

New documents required by the medical device regulation

Payal Bhatia¹, Laura C. Collada Ali²,
Kelly Goodwin Burri³, Gillian Pritchard⁴,
Namrata Singh⁵, Namrata Upadhyay⁶

¹ Medical Minds GmbH, Bern, Switzerland

² Medical Writing and Translation Consultant,
Cogne, Italy

³ Stryker GmbH, Selzach, Switzerland

⁴ Sylexis Limited, Dundee, Scotland, UK

⁵ Turacoz Healthcare Solutions, India

⁶ MD Clinicals, Switzerland

Correspondence to:

Kelly Goodwin Burri
Stryker GmbH
Bohnackerweg 1
2545 Selzach, Switzerland
kelly.goodwinburri@stryker.com

Abstract

This article introduces four documents associated with the new Medical Device Regulation 2017/745: the clinical evaluation plan, post-market clinical follow-up (PMCF) plan and PMCF evaluation report, and the summary of safety and clinical performance. The clinical evaluation plan describes the process that will be used to evaluate the performance and safety of a medical device, eventually resulting in a clinical evaluation report. The PMCF plan describes the procedures to collect post-market clinical data that are presented in the PMCF evaluation report. Finally, the summary of safety and clinical performance presents the relevant clinical evidence related to a medical device to healthcare professionals and patients.

Introduction

After a 3-year transition period, the Medical Device Regulation (MDR) 2017/745¹ should have come into force in May 2020. With MDR implementation now postponed by one year due to the coronavirus pandemic, medical devices marketed in the EU and European Economic Area will now have to comply with the regulation

by May 2021.² For medical writers, implementation of the MDR remains focussed on rethinking clinical evaluation so that it is now a continuous evaluation process with a report – the clinical evaluation report (CER) – produced at regular intervals or when required by new information, and all underpinned by a clinical evaluation plan (CEP). But did you know that the CER and CEP are not the only documents required under MDR? Depending upon the class of device, the following documents may also be necessary: post-market clinical follow-up (PMCF) evaluation plan and report, a summary of safety and clinical performance (SSCP), risk management report, periodic safety update report, and post-market surveillance plan and report.³ This article introduces four of these new documents – the CEP, PMCF evaluation plan and report, and the SSCP. Figure 1 shows where these four documents fit in the development and post-market phases of a medical device. We also highlight new guidance documents under the MDR and describe where existing MEDDEV guidance documents (implementation guidance issued under the Medical Device Directives, a predecessor to the MDR) are still relevant.

Clinical evaluation plan

Our first peek into MDR-compliant documentation begins with the CEP. Clinical evaluation

has been defined by the MDR as “a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer.” The CEP is the starting point of the clinical evaluation process for a medical device that results in a CER. The purpose of a CEP is to define the scope of the clinical evaluation and lay out a systematic process by which the clinical evaluation is conducted. Simply put, a CEP should ideally be prepared early during the development of a medical device to identify the clinical data that needs to be generated for market access. It may also be used in the post-market phase to continually assess the need for new clinical evidence.

The MDR requires a well-defined CEP demonstrating that the manufacturer has thorough procedures in place to confirm compliance with the relevant general safety and performance requirements defined in Annex 1 of the regulation. Annex XIV (Part A) of the MDR defines, point-by-point, the required contents that shall be part of a CEP (Box 1). In addition, chapter 7 of the MEDDEV 2.7/1 Revision 4 defines the topics to be considered during the scoping stage of the clinical evaluation process.⁴ A well-compiled CEP should have elements from

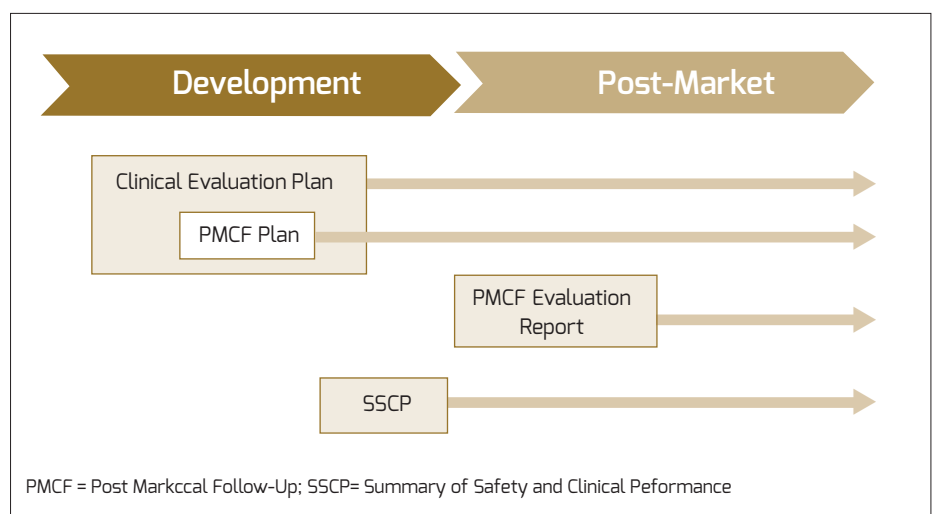


Figure 1. Documents required during medical device development and post-market phases

