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Challenges and best practices in planning and executing PMCF surveys

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Postmarket clinical follow-up (PMCF) surveys are a proven method for collecting the data used for EU Medical Device Regulation (EU MDR) submissions, but there is limited guidance on survey procedure and use. This article explores the challenges in planning and executing high-quality Level 4 and general/usability Level 8 PMCF surveys, as outlined in Appendix III of the Medical Device Coordination Group (MDCG) 2020-6 guidance document. It addresses poor survey design, insufficient statistical justification, unmet endpoints, and recruitment issues. It will also suggest strategies for addressing these challenges and best practices for effectively implementing the survey.

Keywords – clinical evidence, EU MDR, Level 8 surveys, Level 4 surveys, PMCF

Introduction

Since the implementation of the EU MDR in 2021, medical device manufacturers are required to maintain a systematic procedure for proactively collecting evidence, reviewing the safety and performance of their European conformity-marked medical devices, and identifying the need for any necessary corrective actions under Article 2 (point 60) of the EU MDR (also known as Regulation (EU) 2017/745).[1] This process, known as postmarket surveillance (PMS), requires manufacturers to conduct clinical evaluations under the terms of Article 61 of the regulation.

PMCF is a PMS activity. It is a continuous process requiring the collection of real-world clinical data to confirm the safety and performance claims of a medical device throughout its lifetime.[2] Moreover, according to Annex XIV, Part B, of the EU MDR, manufacturers must also fulfill the following PMCF requirements and submit evidence to their respective notified bodies as part of the relevant PMS documentation:[1]

- Confirm the safety and performance of the device throughout its expected lifetime;
- Identify previously unknown side-effects and monitor identified side-effects and contraindications;
- Identify and analyze emergent risks on the basis of factual evidence;
- Ensure the continued acceptability of the benefit-risk ratio; and
- Identify possible systematic misuse or off-label use of the device to verify that the intended purpose is correct.

These EU MDR stipulations increase the regulatory requirements that medical device manufacturers must meet. However, there is a lack of clear and specific guidance within the EU MDR on the requirements for survey process and use, which creates uncertainty among manufacturers about compliance. This article will focus on using surveys for PMCF data collection, addressing the various challenges manufacturers face from planning through to implementation, and suggesting best practices for mitigating the challenges.

Searching for PMCF guidance

PMCF is widely accepted as a method for collecting data on the postmarket safety and performance of medical devices. The Medical Device Coordination Group (MDCG) – an expert alliance established by the EU MDR and EU In Vitro Diagnostic Medical Devices Regulation (Regulation (EU) 2017/746) – has produced and endorsed useful guidance for manufacturers navigating the complexities of the EU MDR (**Table 1**).

These documents are useful for addressing the level of PMCF data required and the key elements of a PMCF study, but they are not survey-specific. However, the guidance can be vague from an individual manufacturer's perspective, making it difficult for them to apply the recommendations effectively. Other sources of PMCF guidance include:

Table 1. Medical Device Coordination Group guidance documents

Document reference	Area of guidance	Document title
MDCG 2020-6[3]	Collecting sufficient clinical evidence for legacy devices	Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under directives 93/42/EEC or 90/385/EEC: A guide for manufacturers and notified bodies
MDCG 2020-7[4]	PMCF plan template	Postmarket clinical follow-up (PMCF) plan template: A guide for manufacturers and notified bodies
MDCG 2020-8[5]	PMCFER template	Postmarket clinical follow-up (PMCF) evaluation report template: A guide for manufacturers and notified bodies

CE, European Conformity; **EEC**, European Economic Community; **EU**, European Union; **MDCG,** Medical Device Coordination Group; **PMCF,** postmarket clinical follow-up; **PMCFER**, postmarket clinical follow-up evaluation report.

- Parts of the previous Medical Devices Directive (MEDDEV) 2.7/1 Revision 4, which still apply despite more recent guidance to support the EU MDR. This includes MEDDEV 2.12/2, which provides further guidance on PMCF studies.[2]
- ISO 14155:2020[6] on good clinical practice in the clinical investigation of medical devices for human subjects provides guidance on all aspects of ISO 14155-compliant clinical investigations in Annex A, which can be narrowed down to what is required for a PMCF survey.[2]
- Notified bodies can offer direction through structured dialogue, however response times can vary, and specific guidance is limited. Notified bodies also offer a range of resources such as papers, guides, webinars, and training courses, which offer opportunities to keep up to date with the latest advice and ask questions.
- Vendors with expertise in conducting PMCF surveys, such as market research agencies and contract research organizations, can provide support with design, implementation, data collection, and reporting of PMCF surveys to ensure compliance with the EU MDR.

