

The role of real-world evidence in post-market clinical follow-up

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Abstract

Post-market clinical follow-up (PMCF) is a mandatory, ongoing process under EU MDR 2017/745, aimed at ensuring the continued safety and performance of medical devices. This manuscript outlines the regulatory requirements, methodologies, and integration of real-world data (RWD) in PMCF activities. It highlights how manufacturers can use RWD from registries, retrospective studies, and user surveys among other sources to fill clinical evidence gaps and support regulatory compliance. Case studies illustrate practical applications of RWD in PMCF. A systematic and data-driven PMCF approach is essential for effective post-market surveillance and the protection of patient health.

Understanding the requirements of post-market clinical follow-up

Post-market clinical follow-up (PMCF) is an integral process of the European Union's Medical Device Regulation (MDR) 2017/745 to continually assess performance and safety once a medical device has entered the market.¹⁻³

It is not a one-off activity but rather an ongoing process that occurs throughout the device's lifecycle, providing manufacturers with updated clinical evidence to support their device's conformity with regulatory requirements. This also includes the collection of clinical

data from real-world use to further evaluate the device when it is used in a broader patient population.²⁻³

Regulatory framework and requirements

According to the MDR, manufacturers must establish and implement a post-market surveillance (PMS) system that includes PMCF as a crucial element.¹⁻³

PMCF must be planned, systematic, and documented, outlining the objectives, methodology, and the clinical data to be collected. The collected data should then be analysed and used to update the clinical evaluation, risk management, PMS and other documents such as the summary of safety and clinical performance (SSCP), if applicable.¹⁻³

PMCF methodologies

There are two primary types of PMCF: general and specific. General PMCF refers to the collection of clinical data that is not tied to a specific clinical question but is gathered as part of routine PMS activities.²⁻³ This data may include, for instance, general feedback from healthcare professionals, information from systematic literature reviews, or data from vigilance databases.^{2,3}

Specific PMCF, on the other hand, refers to targeted activities, such as high-quality user

surveys, post-market studies or data collection from device registries. These activities are used to answer specific questions, e.g., from the clinical evaluation, and to close gaps in the clinical evidence of a medical device.^{2,3}

Both general and specific PMCF activities must be well-documented and conducted in compliance with the MDR's requirements, and other international or local requirements (e.g., ISO 14155 or Good Clinical Practice) with clear objectives and methodologies. Manufacturers are also required to ensure that any clinical findings from PMCF are communicated to the relevant authorities, stakeholders, and users of the device.¹⁻³

When real-world-data comes into play

Real-world-data (RWD) has become an invaluable resource in the post-market phase, particularly within the framework of PMCF. As healthcare evolves and patient care becomes more complex, RWD offers unique insights into the safety, effectiveness, and long-term performance of medical devices when used outside the controlled conditions of clinical investigations across diverse patient populations and clinical settings.

Unlike prospective interventional or randomised controlled trials (RCTs), RWD

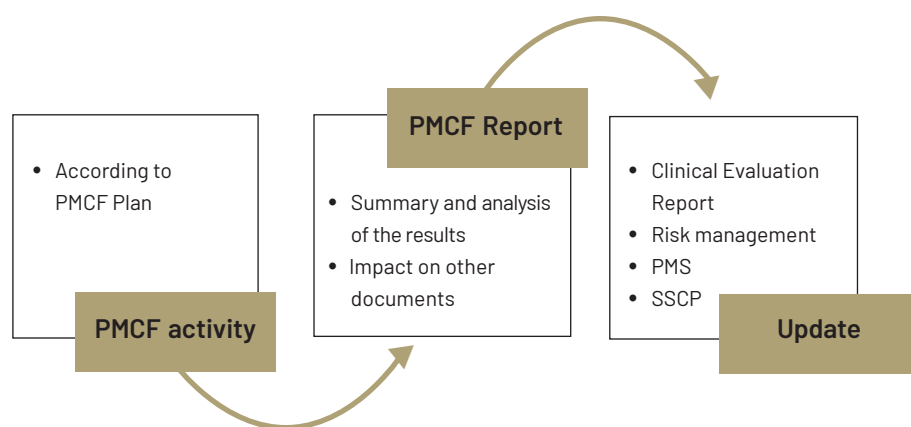


Figure 1. PMCF close connections with other processes

Abbreviations: PMCF, post-market clinical followup; PMS, post-market surveillance; SSCP, Summary of Safety and Clinical Performance.

