MEDTECH NEWS

How to Prepare Your Clinical Evaluation Plan Template in 5 Key Steps

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As the medical device industry evolves and regulatory requirements become more stringent, the need for a well-defined Clinical Evaluation Plan (CEP) has become paramount.

The CEP plays a crucial role in **assessing the safety and performance** of medical devices, ensuring their compliance with Annex XIV of the Regulation (EU) MDR 2017/745 (MDR), MDCG 2020-6, and MEDDEV 2.7.1. Rev.4.

In this article, we will delve into the intricacies of developing a robust Clinical Evaluation Plan using expert regulatory terminology, equipping you with the knowledge to navigate this essential aspect of your MedTech product development.

1. Clinical evaluation of your medical device

The clinical evaluation shall be **thorough and objective**, and both favourable and unfavourable data should be considered for the Clinical Evaluation Plan.

Its depth and extent shall be proportionate and appropriate to the

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evaluation and the selected equivalent device. Notified Bodies highly recommend claiming equivalence against only one equivalent device.

According to MDR Article 61(1) and Annex XIV, manufacturers shall **plan**, conduct and document a clinical evaluation. The planning of the clinical evaluation shall be documented in a Clinical Evaluation Plan.

Moreover, the results of the clinical evaluation and the clinical evidence on which it is based shall be documented in a Clinical Evaluation Report.

2. What is a Clinical Evaluation Plan?

The Clinical Evaluation Plan, also known as CEP, is a documented strategy that outlines the systematic and planned approach for assessing the safety and performance of a medical device throughout its lifecycle.

It provides a comprehensive framework for conducting the clinical evaluation, which includes gathering and analyzing clinical data to establish the device's conformity with the General Safety and Performance Requirements (GSPRs) outlined in Annex I of the MDR.

3. Navigating Annex XIV of MDR 2017/745: What To Consider?

According to the first section of **Part A of Annex XIV of MDR**, the CEP should be established and timely updated by the manufacturer to ensure that the clinical evaluation is planned , continuously conducted, and documented.

The minimum requirements of the CEP outlined in Annex XIV of MDR are:

- An identification of the **GSPRs** that require support from relevant clinical data.
- A specification of the **intended purpose** of the device.

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 indications and intended purpose of the device.
- An indication how **benefit-risk issues** relating to specific components such as use of pharmaceutical, non- viable animal or human tissues, are to be addressed.
- 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.

Moreover, manufacturers should also consider the following points for their Clinical Evaluation Plan:

3.1. Clinical data from systematic scientific literature review

A systematic scientific literature review **should be conducted** to identify available clinical data that are relevant to the device and its intended purpose.

This review should also highlight any gaps in the existing clinical evidence, ensuring a comprehensive understanding of the current knowledge landscape.

Conducting the systematic literature review **based on PRISMA and PICO** methodologies is recommended due to the fact these literature search methods contribute to ensure the systematicity and reproducibility of the search.

3.2. Clinical data from clinical investigations

Properly designed clinical investigations as per the Clinical Development Plan should be designed and conducted for your Clinical Evaluation Plan.

These investigations should aim to generate any new or additional clinical data necessary to address outstanding issues and further establish the safety and performance of the device.

3.3. Clinical data appraisal and suitability

All relevant clinical data **should be appraised** by evaluating their suitability for establishing the safety and performance of the device.

This evaluation should consider the quality, reliability, and relevance of the data, as well as the suggested hierarchy of clinical evidence for confirmation of conformity with relevant GSPRs under the MDR of Appendix III of MDCG 2020-6.

