Post-Market Surveillance Plan

This plan describes product-specific post-market surveillance activities. The general process of how to do post-market surveillance is described in SOP Post-Market Surveillance. Its outputs are saved to the Post-Market Surveillance Report or the Periodic Safety Update Report.

Regulatory References:

EU Regulation 2017/745 (MDR)	Art. 84 and Annex III, Para. 1.1

Product

Product Name	Version	Surveillance Period
<your product name>	*<version>*	*<e.g. 10/2020-10/2021>*

1. General Considerations

> Note: Whatever kind of post-market surveillance activities you define for your product, make sure to map at minimum all of these actions required by the MDR to one activity in section 2 below.

According to Annex III section 1.1 (b) MDR, the post-market surveillance plan shall cover:

MDR Requirement	Activity
A proactive and systematic process to collect any information referred to in point (a). The process shall allow a correct characterization of the performance of the devices and shall also allow a comparison to be made between the device and similar products available on the market	SOP Post-Market Surveillance
Effective and appropriate methods and processes to assess the collected data;	SOP Post-Market Surveillance
Suitable indicators and threshold values that shall be used in the continuous reassessment of the benefit-risk analysis and of the risk management as referred to in Section 3 of Annex I;	PMS Plan - Trend Identification & Reporting
Effective and appropriate methods and tools to investigate complaints and analyze market-related experience collected in the field;	SOP Feedback Management

MDR Requirement	Activity
Methods and protocols to manage the events subject to the trend report as provided for in Article 88, including the methods and protocols to be used to establish any statistically significant increase in the frequency or severity of incidents as well as the observation period;	PMS Plan - Trend Identification & Reporting
Methods and protocols to communicate effectively with competent authorities, notified bodies, economic operators and users;	SOP Vigilance
Reference to procedures to fulfill the manufacturers obligations laid down in Articles 83, 84 and 86;	SOP Post-Market Surveillance
Systematic procedures to identify and initiate appropriate measures including corrective actions;	SOP CAPA
Effective tools to trace and identify devices for which corrective actions might be necessary;	SOP Product Certification and Registration
A PMCF plan as referred to in Part B of Annex XIV, or a justification as to why a PMCF is not applicable.	SOP Clinical Evaluation

2. Data Collection Activities

PMS activity	Responsibility	When?	Documented in?
Incident documentation and analysis of undesirable side effects	QMO	Annually	PMS Report / PSUR
Assess feedback (customer complaints, sales feedback)	Head of Product	Annually	PMS Report / PSUR
Check SOUP for new published issues	Head of Software Development	Biannually	PMS Report / PSUR

PMS activity	Responsibility	When?	Documented in
Research data about similar products in the market	QMO	Annually	PMS Report / PSUR
Conduct post-market clinical follow-up activities as planned	Head of Medical Team	Annually	PMCF Evaluation Report / CER
Research scientific publications	Head of Product	Annually	PMCF Evaluation Report / CER
Research updates of standards and legislation	QMO	Annually	PMS Report / PSUR
Analyze trends, decide on necessary measures and implement them	QMO	Annually	PMS Report / PSUR
Update risk management file	QMO	Annually	Risk Management Report / PMS Report / PSUR
Compile post-market clinical follow-up report	Head of Medical Team	Annually	PMCF Evaluation Report / CER
Compile Periodic Safety Update Report	Head of Product	Annually	PMCF Evaluation Report / CER
Upload PSUR to Eudamed database	QMO	Annually	N/A
Compile post-market surveillance plan and post-market clinical follow-up plan for next surveillance interval	QMO	Annually	PMS & PMCF Plan

PMS activity	Responsibility	When?	Documented in
Volume of sales, an estimate evaluation of the size and other characteristics of the population (such as profession) using the device and, where practicable, the usage frequency of the device, volume of sales by country	QMO	Annually	PMS Report / PSUR

3. Methods and Procedures

Include mandatory data sources in the PMS plan for each product, with additional methods based on risk class and product type. Justify any non-applicability.

3.1 Feedback

Serious Incidents and FSCA

The insert report type, e.g. PMS Report or PSUR will summarize the number of reported serious incidents, their investigation results and any taken subsequent measures.

Non-serious Incidents and Expected Undesirable Side-Effects

The PMS Report or PSUR will summarize the evaluation results and conclusions, including any taken preventive or corrective actions.

