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5-minute guide to:

Post-market clinical follow-up under the EU MDR | Do’s & Don’ts

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By Dr. Martina Hersberger & Dr. Sarah Bosshard

Post-market clinical follow-up (PMCF) has become significantly more rigorous under the EU MDR to ensure enhanced patient safety following a device's entry onto the market.

In this 5-minute guide, our Clinical Consultant Dr. Martina Hersberger and Head of Clinical Dr. Sarah Bosshard share an overview of PMCF and its requirements, along with important advice on the essential do's and don'ts.

What is PMCF?

Forming an important part of post-market surveillance (PMS), PMCF is a mandatory, proactive, and continuous process that updates the clinical evaluation of a medical device.

As per the EU MDR, Annex XIV, Part B, PMCF requires the collection of clinical data to confirm the device's safety and performance in the post-market phase, including the identification of potential risks.

PMCF is mandatory for all devices that fall under EU MDR independent of their risk-class. To fulfil the requirements, device manufacturers must produce a PMCF plan and a PMCF evaluation report.

For certain devices, such as those qualifying under Article 61(10), PMCF may be considered inapplicable - in which case a clear justification must be provided.

What is the purpose of PMCF?

Confirm device safety & performance throughout its expected lifetime

Identify previously unknown side-effects & monitor the identified side-effects / contraindications

Identify & analyse emergent risks

Ensure the continued acceptability of the benefit-risk ratio

Identify possible systematic misuse or off-label use of the device

Source: EU MDR, Annex XIV, Part B, Section 6.1

Creating your PMCF Plan

Your PMCF plan specifies the methods and procedures for proactively collecting and evaluating clinical data from the subject device within its intended purpose - throughout its entire lifecycle, from market launch to discontinuation.

The PMCF Plan may be integrated into the PMS Plan or provided as a standalone document.

Its minimum requirements are outlined in Annex XIV, Part B, Section 6.2 of the MDR and further detailed in MDCG 2020-7. The requirements include the general and specific methods to be applied, a rationale for the appropriateness of the chosen methods, the objectives to be addressed, and a detailed and justified time schedule.

Creating your PMCF Plan | Methods & Procedures

General methods, such as screening of scientific literature and collection of user feedback, facilitate the continuous assessment of the subject device's safety, performance, and overall clinical outcomes.

Specific methods, such as evaluation of suitable registers or PMCF studies, are required to address **clinical data gaps**, for instance insufficient safety and/or performance data on specific indications or subpopulations, identification of possible residual risks, or initial conformity based on equivalence.

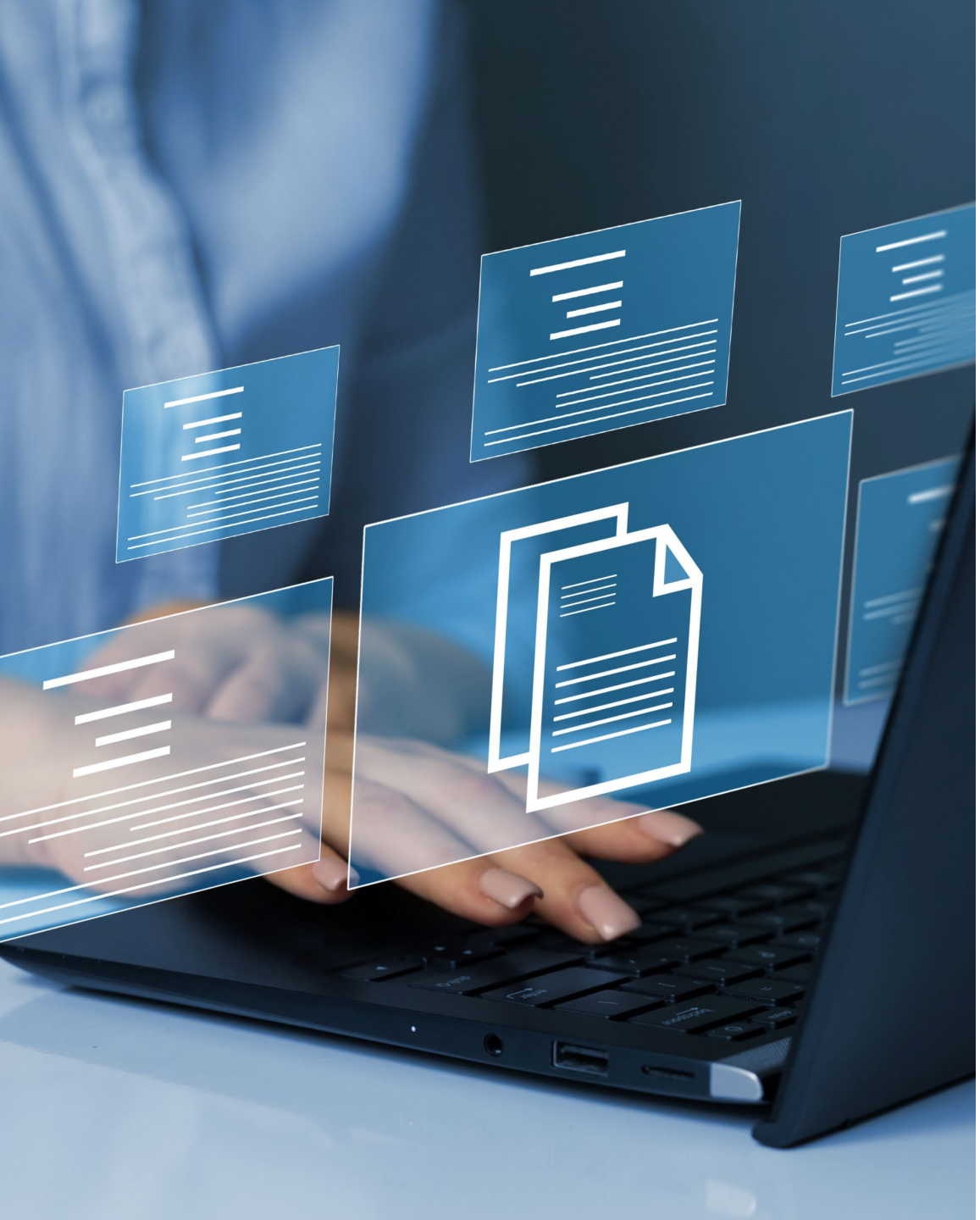
Sufficient evidence is required for all indications, variants, combinations, and patient populations throughout the therapeutic lifetime. Parameters for what merits "sufficient" evidence depends on the device’s degree of innovation, risk profile, risk class, and the current state of the art.

