



White Paper

What does the MDR tell us about post-market surveillance.

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With the [Medical Device Regulation \(MDR\)](#) coming into full force in 2020, medical device companies should prepare for tougher [Post-Market Surveillance \(PMS\)](#) requirements. Companies will need to update their PMS procedures and should budget for more [Post-Market Clinical Follow-up \(PMCF\)](#) studies.

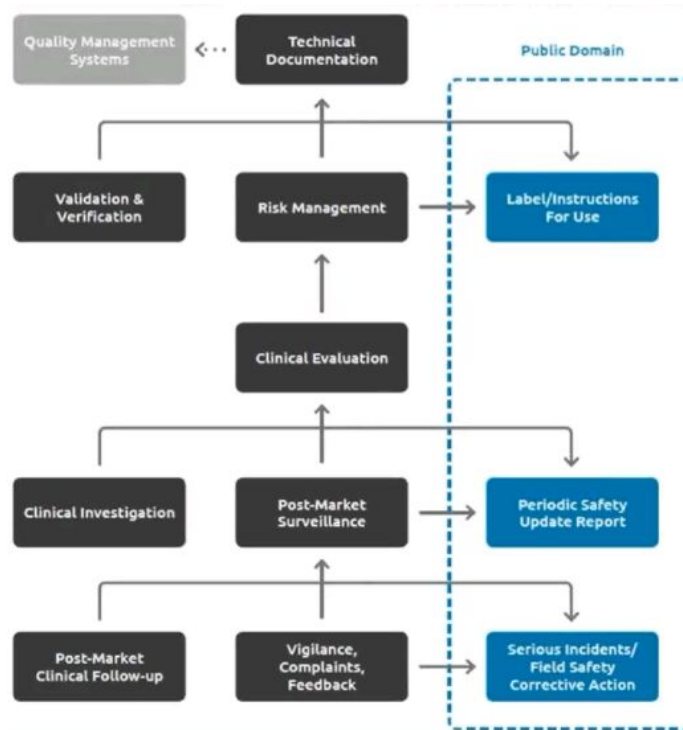
This article will address the role of PMS during the lifecycle of your device, the specific requirements for PMS under the MDR, and how an EDC system can help you fulfill these requirements in a cost-effective way.

1. What is the role of post-market surveillance during the life cycle of your device?

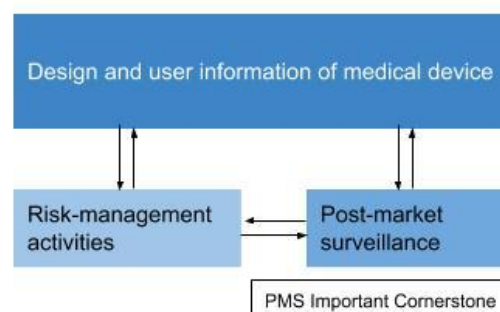
Under the Medical Device Directive (MDD), post-market surveillance was addressed, but it wasn't clearly defined. Instead, separate guidance was provided by notified bodies in the [MEDDEV 2.12-1](#). The MDR now makes this guidance obsolete as it clearly sets out the [PMS requirements for manufacturers](#).

The overall goal behind the process of PMS under the MDR is to install a continuous cycle of device improvement. PMS therefore obliges companies to monitor the quality, performance, and safety of a device throughout the product lifecycle and to apply corrective or preventive actions when necessary. Simply put, a device must

demonstrate it stays in compliance once it is on the market and make updates where necessary.



The data collected during PMS feeds into several reports, including the Clinical Evaluation Report, prepared for CE registration. PMS data thus combines with the data collected during the pre-market phase and becomes an integral part of your Technical Documentation. PMS data should be used to update the manufacturing process, user information, and ultimately the device's design.



2. What are the requirements for post-market surveillance under the MDR?

Under the MDR, manufacturers will need a dedicated [PMS system](#) to collect and review the experiences gained from the device. The PMS system explicitly integrates with your Quality Management System (e.g. ISO 13485) and Risk Management System (e.g. ISO 14971). The PMS system is to be based on a [PMS plan](#) for each device. The [content of the PMS plan](#) should describe a 'proactive and systematic process' for collecting, amongst other things, incident reports, non-serious incidents and side effects, benefit-risk, and user feedback and complaints. The PMS plan should also describe tools and processes for initiating corrective actions when needed.

Reports

Technical file ➤ Clinical Evaluation Report ➤ PMS / Periodic Safety Update Report ➤ PMCF Update Report

Moreover, the PMS plan should include a [Post-Market Clinical Follow-up \(PMCF\) plan](#). The goal of PMCF is to monitor the safety and performance of the device over time. In some cases, it suffices to draw on observations from commercial use. In other cases, a more controlled study set-up will be required.

For example, an implantable device might be advised to maintain a registry of its devices, to track their performance over time. An electronic device treating sleep apnea might send periodic ePRO / eCOA surveys to a sample of patients and correlate this with electronic readouts from the device. Or in another case, a series of reported side effects might trigger a PMCF study to test the extent of these side effects. Although the MDR is clear about having a PMCF plan, its contents will be up to the manufacturer and will depend on the risk and type of the device.

It is no big surprise that the PMS results should be captured in a report. There is a difference in how Class I vs. Class IIa/b & Class III devices are handled. Class I devices should maintain a [PMS report](#), updated when necessary, without any periodic submission requirements. Higher device classes, on the other hand, should output their PMS results into a [Periodic Safety Update Report \(PSUR\)](#). This report is updated

periodically - annually for Class IIb/III and bi-annually for Class IIa devices. The PSUR should include benefit-risk assessments, incidents, corrective actions taken and the findings of PMS and PMCF activities.

Plans

Risk Management Plan > Clinical Evaluation Plan > Post-Market Surveillance Plan > Post-Market Clinical Follow-up Plan

3. How can an EDC system help you manage your clinical data in a cost effective way?

Under the MDR, clinical data collection is required during all parts of the product's lifecycle. PMS data also makes an integral part of your device's clinical evaluation and technical documentation. Collecting and storing this data in a systematic way is therefore of utmost importance. It is advised to (re)evaluate your processes for collecting and managing this data.

Managing this data on paper is not transparent and makes it hard to communicate with authorities. Having all clinical data available in a central system makes sense, so that it is easily accessible for internal communication and audit purposes. For more information, [read our article](#) on the benefits of using an EDC system over paper.

It is clear that clinical data should always be collected in compliance with Good Clinical Practice (GCP) and the General Data Protection Regulation (GDPR). Using an EDC has all measures in place to collect your clinical data in compliance with all relevant standards and regulations.

[Castor EDC](#) offers a single platform for your design validation, clinical investigation, and PMS. Using Castor enables your company to save resources and to collect clinical data in compliance with GCP and GDPR.

Interested in learning more about Castor EDC? [Request a demo now.](#)



Links to other useful resources:

- [4 ways the Medical Device Regulation will impact your device studies](#)
- [Why having a single EDC system for your device company makes sense](#)
- [In-vitro diagnostics regulation: From oversight to overhead](#)
- [4 myths about the benefits of paper-based CRFs](#)
- [ePRO: the electronic solution for questionnaire surveys in medical research](#)
- [Randomization in medical research](#)