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**Planning, designing and
implementing high-quality
(Level 4) post-market
clinical follow-up surveys**



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Planning, designing and implementing high-quality (Level 4) post-market clinical follow-up surveys

Introduction

The introduction of Regulation (EU) 2017/745 on medical devices (MDR)¹ in May 2021 has considerably raised the level of regulatory requirements for the European medical device industry. To continue to CE mark devices across Europe, there are increased expectations on medical device manufacturers for continuous post-market evaluation, clinical data collection and evidence generation for their devices. This is addressed by post-market surveillance (PMS) and post-market clinical follow-up (PMCF), which both focus on the lifecycle approach to post-market monitoring. Medical Device Coordination Group (MDCG) guidance 2020-7² states:

‘The Medical Device Regulation (EU) 2017/745 (MDR) considers the post-market clinical follow-up (PMCF) as a continuous process that updates the clinical evaluation and that shall be addressed in the manufacturer’s post-market surveillance (PMS) plan.’

The aim of PMCF, as stated in Annex XIV, part B, section 6.1 of the MDR, is to:

- confirm the safety and performance, including the clinical benefit if applicable, of the device throughout its expected lifetime;
- identify previously unknown side effects and monitor the identified side effects and contraindications;
- identify and analyse emergent risks on the basis of factual evidence;
- ensure the continued acceptability of the benefit-risk ratio;
- identify possible systematic misuse or off-label use of the device, with a view to verifying that the intended purpose is correct.

PMCF data collection methods can vary, with PMCF clinical investigations requiring a notification under Article 74 of the MDR, or potentially an application under Article 82 of the MDR. Other PMCF activities can include methods documented in a PMCF plan that should consider the aims listed from Annex XIV above. Table 1 groups these sources of data into either generic methods or specific methods, with there being an expectation that several of these activities will be required.

Table 1. Sources of post-market data

More general post-market data sources	More specific post-market data sources
<ul style="list-style-type: none"> Literature reviews* Publications General user feedback/complaints reporting General PMCF surveys (Level 8)* 	<ul style="list-style-type: none"> Clinical investigations Registries* Investigator initiated studies High-quality PMCF surveys (Level 4)*

* PMCF procedures listed in MDCG 2020-7

PMCF surveys have become widely accepted as an appropriate component of PMCF data collection, offering cheaper and quicker access to safety and performance data when compared to PMCF clinical investigations.

Appendix III of the MDCG 2020-6³ guidance document, which applies to legacy devices (i.e. those CE marked under the Directives), ranks data collection methods based on the level of evidence they can provide, with 1 being the highest and 12 being the lowest. These sources of clinical data are presented in Table 2. Between clinical investigations, registries, and other non-clinical sources of data, PMCF surveys fall into two categories, with high-quality user surveys assigned an evidence Level 4, and more general surveys (e.g. those assessing device usability) assigned a lower evidence Level 8.

Table 2. Hierarchy of clinical data and evidence

Rank	Types of clinical data and evidence
1	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 system 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 that derived from surveys
9	Individual case reports on the subjective device
10	Compliance to non-clinical evidence of common specifications considered relevant to device safety and performance
11	Simulated use/animal/cadaveric testing involving healthcare professionals or other end users
12	Pre-clinical and bench testing/compliance standards

This article will focus on the high-quality (Level 4) PMCF surveys as a compliant approach for post-market data collection and outline how to plan, design and implement these for successful submission to the Notified Bodies and for MDR certification.

Surveys as part of the EU MDR

Surveys have been used by medical device manufacturers for a long time; however, in practice, they have predominantly been used for marketing purposes (e.g. market analysis, brand equity, pricing and communication development) rather than to satisfy clinical and regulatory requirements. They are often used more to describe, compare or explain feelings, values, preferences and behaviours, utilising open ended questions, closed questions and Likert/rating scale questions.

Across the medical technology industry, surveys are becoming more commonplace and are seen as a cost effective, quick and efficient method of collecting information, such as PMCF data on the safety and performance of CE marked medical devices. There are several likely drivers that have resulted in the increased focus on surveys to support the clinical evaluation of medical devices, including:

- increased requirements for clinical data with the MDR for both new and ‘legacy’ devices;
- a greater focus on the use of data in the post-marketing phase of a device lifecycle;
- reference to data from high-quality clinical surveys in MDCG guidance such as MDCG 2020-6.