Collecting your clinical data

Once your device is CE-marked, sources of clinical data may include:

- PMCF studies including post-market clinical investigations
- Independent clinical studies conducted using the device
- Data retrieved from the clinical literature, including data on equivalent devices
- Device registries
- PMS clinical data, complaint and incident reports
- User feedback
- Surveys

MDCG 2020-6 advises on data source hierarchy and should be considered when planning PMCF activities.



Compiling your PMCF evaluation report

The PMCF evaluation report documents the findings from the activities foreseen in the PMCF plan.

It may be included as part of the clinical evaluation report (CER) or provided as a standalone document.

While MDR requires the preparation of a PMCF evaluation report, it does not provide specific requirements for its content or structure; these are detailed in MDCG 2020-8.

The findings and conclusions from the PMCF Evaluation Report feed into the clinical evaluation, PMS and risk management documentation, and, where applicable, the Summary of Safety and Clinical Performance (SSCP).

For Class III and implantable medical devices, the report should be updated annually.

PMCF | Do's

Integrate PMCF with clinical evaluation

Ensure a continuous cycle where PMCF findings inform clinical evaluation, and clinical evaluation guides PMCF activities for compliance and risk management.

Develop a structured PMCF Plan

Outline methods for collecting and evaluating clinical data, ensuring the plan aligns with the device's risk class.

Distinguish between data

Recognise the difference between safety and performance data, ensuring that both aspects are properly assessed and addressed in your PMCF activities.

Conduct regular gap analyses

Continuously assess PMCF data against regulatory updates, clinical expectations, and changes in the state-of-the-art, to identify and address gaps.

Structure PMCF activities with clear objectives

Define well-structured objectives and methodologies to ensure meaningful conclusions. If a PMCF investigation is needed, ensure compliance with Annex XV and ISO 14155:2021.

Be transparent about limitations

Clearly communicate the limitations of your PMCF activities and data, while justifying why the available evidence is still valuable for assessing the device's safety and performance.

Engage with your notified body

Maintain ongoing communication to stay updated on evolving PMCF requirements, expectations, and best practices. Work with your notified body to develop your PMCF strategy.

PMCF | Don’ts

Treating PMCF as a one-time task

Re-evaluate your clinical evidence and consequently your PMCF activities on a regular basis for as long as the product is on the market.

Overlooking specific PMCF requirements

Failing to consider RWE, undervaluing user feedback, neglecting low-incidence events, missing emerging trends, or ignoring competitor insights can compromise the effectiveness of PMCF.

Using generic PMCF activities

Avoid using one-size-fits-all approaches. Instead, customise your PMCF activities to address the specific residual risks and uncertainties related to your device’s safety and performance.

Setting impractical expectations

Avoid making unrealistic commitments to PMCF activities that cannot be properly planned or executed.

Underestimating the importance of documentation

Do not neglect thorough documentation of all PMCF activities. Comprehensive records are essential for regulatory submissions and audits.

Disregarding regulatory guidelines

Failing to follow regulatory frameworks can lead to non-compliance and regulatory scrutiny.

Combining PMCF with marketing objectives

Do not combine PMCF data collection with marketing surveys, as this can dilute the focus and effectiveness of clinical data gathering.

Do you have a PMCF challenge? Our Clinical team is ready and happy to help - simply get in touch to start the conversation.

Contact us:

E: info@congenius.ch

T: +41 44 741 04 04

Congenius AG

Riedstrasse 1

CH-8953 Dietikon