Clinical Evaluation Report (CER)

The Clinical Evaluation Report (CER) is a prerequisite document required to be submitted to the regulatory bodies along with the technical file as a part of CE marking, and conformity assessment process before the medical device manufacturer introduces the product in the European market

The Clinical Evaluation Report (CER) provides complete details of a medical device product in its entire life-cycle and is a mandatory document needed for the European Union market for all various types of medical devices, components, and compounds. CER document is prepared based on the clinical evaluation of the medical device and is an important requirement to obtain CE marking.

It is an important part of the Technical file or the Design Dossier of the medical device manufacturer, and they need to be updated with regular reviews throughout the lifetime of the device. The CER is an important live document that needs to be prepared based on solid foundations evidence, and literature reviews of similar products, components, and compounds (Achakri, 2017).

Manufacturers need to comply with European CER requirements that necessitate that the respective device or component achieve their intended purpose without exposing the patients, consumers or users to any adverse risk. Clinical data is recognized as the necessary evidence to validate the safety and performance of the medical devices, which is derived by conducting preclinical and clinical assessments, scientific literature and the clinical experience of comparable equipment.

Evaluation and analysis of the clinical data are essential to validate the clinical safety and performance of the medical device, which is outlined in the Clinical Evaluation Report. Clinical evaluation is an ongoing and continuous process that is integrated into the quality system and carried out throughout the life-cycle of the device.

The initial report is prepared at the beginning of the CER's life cycle and the manufacturer's needs to update CER based on ongoing clinical evaluations. The CER can also be updated as the component of post-market surveillance and vigilance case review.

MEDDEV 2.7.1 Rev. 4 Clinical Evaluation definition

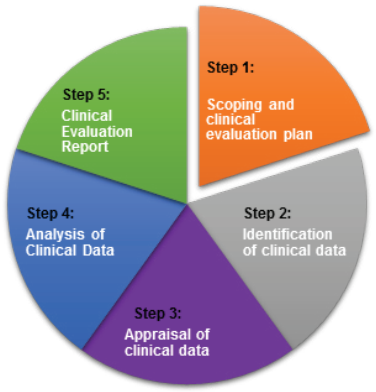
"Clinical evaluation is a methodology sound ongoing procedure to collect and analyze clinical data pertaining to a medical device and to evaluate whether there is sufficient clinical evidence to confirm compliance with relevant essential requirements for safety and performance when using the device according to the manufacture's instruction" for Use".

Major components of Clinical Evaluation Report

Description of the medical device, components and model numbers

- Intended purpose of the device
- Fundamental principles of operation
- Indications and supporting claims
- Overview of relevant pre-clinical data
- State Compliance to standards like MEDDEV 2.7.1

Steps for Clinical Evaluation:



Relevant Standards and Guidelines for Clinical Evaluation

The key applicable guidance standards and the respective guidelines are mentioned below.

- MEDDEV 2.7.1 Rev3 standard provides the European Commission's Guidelines on Medical Devices, which is a complete guide for manufacturers and regulatory authorities relating to clinical data evaluation.
- MEDDEV 2.12-1 Rev8 standard outlines the guidelines on medical device vigilance system.
- MEDDEV 2.12/2 Rev 2 provides the guidelines on medical devices relating to post –market clinical follow-up studies.

Medical device manufacturers need right expertise, and sufficient time to effectively conduct a clinical evaluation and subsequently create a clinical Evaluation Report (CER), thus it is a major challenge (European Commission, 2016).

Hence, many Manufacturers' have realized that the clinical evaluation process is not a standalone activity but relatively a continuous process and take the assistance of qualified professional service providers with strong expertise and experience to prepare an up-to-date CER.

The role of the notified body in the assessment of clinical evaluation reports

The notified body plays a key role in the valuation and verification of clinical evaluation reports and supporting documentation provided by medical device manufacturers to support demonstration of conformity of a device with the Essential Requirements of the relevant Directive. These include:

- Guidance for notified bodies on the assessment of clinical evaluation reports provided by medical device manufacturers as part of technical documentation (including design dossiers) and
- Guidance for notified body in development of their internal procedures for assessment of clinical aspects relating to medical devices. In addition, documents of the Notified Bodies Operations Group (NBOG) should also be consulted. NBOG documents include best practice guides, checklists and forms (Vegher, 2015).

When is clinical evaluation undertaken and why is it important?

Clinical evaluation is conducted throughout the life cycle of a medical device, as an ongoing process.

Usually, it is first performed during the development of a medical device in order to identify data that need to be generated for market access. Clinical evaluation is mandatory for initial CE-marking and it must be actively updated there after.

Clinical evaluation is necessary and important because it ensures that the evaluation of safety and performance of the device 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).

Pepgra CRO assist you with ease through the complexity of all stages of Clinical Evaluation(CE) report

Pepgra can thus help you achieve,

- Regulatory assistance and approval for your CER
- Preparation of clinical trial protocol and comprehensive literature search;
- CERs both for review or full products for approval
- Extensive support in regulatory affairs and approval;
- Extended service through post marketing surveillance and adding to the CER if necessary

About Pepgra

Pepgra are aspirers of the best in quality clinical research and are collaborators for the best in kind research service. Our commitment towards providing the world with quality and safety assessed medicines, medicinal products and devices are indomitable. We aim for our insights into the field of clinical research can optimize your desire to produce quality medicine and other diagnostics. Pepgra offers customised services in the broadened arenas of research that are inclusive of clinical data services with the addendum of post-marketing surveillances.

Pepgra Healthcare Pvt. Ltd. is headquartered in Chennai, India with centres in Dallas, Texas, UK, India, China, and Malaysia and is committed to the utmost in clinical research services evidenced in being a leading CRO.
We began as medical writing service providers and have since forayed into the clinical research domain since the year 2011. Our company has not only grown over the years but has also proved its excellence in the exemplary services we have provided thus far.

References

Achakri, H. (2017). Generating Clinical Evaluation reports A Guide to Effectively Analysing Medical Device Safety and Performance. Retrieved June 15, 2017, from https://www.bsig-roup.com/meddev/LocalFiles/en-US/Whitepa-pers/Generating-clinical-evaluation.pdf

European Commission. (2016). Guidelines on Medical Device.

Vegher, H. (2015). Clinical Evaluation Report Overview and the Literature Review Process. Retrieved from https://ww-w.sla.org/wp-content/uploads/2015/06/1547_ClinicalE-valRptsMedDevice-Vegher-Hana-Vegher.pdf
Reference

Note: All clinical data in the possession of the manufacturer will be considered for the overall analysis and preparation of any requirement put forth.

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