**Post-Market Clinical Follow-Up Evaluation Report**

For

[Device Name]

Manufacturer Name: [Manufacturer name]

Document Number: XXXX

Revision: XXXX

# Approval

**Reviewer**

|  |  |
| --- | --- |
|  | |
| Name: | Date: |
| Title: | Signature: |

**Approver**

|  |  |
| --- | --- |
|  | |
| Name: | Date: |
| Title: | Signature: |
|  | |
| Name: | Date: |
| Title: | Signature: |

# Revision history

Table 1: History of revisions

| **Revision** | **Revision date** | **Description of change** | **Revised by** |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

# Manufacturer contact details

The following table includes the manufacturer details.

Table 2: Contact information

| **Contact information** | **Description** |
| --- | --- |
| Legal manufacturer name: |  |
| Address: |  |
| Single Registration Number (SRN): |  |
| Person responsible for regulatory compliance (PRRC): |  |
| E-mail: |  |
| Phone: |  |
| Fax: |  |
|  |  |
| Authorized Representative: |  |
| Address: |  |
| Contact Person: |  |
| E-mail: |  |
| Phone: |  |
| Fax: |  |

# Medical Device description and specification

No changes applied. Refer to Section B of the PMCF plan

/OR the changes applied are identified below in ***bold and italic***.

## General medical device details.

The following table includes the general information on [Device name] (hereafter named [device short name]).

Table 3: Medical device details

| **Medical device information** | **Description** |
| --- | --- |
| Product or trade name |  |
| Model and type | XXXX / See appendix I |
| Basic UDI-DI |  |
| EMDN code (CND code) | XXXX / See appendix I |
| Certificate number (if applicable) |  |
| Class and classification rule | Class X under Rule Y / Refer to appendix I |
| Expected lifetime | XXXX / See appendix I |
| Novelty: |  |
| * Novel product: | Yes/No if yes describe the novelty |
| * Novel related clinical procedure: | Yes/No if yes describe the novelty |

## General description of the device

Copy/paste from PMCF plan (with modifications in ***bold and italic***)

## List and description of any variants and/or configurations covered by this plan

Copy/paste from PMCF plan (with modifications in ***bold and italic***)

## List of any accessories covered by this plan

Copy/paste from PMCF plan (with modifications in ***bold and italic***)

## Intended purpose

Copy/paste from PMCF plan (with modifications in ***bold and italic***)

## Intended users

Copy/paste from PMCF plan (with modifications in ***bold and italic***)

## Intended patient population

Copy/paste from PMCF plan (with modifications in ***bold and italic***)

## Medical condition(s)

Copy/paste from PMCF plan (with modifications in ***bold and italic***)

## Indications

Copy/paste from PMCF plan (with modifications in ***bold and italic***)

## Contraindications

Copy/paste from PMCF plan (with modifications in ***bold and italic***)

## Warnings

Copy/paste from PMCF plan (with modifications in ***bold and italic***)

# Activities undertaken related to PMCF: results

## Screening of scientific literature for the subject device

### Type of PMCF activity

General procedure and method

### PMCF objectives

Select the appropriate objective(s)

* confirming the safety of the medical device
* confirming the performance of the medical device
* identifying previously unknown side-effects (related to the procedures or to the medical devices).
* monitoring the identified side-effects and contraindications
* identifying and analyzing emergent risks
* ensuring the continued acceptability of the benefit-risk ratio
* identifying possible systematic misuse or off-label use of the device

### Description of PMCF activity

A literature search has been implemented for the period from DD/MM/YYYY to DD/MM/YYYY to detect the published and unpublished articles related to the [device short name] and bring clinical evidence for the demonstration of safety and performance.

The literature search methodology has been carried out in compliance with Section A5 of MEDDEV 2.7/1 rev.4 and in alignment with the last clinical evaluation report (see **Appendix 2 – Reference documents**). Research questions have been constructed using a PICO (Populations, Interventions, Comparators, Outcomes) process to justify the selection of relevant keywords.

