IQVIA MEDTECH

Insight Brief

# Medical Device Clinical Evaluation Reports

*Tips and best practices for EU MDR compliance*

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# Introduction

A Clinical Evaluation Report (CER) is essential for obtaining European market approval for medical devices. The CER describes clinical data to demonstrate safety and performance of the device under evaluation and to evaluate its benefit-risk ratio to the intended patient population.

While CERs are not new, they are subject to more intense scrutiny now that the EU has adopted Medical Device Regulation 2017/745 (MDR).[1] Authorities are also assessing CERs in the post-market phase with increasing frequency.

This brief outlines the expectations of notified bodies (NBs) when reviewing CERs as part of the CE marking process. It also provides suggestions for developing compliant, complete, and accurate documentation.

## Clinical evaluation report contents

The CER includes analyses of pre- and post-market clinical data collected throughout a product's life cycle. These data may include:

- Clinical investigations of the device under evaluation
- Study data reported in scientific literature for an equivalent device
- Peer-reviewed scientific literature of the device under evaluation or its equivalent
- Relevant post-market surveillance data, including post-market clinical follow-up such as physician surveys, complaints, product recalls, etc.

## Meeting strict expectations

In a recommendation issued in September 2013,[3] the European Commission urged NBs to give CERs a longer look. Where conformity assessment is quality systems-dependent, the NB must also confirm that the procedures for clinical evaluation and post-market clinical follow-up are complete, accurate, and correctly implemented.[3]

In addition to increased scrutiny from NBs, medical device companies face the additional burden of updating legacy device documentation to meet MDR requirements. Delays put market access and revenue at risk; therefore, meticulous coordination is required to maintain compliance.

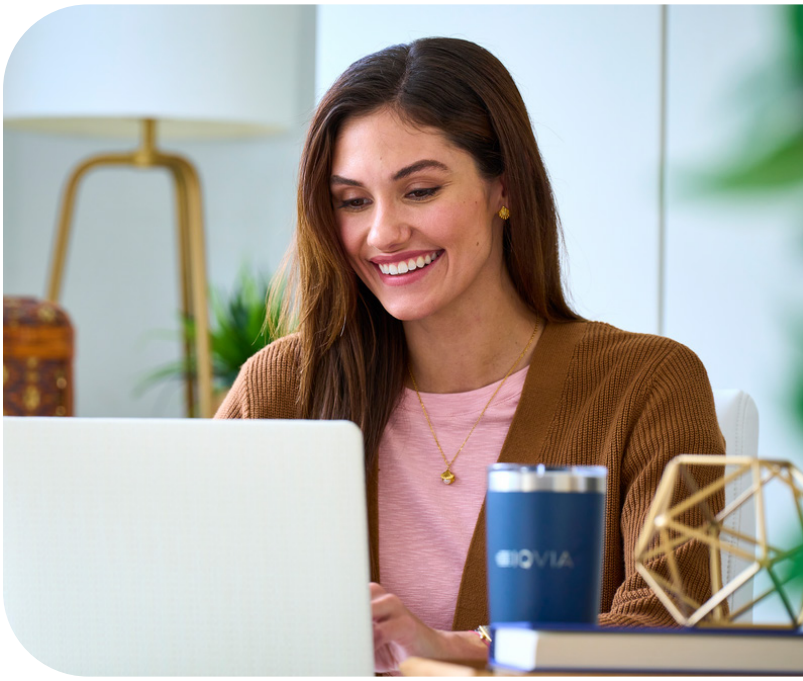
Once a device is approved for entry into the European market, device companies must stay prepared for unannounced audits. Under MDR, NBs should conduct audits and assessments at least once every 12 months.[1] In the post-market phase, we have observed NBs flag CERs for inspection as part of vigilance case review or because of routine market surveillance activities.

**WHAT IS A CLINICAL EVALUATION REPORT?**

The European Commission defines the clinical evaluation as "a methodologically sound ongoing procedure to collect, appraise and analyze clinical data pertaining to a medical device and to evaluate 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."[2] This procedure is presented in written in the corresponding report, the CER, which is required for all risk classes.