Determining the suitability of PMCF surveys for medical devices

PMCF is essential for many medical devices, but its applicability is not universal, and its suitability varies depending on the following factors:[2]

- How long the product has been on the market,
- Its risk classification,
- The availability of clinical data for it,
- The changes to the product since its placement on the market, and
- Any associated new and/or emerging risks.

There are several approaches for collecting follow-up clinical data. It is crucial to select a method that will be suitable for a specific medical device and to plan resources accordingly. This tends to be one of the initial challenges medical device manufacturers face when planning PMCF activities because the chosen method must align with the EU MDR requirements for both the quantity and quality of the clinical data.[7] Typical approaches for sourcing clinical data include clinical investigations, cohort studies, case series, registries, literature reviews, and surveys,[8] with each providing different levels of evidence. The appropriate method depends on the specific device, as well as the results from assessments and evaluations of clinical risks, which guide manufacturers in determining the required level of evidence.[3]

Appendix III of the MDCG 2020-6 guidance document outlines that the level of clinical evidence must be sufficient to demonstrate conformity with the EU MDR's General Safety and Performance Requirements (GSPRs). The appendix ranks various data collection methods according to the quality of evidence they provide, where Level 1 data collection methods (e.g., clinical investigations)

offers the highest quality and most robust form of clinical evidence, and Level 12 data collection methods (e.g., preclinical and bench testing) provides the least comprehensive or conclusive clinical evidence to support the safety and performance of a medical device (**Table 2**).[3]

Before deciding on the approach for gathering data, one should first establish whether clinical data is necessary for demonstrating conformity with the GSPRs or if nonclinical testing methods (such as PMCF surveys) would be sufficient. Under Article 61(10) of the EU MDR, if a manufacturer decides that clinical data is not necessary, they must provide adequate justification for this exception

Table 2. MDCG 2020-6 guidance: Types of clinical data and evidence for demonstrating conformity with the EU MDR[3] (1 = highest level of clinical evidence; 12 = lowest level)

Rank[a]	Types of clinical data and evidence
1b	Results of high-quality clinical investigations covering all device variants, indications, patient populations, duration of treatment effect, etc.
2	Results of high-quality clinical investigations with some gaps
3	Outcomes from high quality clinical data collection systems such as registries
4	Outcomes from studies with potential methodological flaws, but where data can still be quantified and acceptability justified; high quality surveys may also fall into this category
5	Equivalence data (reliable/quantifiable)
6	Evaluation of state of the art, including evaluation of clinical data from similar devices
7	Complaints and vigilance data; curated data
8	Proactive PMS data, such as those derived from surveys
9	Individual case reports on the subject device
10	Compliance with nonclinical elements of common specifications considered relevant to device safety and performance
11	Simulated use/animal/cadaveric testing involving healthcare professionals or other end users
12	Preclinical and bench testing/compliance to standards

MDCG, Medical Device Coordination Group; **PMS,** postmarket surveillance.

[a]MDCG 2020-6 clinical evidence table refers to the structured hierarchy of clinical evidence. This table ranks premarket and postmarket clinical data by strength and relevance, guiding manufacturers on the types and levels of evidence needed to meet EU MDR General Safety and Performance Requirements (GSPRs) for legacy devices.

within the CER, supported by risk classification, nonclinical evidence, established technology, or equivalent device data (providing full technical documentation is available). Even in such cases, a notified body may still recommend a PMCF survey to further strengthen available clinical evidence or address small clinical gaps.[1]

According to **Table 2**, PMCF surveys can be categorized as either high-quality patient/case-specific surveys (Level 4) or general/usability (Level 8) surveys.[9] Medical device manufacturers should carefully consider the type of survey to implement, depending on the device classification and the level of evidence required. Typically:

- **High-quality patient/case-specific Level 4 surveys** can be retrospective or prospective and must, at a minimum, cover indications and safety and performance claims.[2] These surveys are usually associated with higher-risk classification devices or those with larger clinical data gaps or for which there are no previous data (e.g., Class III, long-term implantable, and legacy devices).