The literature search has been defined in a literature search protocol (see **Appendix 4 – Clinical data search protocol**) using the following databases:

* Embase
* PubMed
* Cochrane Library
* Google Scholar
* EU Clinical Trials Register
* Clinicaltrials.gov
* XXXX

The search queries have been defined using the selected keywords in a way to match with the language of each database used and the relevant search limitations (e.g., article type, language, as applicable).

The implementation of literature search has been documented in the literature search report (See **Appendix 5 – Literature search report for S&P)** and resulted a list of articles that have been screened in two stages:

* Level-1 screening is based on the titles and abstracts
* Level-2 screening is based on the full articles

The screening process consisted of the review of each collected article to confirm if it should be included or excluded based on the inclusion/exclusion criteria.

### Deviations to the PMCF plan

No deviation to the PMCF plan described in **Appendix 2 – Reference documents**.

All deviations need to be justified for their impact on the results*.*

### Collected clinical data and appraisal

The implementation of literature searches with the objective to establish the safety and performance profile of [device short name] is described in **Appendix 5 – Literature search report for S&P.**

The following figure describes the selection process used.

Figure 1: Literature search results for [device short name]

Total number of results

n=

Number of results without duplicates

n=

Number of results after Level I screening:

n=

Number of results after Level II screening:

n=

Figure to be completed

The list of articles included after Level II screening is described in **Appendix 8 – List of articles**.

The results of each article are summarized in the following table ordered based on the article's quality using the appraisal criteria defined in **Appendix 3 – Appraisal**.

#### High-quality articles

Table 4: Summary and appraisal of high-quality literature articles

| **Reference** |  | |
| --- | --- | --- |
| **Title:** |  | |
| **Appraisal criteria** | | |
| **Oxford Loe:** | LOE X | |
| **Suitability** | |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **Device** |  | **Application** |  | **Patient** |  | **Report** |  | | |
| **Contribution** | |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **Outcome** |  | **Follow-up** |  | **Statistics** |  | **Clinical significance** |  | | |
| **Rank (MDCG 2020-6)** | Rank 4 / Rank 5 | |
| **Appraisal conclusion** | High quality / low quality / off-label use | |
| **Article description:** | | |
| **Objective:** |  | |
| **Method:** |  | |
| **FU:** |  | |
| **Statistics:** |  | |
| **Demographic data:** | **n=**XX | **Sex:** X males / Y females |
| **mean age:** (from X to Y years old)  describe in more details when necessary and when stratified data are available | **Medical indication:** XXX  Provide stratified data when necessary |
| **Device used:** | Include device name and characteristics when possible (e.g., size, model number, etc.) | |
| **Summary of results** | | |
| **Performance:** | |  |  |  | | --- | --- | --- | | **Endpoints** | **Timepoints** | **Results** | | ***Performance endpoints*** | | | |  |  | Indicate results OR comparative results with p value | |  |  |  | | |
| **Safety:** | |  |  |  | | --- | --- | --- | | **Endpoints** | **Timepoints** | **Results** | | ***Safety endpoints*** | | | |  |  | Indicate results OR comparative results with p value | |  |  |  | | |
| **Clinical risks:** | |  |  |  | | --- | --- | --- | | **Events** | **Number** | **Rate** | |  |  | Indicate rate in relation to time (e.g., PPY) | | |
| **Conclusion of the authors:** | | |
|  | | |

