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AN OVERVIEW OF CLINICAL EVALUATION FOR MEDICAL DEVICES

Clinical evaluation is mandatory for EU MDR compliance and for obtaining the CE marking required for sale of medical devices in Europe.

CONTENTS

Abstract

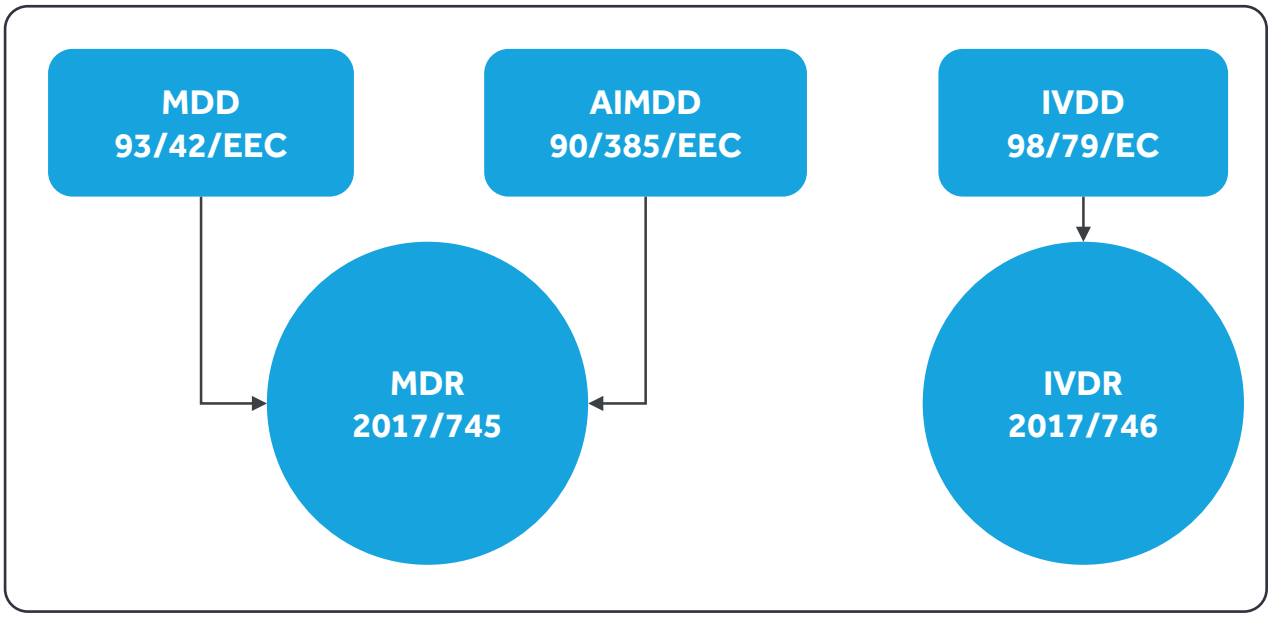
A Clinical Evaluation Report (CER) documents the clinical evaluation of your medical device. A CER consists of analyzed clinical data that was collected either from a clinical investigation of a medical device or the results of other studies on substantially equivalent devices. The CER demonstrates that the device achieves its intended purpose without exposing users and patients to further risk. Clinical evaluation reports are required for all medical devices in Europe. Medical device manufacturers must submit the CER to the notified body as an attachment to the European CE technical file. The technical file is an essential step to obtaining CE marking for a medical device, required to market medical devices in Europe.

Introduction

The European Union (EU) is an economic and political union of 28 member states in Europe. It was founded in 1993 with the aim of creating a closer union between the peoples of Europe and has 23 official languages. The CE marking is mandatory for all products sold within the European Union that fall within the scope of CE marking directives.