- **General/usability Level 8 surveys** tend to be retrospective. This level of evidence cannot be used in isolation to confirm the safety and performance of a medical device, but the surveys can be useful for identifying potential issues arising from reported complaints. These surveys are particularly appropriate for lower-risk classification devices or those with smaller clinical gaps (e.g., short-term–use medical devices, or those with a well-established technology and known risks and established on the market).[3]

Table 3 summarizes the differences between Level 4 and Level 8 surveys.

Table 3. Differences between Levels 4 and 8 PMCF surveys

High-quality patient/case-specific Level 4 surveys *Used for higher-risk classification or those with larger clinical gaps*	**General/usability Level 8 surveys** *Used for lower-risk classification devices or those with smaller clinical gaps*
Each survey represents one patient/case where the device was used	Each survey represents multiple device usages
Ask respondents to complete a survey following each usage of the device (e.g., based upon patient records)	Ask respondents to recollect information based on usage across a set time period, such as the last month
Completion of multiple cases for each respondent	Completion of a single survey by each respondent
Include a combination of retrospective and prospective questions	Will be solely retrospective

Planning for Level 4 and Level 8 PMCF survey implementation

A PMCF plan is a crucial component of the PMS plan, as required by Annex III, Part B, of the EU MDR.[1] The PMCF plan should document the methods and procedures for collecting and evaluating clinical data, refer to the relevant parts of the clinical evaluation report, and clearly define objectives (Annex XIV, Part A).[1] It is important to specify or provide:

- The intended purpose of the medical device,
- The intended users,
- Clear indications and contraindications of the medical device,
- A detailed account of intended clinical benefits,[4]
- Clinical gaps from premarket sources, and
- An assessment of the risks of the selected approach.

Annex XV of the EU MDR[1] and Section C of the MDCG 2020-7 guidance document[4] advise developing a PMCF plan that is scientifically valid and that documents and justifies the specific activities used to gather the necessary information. In addition, device manufacturers should define the aims of their PMCF activities and provide justifications for sample size, timescales, and endpoints in the PMCF survey plan/protocol.[2] The PMCF plan should be updated at least once a year and submitted to the notified body for approval.[4]

As already noted, manufacturers face numerous challenges designing robust PMCF surveys, because of a lack of clear and specific guidance on survey process and use. Some of these challenges are addressed below.

Challenge 1: Poorly defined objectives and endpoints

One fundamental challenge is having clear, well-defined endpoints in the PMCF plan and survey protocol. It is crucial to establish specific safety and performance endpoints and clear acceptance criteria defining how the endpoints will be measured and evaluated to be able to effectively assess whether a medical device meets its intended objective in the real-world setting. Without clear endpoints, data collection can become unfocused and lead to ambiguity in interpreting results. It can also result in inadequate data that cannot support and inform decisions about improvements or corrective actions.

To mitigate these challenges, manufacturers must prioritize devising measurable endpoints and their associated acceptance criteria as part of their PMCF plans and survey protocols. This involves a comprehensive understanding of the medical device's intended use, its associated risks, and the clinical context in which it operates. Identifying clinical gaps by performing a thorough gap analysis on available clinical data will ensure that the clinical evidence is sufficient in quantity and quality for relevant variants, indications, patient populations, and/or anatomical locations.[2] In addition, reviewing data on equivalent or state-of-the-art (SOTA) medical devices and collaborating with

clinical experts, regulatory professionals, and end users during the planning stage can provide valuable insights into what constitutes meaningful safety and performance objectives.

Challenge 2: Statistically unjustified sample size

Annex XV of the EU MDR[10] lists having a statistically sound sample size among the requirements for PMCF surveys. There is no one-size-fits-all approach for setting a sample size for a PMCF survey. As with all elements of a PMCF study, manufacturers must plan extensively to avoid pitfalls, including inadequate statistical justification of their sample size, by considering the intended purpose of the medical device and reviewing the safety and performance data of equivalent/SOTA devices on the market.

When doing so, it is also important to ensure a balance between statistical requirements and feasibility constraints, including ease of recruiting end users and their response rate, device sales, and costs for recruitment, incentives, and translations (if required). It is best practice for manufacturers to work with a statistician to prepare sample size options that consider the objectives, endpoints, acceptance criteria, and feasibility.

