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Free CEP Template

Content & structure for MDR-compliant Clinical Evaluation Plans

Edition 1

This template is a free version of the Mantra Systems CEP Template

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Contents

Introduction

The Clinical Evaluation Plan (CEP) is an important technical document that must be produced in relation to every medical device under the MDR. It documents a plan for conducting a Clinical Evaluation, which is an essential step for any MDR submission.

The CEP is often overlooked and is a very common source of non-conformity. This template is intended to provide a tried-and-tested CEP format that has formed the basis for over 300 successful submissions to date.

A CEP should consist of the following sections:

1. Administrative particulars
2. Introduction
3. Scope of the Clinical Evaluation
4. Subject device overview
5. General Safety & Performance Requirements (GSPRs)
6. Type of evaluation
7. Search protocol – evidence identification, appraisal & analysis plan
8. Plan for analysis of PMS data
9. Clinical Development Plan
10. CEP revision dates

Structure

It is essential that the CEP is well-structured. It is recommended that the user follows the structure of headings, subheadings and sub-subheadings in this template. This will help ensure that the resulting CEP will be well organised and align with requirements for MDR clinical evaluation.

CEP Writing Tips

1. Write objectively and in the third-person
2. Define all terms used
3. Ensure that all points made are referenced. Avoid "naked" opinions that are unsubstantiated
4. If using a text editor such as Microsoft Word, use the "styles" function "heading 1", "heading 2" for headings and sub-headings in the document. This then enables automatic construction of a table of contents that will auto-update to any subsequent changes.

CEP Review Service

If you've already written a CEP and would like an independent review prior to Notified Body submission, we also offer a bespoke CEP review service, facilitating direct and focused feedback from experienced professional CEP writers. Please contact us to discuss this service in more detail.

Support

Please **contact our team** with any questions you may have while using this template.

1. Administrative particulars

This introductory section has three subsections:

1. Title page
2. Contents page
3. Administrative particulars summary

The administrative particulars summary section is intended to give a reviewer quick access to key facts about the subject device, including:

- Name
- Model number
- Basic UDI-DI
- Manufacturer address
- Risk classification
- Intended purpose
- CEP authors
- Date of CEP

2. Introduction

This section sets the scene for the CEP and the Clinical Evaluation to which it relates. It should convey to the review an understanding of the purpose of Clinical Evaluation and the legislative basis for the process.

Key requirements are:

- Summarise the purpose of a Clinical Evaluation and a CEP
- Outline the MDR Articles and Annexes that set out Clinical Evaluation requirements
- Introduce current CEP and provide an overview of methods that will be used

For example:

Introduction

This document outlines a Clinical Evaluation Plan for the [Device name], manufactured by [Manufacturer]. This Plan will be followed during conduct of Clinical Evaluation activities in relation to the device.

Background

To meet requirements for a conformity assessment under the Medical Device Regulation (EU) 2017/745 (MDR), a manufacturer must conduct a clinical evaluation. This must be conducted following MDR Article 61, which requires a medical device manufacturer to demonstrate that there is clinical data to support the safety and performance of the device.

The clinical evaluation process outlined by this CEP details the steps taken by the Manufacturer to define the device (including intended use), define the scope of the Clinical Evaluation Report (CER), and initially define the other stages involved in the clinical evaluation such as to identify, appraise, and analyse any available data, and monitor the Post-Market Surveillance (PMS) data. This process occurs and will be updated throughout the product life cycle.

Clinical Evaluation methodology - overview

The clinical evaluation will be conducted as per the process described in Annex XIV Part A of the MDR; in overview, the process may be summarised as:

Establish/update the clinical evaluation plan;

Identify available technical and pre-clinical data relevant to the device and its intended purpose

Identify available clinical data relevant to the device and its intended purpose through a systematic literature review;

Appraise all available and relevant clinical data by evaluating in terms of its suitability for supporting the safety and performance of the device, alongside other forms of evidence

3. Scope of the clinical evaluation

3.1. Objective

State an objective for the Clinical Evaluation, e.g.:

- Establish conformity of the device with relevant General Safety and Performance Requirements
- Establish suitability for intended purpose
- Establish acceptability of benefit-risk profile

3.2. Hypothesis

The purpose of the hypothesis is to provide a scientific structure to the CEP. Stating a hypothesis in the CEP enables it to be tested through appraisal and analysis of clinical evidence that follows throughout the Clinical Evaluation.

It is sensible to structure the hypothesis around non-inferiority to comparable alternatives identified through SOTA literature review.

4. Subject device overview

4.1. General description of the device

Provide a full description of the medical device.

4.2. Device components

Describe the composition of the device. What materials is the device made from? Does the device incorporate any medicinal substances, tissues or blood products?

4.3. Principles of use

How is the device used in practice?

4.4. Device classification

Why is the subject device a medical device according to the definition in Article 2 MDR?

What regulatory class is the device? Provide justification by directly quoting the (relevant) rules in Annex VIII MDR. Get further guidance on working with MDR Annex VIII.

4.5. Manufacturer and sales history

State the name of the manufacturer, their address, and explain their experience in this field. State whether the manufacturer has any relevant credentials (e.g. ISO 13485-based quality system).

When was the device first CE-marked? In which countries/territories is the device sold? How many units have been sold to date?

4.6. Intended purpose & claims

What is the intended purpose of the device? What claims does the manufacturer make?

4.7. Indications, contraindications and precautions

What are the medical indications and contraindications for use of the device? What precautions and warnings are provided?

4.8. Target population and medical conditions

What is the target disease or condition?

4.9. Accessories or compatible devices

Describe any accessories associated with the device, and any compatible devices that it is designed to interface with.

