PMCF Needs

The aims of PMCF according to Regulation (EU) 2017/745 (MDR):

- Confirm the safety and performance throughout the expected lifetime of the device
- Ensure the continued acceptability of identified risks
- Detect emerging risks on the basis of factual evidence

Circumstances that may justify PMCF studies include, for example (according to MEDDEV 2.12/2 rev2):

- Innovation, e.g., where the design of the device, the materials, substances, the principles of operation, the technology or the medical indications are novel;
- Significant changes to the products or to its intended use for which pre-market clinical evaluation and re-certification has been completed;
- High product related risk e.g. based on design, materials, components, invasiveness, clinical procedures;
- High risk anatomical locations;
- High risk target populations e.g. paediatrics, elderly;
- Severity of disease/treatment challenges;
- Questions of ability to generalise clinical investigation results;
- Unanswered questions of long-term safety and performance;
- Results from any previous clinical investigation, including adverse events or from post-market surveillance activities;
- Identification of previously unstudied subpopulations which may show different benefit/risk-ratio e.g. hip implants in different ethnic populations;
- Continued validation in cases of discrepancy between reasonable premarket follow-up time scales and the expected life of the product;
- Risks identified from the literature or other data sources for similar marketed devices;
- Interaction with other medical products or treatments;
- Verification of safety and performance of device when exposed to a larger and more varied population of clinical users;
- Emergence of new information on safety or performance;
- Where CE marking was based on equivalence.