Table 1. Comparison of data from standard clinical investigations and RWE

Data from “standard” clinical investigations	Data from RWE
Carefully selected inclusion and exclusion criteria	Not limited to a selected patient group
Intended to address a certain hypothesis or clinical question	To confirm the performance and safety in a routine clinical setting
Limited to a predefined sample size and time period	Not necessarily limited to a sample size and suitable to collect data over the device lifetime

reflects the broader population, including patients with various comorbidities, varying degrees of disease severity, and other factors that may not be well represented in traditional clinical trials. The use of RWD provides a more accurate

and comprehensive understanding of how devices perform in real-world settings, helping to identify issues that may not have been detected during pre-market evaluation.⁴ (See Table 1).

Types of real-world data
There are numerous sources of RWD that can be leveraged to support PMCF activities.^{5,6} Some of the most widely used types of RWD are shown in Table 2.

Table 2. Overview of data sources for RWE

Electronic health records (EHRs) EHRs provide large real-world data sets with information about diagnoses, treatment plans and results, and might also include medical device brand names, catalogue numbers/UDI. We also use this data in combination with insurance claims databases. More data vendors are also providing services to analyse unstructured data (clinical notes, imaging) to enable more sophisticated analysis of device performance outcomes. Manufacturers should be aware of potentially limited data quality and bias due to the design or analysis of EHRs.	Retrospective chart review Retrospective reviews of medical records are a great source of real-world performance and safety data that don't rely on user compliance as surveys. Although they require a predefined study protocol and statistical analysis plan, they are more cost-effective than prospective studies with a lower selection bias.
Registries Registries are great sources of RWE with the potential to collect long-term data. So far, national registries are limited to certain devices, such as orthopaedic implants. As an alternative, manufacturers can initiate their own medical device registries. Manufacturer-initiated registries usually follow a predefined study protocol that can be targeted to the collection of the most relevant performance and safety parameters.	Laboratory information systems (LIS) Laboratory information systems store and manage data related to laboratory tests, including blood work, diagnostic imaging, and other tests that inform patient care. These systems can provide important real-world data on how devices perform in relation to specific diagnostic or therapeutic procedures. For instance, devices such as in-vitro diagnostic (IVD) tests or point-of-care testing devices can be tracked through LIS to assess their accuracy, reliability, and potential for misdiagnosis in clinical practice.
Surveys Surveys can be used to collect data from healthcare professionals or patients. They can be designed to collect general feedback on user experience and user satisfaction or to collect data on specific procedures and device usages. Despite their known limitations (e.g., low response rates), they are great tools to reach various users in a relatively short time.	Social media listening Social media listening identifies early signals of safety issues, user concerns, and real-world device performance in general. By monitoring public posts, reviews, and discussions, manufacturers can detect adverse events, misuse, or unmet needs not captured through traditional channels. Analysing this user-generated content provides timely insights; still, it can be difficult to weight against other sources of data which are monitored by health-care professionals.



Image: Freepik

The Role of RWD and RWE in PMCF

The integration of RWD into PMCF activities allows for the continuous monitoring of medical devices' safety and performance.³ By analysing data from a range of real-world sources, manufacturers can identify emerging risks, assess long-term performance, and make necessary adjustments to their products or PMS and PMCF plans.^{1-4,6} RWD provides regulators with a more comprehensive understanding of a device's performance across diverse patient populations and clinical settings.