There are three main directives for medical devices:

- Medical Device Directive (93/42/EEC)
- Active Implantable Medical Device Directive (90/385/EEC)
- In Vitro Diagnostic Device Directive (98/79/EC)



Contents of technical documentation

- Legal manufacturer and general information
- Product description
- Essential requirements (General Safety and Performance Requirements)
- Manufacturing process
- Risk management
- Clinical data
- Labeling
- Device performance
- Product specification
- Special materials
- Post-market surveillance
- Declarations and certificates

Clinical Evaluation Overview

Clinical evaluation is a methodologically sound ongoing procedure to collect, appraise, and analyze clinical data pertaining to a medical device, and to analyze whether there is sufficient clinical evidence to confirm compliance with relevant essential requirements for safety and performance when using the device according to the manufacturer's instructions for use. Clinical evaluation is conducted throughout the life cycle of a medical device as an ongoing process. Usually, it is first performed during product development to identify data needed for market access. Clinical evaluation is mandatory for initial CE marking and must be actively updated thereafter. Clinical evaluation is necessary and important because it ensures that the evaluation of the device's safety and performance is based on sufficient clinical evidence throughout the lifetime that the medical device is on the market. This ongoing process enables manufacturers to provide notified bodies and competent authorities with sufficient clinical evidence for demonstration of conformity of the device with the Essential Requirements throughout its lifetime (for example for CE marking, fulfilment of post-market surveillance and reporting requirements, or during surveillance procedures).

Active update of the CER

Why

- Ratio benefit/risk profile, side effects and risk mitigation measures:
  - Confirmation of safety and acceptance per current state-of-the-art clinical evaluation
  - Accuracy/relevance of device information materials
  - Accuracy of Post Market Surveillance (PMS) plan
- Confirmation of existing claims
- Justification of new claims

