes the methods and procedures for the proactive collection or generation of clinical data. The scope may vary depending on the PMCF activities required and a PMCF master plan may be created which refers to various other plans defining the individual activities. The PMCF plan is updated when necessary, such as when the need for a change is identified in the PMCF report or when the CER has identified changed or additional PMCF requirements.

PMS Plan

In the PMS Plan, the manufacturer defines how the device is to be monitored after it has been placed on the market, including the data to be collected. In the device-specific planning of these activities, the characteristics and associated risks of the device and the findings from the CER must be taken into account. Furthermore, the methods used to evaluate the data and the evaluation criteria are defined. Data collection on the market must be carried out proactively. The PMS plan must be updated if there are new aspects to be considered (e.g. a new clinical benefit), if opportunities for improvement are identified, or if there is a change in the devices. It must also be updated when new data sets become available that should be included in PMS.

PMS (including Vigilance) and PMCF Activities

When planning proactive PMS activities, it is important to consider which activities are to be carried out as PMCF activities, as not every proactive activity conducted as part of the PMS will meet the criteria for PMCF. Typical proactive PMS or PMCF datasets are searches of the scientific literature and published reports on the clinical experience of either your own device or equivalent devices. Information regarding similar devices is also collected as part of an adverse evet or FSCA database search. User surveys can be conducted as either a proactive PMS or a PMCF activity, depending on the survey objective.

Reactive datasets (part of PMS) may include, for example, serious incidents, FSCAs, and trend reports. Information and events are evaluated as soon as they are received, and the corresponding follow-up measures are initiated immediately. In this context, vigilance describes the reporting of serious incidents and FSCAs to the authority. For this purpose, every manufacturer needs an appropriate system in which the evaluation and analysis of such events as well as their timely reporting is ensured. Reporting is carried out via EUDAMED.

PMCF Report

The clinical data and, if applicable, interim results from PMCF activities are summarized and presented in the PMCF report. Data are checked for confirmation of clinical evaluation and the activities for their effectiveness. The PMCF report can also decide on follow-up actions. It is updated regularly, following the data collection periods as set in PMS.

PMS Report and Periodic Safety Update Report (PSUR)

A PMS Report is created for Class I devices and includes a summary of the results from PMS data (including PMCF data) obtained during the data collection period. Based on these results, a conclusion is drawn, which is then input, for example, to the clinical evaluation. Additionally, CAPAs are outlined and justified.

A PSUR is prepared for Class IIa, IIb, and III products and, like the PMS report, contains a summary of the results from market data obtained during the most recent data collection period. Based on these results, a conclusion is drawn which is input for the clinical evaluation, and CAPAs are presented and justified. In addition to the topics included in the PMS report, the PSUR also contains the conclusions from the benefit-risk assessment, the main findings from PMCF, and the volume of sales of the device, as well as further information, e.g. on the frequency of use.

The purpose of both the PMS report and the PSUR is to gain insights into the safety and performance of the device on the market over its entire life cycle, which can be used for further product development and to ensure product safety at all times. The PMS report is prepared as required and should be updated shortly before each update to the clinical evaluation. The PSUR is updated regularly (also for legacy devices) as defined by the device's risk class.

SSCP - Summary of Safety and Clinical Performance

The SSCP report must be prepared for Class III and implantable devices. The purpose of the short report is to present the device in the context of its use, to explain residual risks and any undesirable effects, warnings, and precautions, and to present alternative options with regard to therapy and diagnosis. The SSCP will be referenced in the instructions for use or labeling and will be made available to the public via EUDAMED. It must be written in such a way that it can also be understood by laypersons, if they are the intended users. The SSCP is updated annually.

Our experienced clinical affairs and PMS experts provide you with solution-focused support. Get in touch with us!

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