3.4. Clinical data analysis and conclusions

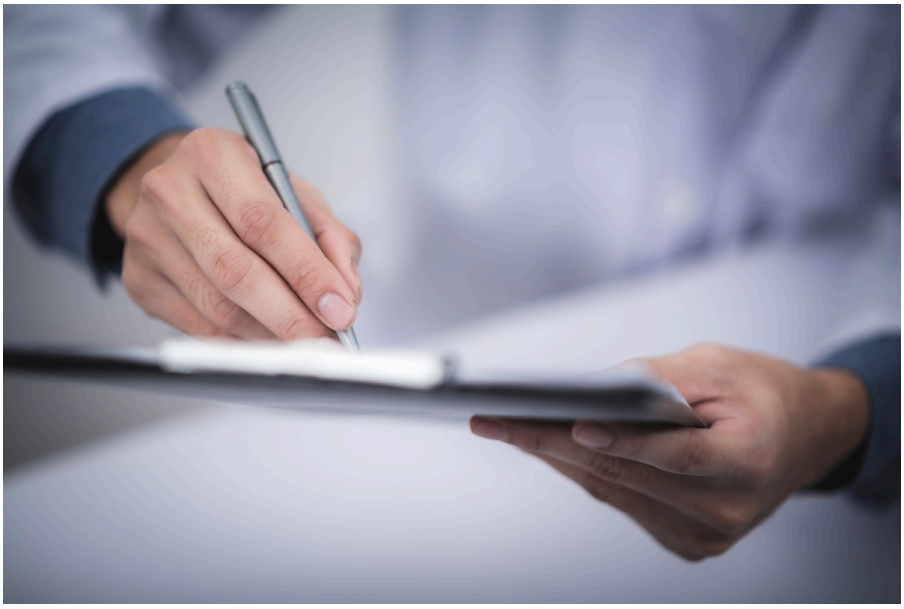
All relevant clinical data should be analyzed, including data from

safety and clinical performance of the device, including its clinical

This process involves rigorous data interpretation, statistical analysis, and consideration of risk-benefit assessments to support robust and evidence-based conclusions for your Clinical Evaluation Plan.

4. Navigating MDCG 2020-6: What To Consider?

The 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 – April 2020” provides detailed guidance on the **clinical evaluation of medical devices** in accordance with the requirements of the MDR.



4.1. Documentation

MDCG 2020-6 points out that manufacturers are required to document a Clinical Evaluation Plan to meet the requirements of MDR Annex XIV, and provides further advice to successfully comply with MDR Annex XIV Section 1a:

- **Identification** of the relevant GSPRs.
- **Specification** of the intended purpose, target groups, indications, contraindications.
- **Detailed description** of intended clinical benefits with relevant and specified clinical outcome parameters.
- **Specification** of qualitative and quantitative aspects of clinical safety and performance.

4.2. Sources of clinical data

Moreover, the Clinical Evaluation Plan shall include the identified sources of clinical data, either:

question of a device for which equivalence to the device in question can be demonstrated; other pre-market data, such as case reports on experience with the use of the device in question).

- **Post-market clinical data:** PMS clinical data, complaint and incident reports; PMCF studies, including post-market clinical investigations; independent clinical studies conducted using the device; device registries; or data retrieved from the literature)
- **New generated clinical data.**

The system of appraisal and analysis of clinical data shall also be presented in the CEP.

4.3. Minimum content

Furthermore, the minimum content for a Clinical Evaluation Plan for legacy devices is presented in Appendix II of this MDCG:

- An identification of the GSPR that **requires 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 contra- indications.
- A detailed description of **intended clinical benefits** to patients with relevant and specified clinical outcome parameters.
- A strategy to identify, analyze and assess **alternative treatments.**
- 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 use of pharmaceutical, non- viable animal or human tissues, are to be addressed.
- A strategy and methodology to identify, analyze and appraise all relevant available clinical data in light of the **changed definition for clinical data.**
- **Evidence for equivalence** if clinical data from an equivalent device is included in the clinical evaluation.
- A definition of the **required level of clinical evidence**, which shall be appropriate in view of the characteristics of the device and its intended purpose.
- A strategy and methodology to systematically collect, summaries and assess **post market surveillance data** to demonstrate continuing safety and performance, and to what extent complaints with regards to safety and performance have been observed with the legacy devices.

Furthermore, Appendix III of MDCG 2020-6 provides a hierarchy of clinical evidence for confirmation of conformity with relevant GSPRs under the

Taking into consideration the suggested hierarchy of clinical evidence as part of the appraisal methodology of your clinical data is recommended.

5. Navigating MEDDEV 2.7.1. Rev.4: What To Consider?

MEDDEV 2.7.1. Rev.4 refers to the fourth revised version of the Medical Device Vigilance Guidance Document.

This document encourages the adoption of a standardized approach to clinical evaluation for medical devices that fall under the regulation of directives 90/385/EEC and 93/42/EEC.

MEDDEV 2.7.1 Rev.4 **continues to be used** even after the implementation of MDR since it offers additional interpretive guidance and practical recommendations that complement the MDR requirements.

Section 7 of MEDDEV 2.7/1 rev. 4 addresses the definition of scope of the clinical evaluation, which constitutes the Stage 0 of a clinical evaluation, and, according to MDR and MDCG 2020-6, states that the manufacturer should set up a Clinical Evaluation Plan for the device **under evaluation.**

Recognizing the **wide range of technologies** employed in medical devices, along with their diverse histories and associated risks, is crucial.