When considering what might be ‘high quality’ or not, this depends on methodological aspects of the study design and execution. There are no descriptions or criteria available to assign a survey as a ‘high quality’ one. Later, this article will explore the methodological aspects of survey planning, design and implementation; before this, it will look at where surveys fit within the MDR and available guidance.

Interestingly, surveys do not receive any mention in the MDR. The MDR has increased the expectation that pre-market clinical investigations are conducted for high-risk devices in particular (Article 61 of the MDR), and also introduced new requirements for PMCF activity (Article 74 and Annex XV of the MDR).

The MDR requires manufacturers to specify/justify the level of clinical evidence (Article 61(1)) that is needed to support their device. Clinical evidence for regulatory purposes is the combination of clinical data and the clinical evaluation that was conducted. Clinical data are defined in Article 2(48) of the MDR as:

‘information concerning safety or performance that is generated from the use of a device and is sourced from the following:

- clinical investigation(s) of the device concerned,
- clinical investigation(s) or other studies reported in scientific literature, of a device for which equivalence to the device in question can be demonstrated,
- reports published in peer reviewed scientific literature on other clinical experience of either the device in question or a device for which equivalence to the device in question can be demonstrated,
- clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up’.

Survey data can be used as a source of clinical data as it typically meets the criteria for the final bullet point listed above.

The MDCG guidance 2020-7, *Post-market clinical follow-up (PMCF) Plan Template – A guide for manufacturers and notified bodies*², states the following when providing some examples of different activities related to PMCF: ‘surveys planned to collect information about the use of the concerned medical device could be described’.

Finally, MDCG 2020-6, as mentioned in the introduction, has brought increased focus on surveys due to their addition in the hierarchy of clinical evidence in Appendix III, whereby surveys are referenced in two separate levels:

- **Level 4** relates to ‘outcomes from studies with potential methodological flaws but where data can still be quantified and acceptability justified’. The guidance notes that ‘high quality surveys may also fall into this category’.
- **Level 8** refers to proactive PMS data, such as that derived from surveys. The table notes that this source of data is ‘not generally considered a high quality source of data due limitations associated with sources of bias and quality of data collection’.

What is a high-quality, Level 4 survey?

Level 4 versus Level 8 surveys

As described earlier, PMCF activities can be categorised as either general or specific, and with PMCF surveys that can also be the case:

- general = Level 8 PMCF surveys;
- specific = Level 4 PMCF surveys.

The MDR notes the requirement for ‘specific’ methods, objectives and procedures; however, for surveys there is no further description of methodology. In practice, there are likely differences between Level 8 and Level 4 PMCF surveys, listed in Table 3 below.

Table 3. Differences between Level 8 and Level 4 PMCF surveys

General, Level 8 PMCF survey	High-quality, Level 4 PMCF survey
<ul style="list-style-type: none"> • Survey completion based across multiple retrospective usages • Respondents asked to complete survey based on recollection • Completion of a single survey per respondent • Questions more focused on general usability 	<ul style="list-style-type: none"> • Each survey represents one patient/case that the device was used for • Respondent asked to complete survey based on each usage by reviewing patient charts/records • Can be retrospective and prospective • Completion of multiple surveys by each respondent • Questions focused specifically on objectives/endpoints

Level 8 surveys can offer a quick and cost-effective option for PMCF data collection; however, it is important to ensure that the justification for an approach that will result in a lower level of evidence and more general feedback is documented. The rationale for when to use the higher quality Level 4 surveys will be laid out in subsequent sections, but it is worth noting that collecting data via this approach will likely require more complex and rigorous planning, a longer fieldwork timeframe and a higher cost. It is also important to ensure that the activity does not meet the definition of a PMCF clinical investigation for the purpose of Article 74 of the MDR, which is discussed in the next section.

Level 4 surveys versus clinical investigations

Level 4 PMCF surveys are being utilised as an acceptable source of PMCF data and, in turn, as a source of clinical data. Alongside the extensive planning that is required to ensure that endpoints, acceptance criteria and sample sizing are statistically justified, it is important to ensure they do not cross over into a clinical investigation. A clinical investigation is defined in Article 2(45) of the MDR as:

‘any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device’.

