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Post-Marketing Surveillance and Vigilance

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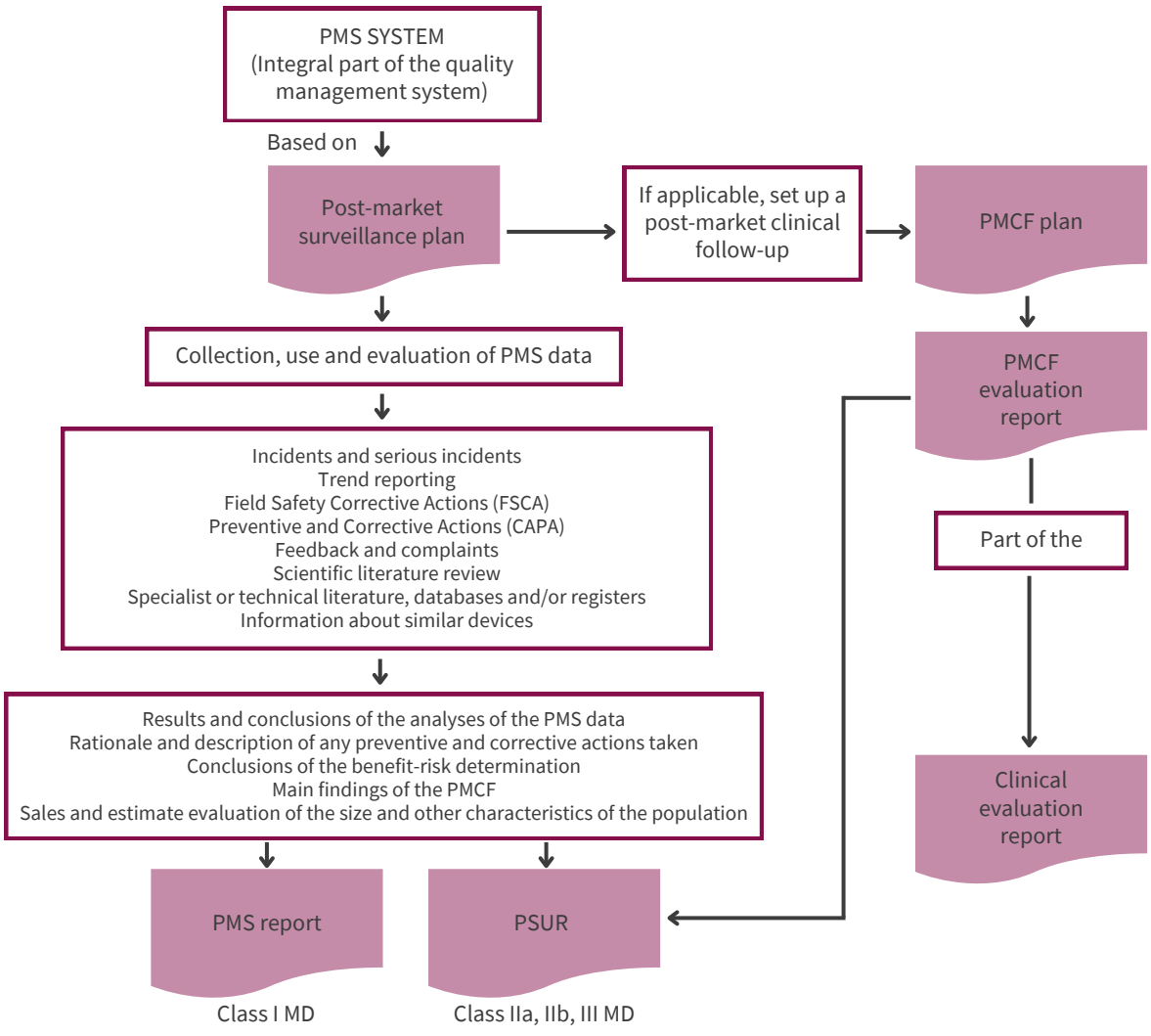
PMS purposes (art. 83)

Data gathered by the Post-Market Surveillance system are used:

1. to update the benefit-risk determination and improve the risk management
2. to update the design and manufacturing information, instructions for use and the labelling
3. to update the clinical evaluation
4. to update the summary of safety and clinical performance (SSCP), if applicable
5. to identify the needs for preventive or corrective action (CAPA) or field safety corrective action (FSCA)
6. to detect and report trends concerning non-serious incidents and undesirable side effects
7. to identify options to improve the usability, performance and safety of a device
8. to contribute to the post-market surveillance of other devices

