Importance of Systematic literature search for Clinical Evaluation (CE)-The Strict Adherence of MEDDEV 2.7.1Rev 4

The Clinical Evaluation Report (CER) comprises of three major parts that present complete clinical evaluation information of the medical device under consideration. The first section is a report of the new clinical investigations of the device conducted by the manufacturer. The second section deals with the unpublished data concerning the biological safety and bench testing of the medical device along with compliance and experience records. The third part of the CER deals with the literature review of the clinical evaluation published on equivalent devices.

A literature review may form the major source of clinical evidence to validate the safety and performance of the established devices in their commercialization approval process, where it may not be feasible to conduct new clinical investigations on the device.

MEDDEV 2.7.1 Rev. 4 literature Searching Definition

"Literature searching is used to identify data not held by the manufacturer that are needed for the clinical evaluation".

Purpose of Literature Search in Clinical Evaluation

A well-conducted literature search can reduce the need the generating relevant data through clinical investigation of the medical device under consideration. Therefore, a good database search knowledge is mandatory (e.g. MEDLINE or Pubmed, EMBASE, Excerpta Medica, the Cochrane Central Trials registries, WHO International Clinical Trial Registry Platform (ICTRP) and Clinical Trials.gov as the expertise who are well versed in conducting systematic review would do that job well.

The expertise would adopt sound non-biased methodology using PICO or PRISMA or MOOSE guidelines to review methods pertinent to the literature review questions.

The important objectives of the literature review are to

- Provide an overview of the performance and intended use of the device through a report of past clinical trials.
- Establish that the particular medical device is broadly similar to another equivalent device in the market.
- Validate that the safety parameters of the device under the close monitoring of the clinical investigator.
- Establish that the particular device is highly safe for use in the day-to-day healthcare delivery field. Requires proper planning and adequate time at every stage of the process. It can have many unforeseen delays in many areas such as clinical data collection, analysis and in the report writing. Thus, the process must be planned and started well in advance of the assessment deadline (Schlosser, 2006).

The clinical evaluation plan needs to specify the selection criteria of the relevant publications to deal with the literature review questions. It shall contain a decisive review of the pertinent scientific literature along with the list of literature reviewed relevant unpublished data about the particular medical device. A good review of appropriate literature relating to the intended use and planned method of use of the medical device is considered significant by the concerned regulatory authorities during the conformity assessment process.

European Regulatory guidelines on Literature Review

The European Commission provides a series of guidance documents to assist medical device manufacturers and other stakeholders in implementing the set directives related to marketing medical devices in the European Union region.

Revision 4 of the guidelines provides detailed information regarding the literature review process for clinical evaluation that includes the directions and the methods to do a relevant literature search, appraisal and search strategies.

The CER needs to have the analysis of data arrived from literature review, results of assessment strategy and the functional list of publication references used in the literature search for clinical investigation.

European Regulatory Framework has established that a well-conducted literature review is significant to

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:

- Ascertain whether a clinical investigation is needed for the medical device under consideration.
- Make a justification for the clinical study, if considered necessary.
- Arrive at a conclusion as to whether the particular medical device is ready for commercialization.

A professional literature search conducted with the use of biomedical literature database that contains up-to-date and deeply indexed information can lead to a comprehensive report, which has complete information relating to the comparison of similar devices, device economics, and adverse device events. The medical device manufacturers can take expert assistance from seasoned professionals to create a comprehensive Clinical Evaluation Report that will facilitate them to obtain regulatory approval in a faster time (Elsevier, 2015).

Sources of literature:

There are multitude sources of clinical literature that can be searched for clinical evaluation.

- Scientific literature databases

- MEDLINE or Pubmed can provide a good starting point for a search. However, with possibly incomplete coverage of European Journals and reduced search features, comprehensiveness may not necessarily be guaranteed.

- Additional databases may need to be used to ensure adequate coverage of devices and therapies in use in Europe, to identify relevant clinical trials and publications of user experience16, and to facilitate searches by device name and manufacturer (e.g. EMBASE/Excerpta Medica, the Cochrane CENTRAL trials register, etc.).

- Information coverage and search features available in scientific databases can change with time. Criteria for selecting adequate databases therefore need to be defined and reevaluated on a regular basis.

- Internet searches

- Non-published data

Non published data are important for many devices and retrieval of such data should be considered, including for monitoring of any changes, e.g.
- The label and IFU of the equivalent device (if equivalence is claimed by the manufacturer) and/or of benchmark devices and other devices.

- Data provided to manufacturers from implant registries.

Pepgra CRO assist you in systematic literature search for Clinical Evaluation Reports preparation

Steeped in experience, Pepgra offers you top quality service in the preparation of CERs. As the very mission of your requirement, we extend our expertise to ensure the need and utility of the clinical trial. For this, extensive research is carried out with the addendum of referring to relevant guidelines such as the MEDDEV 2.7.1 Rev. 4.

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

Elsevier. (2015). Boost the Success of Medical Device Development With Systematic Literature Reviews. Retrieved from https://www.elsevier.com/__data/assets/pdf_-file/0015/109212/R_D-Solutions_Embase_White-Paper_MedicalDevice_DIGITAL.pdf

Schlosser, R. W. (2006). The Role of Systematic Reviews in Evidence-Based Practice, Research, and Development (Technical Brief No. 15). Austin, TX.

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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