#### Low-quality articles

Table 5: Summary and appraisal of low-quality literature article

| **Reference** |  | |
| --- | --- | --- |
| **Title:** |  | |
| **Appraisal criteria** | | |
| **Oxford Loe:** | LOE X | |
| **Suitability** | |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **Device** |  | **Application** |  | **Patient** |  | **Report** |  | | |
| **Contribution** | |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **Outcome** |  | **Follow-up** |  | **Statistics** |  | **Clinical significance** |  | | |
| **Rank (MDCG 2020-6)** | Rank 4 / Rank 5 | |
| **Appraisal conclusion** | High quality / low quality / off-label use | |
| **Article description:** | | |
| **Objective:** |  | |
| **Method:** |  | |
| **FU:** |  | |
| **Statistics:** |  | |
| **Demographic data:** | **n=**XX | **Sex:** X males / Y females |
| **mean age:** (from X to Y years old)  describe in more details when necessary and when stratified data are available | **Medical indication:** XXX  Provide stratified data when necessary |
| **Device used:** | Include device name and characteristics when possible (e.g., size, model number, etc.) | |
| **Summary of results** | | |
| **Performance:** | |  |  |  | | --- | --- | --- | | **Endpoints** | **Timepoints** | **Results** | | ***Performance endpoints*** | | | |  |  | Indicate results OR comparative results with p value | |  |  |  | | |
| **Safety:** | |  |  |  | | --- | --- | --- | | **Endpoints** | **Timepoints** | **Results** | | ***Safety endpoints*** | | | |  |  | Indicate results OR comparative results with p value | |  |  |  | | |
| **Clinical risks:** | |  |  |  | | --- | --- | --- | | **Events** | **Number** | **Rate** | |  |  | Indicate rate in relation to time (e.g., PPY) | | |
| **Conclusion of the authors:** | | |
|  | | |

#### Off-label use

| **Reference** |  | |
| --- | --- | --- |
| **Title:** |  | |
| **Appraisal criteria** | | |
| **Oxford Loe:** | LOE X | |
| **Suitability** | |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **Device** |  | **Application** |  | **Patient** |  | **Report** |  | | |
| **Contribution** | |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **Outcome** |  | **Follow-up** |  | **Statistics** |  | **Clinical significance** |  | | |
| **Rank (MDCG 2020-6)** | Rank 4 / Rank 5 | |
| **Appraisal conclusion** | High quality / low quality / off-label use | |
| **Article description:** | | |
| **Objective:** |  | |
| **Method:** |  | |
| **FU:** |  | |
| **Statistics:** |  | |
| **Demographic data:** | **n=**XX | **Sex:** X males / Y females |
| **mean age:** (from X to Y years old)  describe in more details when necessary and when stratified data are available | **Medical indication:** XXX  Provide stratified data when necessary |
| **Device used:** | Include device name and characteristics when possible (e.g., size, model number, etc.) | |
| **Summary of results** | | |
| **Safety and Performance:** | N/A - Results of device evaluation regarding safety and performance endpoints are not analyzed for off label use articles. Only clinical risks observed are reviewed. | |
| **Clinical risks:** | |  |  |  | | --- | --- | --- | | **Events** | **Number** | **Rate** | |  |  | Indicate rate in relation to time (e.g., PPY) | | |
| **Conclusion of the authors:** | | |
|  | | |

### Analysis of findings

A total of X literature articles has been found to support the safety and performance of [Device short name] including X articles of high quality and X articles of low quality. In addition, X articles have been found for off-label uses.

Identify any systematic misuse / off label use.

X articles are Rank 4 on [Device short name] per MDCG 2020-6 (April 2020).

A total of X patients has been treated/diagnosed with an age from X to X years old. Please stratify the data as required if sub-indications/sub-populations are claimed.

The results obtained for the key criteria defined to support the safety, performance and benefits claims as well as the qualitative and quantitative information related to clinical risks have been summarized in the following tables.

Table 6: Overall summary of literature articles

| **Key Outcome Parameters** | **Timepoint** | **Outcomes** |
| --- | --- | --- |
|  |  |  |
|  |  |  |
|  |  |  |

Table 7: Overall summary of risks in literature articles

| **Clinical risks** | **Event types** | **Analysis** | |
| --- | --- | --- | --- |
| **Occurrence (n)/rate (%)** | **New or existing risks** |
| Device-related risks |  |  | new existing |
|  |  | new existing |
|  |  | new existing |
| Patient-related risks |  |  | new existing |
|  |  | new existing |
|  |  | new existing |

Other critical S&P considerations raised by the PMCF activity:

* XXX

### Impacts on Technical Documentation

Table 8: Impact assessment of literature screening on subject device

| **Impact assessment** | **Conclusion on impact** | **Description / justification** |
| --- | --- | --- |
| Risk Management | Yes No |  |
| Clinical Evaluation | Yes No |  |
| PMS | Yes No |  |
| SSCP | Yes No |  |
| Need of CAPA (including FSCA) | Yes No |  |

## Screening of vigilance and recalls in publicly available database for the subject device

### Type of PMCF activity

General PMCF procedure and method

### PMCF objectives

Select the appropriate objective(s)

* confirming the safety of the medical device
* confirming the performance of the medical device
* identifying previously unknown side-effects (related to the procedures or to the medical devices).
* monitoring the identified side-effects and contraindications
* identifying and analyzing emergent risks
* ensuring the continued acceptability of the benefit-risk ratio
* identifying possible systematic misuse or off-label use of the device

### Description of PMCF activity

A vigilance / recall search has been implemented for the period from DD/MM/YYYY to DD/MM/YYYY to detect the clinical risks (i.e., device problem, patient problems) related to [device short name] and bring additional clinical evidence for the demonstration of safety and performance.

The vigilance / recall search methodology has been carried out using an approach similar to the literature search methodology and in alignment with the last clinical evaluation report (see **Appendix 2 – Reference documents**).

Research questions have been constructed using a PICO process to justify the selection of relevant keywords.

The vigilance / recall search has been defined in a vigilance/recall search protocol (see **Appendix 4 – Clinical data search protocol**) using the following databases:

* FDA MAUDE
* FDA Medical Device Recalls
* ANSM safety information
* Bfarm Field Corrective Actions
* MHRA Alerts, recalls and safety information: drugs and medical devices
* SwissMedic – FSCA and recall
* DAEN (Database of Adverse Event Notifications) - medical devices
* SARA (System for Australian Recall Actions)
* Canadian recalls and safety alerts
* XXXX

The search queries have been defined using the selected keywords in a way to match with the language of each database used and the relevant search limitations (e.g., search period).

The implementation of vigilance / recall search has been documented in the vigilance/recall search report (See **Appendix 6 – Vigilance & Recall search report**) andresults in a list of events that have been screened to determine if applicable to [device short name].

### Deviations to the PMCF plan

No deviation to the PMCF plan described in **Appendix 2 – Reference documents**.

*All deviations need to be justified for their impact on the results.*

### Collected clinical data and appraisal

A search in vigilance and FSCA databases has been conducted to retrieve the clinical risks related to [Device Short Name]. For the period from DD-MM-YYYY to DD-MM-YYYY, a total of XX vigilance and XX FSCA have been retrieved in the publicly available database consulted for the [Device short name].

The results are appraised with a Rank 7 according to the criteria described in **Appendix 3 – Appraisal.**

The following table presents the number of relevant events retrieved for all databases consulted.

Table 9: Results of vigilance/recall search implementation of subject device

| **Database** | **Number of results:** | | | | **Event type** | | | **FSCA** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Total** | **Excluded** | **Duplicate** | **Included** | **Device-related** | **Patient-related** | **Death** |
| FDA MAUDE |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| FDA Medical Device Recalls |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| FDA TPLC |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| ANSM safety information |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| Bfarm Field Corrective Actions |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| MHRA Alerts, recalls and safety information: drugs and medical devices |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| SwissMedic – FSCA and recall |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| DAEN (Database of Adverse Event Notifications) - medical devices |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| SARA (System for Australian Recall Actions) |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| Canadian recalls and safety alerts |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| TOTAL |  |  |  |  |  |  |  |  |

### Analysis of findings

The vigilance and recall review identified clinical risks including undesirable side-effects related to [Device Short Name] as reported in the following table.

