Post-market surveillance for medical devices in the European Union

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What is post-market surveillance?

Post-market surveillance (PMS) is designed to monitor the performance of a marketed medical device by collecting and analyzing field use data. Article 10 of the EU MDR and IVDR requires all device manufacturers to have a Post-Market Surveillance System in place. The main elements of the PMS are laid out in Article 83, and additional details for lower-risk and higher-risk devices are covered in articles 84 and 85, respectively.

In general, a PMS system consists of both proactive activities and reactive, or vigilance, activities. While post-market surveillance and vigilance are sometimes used interchangeably, vigilance consists of separate activities that feed post-market surveillance programs.

Post-market surveillance systems are used to collect and analyze data not only about the manufacturer's device but also about related competitors' devices that are on the market. Data collected through PMS procedures is then used to identify trends that may lead to, among other things, quality improvements, updates to user training and instructions for use, and identification of manufacturing issues.

Note that "market surveillance" encompasses activities performed by a Competent Authority to verify MDR compliance, and should not be confused with the topic of this ebook, "post-market surveillance", which is performed by the manufacturer.

What classes of medical devices require post-market surveillance?

All medical devices marketed in the EU require some level of post-market surveillance, and all medical device manufacturers must implement a post-market surveillance system (PMS). The requirements of the PMS, however, vary and should be "proportionate to the risk class and appropriate for the type of device" (MDR Chapter VII). In particular, the type and frequency of reporting vary based on a device's risk class.

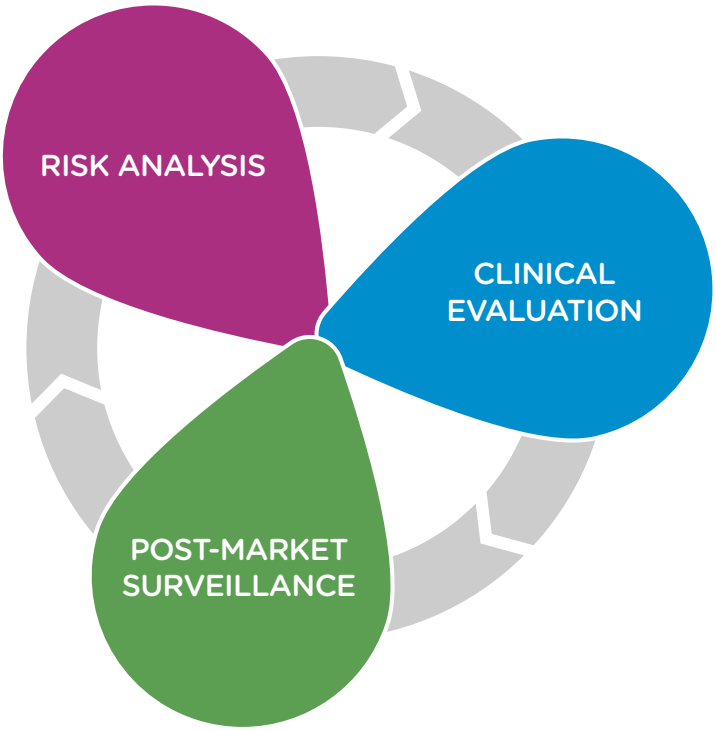
Components of a successful post-market surveillance plan

A post-market surveillance plan (PMS) is an integral part of a manufacturer's quality management system and provides a system for compiling and analyzing data that is relevant to product quality, performance, and safety throughout the entire lifetime of a device. The PMS should also provide methods for determining the need for and implementing any preventative and corrective actions.

A PMS system should include and define:

Surveillance data sources

With the increased focus on proactive risk identification in the MDR, it is important to design post-market surveillance systems that actively acquire knowledge and detect potential risks. It is not sufficient to rely solely on spontaneous reporting by healthcare providers, patients, and other stakeholders.



