Five Steps to Implement PMCF

Step 1: Analyze Needs

Collect questions you want to answer with PMCF data:
a) To close knowledge gaps concerning safety and performance: see clinical evaluation and other reasons for PMCF (see one pager *"PMCF_needs"* according to MEDDEV 2.12)
b) To strengthen supportive claims of your device
c) To gain customer's feedback on your device
Warning: Don't include too many questions not to overwhelm your customer with too much work
Note: Consider possible synergies concerning safety and performance questions within your product portfolio. Is a single PMCF format feasible for the whole product portfolio?

Step 2: Aims and Goals

- Focus on the data you really need
- Draft aims and goals you want to achieve
- Deduce the PMCF parameters
- Justify parameters

Note: Consider sample size and selection bias

Step 3: How to Implement PMCF

- Compile PMCF plan and, if necessary, a clinical study plan
- Draft accompanying documents, like questionnaires, patient information and consent (GDPR!), ethics committee submission documents

Note: Consider some demographic questions, electronic or paper based questionnaire?, built database
Note: implementation of PMCF could be also: regular check of publicly available clinical data (see *one pager "PMCF_methods"*)

Step 4: Perform PMCF

- Select personnel to perform: clinical team, sales reps, external help
- Submit documents to ethics, if needed
- Select study sites

Step 5: Report PMCF Results

- Compile PMCF results
- Draft PMCF reports, probably two versions: one to update the Clinical Evaluation, another for marketing purposes