PMS system overview (art. 83-86, Annex III and Annex XIV Part B)



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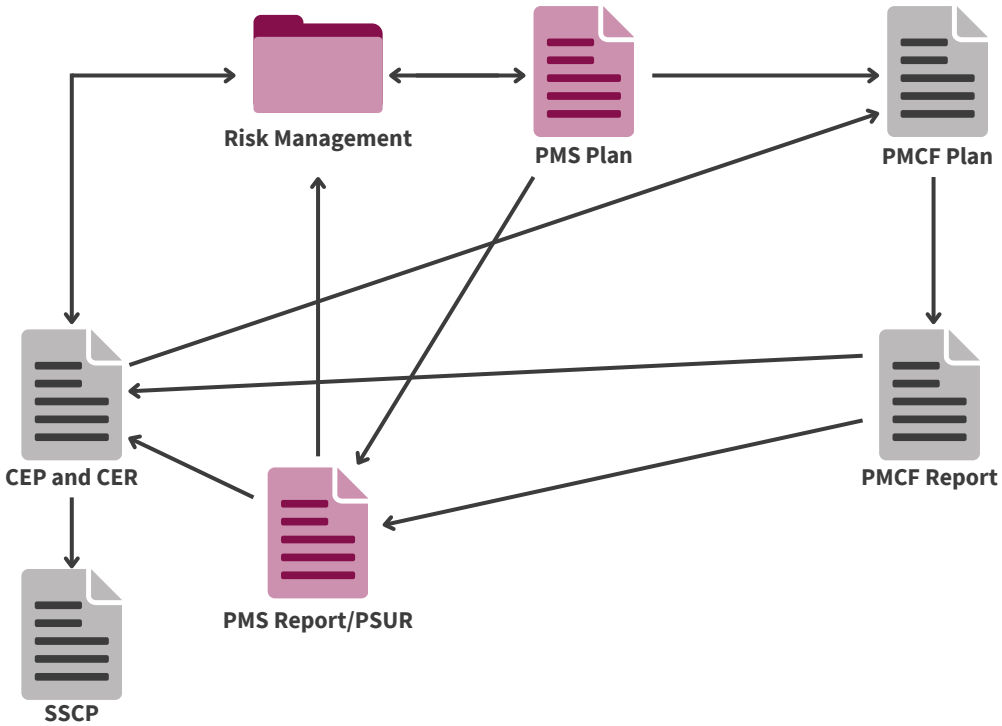
PMS maintenance updates

CLASSIFICATION	DOCUMENT	MINIMUM FREQUENCY
Class I	PMS Report	when necessary
Class IIa	PSUR	at least every 2 years
Class IIb	PSUR	at least every 1 year
Class III	PSUR	at least every 1 year

Synchronisation of PMS, Clinical Evaluation and Risk Management activities is essential.



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Serious incidents and Field Safety Corrective Actions (art. 87 and 89)

Manufacturers have the obligation to report any serious incidents or FSCA in respect of devices made available on the EU market.

Complaint Handling and Vigilance Reporting Process

Initial Assessment:

- **Device-Related Complaint:** Determine if the complaint is related to the device.
- **Type of Device Issue:** Check if it's a malfunction, information inadequacy, or undesirable side-effect.

Incident Criteria Assessment:

- **Incident Under Article 2(64) MDR:** Assess if the complaint meets the definition of an incident.
- **Serious Incident Under Article 2(65) MDR:** Determine if the incident is serious.

Reporting Requirements:

- **Non-serious Incidents:** Record in the QMS, no need to report to the competent authority.
- **Serious Incidents:** Report immediately once a causal relationship is established or is reasonably possible.

Reporting timelines:

- **Serious Public Health Threat:** Within 2 calendar days.
- **Any Serious Incident:** Within 15 calendar days.
- **Death or Serious Deterioration in Health:** Within 10 calendar days.

Periodic summary report (art. 87 (9)) is an alternative reporting regime agreed between the manufacturer and the national competent authorities to communicate similar incidents with the same product or type of product in a consolidated manner. Criteria for periodic summary reporting include situations where; the root cause has been identified, a FSCA has been implemented or where the serious incidents are common and well documented.

Trend reporting (art. 88)

Manufacturers shall report any statistically significant increase in the frequency or severity of incidents The manufacturer shall specify in the post-market surveillance plan:

- Incident management
- Methodology
- Observation period

The reporting of serious incidents, FSCA, FSN, PSR, PSUR and trend report must be carried out through EUDAMED once fully functional (art. 92).

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