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Highlights for Manufacturers

MDCG 2020-13

Clinical evaluation assessment report template

July 2020

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What is a CEAR?

- A Clinical Evaluation Assessment Report (CEAR) is a report used by Notified Bodies to document their findings/conclusions following assessment of the clinical evidence presented by the Manufacturer in the clinical evaluation report (CER) and the related clinical evaluation itself.
- This template **IS NOT A CER TEMPLATE**. This is a template intended to be used by Notified Bodies and **not** Manufacturers. It outlines the **minimum contents** of a CEAR and needs to be incorporated into the process and procedures of the Notified Body.
- The purpose of the document is to ensure a harmonised implementation of medical devices regulations across Notified Bodies.

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Main points of interest for Manufacturers (1)

- ❑ The clinical evaluation is part of the QMS of the Manufacturer
- ❑ The clinical evaluation must be **aligned with** the other contents of the Technical Documentation, i.e. the CER interacts with Risk Management data, Post-surveillance data, Post-market clinical follow-up data, Verification-Validation data and Instructions for Use. Evidence from all sources should be resulting to the same conclusion: there is consistent evidence across them to prove conformity with general Safety and Performance Requirements (GSPRs).

- ❑ Make sure the authors of the CERs fulfil minimum expected requirements
- ❑ Make sure you have provided administrative information required, including proper CER and Technical Documentation referencing
- ❑ Always provide a thorough description of all aspects your device starting by the intended purpose and labelling info (intended population and intended medical field) and focusing on functional aspects (components, operations, accessories, compatibilities, previous generations etc.)
- ❑ NOVEL FEATURES require stringent presentation and corroboration
- ❑ Always identify similar devices (same intended purpose + intended medical field) currently marketed

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Main points of interest for Manufacturers (2)

❑ Clinical Evaluation Plan (CEP): it is mandatory and no way out if it!

✓ What to include:

- ❖ Clear scope
- ❖ Device history and sales data
- ❖ Reference to current labelling documents including Instructions of Use, intended purpose, indications, intended population, intended users, contraindications, warnings & precautions, statement on intended lifetime and clinical benefit

ATTENTION: labelling section will be cross-checked with CER findings and might require revision

- ❖ Identification of clinical claims on performance and safety

ATTENTION: these will have to be supported by sufficient clinical evidence during the CER stage **AND be aligned with available risk management data, post-market surveillance data and literature findings**

- ❖ Clinical development Plan
- ❖ A thorough identification of the intended medical field based on the state of the art in medicine, the acceptability of the benefit-risk ratio for all indications and for the intended purpose of the device, **i.e. the CEP should outline a proper and thorough literature search plan and corresponding eligibility criteria**

❑ Interesting / Tricky point : Common Specifications / Harmonized Standards (!!)

ATTENTION: Since the NB will evaluate this, the Manufacturer should make sure they are referring to the actual version of the Standard they have been certified for. Always provide a rationale for using a given Standard. Add a statement on Standards not yet harmonized with EU-MDR and lack of common Specifications for the device in scope (if applicable)

❑ Equivalence: DON'T claim equivalence unless:

- ❖ Able to provide an equivalence rationale
- ❖ Able to provide evidence on technical, biological & clinical characteristics as per Section 1of Annex XIV
- ❖ For implantable and class III devices: there is a **valid contra**ct between manufacturers allowing ongoing access to the technical documentation as per art.61(5)

Main points of interest for Manufacturers (3)

❑ State of the Art should discuss

- ❖ Medical Fields Concerned
- ❖ Available Guidelines outlining the current standards of care
- ❖ Identification of Alternative Treatment Options
- ❖ Identification of benchmark devices:

ATTENTION: a benchmark device is **NO**T an equivalent device. Identify benchmark devices and use iterature search plan to collect clinical data on them

- ❖ Identification of Performance/Safety Endpoints

ATTENTION: The state of the Art section should always identify the risks associated with the intended medical field and intended purpose of your device. This will be the stepping stone for the analysis of clinical in the CER and conclusion for conformity with GSPRs. **The goal is to prove that a device remains state of the art without introducing new and/or non-mitigated risks when performing as intended**