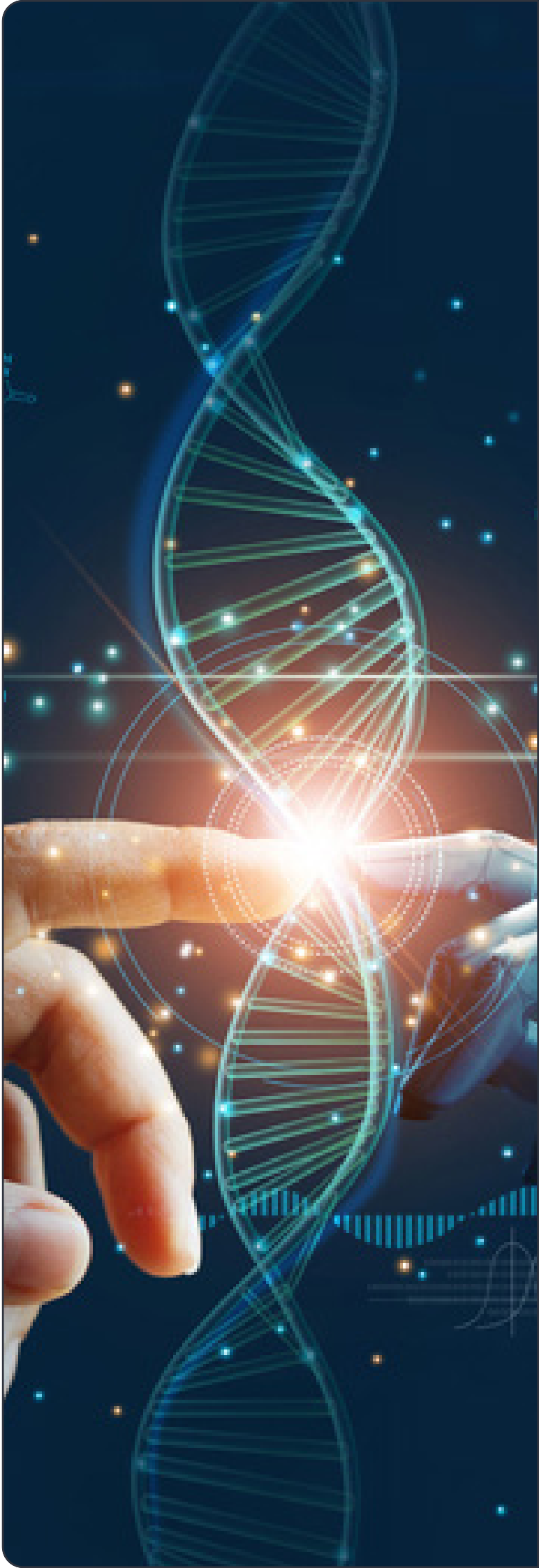
When

- Frequency of CER defined and justified based on criteria (risk, innovation, changes)
- If new information comes from the PMS, potentially impacting the current evaluation
- If no new information comes from the PMS:
  - Annually, if the device carries significant risk and or is not yet well established
  - Every two to five years, if the device is not expected to carry significant risk and is well established

Who should perform the clinical evaluation?

The clinical evaluation should be conducted by a suitably qualified individual or a team, taking into consideration:

- Research methodology, information management, regulatory requirements, and medical writing knowledge
- A qualified degree in the respective field and five years of documented professional experience; or 10 years of documented professional experience if a degree is not a prerequisite for a given task
- Justification of choice of the evaluator(s)
- Declaration of interest of each evaluator
- Technical and scientific knowledge
- Training and experience

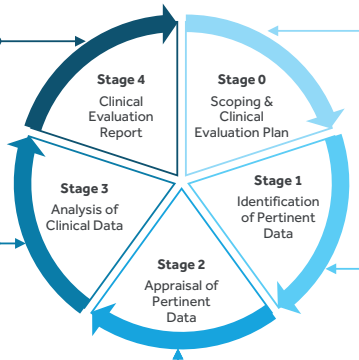


Different Stages of Clinical Evaluation

How Is Clinical Evaluation Performed?

Compilation of data and demonstrating compliance:
Outlines all stages
CER: approved, dated-controlled document

Analysis of Data, whereby conclusions are reached on:
- Compliance with the essential requirements in terms of performance and safety, including the ratio benefit I risk
- The contents of the supporting documents
- Residual risks and uncertainties or questions unanswered (including rare complications, long-term performance, safety during use in "real life"), and if these are acceptable for CE marking, it is necessary that they are followed up by PMS



Freezing the scope and preparation of Clinical Evaluation Plan
- Identification of the devices (models, sizes, software versions, accessories)
- Concise physical and chemical description (materials, incorporated medicinal substances, tissues, or blood products), Mechanical and physicochemical characteristics;
- Technologies used
- Description of innovative aspects of the device
- Place of the device in regard to available treatment / management/ diagnostic options.

Data generated and held by the manufacturer:
- Pre-market clinical investigations
- All clinical data generated from RM activities and the PMS programs
- Pre-clinical data

Data from the literature:
- Clinical data relevant to the device under evaluation (data relating to either the device itself or to equivalent device)
- Current knowledge/state of the art

Biological Equivalence
- Using the same materials or substances in contact with the same human tissues or body fluids
- Exception : devices in contact with contact skin and minor components of devices.

Clinical Equivalence
- Same clinical conditions and same intended purpose
- Same site in the body
- Similar population (including age, gender, anatomy, physiology)
- Not foreseen to deliver significantly different performances

Technical Equivalence
- Used under the same conditions of use
- Have similar specifications and properties (i.e. tensile strength, viscosity, intensity of energy, wavelength, porosity, surface texture.)
- Use similar deployment methods (if applicable)
- Have similar principles of operation and critical performance requirements

