PMCF methods

Collect relevant PMCF data from the following possible sources of available data:

Clinical experience gained

- Recently finished clinical study reports or publications of the medical device under evaluation
- Clinical study reports or publications of equivalent or similar medical devices
- Publications of other manufacturers' equivalent or similar device studies

Feedback from patients and users

- Extract from PMS documentation (complaint data, vigilance data)
- Review of Sales Reps Reports
- Survey of Sales Reps among their customers
- User Survey
- Patient Survey
- Other reports by manufacturers' personnel in contact with patients and/or users, such as oral reports of product experience
- Social Media Data, if available

Screening of scientific literature

- Use of PMSR data of subject device
- Use of same methods defined in CEP/CER documentation of subject device
- Use of PMSR data of similar device(s)
- Use of same methods defined in CEP/CER documentation of similar device(s)
- Use of additional literature searches in specific (new) databases

Screening of other sources of clinical data

- Collect data from ongoing clinical investigations with similar devices
- Collect data from Investigator Initiated Trials (IITs)
- Recent publications known to the manufacturer but not yet included in public databases
- Unpublished data of the manufacturer
- Available public registers
- Available internal registers, including those of related companies
- Commercially available data from registers
- Results of PMCF study with CE-marked medical device