Therefore, Section 7 of MEDDEV 2.7/1 rev. 4 also examines the different aspects to be considered for setting up a CEP depending on the stage in the lifecycle of the product and its regulatory status (i.e., before CE-marking, For CE-marked devices).

Moreover, Appendix A3 of MEDDEV 2.7/1 rev. 4 lists information that can be relevant for planning clinical evaluations. It is paramount that the manufacturer ensures that input for the Clinical Evaluation Plan shows alignment with the device's "label, instructions for use, promotional or

Considerations for your Clinical Evaluation Plan Template MDR-based

At MDx CRO, we recognize the significance of a well-structured Clinical Evaluation Plan (CEP) in ensuring the safety and performance of medical devices.

The design of a Clinical Evaluation Plan (CEP) template according to the Medical Device Regulation (MDR) 2017/745 should be tailored to the specific typology of the manufacturer's device.

This customization is critical as every medical device has unique attributes, different indications for use, target populations, and risk profiles.

Therefore, the use of a generic template for all devices is not recommended. Although it might be tempting to use a "one-size-fits-all" approach for efficiency reasons, such practice could overlook the MDR's specific requirements for each individual device, potentially leading to non-compliance with established safety and efficacy standards.

Additionally, lack of specificity could lead to erroneous or inappropriate conclusions in the clinical evaluation, jeopardizing the device's approval for marketing. In summary, it is essential that each Clinical Evaluation Plan is **designed and tailored specifically for the device being evaluated**, in line with the guidelines of the MDR 2017/745.

Despite the unique considerations required for each device's Clinical Evaluation Plan (CEP) under the MDR 2017/745, we understand the value of having a general framework to start from. Therefore, we will provide a template that serves as a starting point for the development of a Clinical Evaluation Plan.

This template will include **essential elements required under the MDR 2017/745** such as:

- Plan rationale
- Device description
- Clinical background
- Identification of pertinent data sources
- Clinical evaluation method
- Plan for the appraisal of clinical data.

Remember, this is a guide to help initiate the process and not a final document. You will need to tailor the template to fit your specific device, its indications, target population, risk factors, and other device-specific attributes.

Our intention is to help streamline the process, providing

Guidance

To streamline the development process and enhance compliance with regulatory standards, a guidance template of the contents of the CEP is provided below:

- **SECTION 1. SUMMARY**
- **SECTION 2. REFERENCES**
- **SECTION 3. ACRONYMS AND DEFINITIONS**
- **SECTION 4. RESPONSIBILITIES**
- **SECTION 5. SCOPE OF THE CLINICAL PLAN AS PART OF THE CLINICAL EVALUATION**

This section should address GSPR, previous clinical evaluations, CEP and potential deviations to the CEP, IFU and labeling of the device, and risk management.

- **SECTION 6. DEVICE DESCRIPTION**

This section should include device name, device classification, brief device description, device components and materials, and device size and models. In addition, the manufacturer name, the device's generic device group, and the device lifecycle should be indicated.

Moreover, the intended purpose and how the device achieves its intended purpose, the clinical condition, the target patient population and target user group, as well as the contraindications, warnings, cautions, precautions and undesirable effects of the device in question should also be detailed.

- **SECTION 7. CLINICAL BACKGROUND,AND STATE OF ART**

This section should present the sources to be used, the applicable standards and guidance documents, as well as the State Of The Art, including benchmark devise and other available treatment options.

- **SECTION 8. EVALUATION OF THE DEVICE**

This section should address the type of evaluation to be conducted, the safety and performance parameters, the demonstration of device equivalence (if applicable), the sources of clinical data identified, such as data generated and held by the manufacturer data from scientific literature search (i.e., systematic literature review), and data from post-market surveillance and vigilance reporting.

- **SECTION 9. ANALYSIS OF CLINICAL DATA**

This section should present the methods for evaluation of: safety (GSPR 1 to 8), performance (GSPR 1), benefit-risk profile and acceptability of undesirable side effects (GSPR 8), and other additional clinical claims.

Investigations, if applicable

- **SECTION 12. PMS AND PMCF PLANS**
- **SECTION 13. FREQUENCY OF CLINICAL EVALUATION UPDATES**
- **SECTION 14. DATES AND SIGNATURES**
- **SECTION 15. ANNEXES**

This template serves as a valuable resource, guiding you through the essential components of a Clinical Evaluation Plan, from device description and clinical data requirements to risk-benefit analysis and post-market clinical follow-up plans.

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