Table 10: Risks from public vigilance/recall databases

| **Events Reported** | **Event types** | **Analysis** | |
| --- | --- | --- | --- |
| **Occurrence (n)/rate (%)** | **New or existing risks** |
| Device-related risks |  |  | new existing |
|  |  | new existing |
|  |  | new existing |
| Patient-related risks |  |  | new existing |
|  |  | new existing |
|  |  | new existing |

Other critical S&P considerations raised by the PMCF activity:

* XXX

### Impacts on Technical Documentation

Table 11: Impact assessment of vigilance/recall screening on subject device

| **Impact assessment** | **Conclusion on impact** | **Description / justification** |
| --- | --- | --- |
| Risk Management | Yes No |  |
| Clinical Evaluation | Yes No |  |
| PMS | Yes No |  |
| SSCP | Yes No |  |
| Need of CAPA (including FSCA) | Yes No |  |

## Registry

### Type of PMCF activity

Specific PMCF procedure and method

### PMCF objectives

Select the appropriate objective(s)

* confirming the safety of the medical device
* confirming the performance of the medical device
* identifying previously unknown side-effects (related to the procedures or to the medical devices).
* monitoring the identified side-effects and contraindications
* identifying and analyzing emergent risks
* ensuring the continued acceptability of the benefit-risk ratio
* identifying possible systematic misuse or off-label use of the device

### Description of PMCF activity

Clinical data from the registry XXXX Registry name relevant to [device short name] /or medical conditions treated by [device short name], has been collected according to the registry consultation protocol under XXXX rev.Y Document Number. Final / intermediary results are available and documented in the registry consultation report XXXX rev.Y Document Number.

The information relevant to the registry consultation is summarized in the following table.

Table 12: Registry consultation summary and appraisal

| **Device registry requirements** | **Device registry details** |
| --- | --- |
| Study design | Registry |
| Study objective |  |
| Geographic area |  |
| Population |  |
| Number of patients enrolled |  |
| Inclusion/exclusion criteria |  |
| Control group and justification |  |
| Study method |  |
| Follow-up duration |  |
| Endpoints |  |
| Need of notification/approval: | Ethic committee (justification if not): |
| NB (justification if not): |
| CA (justification if not): |
| Status | Select the appropriate status  Ethic Committee approval  CA approval  Recruitment  Ongoing – preliminary results available/not available (% of completeness of FU)  Complete – final results available / not available  Complete, but still ongoing for long-term FU |

### Deviations to the PMCF plan

No deviation to the PMCF plan described in **Appendix 2 – Reference documents**.

*All deviations need to be justified for their impact on the results.*

### Collected clinical data and appraisal

The registry consultation has been carried out to extract the safety and performance data applicable to [Device short name].

The appraisal criteria used for the assessment of data are described in **Appendix 3 – Appraisal**.

The following table further describes the result obtained.

Table 13: Results of registry data consultation on subject device

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Performance endpoint(s)** | Table to be customized as needed   |  |  |  | | --- | --- | --- | | **Endpoints** | **Timepoints** | **Results** | | ***Performance endpoints*** | | | |  |  | Indicate results OR comparative results with p value | |  |  |  | | | | | | | | |
| **Safety endpoint(s)** | Table to be customized as needed   |  |  |  | | --- | --- | --- | | **Endpoints** | **Timepoints** | **Results** | | ***Safety endpoints*** | | | |  |  | Indicate results OR comparative results with p value | |  |  |  | | | | | | | | |
| **Adverse events and side-effects** | Table to be customized as needed   |  |  |  | | --- | --- | --- | | **Events** | **Number** | **Rate** | |  |  | Indicate rate in relation to time (e.g., PPY) | | | | | | | | |
|  | | | | | | | | |
| **Limitations:** | high loss to follow-up, or potential confounding factors that may question the results. | | | | | | | |
| **Deficiency:** | Any device deficiency and any device replacements related to safety and/or performance during the study | | | | | | | |
|  | | | | | | | | |
| **Appraisal:** | **Rank:** |  | **LoE:** |  | **Suitability:** |  | **Contribution:** |  |

### Analysis of findings

The data resulting from the registry consultation are classified under Rank 1 (X studies), Rank 2 (X studies), Rank 3 (X studies) per the MDCG 2020-6 (April 2020). A total of X patients has been treated/diagnosed with an age from X to X years old. Stratify the data as required if sub-indications/sub-populations are claimed.