In the MDR, three types of clinical investigations are documented:

- Article 62 = non-CE marked devices;

- Article 74 = PMCF clinical investigations;
- Article 82 = ‘other’ clinical investigations.

The borderline between surveys and PMCF or ‘other’ clinical investigations is where most consideration and attention is needed.

Surveys are a tool that can help us to find out information about a topic of interest. They do not, in general, involve an intervention or a particular burden for the questionnaire subject, with the exception of consenting and providing information. As can be seen from the definition of ‘clinical investigation’ from Article 2 of MDR, there is a quite broad definition that mentions ‘involving’ patients. When considering the overall wording concerning clinical investigations, with rules for serious adverse event reporting etc., it is implied that clinical investigations are prospective; however, this is not definitively stated.

PMCF clinical investigations have two mentions in Article 74(1) of the MDR, and only one of these references mentions the additionally invasive or burdensome procedures. As such, it is legally possible that a PMCF investigation without these additionally invasive or burdensome procedures could be interpreted to fall under Article 74(1). For this reason, in cases of doubt, checking national guidance and consultation with the national Competent Authority may be helpful.

In addition to this, PMCF surveys conducted on CE marked devices within the intended purpose and without any additional burdensome and/or invasive procedures, may fall outside the definition of a PMCF investigation, but may fall under ‘other’ clinical investigations.

PMCF survey plan/protocol

As mentioned above, thorough and comprehensive planning is integral to collecting useable data from high-quality, Level 4 PMCF surveys for MDR submissions. The systematic planning of the PMCF survey should begin as soon as surveys are defined as an appropriate data collection method in the PMCF plan. As per MDCG 2020-7, the PMCF plan must specify the methods and procedures set up by the manufacturer to proactively collect and evaluate clinical data, for devices placed on the market or put into service within their intended purpose. Section C of MDCG 2020-7 also states that manufacturers are expected to describe the different activities that will be conducted in the post-market phase. This includes general and specific methods/procedures to be conducted in relation to the product covered by the scope of PMCF. The aim of each activity needs to be described, as well as the rationale for the appropriateness of the chosen general and specific methods to achieve those objectives. The timelines of those activities must be also defined quarterly, or at least yearly.

When planning a high-quality, Level 4 PMCF survey, a robust rationale should be provided within the PMCF plan and the subsequent PMCF survey plan/protocol on why a high-quality, Level 4 survey is deemed a suitable method, and why this level of data will be ‘sufficient’. This should include:

- Defining where the need for conducting the PMCF activity is coming from (as an output of the clinical evaluation report, PMS, risk management report, previous PMCF report, to address non-conformities raised by a Notified Body, etc.).
- Providing the description of the activity, and if it is a general or specific procedure/method.
- Defining the aim of this activity.
- Describing the rationale for the appropriateness of the chosen methods/procedures, including:
 - justification for sample size, timescales and endpoints;
 - justification for the comparator, on the basis of intended purpose and state of the art;
 - justification of the study design on the basis of all of the above, and why it is sufficient to ensure representative patient populations and provide for adequate controls on sources of bias (an evaluation of the potential sources of bias should form part of this);
 - a statistical justification for the expected quality of outcomes, and justification for why this is satisfactory in light of the residual risks.
- Providing the timelines for the activity.

When to conduct a high-quality, Level 4 PMCF survey

There are many variables that must be considered when determining which survey approach (Level 8 versus Level 4) is appropriate for each medical device. Table 4 below summarises some of those factors.

Table 4. Factors to consider when determining which PMCF survey approach to use

General, Level 8 PMCF survey	High-quality, Level 4 PMCF survey
<ul style="list-style-type: none"> • Lower risk classifications • Longer time on the market (well established) • Lower risk of clinical data gaps • Transient/short term use devices 	<ul style="list-style-type: none"> • Higher risk classifications • Shorter time on the market (less well established) • Clinical data gaps (e.g. for ‘legacy’ devices) • Long term uses/implantable devices

Objectives and endpoints

To be deemed a high-quality, Level 4 PMCF survey, clear objectives and endpoints need to be outlined. As per the aim of PMCF, the survey will be used to confirm the safety and performance of the device

in question, and the objectives and endpoints should be focused specifically on safety and performance.