Challenge 3: Poor or ill-defined statistical analysis plan

In addition to determining a statistically sound sample size, Annex XV also mandates that manufacturers prepare a statistical analysis plan.[1] Clinical evidence is integral to PMCF, so considerations should be made regarding how the data will be analyzed and presented. Specifically, manufacturers must be able to report whether the endpoints for the safety and performance objectives outlined in the plan can meet the predefined acceptance criteria. It is therefore important that the acceptance criteria are well defined in the statistical analysis plan and fully align before PMCF activity begins.

Annex XIV, Part B, of the EU MDR details how a time schedule for analyzing PMCF data and reporting must be provided.[1] The PMCF evaluation report should analyze and document the findings and results and submit them in the clinical evaluation report (CER) and technical documentation. This should include a statistical plan.[1] Section G of the MDCG 2020-8 states that the conclusions in the report should highlight any need for preventive or corrective actions.[5] Therefore, it is essential to plan the PMCF activities with consideration of how to report on the findings.

If PMCF surveys have been used, data can be presented in Microsoft Excel or analyzed in tabulation software. Depending on the type of data, descriptive statistics are appropriate for respondent-level questions, whereas confidence intervals can be used to confirm safety and performance objectives. In addition, the PMCF evaluation report should note any deviations from the PMCF plan and the justifications.[5]

Challenge 4: Inconsistencies with other technical documentation
Inconsistencies across documentation, such as the CER, survey protocol, and the PMCF plan, make it difficult to conduct PMCF studies and collect clinical evidence. Annex III of the EU MDR notes that medical device manufacturers are required to present the documentation in a "clear, organised, readily searchable and unambiguous manner."[1] Examples of inconsistent documentation can relate to discrepancies in the safety and performance objectives, the types of adverse events or side effects typically associated with the medical device listed, or statistical methods. Therefore, it is important to ensure that all documentation has been reviewed thoroughly, cross-referenced, and approved before proceeding with any data collection activities.

Challenge 5: Lack of contingency plans
During PMCF survey distribution, there may be circumstances that could contribute to deviations from the PMCF survey plan or protocol. These circumstances could include difficulty in the recruitment of end users (due to low sales), targeting hard-to-reach end users (see section achieving target sample size), and/or achieving specific quotas (e.g., for device variants/configurations and patient age groups). It is therefore important to identify potential feasibility issues during the planning phase and develop contingency plans to address these before survey distribution.

Depending on the stage of the project, examples of contingency plans to overcome these challenges could include:

- Collating recent information on the number of devices which have been sold to establish whether there are a sufficient number of users to participate in the survey;[8]
- Updating the questionnaire as necessary;
- Recontacting respondents to gain information; or
- Inviting new respondents to participate in the survey if needed to fulfill the sample size.

Any deviations from the PMCF survey plan or increases in sample size must be justified and documented in the PMCF survey protocol and evaluation report.

Designing a robust Level 4 and Level 8 PMCF survey

Well-designed survey questionnaires are integral to successful PMCF implementation. There are multiple factors that contribute to a well-designed PMCF survey. A key factor among them is that the survey must allow the manufacturer to collect data that can align with what was set out in the PMCF survey plan or protocol. This section will provide examples and considerations for the best practices in PMCF survey design based on the authors' experience.

PMCF surveys must align with the defined endpoints. They should be drafted to directly address the identified safety and performance objectives and that the

collected data is relevant, actionable, and can be analyzed in accordance with the PMCF survey plan or protocol. This alignment is critical, because poorly designed questionnaires can lead to irrelevant or incomplete data, which would hinder effective data analysis and ultimately fail to capture important insights about the device's real-world safety and performance.

By prioritizing these elements, manufacturers can enhance the effectiveness of their PMCF activities and better ensure improved patient safety and performance in the market. An example of poor survey design for a Level 4 (high-quality patient/case specific) survey would involve focusing on usability and general satisfaction as opposed to a clinical focus, which would not allow for confirmation of the intended use. In addition, the data would not align with the specific acceptance criteria relating to the device's safety and performance.

A further consideration for selecting and designing PMCF surveys is whether it would be possible to collect long-term data effectively. For example, it is a challenge to collect long-term safety and performance data for implantable devices, and only a well-designed Level 4 survey would be able to collect this information for specific device types (i.e., a survey where follow-ups are performed by the same healthcare professional and the information is documented within patient charts). This highlights the importance of investing the proper time and resources at the planning and design stages when considering the implementation of a PMCF survey.