The results obtained for the key safety and performance criteria defined to support the safety, performance and benefits claims as well as the qualitative and quantitative information related to clinical risks have been summarized in the following tables.

Table 14: Overall summary of registry data

| **Key Outcome Parameters** | **Timepoint** | **Outcomes** |
| --- | --- | --- |
|  |  |  |
|  |  |  |
|  |  |  |

Table 15: Overall summary of risks of registry data

| **Clinical risks** | **Event types** | **Analysis** | |
| --- | --- | --- | --- |
| **Occurrence (n)/rate (%)** | **New or existing risks** |
| Device-related risks |  |  | new existing |
|  |  | new existing |
|  |  | new existing |
| Patient-related risks |  |  | new existing |
|  |  | new existing |
|  |  | new existing |

Other critical S&P considerations raised by the PMCF activity:

* XXX

### Impacts on Technical Documentation

Table 16: Impact assessment of registry data on subject device

| **Impact assessment** | **Conclusion on impact** | **Description / justification** |
| --- | --- | --- |
| Risk Management | Yes No |  |
| Clinical Evaluation | Yes No |  |
| PMS | Yes No |  |
| SSCP | Yes No |  |
| Need of CAPA (including FSCA) | Yes No |  |

## PMCF investigation

### Type of PMCF activity

Specific PMCF procedure and method

### PMCF objectives

Select the appropriate objective(s)

* confirming the safety of the medical device
* confirming the performance of the medical device
* identifying previously unknown side-effects (related to the procedures or to the medical devices).
* monitoring the identified side-effects and contraindications
* identifying and analyzing emergent risks
* ensuring the continued acceptability of the benefit-risk ratio
* identifying possible systematic misuse or off-label use of the device

### Description of PMCF activity

Clinical data from the PMCF investigation titled, XXXX clinical investigation name relevant to [device short name] have been collected according to the PMCF investigation protocol under XXXX rev.Y Document Number. Final / intermediary results are available and documented in the PMCF investigation report XXXX rev.Y Document Number.

The information relevant to the PMCF investigation is summarized in the following table.

Table 17: PMCF investigation summary and appraisal

| **PMCF investigation requirements** | **PMCF investigation details** |
| --- | --- |
| Study design | PMCF investigation |
| Study objective |  |
| Geographic area |  |
| Population |  |
| Number of patients enrolled |  |
| Inclusion/exclusion criteria |  |
| Control group and justification |  |
| Investigator(s) |  |
| Investigation site(s) |  |
| Study method |  |
| Follow-up duration |  |
| Endpoints |  |
| Need of notification/approval: | Ethic committee (justification if not): |
| NB (justification if not): |
| CA (justification if not): |
| Status | Select the appropriate status  Ethic Committee approval  CA approval  Recruitment  Ongoing – preliminary results available/not available (% of completeness of FU)  Complete – final results available / not available  Complete, but still ongoing for long-term FU |

### Deviations to the PMCF plan

No deviation to the PMCF plan described in **Appendix 2 – Reference documents**.

*All deviations need to be justified for their impact on the results.*

### Collected clinical data and appraisal

The PMCF investigation has been carried out to extract the safety and performance data applicable to [Device short name].

The appraisal criteria used for the assessment of data are described in **Appendix 3 – Appraisal.**

The following table further describes the result obtained.