They can also help bridge gaps in clinical investigation data, particularly for devices that are used in rare conditions with unique patient populations, ensuring that regulatory decisions are based on the best available evidence.⁶ As an example, we typically use RWD to support very narrow indications (e.g., distal femur fracture with intra-articular extension). Another important use is to provide paediatric data. In both cases, running a traditional clinical investigation to collect this data would be very time consuming (long enrolment with few sites, hurdles for approvals of paediatric studies) and expensive.

Case study 1 – Registries for RWE

Situation: A manufacturer of orthopaedic implants, which are considered as medium to high-risk devices, wanted to use publicly available joint prosthesis registries to retrieve performance and safety data for their medical device. National joint registries are valuable sources of RWE, especially for orthopaedic implants, due to their long-term follow-up data.⁶

Problem: However, these registries typically do not provide device-specific data in their standard annual reports, limiting manufacturers' ability to assess and compare individual device performance.

Solution: To address this, an orthopaedic implant manufacturer requested two additional device-specific reports from the registry owner: one focusing on their own device and another on a group of benchmark devices. These reports enabled direct comparison with the State of the Art and will now be received annually. This approach enhances the value of the registry as a continuous RWE source.

Potential challenge: Smaller registries may not have the resources available to generate custom reports for manufacturers or may not agree to provide data for comparator products.

Case study 2 – Retrospective medical records review for RWE

Situation: A manufacturer of vascular stents, considered as high-risk devices, had strong clinical evidence supporting the device's use in lower leg arteries, aligning with part of its intended use.

Problem: The device's broad indication – including use in upper thigh arteries – lacked robust clinical evidence, relying only on isolated case reports.

Solution: To address this gap, the manufacturer identified a hospital that frequently used the stent for upper thigh lesions. They conducted a retrospective analysis of the hospital's database, successfully gathering performance and safety data to support the broader indication.

Potential challenge: This is not typically a continuous activity, and a single centre may not have sufficient volume to provide enough cases for the specific indication.

Case study 3 – User surveys for RWE

Situation: A manufacturer offered low risk medical devices primarily used as accessories in interventional procedures. These devices had a low-risk profile and were not typically featured in scientific publications.

Problem: Given their accessory role and simplicity, it was neither practical nor necessary to conduct clinical studies, yet the manufacturer still needed performance and safety data to support the device's use.

Solution: The manufacturer implemented a user survey using a simple case report form to be completed during or immediately after an intervention with the device. This approach enabled the collection of relevant data on technical performance and potential safety events. Short-term follow-up was sufficient due to the device's nature and intended use.

Potential challenge: User surveys for RWE in PMCF may face challenges with response bias, limited clinical depth, and inconsistent data quality, potentially undermining the reliability of safety and performance insights.

Case study 4 – Social media listening for RWE

Situation: A manufacturer of wearable cardiac monitors aimed to enhance post-market surveillance by exploring non-traditional data sources.

Problem: Despite formal reporting channels, some users shared device issues –such as skin irritation or inaccurate readings – only through social media platforms. These signals were missed by conventional PMS systems.

Solution: The manufacturer implemented a social media listening tool to monitor public posts related to their product. This enabled early identification of recurring user complaints, prompting further analysis of the published literature, complaints and incidents databases, and other sources. The approach improved patient safety and supplemented traditional PMS data.

Potential challenge: It may be more cost-effective for companies to embed social media listening as part of an overall vigilance strategy rather than using for a single product PMCF needs.

Conclusion

Post-market clinical follow-up (PMCF) is a critical component of the EU MDR framework, ensuring that medical devices continue to meet safety and performance standards throughout their lifecycle.¹ As demonstrated in this manuscript, PMCF must be systematic, targeted, and responsive to evolving clinical needs and regulatory expectations. The integration of RWD

significantly enhances the PMCF process by providing timely, relevant insights from diverse patient populations and clinical settings. Whether through registries, retrospective studies, or user surveys, leveraging RWD enables manufacturers to close evidence gaps, refine risk management, and maintain regulatory compliance. As healthcare systems and data infrastructures evolve, robust PMCF strategies grounded in real-world evidence will be essential for ensuring device safety and public health.

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Disclosures and conflicts of interest

The author declares no conflicts of interest.

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