Additionally, when designing a PMCF survey for implementation, it is also important to consider that the questionnaire will be hosted on an online survey platform. This format can enhance efficiency but also introduce certain complexities, as outlined in **Table 4**, requiring careful attention to user experience, digital accessibility and device compatibility.

Table 4. Evaluation of online surveys as a method to collect postmarket clinical data on medical devices

Benefits	Limitations
– Can reach respondents virtually across the globe – Programming capabilities that support different question types, routing, and logic – Quicker and more user-friendly for respondents vs. paper-based methods – Respondents can pause the survey and return later without losing progress – Reduction in manual data entry and data collection – Data can be extracted into multiple formats, such as Microsoft Excel and SPSS – Language overlay capabilities result in seamless translations	– Require a validated survey software and experienced programming teams – Thorough validation and testing procedures are required – Difficult to follow up with respondents for clarification – Survey logic and routing must be tested carefully – Must comply with relevant guidance and regulations where appropriate (e.g., ISO 14155[6] and General Data Protection Regulation[11])

Survey questions must be tailored for the target audience to prevent respondent fatigue, misunderstanding, and disengagement – all of which are more likely to occur in an online setting where attention spans may be shorter and drop-out risk is higher. Key recommendations to enhance respondent experience and engagement when completing the PMCF survey using an online format include:

- Limiting the survey length so that it does not exceed 15-20 minutes;
- Translating the survey into the local language(s);
- Providing information on the purpose of the survey (e.g., outlining that it is for EU MDR purposes and not a marketing survey);
- Having an appropriate choice of question types (e.g., single code, multicode, and open-ended);
- Devising clear, understandable questions and providing adequate instructions for completion (e.g., patient chart requirements);
- Placing endpoint-related questions early in the survey; and
- Minimizing the collection of personal data, where possible (e.g., only for adverse event reporting purposes, if required).

Survey questionnaires designed with the online format in mind can help ensure high-quality responses, improved completion rates, and better user experience for respondents.

Achieving target sample size

Once the survey has been designed, the next stage is to recruit the end users. Recruitment can be a challenge for manufacturers, and it is important to consider how best to maximize feasibility and achieve the desired sample size early in the process.

Manufacturers can face barriers such as low sales volumes, hard-to-reach end users, ineffective recruitment approaches, and distribution methods. In addition to these barriers, the length of time required for data collection is often underestimated. As with all stages within the PMCF survey process, having a strategic plan for the recruitment of end users is key, including contingencies for not fulfilling sample size.

- Begin by **clarifying the types of respondents** to target (i.e., healthcare professionals who are based in a specific country where the device is sold and work with typical users of the subject medical device). Starting too broadly can result in poor data and a low response rate.

- Consider the **appropriate recruitment approach** and whether manufacturers can recruit directly (e.g., through known contacts or representatives and marketing). If recruitment cannot be conducted directly, consider whether outsourcing the recruitment is a possibility,

for example, engaging a healthcare professional panel. These methods can be used alone or in combination, each with its benefits and limitations.

- Allow **sufficient time** for recruitment. The collection of adequate survey data typically takes three to six months, depending on feasibility.

- Have **contingencies** in place:
  - Use supplementary markets (e.g., the US, where patient characteristics are similar to those in Europe);
  - Increase the number of cases/surveys an individual respondent can complete if conducting a Level 4 survey;
  - Use hybrid recruitment approaches; and
  - Conduct continual reviews of the statistical impact on the analysis if there is a sample size shortfall.

Besides difficulty recruiting end users, low response rates hinder data collection and can cause delays in achieving the target sample size . As previously mentioned, there are a number of steps that can be taken to maximize response rates, including but not limited to:

- Outlining the purpose of the PMCF survey,
- Designing Level 4 surveys to align as much as possible with patient chart data or standard of care
- Avoiding lengthy and complex surveys
- Compensating end users for their time

Potential for bias

Bias can have a significant effect on data validity and reliability. The MDCG 2020-7 guidance document outlines the importance of recognizing and minimizing such occurrences.[4] It identifies several biases that may arise during clinical investigations, including selection and reporting bias, both of which should be considered when implementing PMCF surveys. To mitigate these biases and ensure collected evidence is credible, MDCG 2020-7 emphasizes that manufacturers must have adequate controls in place and encourages manufacturers to design studies that reduce such occurrences by using strategies such as randomization and blinding.[4]

In the context of PMCF surveys, several sources of bias can affect data quality. For example, leading questions can skew results. Therefore, surveys should be designed with best practices in mind (as outlined in the section on designing a robust PMCF survey) and refrain from using nonneutral language. For example, survey questions should be phrased in a way that allows respondents to provide an answer that reflects their actual experience with the medical device rather

than being influenced by the wording of the questions. In addition, the potential for bias is higher in general/usability Level 8 surveys compared with high-quality patient/case-specific Level 4 surveys, as respondents are required to recollect their usage of the device over a longer period. To reduce this bias, surveys should prompt respondents to refer to medical records and patient charts from consecutive cases, if possible (especially for Level 4 surveys).

