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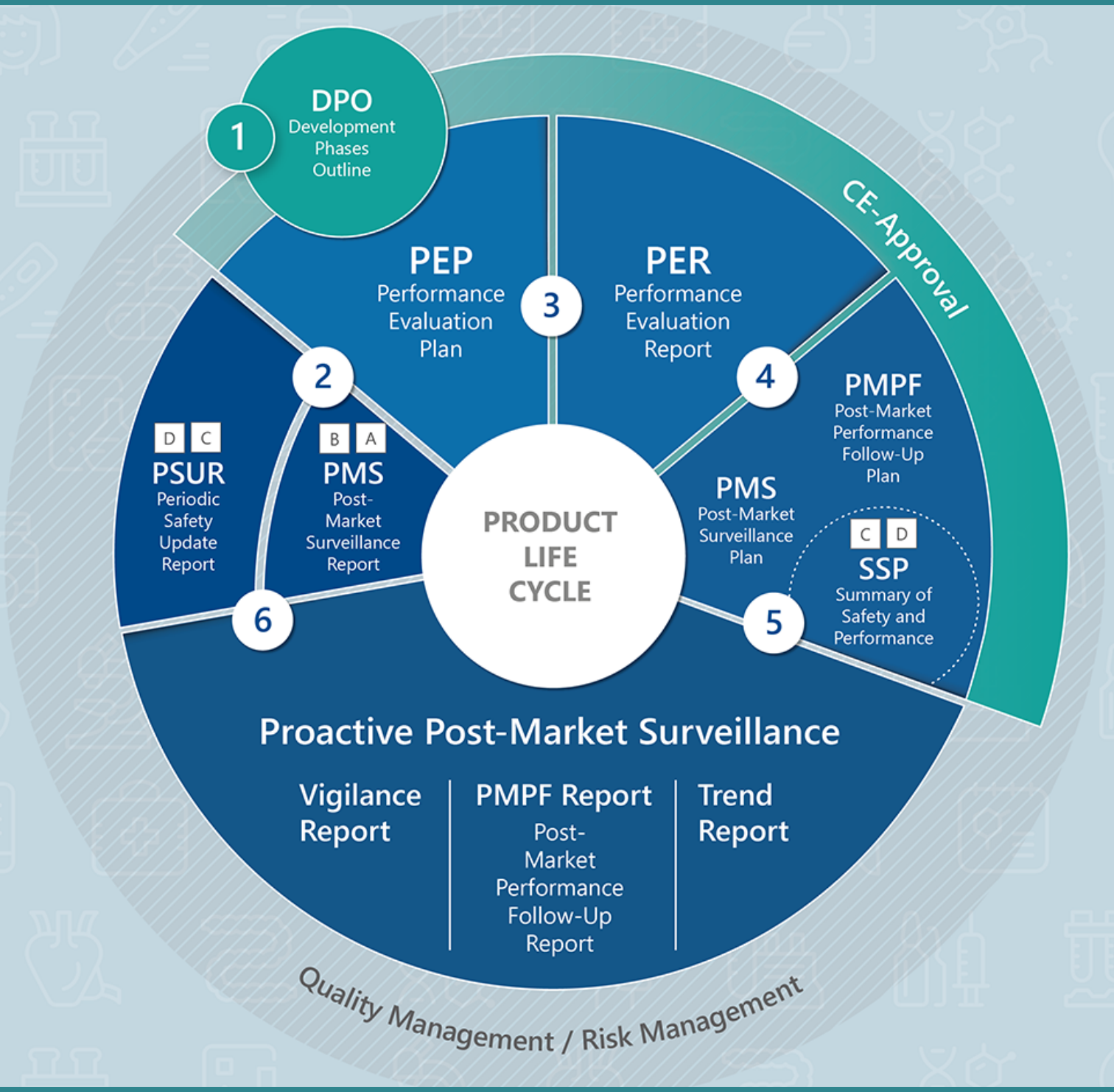
IVDR: Product Lifecycle Reporting

The IVDR defines new responsibilities for you as an IVD medical device manufacturer such as the 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.



Metecon GmbH Q7 21 68161 Mannheim T: +49 621 123469-00 info@metecon.de www.metecon.de

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Explanation of the phases

1 DPO (Development Phases Outline)

At the beginning of the development process, 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 PEP (Performance Evaluation Plan)

Prior to conducting the clinical evaluation, 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 PER (Performance 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. Finally, the need for further clinical data is discussed (PMCF activities) and passed on to PMS.

4 PMS Plan/PMPF Plan/SSP

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 Proactive PMS: Vigilance Report, PMPF Report, Trends

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 PSUR/PMS Report

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.

Good luck with Product Lifecycle Reporting!

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