A primary endpoint commonly covers device performance/technical success, and focuses on the ability of the subject device to perform its intended purpose effectively. Secondary endpoint(s) commonly cover other performance measures or specific safety measures, such as adverse event/complication rates.

The acceptance criteria for both endpoints should be based on a thorough clinical evaluation of both the subject device and the state of the art/benchmark devices, such as review of the literature. The data collected on both the primary and secondary endpoints will be used to confirm the benefit-risk ratio of the device.

Sampling

Once the endpoints and acceptance criteria have been determined, the statistical considerations for how to calculate the sample size (the number of subjects or data points that need to be collected) can be looked at. For PMCF surveys to be classified as ‘high quality’ and Level 4, the sample size must be statistically valid so that the endpoints can be evaluated effectively against the acceptance criteria. For example, MDCF 2020-7 states ‘retrospective surveys with no justification other than “this should demonstrate the expected quality of evidence that we require,” but without showing a statistical rationale, are not acceptable’.

There are many appropriate sample size calculations that can be used, and these differ significantly depending on whether equivalence, superiority or non-inferiority is being tested when comparing the subject device to the state of the art⁴. Detailed justification should be drawn in the PMCF survey protocol to rationalise the test used and the resulting sample size. It is worth noting that high-quality, Level 4 surveys will be designed to collect data on a specific, individual case or patient, meaning that the resulting sample size will represent the number of cases that the data will need to be collected on, rather than the number of individual respondents completing the survey.

Once the sample size has been set, it is important to ensure that the study population and any specific datapoints that need to be captured are laid out prior to implementation. These may include, but are not limited to, the following:

- who the end users/respondents are (e.g. speciality);
- countries that will be covered (higher sales markets should be considered);
- device variants/sizes to ensure full coverage;
- patient populations to ensure full coverage across the intended use.

Other planning considerations

There are many more aspects that need to be included within the survey plan/protocol, including information on the device itself (e.g. intended use, indication, expected lifetime), how the surveys will be implemented/distributed, timelines and procedures for early survey termination or survey extension, and compliance considerations.

The next section of this article will focus on how to design a PMCF survey to ensure alignment with the requirements for a high-quality, Level 4 survey.

PMCF survey design

One of the most critical stages of a high-quality, Level 4 survey approach is ensuring that the survey itself is designed appropriately. Building upon what has been laid out in the PMCF survey plan/protocol is fundamental and it is imperative that the objectives and endpoints can be addressed in a manner that allows the data to be collected and aligned against these and the acceptance criteria. If the endpoints and the objectives are missed or fail to be addressed accurately, this could result in the data being disregarded and/or the survey being repeated, resulting in cost, time and resource implications and ultimately a risk to timely and compliant MDR submissions.

Hopefully, the objectives and endpoints that will form the research question will be well defined within the survey protocol, meaning that the format and type of questions can be discussed. In Table 3, the differences between Level 4 and Level 8 surveys were laid out, and this described some of the design considerations.

The case/patient specific nature of high-quality, Level 4 surveys and the need to collect specific information on an individual case, very often derived from patient records or charts, necessitate a good understanding of what information is included in the patient records/charts.

The survey questions can be a mix of closed ended (single-code, multi-code, numerical etc.) and open ended/free text questions. It is important to avoid any leading questions and ensure they are clear and easy to read, with the overall survey being short (approximately 10 to 15 minutes), concise and not overly burdensome for the respondent. The language that is used should be linked to the audience that it is referring to (e.g. a survey aimed at healthcare professionals will be worded very differently to one aimed at patients). It is essential for the survey to be structured with a view to obtaining accurate data, increasing respondents' engagement and expediting reporting of the results.

Depending on how the end users are identified and invited to complete the survey, there may or may not be a pre-screening section of the survey. Nonetheless, surveys can be set up in a number of ways but will typically follow the order set out in Figure 1 *below*.

