mantrasystems

Clinical Evaluation Plan Template

Produce EU MDR-compliant CEPs for any class of medical device using a proven structure designed by experts

Edition 1.0

Free sample

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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. The Clinical Evaluation Plan (CEP) is a step-by-step plan or road map for conducting clinical evaluation activities in relation to a medical device. It covers the scope, methodology, and systematic approach to proceeding with the clinical evaluation and reaching a conclusion, as well as how to document it in a CER.

A clinical evaluation is performed through the objective assessment of all clinical evidence relating to the subject medical device, whether favourable or unfavourable, in order to determine whether a device meets its obligations under the MDR. Specifically, it considers whether evidence supports conformity with all relevant General Safety and Performance Requirements (GSPRs), conformity with the device's intended purpose, and a favourable benefit-risk profile.

A CEP consists of the following sections:

- Administrative particulars
- Introduction
- Hypothesis and objectives
- Summary of clinical evaluation methodologies
- Scope of the clinical evaluation
- Device description, classification, characteristics, variants and manufacturer details
- Device components, principles of operation, manufacturing process, sterilisation/ storage/ handling conditions
- Intended purpose with intended population
- Indications, warnings and contraindications
- Intended clinical benefits
- Similar and (where relevant) equivalent device(s)
- GSPRs- relevant GSPRs and non-relevant GSPRs & justifications
- Evaluation methodologies - methods used for demonstrating clinical safety and performance of the subject device
- Literature search protocol including evidence identification plan and inclusion / exclusion criteria
- Methods for appraising evidence (weighting and justification)
- Clinical evidence analysis plan
- Methods for assessing tenefit-risk profile of the device, including acceptability of the residual risks
- Clinical development plan
- CEP revision dates

How to use this template

This document provides a template that describes, step-by-step, how to construct a CEP for compliance with the EU MDR.

The template is arranged into numbered sections that reflect the full range of requirements for a Clinical Evaluation Plan under the MDR. **Your completed CEP should be organised according to the sections in this template, as relevant.** Each section contains some or all of the following:

REQUIRED

Required information provides an outline for section content and is often written as a set of questions. These address the bulk of the content required for the CEP and responding to the questions in prose will populate the section.

INSTRUCTION

Instructions should be followed in order to meet requirements.

GUIDANCE

Outlines the purpose of the section and gives general guidance and background information.

TRANSPOSE

These short sections should be added as written into the completed CEP, with modifications as needed to make them device specific.

EXAMPLE

Illustrative examples use fictional medical devices to give guidance on structure and writing style. Any cross-applicability to 'real' devices is unintended.

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 will address all aspects of MDR clinical evaluation.

This document is constructed in accordance with guidelines documented in MEDDEV 2.7/1 rev 4, The Medical Device Regulation (MDR) 2017 / 745, and relevant 2019 and 2020 MDCG guidelines.

Each section that follows should be understood to constitute a section of the CEP, with the section title representing the main heading for that section.

CEP writing tips

1. Write objectively and in the third-person
2. Define all terms used
3. 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.

Support

Contact our team with any questions you may have while using this template and for information about our CEP services:

- contact@mantrasystems.co.uk
- www.mantrasystems.co.uk/contact

CEP review service

We also offer a bespoke CEP review service, facilitating direct and focused CEP feedback from our MDR-trained medical professionals. Please contact us to discuss this service in more detail.

1. Administrative particulars

GUIDANCE

This introductory section has three subsections:

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

The **title page** should show an image of the device, the title "[product name] Clinical Evaluation Plan", the name of the manufacturer, and the month / year of completion of the CEP. The title page will not be assessed by the regulatory reviewer.

The **contents page** should show the sections and subsections that constitute the CEP itself, with appropriate page numbers referenced. Using heading styles in a word processor will enable this section to be built and updated automatically.

The **administrative particulars summary** section is intended to give a reviewer quick access to key facts about the subject device.

REQUIRED

The administrative particulars summary should provide quick-reference access to the following information, ideally formulated in a table on a single page:

- Device name, model and type (if relevant)
    - e.g. Mantra e-steth
- Basic UDI system (if available)
- Product GMDN code (if available)
- Risk Classification
- Manufacturer name, address and Single Registration Number (SRN) if known
- Intended purpose of device
    - this should be identical to the full wording of Intended Purpose in main section of CEP and the device IFU.
- Date completed.

GUIDANCE

If preferred, the Administrative Particulars section may be populated at the end of the writing process using information from the main body of the CEP.

2. Introduction

GUIDANCE

The introduction of CEP contains 3 subsections:

1. Background
2. Objective
3. Summary of clinical evaluation methodologies

Content of the introduction section should include a statement that:

TRANSPOSE

This document presents a Clinical Evaluation Plan for [subject device] manufactured by [manufacturer name and address]. The plan outlined in this document will be followed during the conduct of Clinical Evaluation activities in relation to the device.

2.1. Background

REQUIRED

- A paragraph summarising the purpose of a Clinical Evaluation Plan
- A paragraph summarising the MDR requirements for a Clinical Evaluation Plan
- A paragraph introducing the current Clinical Evaluation Plan

TRANSPOSE

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. Additionally, Article 61 requires that any claims made in relation to the device's safety and performance under normal conditions of use are shown in evidence to be achieved. It is also a requirement that an evaluation of undesirable side-effects and acceptability of the benefit-risk ratio referred to in Sections 1 and 8 of MDR Annex I shall be based on clinical data providing clinical evidence meeting a test on sufficiency, including where applicable, relevant data as referred to in MDR Annex III.

