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www.makrocare.com
medtech@makrocare.com

Post-Market Clinical Follow-Up Studies for Medical Devices

PMCF studies are not intended to replace the premarket data necessary for market authorization. While clinical evidence is an essential element of the premarket conformity assessment process to demonstrate conformity to Essential Principles, it is important to recognize that there may be limitations in the clinical data available in the premarket phase. Also, for some devices based on scientifically well-established technologies, it may be important to recognize that there may be limitations in the applicability of clinical data from comparable devices to the device in question.

Circumstances where PMCF is required

- Unanswered questions of long-term safety, and clinical performance and/or effectiveness.
- Novel technologies or new intended use.
- Higher-risk device and use scenarios- Higher risk anatomical locations; or higher severity of disease/treatment challenges.
- Uncertainties in generalizing clinical investigation results; Generalizing results from study populations to other populations, e.g. from adults to children, from an ethnicity to others. Generalizing results from other jurisdictions to intended jurisdictions.
- Devices approved with clinical data from comparable/equivalent devices and/or preclinical data.
- For devices where urgent market access in public health emergencies.
- Rare anticipated adverse events. Rare anticipated adverse events (e.g. stent thrombosis of the coronary stent) may be difficult to assess in a premarket study but could potentially be identified using large datasets.
- Effectiveness for a known risk. Mitigations may be necessary for known safety risks associated with the use of the device. Confirmation of the adequacy of the mitigation may be evaluated post-market.

Elements of PMCF study

PMCF studies are performed on a device within its intended use/purpose(s) according to the instructions for use. It is important to note that PMCF studies must be conducted according to applicable laws and regulations, ethical requirements and should follow appropriate guidance and standards. Following are major elements for any PMCF study:

- Clearly stated objective(s)
- Scientifically sound study design with an appropriate rationale and statistical analysis methods summarized in a study plan
- Implementation of the study according to the plan.

Interpretation of the results and appropriate conclusion(s) also required.

Objective:

The objective(s) of the study should be stated clearly and should address one or more remaining or newly developed uncertainties related to the safety, and clinical performance and/or effectiveness of the device.

Design:

The study should be designed to address the objective(s) of the study. The PMCF study can take several forms, for example:

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

Several factors should be considered during the design of the study, for example:

- Study setting including the locations and selection of sites and investigators
- Study population by inclusion and exclusion criteria, and the sources and methods for the selection of subjects
- Appropriate controls/comparison groups if comparative studies
- Valid sample size
- Sources of data including real world clinical experience and methods of assessment
- Proper Follow-up duration
- Potential sources of bias and control methods
- Sound statistical methods and impact of potential factors

Implementation:

The study should be executed according to the study plan, and the collected data should be analyzed and interpreted to draw the conclusion.

Some factors should be considered during the implementation of the study, for example:

- Data collection: validated measurement methods/instruments should be utilized and heterogeneity of data should be considered and controlled.
- Quality control: investigator selection, training, inspection and supervision of the study should be performed to ensure quality.
- Results reporting and interpretation: Study report should be developed to demonstrate if conclusions relate back to original objective(s) and hypothesis/hypotheses.

The use of information from PMCF study

The data and conclusions derived from the PMCF studies are part of the post-market surveillance program and used as input to the clinical evaluation and risk management process. This may result in the need to reassess whether the device continues to comply with the Essential Principles. Such assessment may result in corrective or preventive actions, for example:

- Changes to the labeling/instructions for use
- Changes to manufacturing processes
- Changes to the device design
- Public health notifications
- Become the part of premarket clinical evidence when applying for marketing authorization in other jurisdictions.

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