Box 1. Required contents of the clinical evaluation plan

To plan, continuously conduct and document a clinical evaluation, manufacturers shall establish and update a clinical evaluation plan, which shall include at least:

- an identification of the general safety and performance requirements that require support from relevant clinical data;
- a specification of the intended purpose of the device;
- a clear specification of intended target groups with clear indications and contraindications;
- a detailed description of intended clinical benefits to patients with relevant and specified clinical outcome parameters;
- a specification of methods to be used for examination of qualitative and quantitative aspects of clinical safety with clear reference to the determination of residual risks and side-effects;
- an indicative list and specification of parameters to be used to determine, based on the state of the art in medicine, the acceptability of the benefit-risk ratio for the various indications and for the intended purpose or purposes of the device;
- an indication how benefit-risk issues relating to specific components such as the use of pharmaceutical, non-viable animal or human tissues, are to be addressed; and
- a clinical development plan indicating progression from exploratory investigations, such as first-in-man studies, feasibility and pilot studies, to confirmatory investigations, such as pivotal clinical investigations, and a PMCF with an indication of milestones and a description of potential acceptance criteria.

Source: MDR 2017/745 Annex XIV Part A¹

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both the MDR and the MEDDEV guidelines.

While the European Commission, in the form of the Medical Device Coordination Group (MDCG), provides a range of guidance documents to assist stakeholders in implementing the medical device regulations (including the other materials discussed in this article), it lacks guidance on preparing a CEP. Moreover, this topic is still not part of the planned MDCG guidance documents.

The CEP is an important document for the different parties involved in the product life cycle. These include, among others, the manufacturer, the Notified Body and their experts, the Competent Authorities in Europe, and regulators in general (for example, delegates of the European Commission when they carry out a joint audit of the Notified Body). The CEP may also be used in submissions to other health authorities abroad that rely on the CE mark technical documentation, e.g., for the Australian regulatory submission pathway or some countries in Latin America.

Writing a CEP is a team effort, requiring information that comes from multiple sources.

The CEP is a living document that needs to be updated proactively on a regular basis.

In addition to medical writers, the teams, departments, or professionals involved in creating a CEP primarily include people from the clinical and medical affairs team, the regulatory affairs team, the vigilance/post-market surveillance team such as device safety specialists, the R&D team such as product development or maintenance engineers, the marketing team such as product managers, and the clinical experts. The medical writer will need input from documents, including parts of the design history file, instructions for use (IFU), and other accompanying documents, such as surgical techniques or product brochures, verification and validation plans, post-market surveillance and PMCF plans, clinical investigation protocols (for carrying out clinical investigations if needed), and the risk management plan.

The CEP is a living document that needs to be updated proactively on a regular basis. The MDR and MEDDEV do not provide explicit guidance on the frequency of CEP updates, but the document should be reviewed during the CER update process to determine if any changes are needed.

To summarise, a CEP is a scoping document that allows the manufacturer to put in place the necessary plans required to evaluate the performance and safety of their medical device. It should include elements defined by both the MDR and the MEDDEV. Moreover, the CEP must be updated regularly by the manufacturer. Eventually, it will result in a CER.

PMCF evaluation plan and report

Post-Market Clinical Follow-Up (PMCF) is part of post-market surveillance and was required under the Medical Devices Directive (MDD) amendment 2007/47/EC⁵ with guidance provided in MEDDEV 2.12/2 rev. 2.⁶ PMCF is the process of collecting clinical data on a CE-marked device to confirm clinical performance and safety during the device's expected lifetime.³ It is also a means of determining the acceptability of identified risks and of detecting emerging risks by gathering long term data from a larger patient population than is possible during device development. The PMCF plan describes the methods and procedures the manufacturer will use to collect clinical data for the CE-marked device.⁶ These data are presented in the PMCF

Box 2. Required contents of the PMCF Plan

The PMCF plan shall specify methods and procedures for proactively collecting and evaluating clinical data with the aim of:

