CER: new MEDDEV 2.7.1 REV 4

WHY IS THIS MORE COMPLEX NOW…

In July'2016, the EU has published Rev.4 of MEDDEV 2.7.1 on clinical Evaluation for medical devices. The new guidance document describes the requirements in a more detailed and prescriptive manner, in order to execute an adequate clinical evaluation of your devices. Throughout the new guidelines, it emphasizes on how to perform the process, document the results in a clinical evaluation report, include it in the technical documentation, and submit it to a Notified Body for review. Few significant changes in revised guidelines are as under:

Scientific validity of data: 9.3.1 of the new revision emphasizing on demonstration of scientific validity of data, including statistical considerations as well as addressing factors which may affect the scientific validity of different types of datasets. Also, it describes the clinical evaluation process and factors in details, which could affect the completeness, objectivity or data weightage, literature search, retrieval methods, data appraisals, data analysis demonstration of conformity.

Qualifications of Authors/Evaluators: 6.4 of the MEDDEV2.7.1 Rev 4 describes that the evaluators must have knowledge of clinical investigation design and biostatistics, regulatory requirements and experience in medical writing. Furthermore, they must have a higher degree and 5 years of documented professional experience or 10 years of documented professional experience if a higher degree is not a prerequisite for a given task. There is an escape clause for cases where the manufacturer can document and justify deviations from the above.

Benefit Risk: 7 & A7.2. of the revised document provide guidance on the process of Conformity assessment with requirement on acceptable benefit/risk profile with the intended purpose are minimized and acceptable when weighed against the benefits to the patient with a high level of protection of health and safety, emphasizing on clinical evidence,

Equivalence: One of the largest changes in this revision is the demonstration of "equivalence", which may become challenging for the manufacturer. Meeting requirement of three general criteria i.e., Clinical, Technical, Biological are to be fulfilled by a single device now for "equivalence". MEDDEV2.7.1.rev 4 describes that design differences and relevant impacts on clinical safety and performance must be described in detail along with comparative drawings and diagrams. Thus, each individual device & claimed equivalent device must meet all three equivalence criteria. In addition to it, the manufacturer is to include non–clinical (pre-clinical reports), in the technical documentation of the device as well establishing equivalence. Equivalent devices (Predicates) being compared should have the same material and should be for the same intended use and clinical indication as compared with the relevant subject device.

If non-CE marked devices are to be claimed equivalent, differences in patient population or clinical practice between the jurisdictions where the product is approved and the EU must be justified, the only clinical data that are considered as relevant are those obtained from a medical

device that conforms to the requirements of the MDD/AIMD. Thus, for any non-CE Marked devices (e.g. approved with US 510k or PMA clearance) are to be claimed as "equivalent", the manufacturer must justify any issues concerning differences in patient population or clinical practice between the two jurisdictions of the country of approval and the EU.

Sources & Types of Clinical Data		
State of the Art	Alternative Treatments	Equivalent Devices
Equivalence / Similarities	Technical & Biological Similarities	Single Device Data
Literature Search	Clinical Database	Authority Database
PMCF	Complaint database	Incidents, Adverse Events Reports
Clinical Investigation	Risk Management	Medical Condition, Safety

Table.1

Access to data for equivalent devices: Revision 4 also requires that the Notified Body should challenge the ability of the manufacturer to access information that are relevant to the demonstration of equivalence. Demonstration of equivalence might be difficult or impossible in case of limited access to the technical documentation of the devices

Post Market Surveillance (PMS) and Post Market Clinical Follow-up (PMCF): have been discussed throughout in Revision 4 as the links between clinical evaluations, PMS and PMCF are reinforced. The NB requirements have been highlighted to ensure that PMCF is planned and justified for the data /information and conclusions documented in the CER.

Timeline: on the basis of the "Significant Risk", a manufacturer must proactively define and justify the frequency updating CER. 6.2.3 of Rev4 describes that the CER must be updated at least annually if the device includes "significant risk" or is not "well established", and every 2 to 5 years if device has no "significant risk" and is well established; Even this frequency must be justified by the manufacturer and should be coordinated with their NB with regard to their expectations for renewal of certificates.

The MEDDEV 2.7.1 Rev 4 is already in live and you need to follow this, if you have products in Market can be downloaded from our website: **www.makrocare.com**

For further information:
http://ec.europa.eu/growth/sectors/medical-devices/guidance_en;
http://ec.europa.eu/DocsRoom/documents/17522/attachments/1/translations/