4.10. Diagnostic / Therapeutic alternatives

Set out alternative ways of solving the same clinical problem. Note that this is distinct to 'similar devices' below.

For example, if the subject device is a hip implant, similar devices will be other types of hip implant while 'therapeutic alternatives' might be hip resurfacing, steroid injection, physiotherapy, etc. The objective is to place the subject device and similar devices into clinical context.

4.11. Similar devices

Give an overview of any similar devices that have been identified (whether in EU or in other territories).

5. General Safety & Performance Requirements (GSPRs)

Build a table that briefly summarises an analysis of the GSPRs to determine which are, and are not, relevant. Note that this does not need to replicate a separate GSPR checklist; the best approach is to leave justifications etc in the main checklist, and include just a brief (1 page) summary here.

Mantra Systems has produced a video offering further advice on **how to identify GSPRs**.

6. Type of evaluation

Will the evaluation follow the literature route, equivalence route, route under MDR Article 61(10), or some other route? Specify here.

6.1. Methods used for examining clinical safety & performance

Give a specification of methods that will be used for examining both qualitative and quantitative aspects of clinical safety of the device. This could include a thorough and objective systematic literature review.

6.2. Determination of clinical outcome parameters

An essential input to Clinical Evaluation under MDR is to define clinical outcome parameters from a SOTA review. These are qualitative types of clinical outcome that have been consistently reported in studies relating to similar devices - in other words, the literature has determined they are important and relevant.

Identify and list clinical outcome parameters to be used in the Clinical Evaluation. Include a justification for their selection.

6.3. Determination of safety & performance objectives

Safety & performance objectives are 'benchmark values' against which safety & performance of the subject device will be examined. These are quantitative and relate to each of the clinical outcome parameters listed above. Ideally, they are derived as a weighted mean of outcomes from all sources in the SOTA review that reported that outcome parameter.

Build a table of safety & performance objectives and explain how they were derived (and / or link to a separate SOTA review that contains the full calculations).

7. Search protocol: evidence identification, appraisal and analysis plan

A full search protocol must be documented, setting out a plan for the identification, appraisal and analysis of clinical evidence relating to the subject device (and equivalent device, if relevant).

Specifically, the search protocol must outline a plan for:

- identifying clinical evidence
- performing an appraisal of identified data sources / evidence
- analysing appraised evidence

Consider that clinical evidence must include both independent evidence and that produced by the manufacturer.

7.1. Level of clinical evidence sufficient to support conformity

“Level of evidence” relates to an assessment of the strength of individual evidence sources and to the overall strength of the entire body of evidence relating to a device. Accordingly, it is necessary to consider and state the level of evidence required to support conformity, in terms of quality, quantity, and other relevant parameters.

7.2. Identifying clinical evidence

How will clinical evidence be identified?

Clinical evidence should be identified from two primary sources:

- Data generated and held by the manufacturer
- Data produced independently

What sources databases will be searched, and how can this approach be justified? What principles will be used for exclusion of sources, and how is this justified? How will data duplication be avoided? How will results be reported?

Ideally, use validated techniques such as PICO for construction of research questions and search terms.

Remember that each excluded source will need to be recorded and justified.

7.3. Appraising clinical evidence

Appraisal determines the value of the identified data and its potential contribution to the evaluation.

Appraisal needs to be objective, systematic and unbiased. Document an appraisal plan that describes the procedure and criteria used for the appraisal.

The plan should include:

- Criteria for determining the methodological quality and the scientific validity of each data source
- Criteria that determine the relevance of each source to the clinical evaluation
- Criteria for weighting the contribution of each source to the overall clinical evaluation.

7.4. Analysing clinical evidence

Analysis is to determine whether the appraised clinical evidence collectively demonstrates conformity with the relevant GSPRs, suitability for intended purpose, and a favourable benefit-risk profile for the device. An analysis plan should be documented in this section.

How will suitability for intended purpose be demonstrated?

How will safety & performance of subject device be compared with objectives derived from SOTA? What statistical methods will be employed?

How will benefit-risk ratio be determined? Ideally, provide a quantitative method: how will risks be quantified? How will benefits be quantified? How will benefits be mathematically compared with risks to produce a ratio? What is the justification for the method?

8. PMS Outcomes and plan for analysis of PMS data

Briefly summarise the existing PMS Plan with an emphasis on sources of PMS data. What data collection methods and methods of analysis are employed during PMS activities?

How will PMS data be analysed during Clinical Evaluation? Specifically, focus on how PMS outcomes will be aligned with risks, benefits, conclusions on safety / suitability for intended purpose and information supplied with the device.

9. Clinical development plan

Document an overview of a clinical development plan for the device, indicating progression through the following stages:

- Pre-clinical investigations
- First-in-man studies
- Feasibility or pilot studies
- Confirmatory investigations
- Pivotal clinical investigations
- PMCF

This is essential for devices that are new to market; it becomes less relevant for legacy devices with an extensive market (and clinical evidence) history.

10. Updates to the CEP

State how often the CEP will be updated. Identify any events or outcomes that would lead to this update being brought forward. Provide justifications (usually based on classification of the device).

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Mantra Systems offers a review service for CEPs produced using this free template. Our professional CEP writers will conduct a thorough review of your CEP against comprehensive marking criteria, providing you with detailed feedback and closing gaps and omissions against requirements.

Deliverables include:

- Completed checklist against line-by-line criteria
- CEP review report
- Live one-to-one feedback call with a Clinical Evaluation professional

Eliminate concerns over conformity and gain confidence and clarity in your CEP submissions. Please contact our team to arrange your CEP review.