Clinical Evaluation Report (CER) in a more Stringent Regulatory Environment- Now, subject to more intense scrutiny by Notified Bodies

European regulatory framework has established rules that govern the development, manufacturing, and marketing of medical devices in the European market. Both European and non-European medical device manufacturer's fall under the purview of the regulatory framework, which is established to provide confidence to the clinicians and the patients that the medical devices and the implantable devices used in the region have been validated for their potential benefits and certified as safe for usage.

European regulatory framework's MEDDEV guidelines promote a uniform approach to the conformity assessment procedures for the medical device manufacturers and the notified bodies associated with the evaluation process. MEDDEV 2.7.1 Rev 4 guidelines provide guidance relating to the proper evaluation of clinical safety and the performance of the medical devices for the manufacturers.
Clinical Evaluation Report (CER) is an important document that is a part of the conformity assessment process, which is carried out throughout the life-cycle of the device. The CE reports provide conclusive information about the clinical safety and the performance of the medical device by bringing together all relevant clinical data and making a proper analysis of the data.

CER and Pre-market phase

Clinical evaluation is undertaken in the initial phase of the conformity assessment, which is conducted for the purpose of obtaining CE mark, the marketing license to market the products in the European Union region.

The CE report needs to be revised periodically to update the concerned authorities whenever the manufacturers have made changes to the device's design, manufacturing process or their intended use.

The CER is also needed to inform the authorities about the risk analysis of the device, which is done to identify the potential risks and areas of concern and to update them on the risk mitigation measures undertaken by the manufacturers (U.S. Department of Health and Human Services, 2014).

CER and Post market phase

In the post-market phase, clinical evaluation of the device is continued with the maintenance of surveillance programs to monitor device safety and performance. The updated CER can include adverse incident reports, results from published literature reviews on the actual device or similar products, and clinical investigations.

Post-market clinical follow-up (PMCF) study:

"A study carried out following the CE marking of a device and intended to answer specific questions relating to clinical safety or performance (i.e. residual risks) of a device when used in accordance with its approved labelling".

Post Market Clinical Follow-up (PMCF)

The medical device's clinical data collected in the pre-market phase may be too limited that may not be sufficient to identify events or incidents with the rare occurrence. Post Market Clinical Follow-up involves an ongoing collection of clinical data based on the user experience of the device after its introduction in the market.

Regulatory requirements mandate medical device manufacturers conduct Post Market Surveillance plan that includes PMCF with the objective of identifying new risks unforeseen in the pre-market phase. The manufacturer's needs to analyze the clinical data obtained from the PMCF to arrive at meaningful conclusions about the benefits and the risks of the device and has to report the current understanding to the relevant authorities in CER on a periodic basis.

CE report is needed to update the results of the Post-Market Clinical follow-up along with the vigilance and complaints to comply with the regulatory requirements. Thus, CE Report is an important prerequisite for introducing and continuing to market medical devices in European Union regions, which requires high expertise and sufficient time allocation for initial preparation and subsequent updating process (Katta, 2015).

Design of PMCF studies

PMCF studies should be designed to address the objective(s) of the study. The design may vary based on the objective(s), study hypothesis research question and endpoints and should be scientifically sound to allow for valid conclusions to be drawn.

PMCF studies can follow several methodologies, for example:

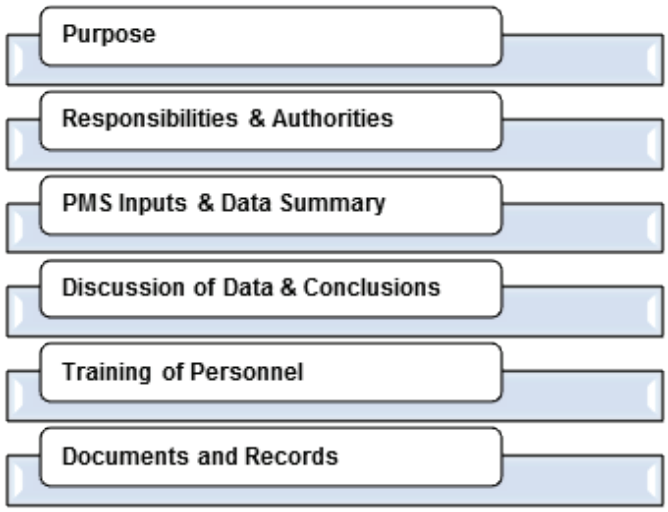
- The extended follow-up of patients enrolled in premarket investigations;
- A new clinical investigation;
- a review of data derived from a device registry; or
- a review of relevant retrospective data from patients previously exposed to the device.

The clinical investigation plan/study plan should identify and where needed justify at a minimum:

- the study population (corresponding to the CE-mark scope);
- inclusion/exclusion criteria;
- rational and justification of the chosen study design including use of
- controls/control groups (where relevant; randomised or not);
- the selection of sites and investigators;
- study objectives and related study endpoints and statistical considerations;
- the number of subjects involved;
- the duration of patient follow-up & the data to be collected;
- the analysis plan including any interim reporting where appropriate to
- ensure continuous risk management based on clinical data;
- and procedures/criteria for early study termination;
- ethical considerations;

methods of quality control of data where appropriate.

PMS plan template:



Pepgra CRO assist you in Preparing Pre-Market Phase and Post Market Clinical Follow Up for Clinical Evaluation(CE)

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

Katta, J. (2015). Post Market Surveillance (including PMCF): common non compliances. Retrieved from https://www.bsig-roup.com/meddev/LocalFiles/nl-NL/Events/B-SI-md-UK-roadshow-post-production-phase-feb-2015-presentation-UK-EN.pdf

U.S. Department of Health and Human Services. (2014). Content of Premarket Submissions for Management of Cybersecurity in Medical Devices. Retrieved from https://ww-w.fda.gov/downloads/medicaldevices/deviceregulation-andguidance/guidancedocuments/ucm356190.pdf

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

Pepgra
Drives Innovation

Contact us
India: +91-8754446690
UK.: +44-1143520021
U.S. Direct: +1-972-502-9262
Website:www.pepgra.com
Email:info@pepgra.com