Response bias is another concern, particularly when respondents are aware of the manufacturer's involvement and therefore may refrain from reporting adverse events or performance issues because they fear repercussions or are concerned about their perceived loyalty to the manufacturer or the anonymity of their responses. While leveraging existing relationships with end-users may be preferable (see section on achieving target sample size), especially for devices with low sales or devices used in niche specialties (e.g., medical devices used by a small, highly specialized group of clinicians or in rare or specific procedures), this recruitment approach can inadvertently distort findings. Therefore, it is important to carefully consider the risk of response bias when deciding on the recruitment approach.

Establishing quality control measures

PMCF surveys can generate high volumes of data. If an organization does not have sufficient methods for managing and reviewing collected data on an ongoing basis, there is a risk the data could be insufficient or unreliable. This may result from programming errors within the survey or targeting inappropriate respondents. Methods to address poor quality data include stringent validation and quality control measures.

Once the questionnaire has been reviewed and approved by the medical device manufacturer or associated bodies, the next phase is distributing the survey to potential respondents. This section will refer to online surveys, which tend to be the most simple and cost-effective method.[2] The questionnaire file can be transferred onto a reputable survey hosting programming website, which can enhance the respondent experience and survey performance.

Testing and validation of the survey

Manufacturers should refer to the guidance in ISO 14155:2020 when conducting PMCF surveys on medical devices for human subjects.[6] The document outlines good clinical practice and reiterates the significance of validating electronic clinical data systems in Section 7.8.3. Manufacturers should ensure that their functionality testing, data collection and handling, and change control processes align with this document.[6] As programming errors in the survey could risk the effectiveness of the data collection, it is essential to undertake rigorous testing of the programmed survey through user acceptance testing. Once any issues have been addressed, the online survey should be retested to ensure that any implemented changes in other survey areas have been accounted for. The key aspects for review are to ensure that:

- The phrasing of the questions, answer options, and instruction text minimize misunderstanding;
- The routing logic and termination points function as expected throughout the survey;
- Error messages are displayed if responses have not been provided for questions where they are required, and respondents cannot continue until an answer is provided;
- Respondents can only enter valid dates, numeric values, or characters within a specific range; and
- The general style, user experience, and length of time to complete the survey have been considered.

Screening and quality control measures

Online surveys can present challenges such as respondent identity and specialty validation. Manufacturers might use healthcare professional panels that conduct extensive verification checks on respondents during the onboarding process to confirm and validate their credentials and workplaces. During the survey design stage, screening questions relating to specialties, years of experience, manufacturer, device types, and usage volumes should be included. One method to alidate this is to include a combination of open-ended and multiple-choice questions to cross-reference responses. In relation to this, it is important to conduct reviews of the data collected at regular intervals. If there are any concerns about a respondent's answers – provided that consent has been given – they should be contacted to clarification before they are accepted into the study. It is imperative to have a reliable dataset because it is used to confirm safety and performance objectives.

The soft launch phase

In addition to extensive programming testing, there should also be a soft launch phase. This involves distributing the survey to a limited number of respondents (e.g., five to ten), thoroughly reviewing the data collected against the routing steps, and reviewing the quality of the data collected. Due to the small sample size obtained during this early stage of the survey launch, it is possible that some questions – such as those related to adverse events – may have no responses if such events have not been reported.). Therefore, all survey questions and data points should be monitored throughout fieldwork. If any programming-related issues have been identified, it is crucial to pause fieldwork immediately to implement the necessary corrections.

Data analysis

Data collected from PMCF surveys should be presented within a PMCF survey or evaluation report in accordance with the PMCF survey plan or protocol to ensure that all endpoints are analyzed statistically. Depending on the data, some data points, especially those relating to the safety and performance endpoints, will be analyzed through descriptive statistics (e.g., count, percentage, and confidence intervals) to provide insights into how the adverse

event and technical/success rate compare with their respective and predefined acceptance criteria. This analysis will allow manufacturers to identify emerging unexpected risks or significant increases in known risks, thereby monitoring the ongoing acceptability of the device's benefit-risk profile.