## Nine tips for creating compliant clinical evaluation reports

- **Develop a thorough Clinical Evaluation Plan (CEP).** A CEP outlines a defined strategy for conducting an adequate clinical evaluation. CEP requirements are detailed in EU MDR 2017/745, Article 61, Annex XIV, Part A, Paragraph 1.
- **Conduct a systematic and reproducible literature search** relevant to the device under evaluation and benchmark devices. Include multiple databases in your search, and use the PICO method (Patient/Population, Intervention, Comparator/Control, Outcome) to guide your search. Demonstrate the scientific validity of data and include both quantitative and qualitative analyses when applicable.
- **Present stratified clinical data** to justify the indications listed in the intended purpose. Note: medical device companies are required to include stratified clinical data for all device variants listed in the CER.
- **Outline specific and measurable objectives for the CER.** Link these objectives to safety, performance, and benefit-risk endpoints.
- **Provide sufficient data for a conformity assessment.** Notified bodies will want to see sufficient preclinical and clinical data as well as post-market surveillance (PMS) outcomes. Also include a comparative evaluation of alternatives to the device under evaluation.
- **Thoroughly evaluate risks.** Evaluate anticipated risks and, in post-market settings, reported adverse events, via multiple sources, including scientific literature, complaints and vigilance data, and health authority databases. Acceptability of residual risks and exhaustive evaluation of the benefit-risk profile are mandated.
- **Substantiate clinical claims** listed in marketing brochures, labelling, and packing information, and other promotional materials. Include evidence that supports marketing claims in the CER.
- **Recruit CER authors and evaluators with adequate experience.** Regulatory authorities will check these individuals' educational and professional backgrounds. The CVs of all authors should be appended to the CER.
- **Update CERs regularly.** Manufacturers must update CERs every two to five years depending on the class of the device. Manufacturers of high-risk devices must update those CERs annually.



## MDCG Guidelines for creating clinical evaluation reports

The Medical Device Coordination Group (MDCG) provides nonbinding recommendations related to CERs. The organization has issued multiple guidelines related to CER preparation. While most guidelines apply to new devices, MDGC 2020-5[4] and MDCG 2020-6[5] provide information for legacy devices.

- **MDCG 2020-5 Clinical Evaluation – Equivalence. A guide for manufacturers and notified bodies.** This guideline outlines the requirements of establishing equivalence according to EU MDR 2017/745. Refer to Annex 1 for guidance on demonstrating equivalence between two devices.

- **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.** This guideline helps manufacturers evaluate if their clinical data are sufficient to demonstrate conformity with the general safety and performance requirements (GSPRs) for legacy devices. Annex III outlines the hierarchy of clinical data with appropriate ranking that can be suitably used by the manufacturer.

## Clinical evaluation report updates

CERs must be updated on a regular basis. Update frequency depends on the following factors:

- Device risk classification
- Whether the device is well established
- Design changes or changes to the intended use
- Changes to manufacturing procedures
- New information discovered during post-market surveillance (PMS) that may change the current evaluation

Implement a periodic update schedule to review data sources relevant to the clinical evaluation, including any new clinical studies published during the product's life cycle. At the same time, review and update the GSPR checklist, risk management report, PMS report, among other key CER elements.

## How IQVIA MedTech assists with clinical evaluation reports

A CER is one of the more critical documents required to obtain a CE Mark. Review the requirements carefully — notified bodies will reject incomplete CERs. Because notified bodies are reviewing CERs with increased scrutiny, consider partnering with an experienced regulatory partner to ensure your CER, as well as your entire technical file, is complete, accurate, and in compliance with the latest regulations.

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**Navigating Clinical Evaluation Challenges with IQVIA MedTech**

**Your Partner in creating non-biased, evidence-based clinical evaluations for Class I, II, and III medical devices.**

**Expertise in regulatory compliance**
Navigate complex and evolving regulatory requirements with our deep understanding of EU MDR and other global standards.

**Comprehensive data collection**
Ensure robust and relevant clinical data through our meticulous data collection and literature review processes.

**Proven strategies**
Comprehensive regulatory writing and review services that prioritize General Safety and Performance Requirements (GSPRs), benefit-risk analysis, and identification of off-label use.

**Resource optimization**
Efficiently manage resources and mitigate risks for successful project outcomes including timely submissions.

**Collaborative partnership**
Trust in our supportive and constructive consultation for regulatory writing.

# References


1. REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
2. European Commission 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
3. Commission Recommendation of 24 September 2013 on the audits and assessments performed by notified bodies in the field of medical devices (2013/473/EU)
4. MDCG 2022-21 GUIDANCE ON PERIODIC SAFETY UPDATE REPORT (PSUR) ACCORDING TO REGULATION (EU) 2017/745 (MDR)
5. 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

# About the authors

**JULIA TREMBINSKI, PHD**
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Julia Trembinski brings over five years of experience in medical writing to her role at IQVIA MedTech. Julia excels in preparing a variety of clinical and scientific documents, including Clinical Investigation Plans (CIP), Master Informed Consent Forms (ICF), Clinical Study Reports (CSR), and Investigator's Brochures (IB). She plays a crucial role in assisting clients with study design to meet their business and regulatory goals, while ensuring the scientific rigor and compliance of technical documents against international standards and local regulations.

Julia holds a PhD in Molecular Cardiology from the University of Frankfurt, Germany. She also earned a Master of Science in Cellular and Molecular Neuroscience from the University of Tübingen, Germany, and a Bachelor of Science in Biomedical Science from the University of Marburg, Germany.

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