Contents of a Clinical Evaluation Report

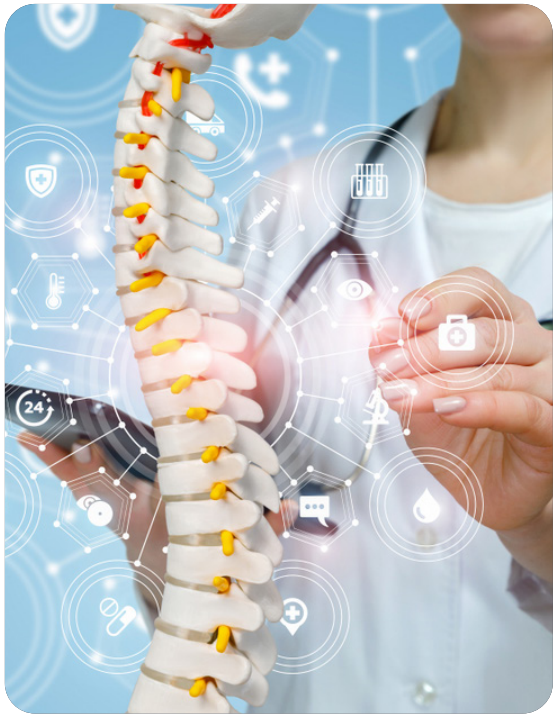
- Executive Summary
- Scope
- State-of-the -Art Evaluation
- Subject Device Description
- Equivalence Study
- Data Sources—Identification and Appraisal
- Post-Market Experience and Surveillance
- Risk Benefit Analysis
- Conclusion

Challenges in Clinical Evaluation

- Updated risk management data, where full risk management data are defined as delivery of the following: Risk analysis report + Failure Mode and Effects Analysis (FMEA) + Process Failure Mode and Effects Analysis (PFMEA) + Risk management report.
- Biocompatibility reports.
- Verification and validation (V&V) testing reports.
- Full PMS data as an indication of an active PMS program, where full PMS data are defined as delivery of all the following: Sales + Complaints + Trend reporting + Corrective and Preventative Actions (CAPAs) if issued + Field Safety Corrective Actions (FSCAs) if applicable + PMCF data + data from registries.
- Technical documentation as per Annexes II and III to the MDR.
- Copies of the instructions for use (IFU) and other applicable labeling documents.
- Essential Requirement (ER)/General Safety and Performance Requirement (GSPR) checklists.
- Compliance with applicable standards.
- Previously released CER, regardless of its compliance statement.

Conclusion

Most medical device companies are racing against time to ensure compliance to EU MDR-217/745 where clinical evaluation is critical. Cyient offers a one-stop solution for helping medical device companies with clinical evaluation for regulatory compliance. Empowered by our Quality Assurance and Regulatory Affairs (QARA) CoE, Cyient has certified professionals across all functions who have the required skill sets and expertise to support medical device companies throughout the clinical evaluation of medical devices.



About the Author

Abhishek Kumar is an SME in Medical Device Regulatory and Quality Assurance services. He has over 12 years of experience and has–

- Successfully led the work group for the EU MDR-2017/745 sustenance program to identify and explain business opportunities to the sales teams
- Successfully handled the entire engagement program for a US-based medical device company
- Successfully supported in the gap assessment, remediation, and submission of 45+ technical documentations as per EU MDR
- Successfully supported the creation of 40+ CERs for Class I, II, and III medical devices as per MEDDEV 2.7.1 Rev-4
- Successfully developed proposals for various engagements for the US, Europe, ASEAN, China, Taiwan, and Japan markets
- Successfully prepared and implemented the regulatory plan for NPD for 90+ countries by analyzing project feasibility, freezing the regulatory requirements, and coordinating with various cross-functional teams

About Cyient

Cyient (Estd: 1991, NSE: CYIENT) is a leading global engineering and technology solutions company. We are a Design, Build, and Maintain partner for leading organizations worldwide. We leverage digital technologies, advanced analytics capabilities, and our domain knowledge and technical expertise, to solve complex business problems.

We partner with customers to operate as part of their extended team in ways that best suit their organization's culture and requirements. Our industry focus includes aerospace and defense, healthcare, telecommunications, rail transportation, semiconductor, geospatial, industrial, and energy. We are committed to designing tomorrow together with our stakeholders and being a culturally inclusive, socially responsible, and environmentally sustainable organization.

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