Given that PMCF surveys can generate a substantial volume of complaint data, this can pose significant challenges (e.g., creating data silos) for complaint handling teams. Manufacturers should prepare for this by expanding personnel and training to ensure timely and accurate investigation of adverse events and performance issues, as well as optimizing their processes to effectively manage the influx and complexities of complaint data.

Conclusion

Under the EU MDR, PMCF surveys are an essential tool for manufacturers to collect real-world data on the safety and performance of their medical devices. Despite the challenges associated with planning and executing high-quality patient/case specific Level 4 and general/usability Level 8 PMCF surveys, it is important to adhere to regulatory requirements and implement best practices where possible. Manufacturers can improve the effectiveness of their PMCF surveys by addressing common obstacles such as poorly defined objectives, inadequate statistical justification, and potential biases. In addition, PMCF surveys offer the benefit of lower costs and shorter timelines compared with other data collection types such as clinical investigations and registries. Furthermore, the rigorous analysis and systematic presentation of survey data will aid in fulfilling regulatory obligations and contribute to the ongoing evaluation of the device's benefit-risk profile.

Abbreviations

CER, clinical evaluation report; **EEC,** European Economic Community; **EU,** European Union; **EU MDR,** European Union Medical Device Regulation; **GSPRs,** General Safety and Performance Requirements; **ISO,** International Organization for Standardization; **MEDDEV,** Medical Devices Directive; **MDCG,** Medical Device Coordination Group; **PMCF**, postmarket clinical follow-up; **PMS,** postmarket surveillance; **SOTA**, state of the art.

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References

All references were last checked and verified on 3 June 2025.

1. Official Journal of the European Union. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. Accessed 31 January 2025. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745
2. British Standards Institute. EU MDR – Post market clinical follow-up: gaining real-world evidence challenges and solutions. Dated September 2024. Accessed 31 January 2025. https://www.bsigroup.com/en-GB/insights-and-media/insights/whitepapers/eu-mdr-post-market-clinical-follow-up/
3. Medical Device Coordination Group. MDCG 2020-6 – Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC – a guide for manufacturers and notified bodies. Dated April 2020. Accessed 31 January 2025. https://ec.europa.eu/docsroom/documents/40904 09/md_mdcg_2020_6_guidance_sufficient_clinical_evidence_en_0.pdf
4. Medical Device Coordination Group. MDCG 2020-7 – Post-market clinical follow-up (PMCF) plan template – a guide for manufacturers and notified bodies. Dated April 2020. Accessed 31 January 2025. https://health.ec.europa.eu/system/files/2020-09/md_mdcg_2020_7_guidance_pmcf_plan_template_en_0.pdf
5. Medical Device Coordination Group. MDCG 2020-8 – Post-market clinical follow-up (PMCF) evaluation report template – a guide for manufacturers and notified bodies. Dated April 2020. Accessed 31 January 2025. https://health.ec.europa.eu/system/files/2020-09/md_mdcg_2020_8_guidance_pmcf_evaluation_report_en_0.pdf
6. International Organization for Standardization. ISO 14155:2020 Clinical investigation of medical devices for human subjects — Good clinical practice. 3rd ed. Published 2020. https://www.iso.org/standard/71690.html
7. Kearney, B, McDermott, O. The challenges for manufacturers of the increased clinical evaluation in the European medical device regulations: a quantitative study. Ther Innov Regul Sci. Published 17 May 2023. Accessed 7 February 2025. https://pubmed.ncbi.nlm.nih.gov/37198369/

8. Greenlight Guru. Selecting the ideal PMCF activity. Updated December 2023. Accessed 7 February 2025. https://www.greenlight.guru/blog/selecting-the-ideal-pmcf-activity
9. QMed. High-quality (level 4) PMCF surveys – what are they? Published 23 May 2023. Accessed 14 February 2025. https://www.mddionline.com/regulatory-quality/high-quality-level-4-pmcf-surveys-what-are-they-
10. Medical Device Regulation. Annex XV clinical investigations. Dated 14 August 2019. Accessed 31 January 2025. https://www.medical-device-regulation.eu/2019/08/14/annex-xv/
11. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). Accessed 1 July 2025. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679