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Ensuring Medical Device Excellence

A Guide to Clinical Evaluation under Medical Device Regulation (EU) 2017/745

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Objective: Ensuring Safety & Performance

Establishing and maintaining proof that medical devices are safe for use and achieving intended performance throughout their expected lifespan.

Clinical Evaluation: A Lifelong Cycle

A continuous assessment process integral to the company's quality management system, conducted by qualified personnel. It ensures medical devices meet regulations and standards from initial conception through post-market feedback.

Building the Evidence Base

Gathering and evaluating critical documents, including Clinical Evaluation Plan (CEP), Clinical Evaluation Report (CER), Literature Search Protocol (LSP), Literature Search Report (LSR), and clinical study reports to prepare a comprehensive evaluation.

These documents shall be intrinsically aligned and consistent with other essential modules of technical documentation required for medical device certification, such as general safety and performance requirements checklist, risk assessment, usability, biocompatibility, software validation (if applicable), label and instructions for use, and post-market surveillance.

Ongoing monitoring using Post-Market Clinical Follow-up (PMCF) plan and reports to ensure continuous adaptation to real-world data and maintaining compliance.

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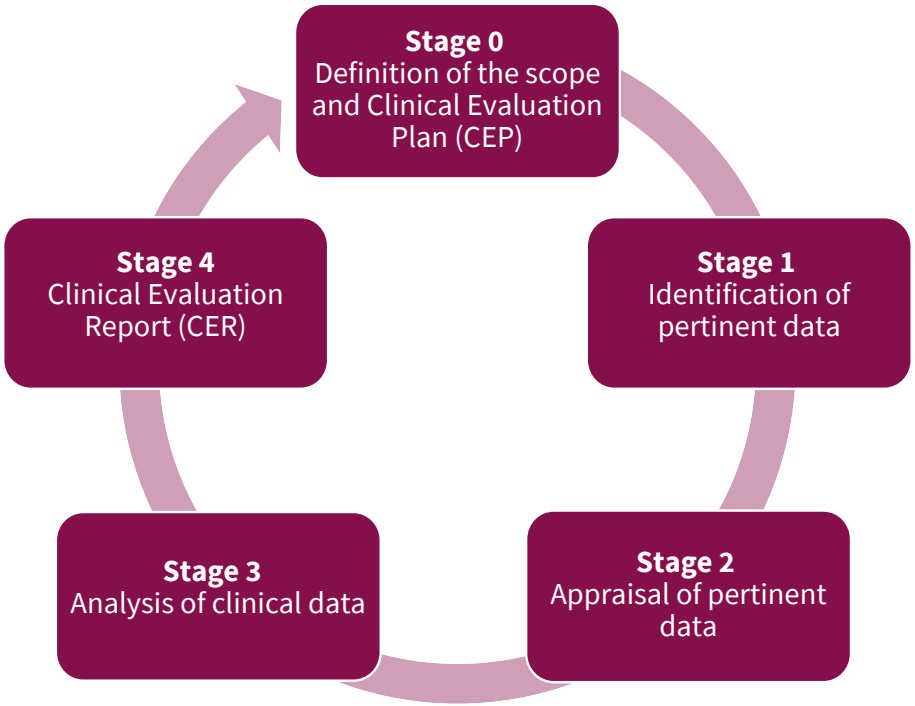
Example of CER structure

1. Scope of the Clinical evaluation.
2. Clinical background, current knowledge, state of the art.
3. Device under evaluation:
   a. Type of evaluation
   b. Demonstration of equivalence (if claimed)
   c. Clinical data generated and held by the manufacturer
   d. Clinical data from literature
   e. Summary and appraisal of clinical data
   f. Requirement on performance
   g. Requirement on acceptability of side effects
4. Conclusions.
5. Date of the next evaluation.
6. Dates and signatures.
7. Qualification of the responsible evaluations.
8. References.



Clinical evaluations must be updated annually for class III or IIb implantable products.

Clinical evaluations must be updated every 2-5 years for low risk class products.

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Clinical evaluation pathways

Clinical evaluation	Device type	Clinical evidence
Article 61(3)	All type of devices	• Clinical evidence • Equivalence
Article 61(4)	Implantable and Class III devices	• Equivalence claimed with a device of the same manufacturer • PMCF study
Article 61(5)	Implantable and Class III devices	• Equivalence claimed with a device of other manufacturer (agreement for accessing technical documentation)
Article 61(6a)	Legacy implantable and Class III devices	• Clinical evaluation based on sufficient clinical evidence • Common specifications
Article 61(6b)	Well-established technology devices	• Clinical evaluation based on sufficient clinical evidence • Common specifications
Article 61(9)	Annex XVI device (without an intended medical purpose)	• Clinical evaluation based on relevant safety data including data from PMS, PMCF, and clinical investigation, if applicable.
Article 61(10)	Low-risk devices without clinical benefit (e.g., medical device sterilizer, devices for medical product administration)	• Clinical evaluation based on non-clinical testing. • Clinical ecaluation based on risk-management justification, usability and intended clinical performance.

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Standard and Guidelines Overview

MEDDEV 2.7/1 rev.4 Clinical evaluation: a guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC June 2016
MDCG 2020-5 Clinical Evaluation - Equivalence A guide for manufacturers and notified bodies April 2020
MDCG 2020-7 Post-market clinical follow-up (PMCF) Plan Template: A guide for manufacturers and notified bodies April 2020
MDCG 2020-8 Guidance on PMCF evaluation report template April 2020
MDCG 2020-6 Guidance on sufficient clinical evidence for legacy devices April 2020
MDCG 2020-13 Clinical evaluation assessment report template July 2020
MDCG 2019-9 Rev.1 Summary of safety and clinical performance March 2022
MDCG 2022-21 Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745 December 2022
ISO 14155:2020 Clinical investigation of medical devices for human subjects - Good clinical plactices

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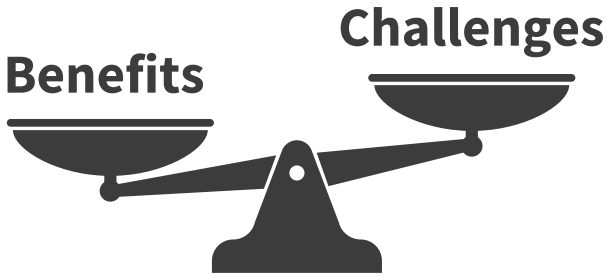

Achieving Compliance: Benefits vs. Challenges

Adhering to MDR 2017/745 ensures high standards of device safety and increases patient and user trust, outweighing the rigorous demands of compliance.

Main challenges

- Identification of correct clinical evaluation pathway.
- Amount of data needed to generate “sufficient clinical evidence”.
- Maintaining consistency and traceability of information across CEP, CER, IFU, risk management and post-market.
- Time for resolution of clinical queries from the notified body.

Common reason for outsourcing generation of clinical evaluation documentation

- Lack of internal expertise.
- More cost effective.
- Lack of time and resources to generate and maintain the required documentation.

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WHY WORK WITH US?

ASPHALION MedTech

- **Multidisciplinary team: clinical & regulatory affairs and quality assurance**
- **Pragmatic approach to guide medtech developers**
- **Experience with a wide variety of medical technologies**
- **Flexible collaboration model for start-ups, SMEs and large companies**
- **Optimization of Time to Market**
- **Tailored services**

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