MDR Article 61, Section 3(a) stipulates that clinical evaluation shall follow a defined, methodologically sound procedure based on a critical evaluation of available, relevant scientific literature related to the safety, performance, design characteristics, and intended purpose of the device, and that the data demonstrate compliance with applicable MDR Annex I General Safety and Performance Requirements (GSPRs). It calls for a critical evaluation of all available clinical investigation results, taking into consideration MDR requirements and adopted acts, and consideration of all relevant currently available treatment options for the same purpose.

The clinical evaluation process outlined by this Clinical Evaluation Plan (CEP) details the steps taken by [Manufacturer name] to define the device (including intended use), the scope of the Clinical Evaluation, and other stages involved in the clinical evaluation such

as the identification, appraisal and analysis of clinical data, including Post-Market Surveillance (PMS) data. This clinical evaluation process occurs and will be updated throughout the product life cycle.

2.2. Objective

INSTRUCTION

State the objective of the Clinical Evaluation Plan.

TRANSPOSE

The objective of this CEP is to document a method for conducting the ongoing clinical evaluation process for [subject device] to demonstrate device conformity with Article 61 and Annex XIV, Part A of the MDR. It defines the methodological and systematic approach to proceed and reach a conclusion on the clinical evaluation process and document it in the Clinical Evaluation Report (CER) of [subject device].

2.3. Summary of clinical evaluation methodology

TRANSPOSE

This clinical evaluation plan, [document name and number] is created under the European Union (EU) Medical Device Regulation 2017 / 745 (MDR) Article 61 and Annex XIV Part A, and (as still relevant) MEDDEV 2.7.1 Rev 4, Clinical Evaluation: A Guide for Manufacturers and Notified Bodies under Directives 93/42/EEC and 90/385/EEC.

2.3.1. Methods used to perform clinical evaluation

TRANSPOSE

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 clinical data relevant to the device and its intended purpose and any gaps in clinical evidence through a systematic literature review;
- Appraise all relevant clinical data by evaluating in terms of its suitability for establishing the safety and performance of the device;
- Generate any new or additional clinical data needed to address outstanding issues through properly designed clinical investigations by the clinical development plan;
- Analyse relevant clinical data to establish conclusions regarding the safety and clinical performance of the device, including its clinical benefits.

Subsequent sections of this CEP will set out a detailed plan for each of the above elements. Results of the clinical evaluation and its supporting clinical evidence will be documented in the CER.

2.3.2. Device revisions/changes since previous CEP revision

REQUIRED

List any changes and modifications made to the subject device since the previous CEP revision.

INSTRUCTION

For clear presentation, try to express all the changes in tabular form with the change implemented date, change ID/reference, description and current status.

GUIDANCE

Clinical data collected before the implementation of these changes are likely to be still applicable to the current clinical evaluation and should therefore be included, unless changes to the made to the device will have substantively altered the safety or performance profile of the device.

EXAMPLE

Design Change Description			
Change ID/reference	**Date**	**Justification for change**	**Current status**

3. Scope of the clinical evaluation

3.1. Hypothesis

GUIDANCE

The purpose of the hypothesis is to provide a scientific structure to the Clinical Evaluation process. Stating a hypothesis in the CEP and at the start of the CER enables it to be tested through the identification, appraisal, and analysis of clinical evidence in the CER.

REQUIRED

State a general hypothesis that will be tested by the process of clinical evaluation. The following example, adapted accordingly, would be appropriate:

TRANSPOSE

The clinical evaluation will examine the general hypothesis that the available body of clinical evidence collectively will demonstrate conformity of the subject device with the relevant MDR Annex I General Safety and Performance Requirements (GSPRs), suitability for intended purpose, and an acceptable benefit-risk profile for the device.

REQUIRED

It is then necessary to formulate a specific hypothesis based around performance criteria relating to the specific device. Often, this will rely upon the results of a literature review that has been completed in the past which may reveal key performance criteria for the device. Where possible, strive to use quantitative hypothesis elements, although use of qualitative components is reasonable where no appropriate quantitative measure exists.

EXAMPLE

The subject device is intended to, following correct use under normal conditions, enable the detection, amplification and recording of sounds from the heart, lungs, arteries, veins, and other internal organs such that positive and negative predictive values of findings following use are non-inferior to those obtained using comparable alternative devices established in the art.

Use of the subject device will be associated with:

1. Type of adverse events (qualitative) and number of adverse events (quantitative) that are no more severe (qualitative) or frequent (as a percentage of sales) than those seen in relation to comparable alternatives in the art.

2. An overall adverse event rate (as a percentage of sales) that is no worse than quantitative benchmarks established in the art.

3.2. Devices covered by the clinical evaluation

Begin this section with text that resembles the following, adapted according to the specifics of the subject device:

TRANSPOSE

Details of the device/devices covered in the clinical evaluation are provided below. Classification of the current device according to EU Medical Device Regulation 2017/745 (MDR), Annex VIII, [Rule number] is.....

REQUIRED

State the device family name (if applicable) or name of the device, device short name (if applicable), device model name/number, basic UDI-DI, one sentence description, CND code.

INSTRUCTION

For clear presentation, try to express the details in tabular form.