Clinical Development Plan vs. PMCF

Annex XIV, part A

1. To plan, continuously conduct and document a clinical evaluation, manufacturers shall:
(a) establish and update a clinical evaluation plan, which shall include at least:
[…..]
- ❑ **a clinical development plan indicating progression from exploratory investigations, such as first-in-man studies, feasibility and pilot studies, to confirmatory investigations, such as pivotal clinical investigations, and a PMCF as referred to in Part B of this Annex with an indication of milestones and a description of potential acceptance criteria**

A CDP is the overview of a medical device's design history and includes its completed, ongoing and planned clinical research activities

A CDP is a dynamic process expected to be continuously "enriched" by post-market surveillance (PM) & post-market clinical follow-up (PMCF) activities.

The CDP serves as:
- ❑ An input to CEP and PMCF plan
- ❑ A mean to identify emerging clinical evidence needs based on new regulatory and/or marketing requirements
- ❑ A mean to plan clinical research activities throughout the lifetime of a medical device

Input for CDPs comes from:
- ❑ Clinical Research
- ❑ R&D on potential design changes that have a clinical impact
- ❑ RA new requirements (e.g. need to provide more clinical evidence)
- ❑ Marketing on new claims that require substantiation

CDP contents:
- ❑ Design & development phase: exploratory investigations, e.g. first in man studies, feasibility & pilot studies
- ❑ Post-Marketing phase: investigator and/or sponsor-initiated studies, including pivotal clinical investigations and PMCF activities

It is the clinical experience throughout the lifetime of a medical device with respect to design changes and PMS data that **feeds the CDP** with information on risks, safety and performance and dictates the need (or not) for further clinical investigations

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Sources of data for PMCF
- ❑ Clinical Investigations
- ❑ Registries
- ❑ Surveys: retrospective and/or prospective
- ❑ Literature

Annex XIV, part B

PMCF shall be understood to be a continuous process that updates the clinical evaluation referred to in Article 61 and Part A of this Annex **and shall be addressed in the manufacturer's post-market surveillance plan.** When conducting PMCF, the manufacturer shall **proactively collect and evaluate clinical data** from the use in or on humans of a device which bears the CE marking and is placed on the market or put into service within its intended purpose as referred to in the relevant conformity assessment procedure, with the aim of **confirming the safety and performance throughout the expected lifetime of the device,** of **ensuring the continued acceptability of identified risks** and of **detecting emerging risks on the basis of factual evidence.**

PMCF study
- ❑ The device is already CE marked and used within its intended purpose
- ❑ All patient groups within the stated intended use are included during PMCF

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Clinical investigation
- ❑ The devices may not yet be CE marked for the intended purpose used in the study.
- ❑ Eligibility criteria are stricter than those in the intended use statement (label, IFU etc.)

Aspects to consider when defining the need for a PMCF studies
- ❑ **Equivalence**: Is your medical device marketed based on equivalence?
- ❑ **Device description**: Is your device 'novel' with respect to design, components, used substances, mode of action?
- ❑ **Significant changes**: Have there been 'significant' changes as per EU-MDR to your device's design and/or intended use?
- ❑ **Labelling**:
- ✓ Is there 'sufficient' clinical evidence to support your device's indications?
- ✓ Have you identified higher/increased risk(s) in specific populations (e.g. elderly, children, patients with a specific comorbidity) that would require further investigation to establish a positive benefit-risk ratio?
- ✓ Does the real-world use of your device continue to support the contra-indications statement?
- ❑ **Clinical claims**: Are the clinical claims of safety and performance made for your device sufficiently supported by clinical evidence?
- ❑ **Post-market Surveillance:**
- ✓ Have there been new data on the safety and performance of your device in the literature?
- ✓ Have there been new adverse events reported not included in your Risk Management report?
- ✓ Does the clinical evidence on your device support its continued market acceptance?
- ❑ **Expected Lifetime:** Is the full expected lifetime of your device 'covered' with safety and performance clinical evidence?