- a. the general methods and procedures of the PMCF to be applied, such as the gathering of clinical experience gained, feedback from users, screening of scientific literature and other sources of clinical data;
- b. the specific methods and procedures of PMCF to be applied, such as evaluation of suitable registers or PMCF studies;
- c. a rationale for the appropriateness of the methods and procedures referred to in points (a) and (b);
- d. a reference to the relevant parts of the clinical evaluation report referred to in Section 4 and to the risk management referred to in Section 3 of Annex I (of the MDR);
- e. the specific objectives to be addressed by the PMCF;
- f. an evaluation of the clinical data relating to equivalent or similar devices;
- g. reference to any relevant common specifications, harmonised standards when used by the manufacturer, and relevant guidance on PMCF; and
- h. a detailed and adequately justified time schedule for PMCF activities (e.g., analysis of PMCF data and reporting) to be undertaken by the manufacturer.

Source: MDR 2017/745 Annex XIV Part B¹

evaluation report, which contributes to the clinical evaluation of the device and is part of the CER and the technical documentation.¹

A PMCF plan and report were required under MDD; the clinical requirements have not changed with MDR, but the procedure for demonstrating compliance has changed.³ MEDDEV 2.12/2 gives guidance stating that “the requirement for PMCF studies is based on the identification of possible residual risks and/or unclarity on long term clinical performance that may impact the benefit/risk ratio” and cites examples of when a PMCF study might be justified.⁶ But the MEDDEV guidance is not legally binding, and non-compliance with a MEDDEV guidance could not be a reason for non-compliance with the MDD.³ Thus, manufacturers could decide that a PMCF study was not necessary and that their approach to PMCF was acceptable. MDR now makes it clear that PMCF is not an option but a requirement.

Annex XIV part B of the MDR specifies the methods and procedures for proactively collecting and evaluating clinical data with the aims of:

- Confirming the safety and performance of the device throughout its expected lifetime

- Identifying previously unknown side-effects and monitoring identified side effects and contraindications
- Identifying and analysing emergent risks
- Ensuring the continued acceptability of the benefit-risk ratio
- Identifying possible systematic misuse or off-label use of the device

The Annex also specifies the required contents of the PMCF plan (Box 2). The MDCG has recently published additional guidance in the form of templates for both the PMCF plan and the PMCF evaluation report.^{7,8} The templates lay out in more detail the required content and structure expected for each of these documents to describe, among other aspects, the activities undertaken related to PMCF and the results of those activities, an evaluation of clinical data relating to equivalent or similar devices, and for the report, a summary of the impact of the results on the technical documentation.

Medical writers are increasingly involved in writing PMCF plans and, in due course, PMCF

evaluation reports. Writers work together with clinical operations who oversee clinical investigations and device registries, post-market surveillance, regulatory, and quality assurance groups in order to prepare PMCF plans and reports.

The PMCF plan is prepared during the development of the medical device together with the CEP (Figure 1). It will be summarised in the initial CER and is part of the technical documentation submitted for conformity assessment. The PMCF plan will be scrutinised by the Notified Body, who will determine whether there are already sufficient clinical data and if the proposed PMCF plan will address any identified gaps in clinical evidence. Once the device is CE-marked, the PMCF findings are analysed and presented in the PMCF evaluation report. This report is prepared annually for class III and implantable devices, every two to five years or as required for class IIa and IIb devices, and as needed for class I medical devices.³ The PMCF report should be produced in time for inclusion in an updated CER. The PMCF plan should be reviewed and updated as part of the clinical evaluation of a medical device.

To summarise, the PMCF plan and evaluation report are part of post-market surveillance. The PMCF plan describes the methods and procedures to be used to collect clinical data for the CE-marked device, which are then analysed and presented in the evaluation report.

Summary of safety and clinical performance

The SSCP is an entirely new requirement under MDR. According to Article 32 of the MDR manufacturers shall prepare an SSCP for implantable devices and class III devices, other than custom-made or investigational devices. The SSCP should provide an objective and balanced summary of the clinical evaluation results of all the available clinical data related to the device in question, whether favourable, unfavourable, or inconclusive, among other information. It is not intended to provide general advice on diagnosis or treatment of a medical condition, replace the device’s IFU, or replace mandatory information on patient implant cards or any other mandatory document.⁹ The required content of the SSCP is

Medical writers are increasingly involved in writing PMCF plans and, in due course, PMCF evaluation reports.

Box 3. Required contents of the summary of safety and clinical performance

The summary of safety and clinical performance shall include at least the following aspects:

- a. the identification of the device and the manufacturer;
- b. the intended purpose of the device and any indications, contraindications and target populations;
- c. a comprehensive description of the device;
- d. possible diagnostic or therapeutic alternatives;
- e. reference to any harmonised standards and Common Specifications applied;
- f. the summary of the clinical evaluation, and relevant information on post-market clinical follow-up;
- g. suggested profile and training for users;
- h. information on any residual risks and any undesirable effects, warnings and precautions.