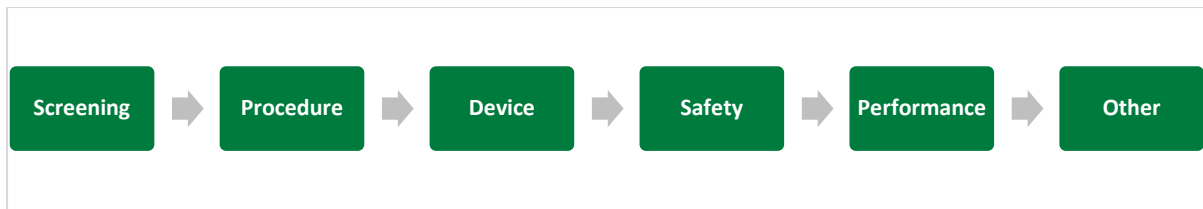


Figure 1. Typical order for a survey to follow

Other questions, unrelated to the endpoints, can be added and provide use from a business perspective as it is possible to collect extra information that can be used for additional purposes (e.g. marketing). It is, however, very important not to lose focus as to the aims of the survey (i.e. to collect PMCF data) and to concentrate on collecting data on the specific objectives and endpoints. Any additional questions must not threaten to disrupt this focus, which ultimately should be clinical.

Other considerations for the design of the survey are linked to how best to implement the survey itself, which will be discussed in the next section. As each survey will represent an individual case/device usage, respondents may qualify to complete multiple surveys if they are regular users of the device. It is vital, therefore, to think carefully about the timeframe in which respondents can complete the survey for a particular case: balancing a long enough timeframe to ensure response/qualification rate and also short enough to remove any recollection bias and decrease in the quality and accuracy of the data itself. A landing page prior to the main survey(s) can be useful to explain what is required of respondents and allow them a base to save progress if they plan to complete multiple surveys, especially if allowing for a prospective approach.

Implementation

The implementation stage of a high-quality, Level 4 PMCF survey is critical, as if the survey is unable to reach the relevant respondents and achieve the target sample, then all the hard work in the pre-implementation stage will be wasted. The implementation process is very often overlooked but is probably the most critical piece to ensure success. Considerations must be made on whether to take this on internally or to outsource, and the following must be taken into account:

- What format will the survey be in (e.g. paper, online, etc.)?
- How will the respondents/end users be identified and recruited?
- How will engagement be maximised (e.g. purpose provided, compensation, etc.)?
- Are there internal resources to manage fieldwork and perform regular data checks?
- How will the data be collected, stored, validated and processed?
- What back-up plans are in place should issues arise (e.g. sample size is unachievable)?

With the above in mind, realistic timelines should be built in and worked against to ensure deadlines are met. A standard high-quality, Level 4 survey will take anywhere between four to six months to be conducted from start to finish, with the implementation period representing approximately half of that time. Resources should also be considered: whether there is sufficient manpower internally to take on each stage of the process, or whether external expertise and support is required (which in turn results in onboarding and additional approval stages).

PMCF survey analysis

Once all the data have been collected from the Level 4 PMCF survey, they will need to be cleaned, analysed and compiled within a PMCF evaluation report. The MDCG 2020-8⁵ guidance document has become a helpful resource in this process, by providing guidance on how to:

- analyse PMCF survey data effectively by performing a statistical analysis;
- interpret PMCF survey data in the context of the subject device's intended purpose, patient population and other relevant factors;
- report on PMCF survey data using their report template as a point of reference.

To summarise, the survey data should be used to examine whether the performance and safety of the subject device align with any identified equivalent or similar devices. This is achieved by considering the data in the context of the acceptance criteria of the primary and secondary objectives and endpoints outlined in the PMCF survey protocol/plan.

To address the primary objectives of the survey, data associated with the performance of the subject device when used in accordance with the intended purpose should be compared against the corresponding acceptance criteria. An acceptance criterion sets the minimum or lower bound success rate based on existing data from the subject or similar devices and serves to determine whether the subject device meets the expected performance standards.

To address the secondary objectives of the survey, data pertaining to safety aspects, such as adverse events encountered during use of the subject device should be evaluated. At this stage, it is necessary to identify what the adverse events were, whether they are new or unidentified by comparing against the clinical and risk documentation, the proportion in which the events occurred and the relatedness of the events to the use of the device. Together, these data are compared against the acceptance criterion of the secondary objective and endpoint, which typically refers to the highest proportion of cases in which an adverse event should be encountered during use of the subject or similar devices.