In addition to information coming from Clinical Evaluation Reports and complaint and adverse event reporting, typical sources of surveillance data include:

- **Social media networks**
  Because many of your stakeholders may be communicating on social media networks, it is important to employ social listening techniques and/or tools to identify issues and concerning trends as they develop.
- **Industry and academic literature**
  Any studies, academic papers, and other literature that addresses similar devices or the specific use cases for which your device is designed should be evaluated. In particular, risk factors and adverse events identified with similar devices should be closely examined. It is also important to identify newer technologies that may affect the benefit-risk ratio and establish a new definition of "state of the art" for the device type.
- **EUDAMED**
  While the European Database on Medical Devices (EUDAMED) is not yet fully functional, it is intended to provide a living picture of the lifecycle of all medical devices marketed in the EU. Manufacturers should take special care to consider information for similar devices made available through the EUDAMED system in the future.
- **Registries**
  Patient, disease, and device registries can provide information that informs the clinical evaluation process which provides input into the post-market surveillance system.

Data analysis methodology

A well-defined data analysis methodology will accurately identify trends and lead to defendable decisions in the application of post-market experience. Once the necessary information has been identified and collected, and potentially cleaned of incomplete or otherwise unusable data, the data needs to be analyzed.

The goal is to identify meaningful trends, correlations, variations, and patterns that can lead to improvements in the safety and efficacy of the device. There are many data analysis tools available that can assist with:

- **Regression analysis** that will identify correlations between data (e.g. the device location/geography correlates to battery life).
- **Data visualization** that can be useful in spotting trends in the data.
- **Predictive analytics**, which can be particularly useful with large data sets, to identify future trends based on historical data.
- **Data mining**, which is also normally used with large data sets, to organize data and identify data groups for further analysis.

Benefit-risk indicators and thresholds

The MDR requires that medical device manufacturers not only demonstrate the clinical benefit of their device but also quantify the benefit-risk ratio. The benefit of a device must be shown to clearly outweigh the risk for it to gain market approval. Article 2 (24) of the MDR defines the benefit-risk determination as "the analysis of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose when used in accordance with the intended purpose given by the manufacturer."

A PMS system should clearly define benefit-risk calculations and the data used to support them. Post-market surveillance activities are critical in order to re-evaluate and maintain the benefit-risk calculations and determinations of a device throughout its life. Information that is gained through a PMS system can lead to:

- Identification of new risk factors.
- Adjustments to risk frequency and/or severity values based on actual use data.
- Adjustments to established risk calculations based on new "state of the art" technologies becoming available.
- Adjustments to established benefit calculations based on actual use data.

Complaint and feedback handling processes

While complaint handling and other feedback tracking are more often described as part of post-market vigilance systems, they play a role in the more proactive post-market surveillance processes as well. A PMS system should define:

- The sources of market feedback, including complaint records.
- An evaluation of the value of the data in each data source.
- A description of how data will be used and evaluated.

Complaints and feedback, including adverse events, should serve as input into a post-market surveillance system. This data is especially useful when collected over a period of time long enough to identify trends and relationships between device issues and other data points (e.g. user age or geographic location).

Corrective Action procedures

Corrective and preventative action (CAPA) processes should be detailed within a company's quality management system, but will also be referred to in the post-market surveillance plan.

Corrective action plans define procedures for identifying issues that need to be addressed, often through field safety corrective actions (FSCA). An FSCA is designed to resolve an immediate issue, but will not necessarily identify the root cause or put in place preventative measures. A good CAPA plan will identify trends and potential issues that will be fed into the post-market surveillance system for further investigation and potential action to ensure a device's continuing safety and efficacy.

Device tracing methods

In order to fully evaluate the post-market performance of a device, and to be able to address issues with devices in the field, a manufacturer must be able to track and trace devices through the full product life cycle. The Unique Device Identifier (UDI), a requirement under the MDR, is the basis for product identification, but a PMS system must also include or reference the processes and procedures for the traceability of devices in the field.

