Clinical Evaluation Reports
Medical devices

A Clinical Evaluation Report (CER) is an important document required for the EU market for all classes of new and existing devices, detailing the clinical evaluation of a product throughout its life-cycle. Whilst the requirement to have a CER is not new, it is subject to more intense scrutiny by Notified Bodies in the conformity assessment phase, and CERs are increasingly being assessed in the post-market phase.

The fundamental requirement is that the clinical evaluation of the medical device must be based on clinical data and follow a “defined and methodologically sound procedure” (MDD\(^1\) Annex X: Clinical Evaluation). Furthermore, this clinical evaluation must be documented: “the clinical evaluation and its outcome shall be documented. This documentation shall be included and/or fully referenced in the technical documentation of the device.” (MDD, Annex X, Sec 1.1b).

**Increasingly strict expectations**
Attention was focused on CERs in 2013 when the European Commission took steps to reinforce the medical device regulatory system, pending the adoption of the new medical device Regulations. Specifically, the Commission Recommendation on audits and assessments by Notified Bodies\(^2\) called up the need to take action to avoid omissions and mistakes in the verification by Notified Bodies of clinical evaluation and post-market clinical follow-up. The Recommendation reinforces the requirement, in the case of design dossier review and type examination, for the Notified Body to review the clinical evaluation, and, importantly, to verify that the Clinical Evaluation Report is up to date. Where conformity assessment is quality systems dependant, the Notified Body will focus on ensuring that the procedure for clinical evaluation and post-market clinical follow-up is complete, accurate and correctly implemented. CERs will be sampled for examination.

With unannounced audits now actively being carried out, manufacturers have to ensure that their CERs are up to date, and their procedures are implemented at all times.

Equally, in the post-market phase, we have observed Competent Authorities calling in CERs for inspection as part of vigilance case review, or as a result of routine market surveillance activities.

**Guidance from the Medical Devices Experts Group (MDEG)**
**MEDDEV 2.7.1**
The current Rev. 4 of the guidance document MEDDEV 2.7.1\(^3\), was issued in June 2016, applicable to both the MDD and the Active Implantable Medical Devices Directive\(^4\). The guidance aims to clarify specific terms and provide guidance in the interpretation and practical execution of the requirements of the MDD and AIMDD with regard to clinical evaluation and in particular on CERs. The June 2016 guidance is a substantial revision and Notified Bodies expected manufacturers to revise their procedures immediately, to take account of the new guidance and, at the next audit, to have a CER available which has been written to follow the new guidance. In some cases this means substantial re-working of both procedures and CERs.

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**MEDDEV 2.7.1 Rev. 4 definition of Clinical Evaluation**
“a methodologically sound ongoing procedure to collect, appraise and analyse 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.”

**What is required to update Clinical Evaluation Reports?**
A CER is required for the initial CE Marking, and it must be actively updated thereafter and on a regular basis. Manufacturers need to define and justify the frequency of updating, based on e.g. risk; whether the device is well established; design changes or changes to manufacturing procedures. New information from post-market surveillance with the potential to change the current evaluation should also trigger an active update. Manufacturers are advised to implement a periodic update schedule to review all data sources of clinical evaluations, to include any and all new clinical studies/articles that have been published during the
product’s life-cycle. Updates to other key documentation should be taken into account, such as the ER checklist, risk management report, post-market surveillance and the complaints file, etc.

We also recommend that company procedures governing clinical evaluations are reviewed, and amended if necessary, to reflect the MEDDEV 2.7.1 guidelines and encompass all Notified Body requirements and any feedback from NBs and/or Competent Authorities.

**Why use QuintilesIMS for Clinical Evaluation Reports?**

Backed up by years of experience and an extensive knowledge of the MDD, QuintilesIMS can help you prepare Clinical Evaluation Reports. As a first step in the process, we can help you decide if a clinical trial is necessary and then ensure that you collect the right clinical data in line with the requirements and the guidance, as set out in MEDDEV 2.7.1 Rev. 4. For some products there may be sufficient clinical experience in the current published literature. In such cases, QuintilesIMS can compile this data in an efficient, compliant, user-friendly format. Other products may require a clinical trial to meet the essential requirements or to provide data to support commercialization.

We can review existing Clinical Evaluation Reports against the MDD and MEDDEV 2.7.1 Rev. 4 and identify all areas of the documentation where a Notified Body or Competent Authority may state that the existing documentation is not sufficiently comprehensive, then make proposals to strengthen the document and, if requested, perform the update for you.

**Key features of MEDDEV 2.7.1 Rev. 4**

- **Stage 0 – scoping:** this new preliminary stage is intended to define the scope of the CER based on the ERs to be addressed from a clinical perspective and the nature and history of the device;
- **much more detail on the proposed structure and content of a CER;**
- **demonstration of equivalence:** Rev. 4 provides strict new guidance on equivalence, including: that all three characteristics (clinical, biological, technical) must be fulfilled; if equivalence is claimed for more than one device, this must be fully investigated, demonstrated and described in the CER for each device; relevant data are data obtained from equivalent devices which are CE marked and used as documented in the IFU;
- **additional requirements for the qualifications of the individual or team who can conduct the evaluation;**
- **more details on the role of NBs in reviewing CERs, and more requirements relating to the expertise, resources and competence required of NB.**

Working with you, QuintilesIMS can:

- help achieve agreement with your Notified Body on the clinical data required;
- review all existing CERs against current guidance and legislation;
- prepare a literature search protocol and perform a literature search;
- author full product CERs or provide updates to CERs post review;
- support manufacturers who are currently reviewing internal procedures to ensure all procedures are robust and address all regulatory requirements and guidance;
- provide advice on best practices for post-market surveillance and reviewing relevant data for the CER update.

**Note** Based on the final draft of the Medical Devices Regulation (MDR, June 2016), CERs will continue to be required, albeit with somewhat slightly different provisions. The current MEDDEV 2.7.1 guidance specifically refers to the MDD and AIMDD and may be revised when the MDR is implemented. QuintilesIMS is able to support manufacturers in their transition from the MDD / AIMDD to the MDR, in all areas of regulatory and quality compliance.

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