Given that survey data are collected across a sample of device users and usage, the observed success and adverse event rate may not be representative of the entire population. To account for this uncertainty, confidence intervals are constructed, which provide the range in which the data collected within the survey must fall to provide assurance that the acceptable success and adverse event rates have been met. The width of confidence intervals depends on several factors, of which the main one is the sample size. The level of confidence, therefore, should be defined before survey implementation, to identify a sample size that provides the highest level of confidence, certainty, and precision in the observed data. For Level 4 PMCF surveys, the level of confidence is usually set at 95%, and enables manufacturers to perform the benefit-risk analysis of their subject device more accurately. Other data points, such as exploratory endpoints, for which no acceptance criteria are defined should be analysed via simple counts and percentages and can feed into the reviews of any relevant risk or clinical documentation.

It is important to ensure that there is a clear log that documents how the data have been received, processed and analysed. Utilising software to support with the analysis, outside of the standard use of Microsoft Excel, can be beneficial and aid with the automation, and reduction of human error, for this process.

PMCF is an ongoing, cyclical process (see Figure 2), and in addition to the PMCF evaluation report, results from PMCF activities should be fed back into clinical documentation, including the:

- Clinical Evaluation Report (CER);
- risk management documents;
- Periodic Safety Update Report (PSUR);
- Summary of Safety and Clinical Performance (SSCP).

Furthermore, learnings from the survey data should also be used to update design documents, labelling, the PMS and PMCF plan.

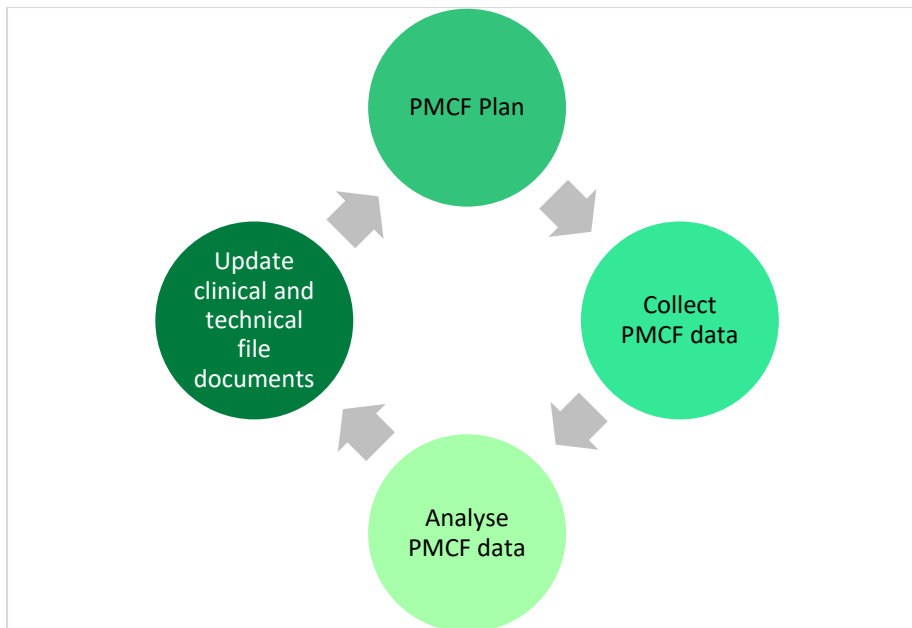


Figure 2. PMCF is an ongoing, cyclical process

Conclusions

PMCF surveys are an important and pragmatic means of supporting post-market activity of manufacturers for the MDR. MDCG 2020-6 encourages their use, in particular for ‘legacy’ device manufacturers who are transitioning their device from compliance with the Directives to the MDR. There are no standard templates, definitions or methodologies for this activity, however, and this article demonstrates some practices which can support manufacturers in undertaking this activity in a compliant way. Institutional approvals for access to chart data need to be considered. The use of personal data and compliance with applicable regulations such as the General Data Protection Regulation is important, in particular with respect to Level 4 surveys. Further work is needed to develop medical device survey methodologies, to better delineate survey activity from clinical investigations, and to describe best practice criteria for conducting surveys.

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