Post-market clinical follow-up (PMCF) plan

A post-market clinical follow-up plan (PMCF) is used to confirm the real-world clinical performance and safety of a medical device. PMCF activities occur after a device receives a CE mark and are intended to supplement existing pre-market clinical and non-clinical trial data.

There is no guidance on the specific format of PMCF activities or output, but they often take the form of formal clinical studies. PMCF data may also come from available market feedback and curated studies or literature. See Annex XIV for additional information.

A PMCF plan must be designed to supplement pre-market clinical activities and address the full life cycle of the device.

PMS data requirements

In determining the data to be gathered by your PMS system, consider the risk profile of your device and establish the necessary data elements necessary to:

- Confirm the benefit-risk determination and improve risk management.
- Confirm the design and manufacturing information, instructions for use, and labeling.
- Support the clinical evaluation process.
- Confirm the summary of safety and clinical performance (where applicable by risk)
- Identify the need for preventative, corrective, or field safety corrective actions.
- Identify options for improving the usability, performance, and safety of the device.
- Contribute to the post-market surveillance of other devices (when applicable).
- Detect and report trends that indicate statistically significant increases in the frequency or severity of incidents that are not categorized as "serious" incidents per post-market vigilance requirements.

Post-market surveillance system goals

Post-market surveillance systems serve three main purposes:

1. Monitoring medical device safety and performance with the goal of identifying potential areas of improvement or concerning trends beyond those that rise to the level of serious adverse events.
2. Maintaining an accurate benefit-risk calculation and ensuring compliance with current regulations, including the collection of all data necessary for post-market surveillance reporting.
3. Providing the system and methodology for the life cycle management of each device. This includes identifying newer technologies that may be considered "state of the art."

Required post-market surveillance reporting

Class I devices

Class I devices require a Post Market Surveillance Report (PMSR). The PMSR is part of the technical documentation described in Annex III 1.2 and, for custom-made devices, Annex XIII, Section 2. While there is no specific requirement for how often a PMSR needs to be updated, a minimum of every 3 years is recommended. The PMSR should be updated more frequently if the manufacturer deems it necessary.

The PMSR should contain:

1. A summary of the post-market surveillance data that is defined in the PMS plan, along with results and conclusions drawn from the analysis of the data.
2. A description of preventative and corrective actions taken during the reporting period.

Class IIa, IIb, and III devices

Higher-risk devices require a Periodic Safety Update Report (PSUR). As with a PMSR, a PSUR is part of the technical documentation (or the equivalent for custom-made devices). A PSUR must be produced at least annually. Class III devices require that the updated PSUR be submitted to the notified body for review via the EUDAMED database. These post-market requirements are currently in place under the EU MDR, but as of the date this book was published, the EUDAMED database is not fully functional and is not accepting PSUR reports.

A PSUR should include, at a minimum, the following for the period covered by the report:

1. A summary of all relevant post-market surveillance data and related analysis and assessments.
2. Descriptions and rationale for preventative and corrective actions taken.
3. The main findings of the Post-Market Clinical Follow-up (PMCF) activities.
4. All conclusions from the reassessment of the benefit-risk determination.
5. Data on sales volumes and estimates of user populations and frequency of use.

Embracing post-market surveillance as an integral part of your quality program

A post-market surveillance program must be implemented alongside your company's quality management system (QMS). The PMS program will drive conclusions based on the compiled post-market data, and will generate input to be applied directly into the QMS to ensure that product quality, performance, and safety are maintained throughout the full life cycle of each device.

Getting started with post-market surveillance

If you are just getting started with a post-market surveillance program, begin with the following:

1. Based on your device classification, determine the type of surveillance and reporting that will be required.
2. Identify the sources of post-market surveillance information that you will use.
3. Generate the data analysis and reporting that will determine the benefit-risk ratio for your device(s).
4. Create a post-market clinical follow-up plan (PMCF)

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