Proactively gathered Feedback

Proactively collect feedback from distributors, users, and importers, including inputs not considered in previous sections. This encompasses feedback on usability, both positive and regarding issues, gathered through client visits, conferences, and events. General market feedback will also be actively obtained during client visits, conferences, fairs, and specified events. Specify objectives, acceptance criteria, and responsible persons for these activities. The aim is to identify new risks, verify existing ones, and assess benefits and use-related aspects of the medical device. Evaluate and summarize the gathered information. If potential serious incidents arise, follow the SOP Vigilance. The PMS Report or PSURwill summarize the results.

3.2 Trend Identification and Reporting

According to the MDR, Article 88 non-serious incidents and expected undesirable side-effects are subject to trend analysis. Statistically significant increases in the frequency or severity will be reported. There are three types of changes that can be indicated by a trend analysis:

- a sudden significant deviation like an outlier or spike, respectively;
- significant trends, i.e. repetitive deviations or continuous drifting away from the history of earlier values;
- detection by visual inspection, whether the data are subject to cyclic effects, e.g. of calendar events like summer holidays or end of budget periods.

All incidents deemed non-serious and anticipated undesirable side-effects will undergo meticulous documentation and categorization, encompassing occurrences such as the arrival of a non-sterile device or a software crash. This process is crucial for maintaining a standardized approach, ensuring comparability across different incidents. To achieve this, normalization will be applied, factoring in the respective sales numbers or the number of installed devices per month.

The data obtained will be graphically represented for each incident category, portraying the number of normalized incidents against the corresponding month. This visualization serves to illuminate the temporal progression of these incidents over time, facilitating a comprehensive understanding of trends and patterns. Adhering to the guidelines outlined in ISO/TR 20416 for Medical Devices - PMS for manufacturers, Rule 3 of the Nelson Rules will be employed to detect trends. A trend is detected, where six or more points in a row exhibit a continuous upward trajectory. In addition, long term trends are detected by visual inspection and review of the plotted incidents. If a trend is detected, a CAPA will be opened to investigate the incidents.

3.3. Databases and Registers

> Specify applicable literature databases, e.g. PubMed, Embase, COCHRANE, etc. for the gathering of clinical data. If you have a separate PMCF plan which already contains the literature search as one of the planned PMCF activities, you may provide a brief statement that there is a search strategy for literature in the PMCF plan.

SOUP Incident Reports

Check device SOUP list and research incident reports from last 12 months.

Technical, Specialist & Regulatory Information

Applicable literature are product standards and guidelines as documented in the checklist of General Safety and Performance Requirements according to Annex I of Regulation (EU) 2017/745. These serve to determine the current state of the art and possible technical improvements and will be monitored on a yearly basis for changes and renewals. Furthermore, the Medical Device Coordination Group (MDCG) publications (guidance documents) will be reviewed with regards to guidance on interpretation of process- or product-relevant interpretations of regulatory requirements in the Regulation (EU) 2017/745. The < PMS Report or PSUR> will summarize the results.

Other Publicly Available Information about Similar Medical Devices

Identify the databases to be utilized for investigating incidents and recalls related to comparable devices (e.g., through MAUDE, BfArM, MHRA). Clearly outline the similar devices and establish appropriate search and evaluation criteria. A sample approach is provided below:

Database	BfArM
Criteria:	Safety Information (Safety warnings, alerts and recalls)
Timeframe:	January 1 – December 31 2020
Search terms:	E.g. Similar Device Name

3.4. PMCF

If PMCF is exempt, add a justification.

PMCF may only be exempt under one of the two following conditions:

The demonstration of conformity with general safety and performance requirements based on clinical data is not deemed appropriate, and adequate justification for the non-applicability of a clinical evaluation report has been given; or It is a product without an intended medical purpose (see Annex XVI of Regulation (EU) 2017/745).

Otherwise:

A PMCF plan has been developed for this device to consistently collect relevant clinical data, confirming the benefit-risk determination in the Risk Management Report and Clinical Evaluation Report. This includes assessing clinical safety, performance, any claims, and its alignment with the current state of the art. The specific PMCF activities are contingent on factors such as device innovation, the availability of adequate clinical data, inherent risks, and device type. These considerations have guided the planning of suitable PMCF methods.

4. Planned PMS Report/ Periodic Safety Update Report (PSUR)

Please state the month and year of the planned PMS report (for Class I devices)/ of the PSUR (for all other devices).