❑ Literature Search Protocol

ATTENTION: A Manufacturer will need a different ''protocol'' for the State of the Art discussion and device-specific searches. The Manufacturer will need to document and provide a rationale for

- ❖ Methodology
- ❖ Search terms
- ❖ Databases used
- ❖ Filters used
- ❖ Inclusion-exclusion criteria
- ❖ **Appraisal criteria including levels of evidence, data contribution and data suitability**

ATTENTION: The Manufacturer will need to provide to the NB **all** literature search documentation (protocols, reports, list of rejected articles with rationale, full-text articles etc.)

❑ Clinical Investigations

- ❖ The Manufacturer will need to provide all relevant documentation, evidence of compliance to both EU-MDR and ISO14155 as well as correspondence with Competent Authorities and a rationale on why a clinical investigation was not publicly registered or published (if applicable)

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Main points of interest for Manufacturers (4)

❑ Post-market Surveillance Data and PMCF

- ❖ Reviewed documents include:
  - PMS plan,
  - PMS Report (where applicable)

  ATTENTION: internal PMS data should always present sales data, complaints and potential CAPAs and FSCAs along with implemented activities for their management
  - **PMCF plan (mandatory for all medical devices; a rationale is needed id no PMCF is planned)**
  - PMCF report (where applicable),
  - PSUR (where applicable and if available)

  ATTENTION: For implantable or class III devices for which clinical investigation(s) have not been performed in accordance with Art. 61(4), the PMCF plan should include post-market clinical studies to demonstrate the safety & performance of the device.

❑ Instructions for Use, Labelling, SSCP

- ❖ At the end of the road, the Manufacturer should be able to provide a statement that the device's IFU either remains accurate or has undergone a revision based on the combinatorial consideration of the following:
  - **The cumulative clinical evidence coming out of literature, internal PMS, external vigilance data, risk management data (including residual risk report) supports the intended purpose and all labelling statements including indications, contraindications, warnings and precautions, intended population, intended users, clinical benefits and intended lifetime**

❑ Summary of available data and conclusions

The Manufacturer should provide a CER with sufficient clinical evidence to:

- ❖ Demonstrate compliance with the relevant GSPRs

ATTENTION: each one of the relevant GSPRs should be separately discussed summarizing respective evidence

- ❖ Support intended purpose, clinical claims and the information included in the IFU and SSCP (if applicable)

❑ Benefit-Risk conclusions

- ❖ **The underlying purpose of a CER is to provide evidence that ALL risks that could have a significant impact in the benefit-risk analysis have been identified in the clinical evaluation AND have been aligned with the risk management, i.e. all risks have been cross-checked with the literature and have been mitigated down to the point where it can be stated that the benefit/risk profile for the target devices has an acceptable risk level when weighed against the benefits to the patient**

Main points of interest for Manufacturers (5)

❑ Specific Considerations

❖ Clinical Evaluation Consultation Procedure for certain class III and IIb devices as per Art. 54

- Rationale on why this might not be applicable (e.g. renewal of a certificate issued under MDR)
- The principles of the clinical evaluation for the device type or category would still need to be addressed
- The expert panel will address the novel aspects of the devices, the benefit-risk determination and the consistence of clinical evidence with intended purpose and PMCF

❖ Demonstration of conformity based on clinical data is not deemed appropriate as per. Art. 61(10)

- Even if claimed, the Manufacturer still needs to perform a clinical evaluation
- The Manufacturer will need to provide evidence with respect to performance evaluation, bench testing and preclinical data to claim conformity with GSPRs
- **The Manufacturer cannot make any claims, which would require clinical data to substantiate them AND should be able to state that the intended performance is achieved and proved only with non-clinical data**

❖ Voluntary Clinical Consultation on the Clinical Development Strategy as per Art. 61(2)

- The Manufacturer will need to consider, address and include in the CER the expert panel's comments. A rationale for any divergences should be provided