Source: MDR 2017/745 Article 32(2)¹

summarised in Box 3. In addition to the contents defined by MDR Article 32, medical writers can refer to the MDCG guidance document for direction on how to prepare the SSCP and the minimum content required.⁹

The SSCP is written specifically for the end users of a medical device, including both healthcare professionals and, if relevant, patients. The manufacturer has the responsibility of deciding whether content for patients is needed. Information written for patients is mandatory for implantable devices for which patients will be given implant cards and class III devices that are intended to be used directly by patients but may not be needed for exempt devices such as sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors. If the SSCP contains information for both healthcare professionals and patients, the document should incorporate separate and clearly distinguishable sections tailored to each audience. The SSCP will be publicly available on the European database on medical devices (Eudamed) when this is ready for use (expected in May 2022). Additionally, the device IFU needs to contain all information required to find the SSCP on Eudamed, including the URL to the Eudamed public website (once available) and linked to the Basic UDI-DI, the unique identification number for the device.

The team involved in writing an SSCP relies on the quality of input documents. The writer may need inputs from the medical advisor/clinical expert, medical affairs, clinical research, and regulatory affairs teams. Because the SSCP is

in the public domain, it may also be subject to an extensive review and require approvals from legal, trademark, and communications or marketing departments. Ultimately, Notified Bodies are the final reviewers of the document, as they need to validate it before it is finalised and published on Eudamed. The source of information required to write the SSCP comes from the technical documentation of the device, which includes design verification/validation reports, risk management report/file, the CER, post-market surveillance and PMCF plans and report, and the IFU. The CER is the most important input document for the SSCP. The PMCF plan and report may also be an input document for the SSCP, although this content is often also addressed in the CER.

The SSCP needs to be ready for product launch and updated whenever there are any updates to the PMCF evaluation report, the periodic safety update report, and the CER. The final SSCP must be translated following the specific member state requirements for the IFU,⁹ depending on whether the information is required for healthcare professionals or patients or both. If the selection of European languages for the SSCP does not include English, an English translation should be submitted for healthcare professionals in all member states. There should be one SSCP for each language and the language translation should be validated by the Notified Body.

To summarise, the SSCP is intended to provide a summary of the clinical evidence related to the safety and clinical performance of

a medical device to healthcare professionals and, if relevant, patients. The document will provide a publicly available source of information for intended users validated by the Notified Bodies.

Conclusions

The MDR introduces several new documentation requirements for medical devices. Additional detailed guidance on how to incorporate the MDR requirements into specific documents is still being developed by the MDCG with templates currently available for the PMCF plan, PMCF evaluation report, and the SSCP. The postponement of MDR implementation gives the medical device writer additional time to become familiar with the new document requirements and upgrade the skills and expertise required.

Disclaimers

The opinions expressed in this article are the authors' own and not necessarily shared by their employers or EMWA.

Conflicts of interest

The authors declare no conflicts of interest.

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Author information

Payal Bhatia, PhD, is a senior medical writer at a medical writing and consulting company in Switzerland. Her daily business includes preparing manuscripts, CEPs and reports, and other regulatory documents for medical devices, mainly in the field of orthopaedics. She has been an active member of EMWA since 2015.

Laura C. Collada Ali is a medical writing and translation consultant with more than 20 years of experience in delivering multilingual authoring services for leading pharmaceutical and medical device companies. She regularly prepares CEP, SSCPs, and PMCF related documents for medical devices in the fields of orthopaedics and traumatology.

Kelly Goodwin Burri is a senior medical writer for a medical device manufacturer preparing CERs and related documentation in the fields of orthopaedics and traumatology. She has more than 15 years of experience in bioengineering research, clinical research and development, epidemiology, and patient registry management.

Gillian Pritchard, MSc, MRCP, MFPM, MBA, is the director of Sylexis Limited, a consultancy providing regulatory writing services for pharmaceutical and medical device companies since 2006. Gillian also leads several workshops for EMWA.

Dr Namrata Singh, MBBS, DNB (Pediatrics), MBA, is the founder member of Turacoz Healthcare Solutions, a medical writing and consultancy agency. She has experience in working across complete product life cycle (medical, regulatory and marketing divisions) for pharmaceutical, medical devices and diagnostics.

Dr Namrata Upadhyay, dr.dent.med, CMDA, is a medical device clinical and regulatory associate. She has experience in CA/RA/QA consulting and as a freelancer in medical writing and medical communications with an expertise in dental devices.