Clinical Evaluation Plan

The Clinical Evaluation Plan defines methods for creating and updating the Clinical Evaluation Report. This plan is updated later by the post-market clinical follow-up, e.g., to include new search criteria for the literature search.

> While the content of the Clinical Evaluation is simple, writing it, coming up with the right structure and forming a sensible line of reasoning (equivalence) can be a bit tricky.
>
> These are the guidance documents on Clinical Evaluation. If you're the person writing it, you should read them:
>
> - Regulation (EU) on Medical Devices 2017/745
> - MEDDEV 2.7/1 "CLINICAL EVALUATION"
> - MDCG 2020-1 Guidance on Clinical Evaluation & Performance Evaluation of Medical Device Software
> - MDCG 2020-5 Guidance on Clinical Evaluation – Equivalence
> - MDCG 2020-6 Guidance on Sufficient Clinical Evidence for Legacy Devices
> - MDCG 2020-13 Clinical Evaluation Assessment Report Template
> - GHTF 2006 Clinical Evaluation
>
> The following checklist provides an overview of possible documents and information that may be relevant for the clinical evaluation.
>
> - Intended use
> - Product description (indications/ contraindications)
> - Instructions for use
> - List of potential equivalent products (competitors, predecessor model)
> - Instructions for use/marketing brochures of the competitor or predecessor model
> - Comparison of the equivalent products
> - Information on possible alternative treatment methods
> - List of marketing claims that are advertised (especially clinical claims)
> - Marketing brochures
> - Risk management files (plan, analysis and report), annual risk management reports
> - Usability file/ user studies
> - PMS/PMCF plan
> - PMS report/ PSUR
> - Sales figures of the product or predecessor product (incl. details of the period)
> - Complaint handling; number of safety-related incidents reported (incl. details of the time period)

- Reports on clinical studies/clinical trials conducted
- Relevant preclinical studies or test reports that support safety and performance
- Checklist of general safety and performance requirements
- Previous clinical evaluation of the product or predecessor model
- List of relevant literature or guidelines
- Software tests

1. Purpose and Scope

According to the Regulation (EU) 2017/745, Article 61 and ANNEX XIV, the evaluation of the clinical performance and safety as well as the clinical benefit must be based on 'clinical data' and is required for all medical device classes. The clinical evaluation report and the clinical data on which it is based, verifies the clinical safety and performance of the <device name>. This clinical evaluation plan outlines the scope of the clinical evaluation.

2. Definitions

Definition / Abbrevitation	Description
MDR	Regulation (EU) 2017/745
[...]	[...]

3. Product Information

Manufacturer:
Product name:
Product models:
CE marking:
Classification:

Further information regarding the device (e.g. intended user group, indications, contraindications can be found in the document ISD - Intended Use (provide a reference).

4. Clinical Benefits

Describe the intended clinical benefit(s) of the device.

The clinical evaluation report compares the recognized benefits of the device with its associated risks, facilitating a comprehensive benefit-risk assessment.

5. Clinical Claims

All claims related to the <medical device> can be found in the table below. These claims will be thoroughly examined as part of the literature search in the clinical evaluation.

No.	Claim	Source	Reference
1	<Our device reduces procedure time by 20%>	<Website / promotional material>	<Usability study / Literature analysis (addressed in clinical evaluation report) / verification and validation / PMS data; PMCF data>
...			

If there are no claims: No claims require validation through the clinical evaluation

6. Risk Management

A risk analysis, conducted in compliance with EN ISO 14971 for the <medical device>, is currently documented in:

- SOP Risk management
- Risk Management Plan
- Risk Analysis
- Risk Management Report

The risk management plan/process of the medical device outlines the methodologies employed to scrutinize both qualitative and quantitative aspects of clinical safety. The analysis of clinical data will encompass all residual risks and side-effects. Additionally, any hazards, risks, and side-effects identified in the clinical evaluation report will undergo evaluation in the risk management file. The device's risks will be assessed against its identified benefits to conduct a comprehensive benefit-risk assessment.

7. Clinical Development Plan

Provide a brief overview of all the clinical investigations that have either been performed, are ongoing, or are planned in the near future.

If you have no studies: For the device we did not conduct clinical studies. Describe your justification.

8. Clinical Evidence

Clinical evaluation is an on-going process, conducted throughout the life cycle of a MDSW. Both favorable and unfavorable data considered in the clinical evaluation shall be included in the technical documentation.

Three key components will be taken into account when compiling clinical evidence:

Valid clinical association

Demonstrate that it corresponds to the clinical situation, condition, indication or parameter defined in the intended purpose of the MDSW

Technical performance

Demonstration of the MDSW's ability to accurately, reliably and precisely generate the intended output, from the input data.

Clinical performance Demonstration of a MDSW's ability to yield clinically relevant output in accordance with the intended purpose

9. Post-market surveillance

The following databases will be searched:

- MHRA (Medicines and Healthcare products Regulatory Agency)
- Swissmedic
- BfArM (Bundesinstitut für Arzneimittel und Medizinprodukte)
- FDA database MAUDE
- FDA database for recalls

In addition, a PMCF plan is in place according to MDR, Annex XIV Part B.