Table 18: Results of PMCF investigation on subject device

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Performance endpoint(s)** | Table to be customized as needed   |  |  |  | | --- | --- | --- | | **Endpoints** | **Timepoints** | **Results** | | ***Performance endpoints*** | | | |  |  | Indicate results OR comparative results with p value | |  |  |  | | | | | | | | |
| **Safety endpoint(s)** | Table to be customized as needed   |  |  |  | | --- | --- | --- | | **Endpoints** | **Timepoints** | **Results** | | ***Safety endpoints*** | | | |  |  | Indicate results OR comparative results with p value | |  |  |  | | | | | | | | |
| **Adverse events and side-effects** | Table to be customized as needed   |  |  |  | | --- | --- | --- | | **Events** | **Number** | **Rate** | |  |  | Indicate rate in relation to time (e.g., PPY) | | | | | | | | |
|  | | | | | | | | |
| **Limitations:** | high loss to follow-up, or potential confounding factors that may question the results. | | | | | | | |
| **Deficiency:** | Any device deficiency and any device replacements related to safety and/or performance during the study | | | | | | | |
|  | | | | | | | | |
| **Appraisal:** | **Rank:** |  | **LoE:** |  | **Suitability:** |  | **Contribution:** |  |

### Analysis of findings

The data resulting from the PMCF investigation are classified under Rank 1 (X studies), Rank 2 (X studies), Rank 3 (X studies) per the MDCG 2020-6 (April 2020). A total of X patients has been treated/diagnosed with an age from X to X years old. Stratify the data as required if sub-indications/sub-populations are claimed.

The results obtained for the key safety and performance criteria defined to support the safety, performance and benefits claims as well as the qualitative and quantitative information related to clinical risks have been summarized in the following tables.

Table 19: Overall summary of PMCF investigation

| **Key Outcome Parameters** | **Timepoint** | **Outcomes** |
| --- | --- | --- |
|  |  |  |
|  |  |  |
|  |  |  |

Table 20: Overall summary of risks of PMCF investigation

| **Clinical risks** | **Event types** | **Analysis** | |
| --- | --- | --- | --- |
| **Occurrence (n)/rate (%)** | **New or existing risks** |
| Device-related risks |  |  | new existing |
|  |  | new existing |
|  |  | new existing |
| Patient-related risks |  |  | new existing |
|  |  | new existing |
|  |  | new existing |

Other critical S&P considerations raised by the PMCF activity:

* XXX

### Impacts on Technical Documentation

Table 21: Impact assessment of PMCF investigation data on subject device

| **Impact assessment** | **Conclusion on impact** | **Description / justification** |
| --- | --- | --- |
| Risk Management | Yes No |  |
| Clinical Evaluation | Yes No |  |
| PMS | Yes No |  |
| SSCP | Yes No |  |
| Need of CAPA (including FSCA) | Yes No |  |

## Patient/user survey

### Type of PMCF activity

Specific PMCF procedure and method

### PMCF objectives

Select the appropriate objective(s)

* confirming the safety of the medical device
* confirming the performance of the medical device
* identifying previously unknown side-effects (related to the procedures or to the medical devices).
* monitoring the identified side-effects and contraindications
* identifying and analyzing emergent risks
* ensuring the continued acceptability of the benefit-risk ratio
* identifying possible systematic misuse or off-label use of the device

### Description of PMCF activity

Clinical data from the patient/user survey relevant to [device short name] have been collected according to the patient/user survey protocol under XXXX rev.Y Document Number. Final / intermediary results are available and documented in the patient/user survey report XXXX rev.Y Document Number.

The information relevant to the patient/user survey is summarized in the following table.

Table 22: PMCF investigation summary and appraisal

| **Patient/user survey requirements** | **Patient/user survey details** |
| --- | --- |
| Study design | Patient/user survey |
| Study objective |  |
| Geographic area |  |
| Population |  |
| Number of patients enrolled |  |
| Inclusion/exclusion criteria |  |
| Investigator(s) | If in specific site |
| Investigation site(s) | If in specific site |
| Study method |  |
| Follow-up duration |  |
| Endpoints |  |
| Need of notification/approval: | Ethic committee (justification if not): |
| NB (justification if not): |
| CA (justification if not): |
| Status | Select the appropriate status  Ethic Committee approval  CA approval  Recruitment  Ongoing – preliminary results available/not available (% of completeness of FU)  Complete – final results available / not available  Complete, but still ongoing for long-term FU |

### Deviations to the PMCF plan

No deviation to the PMCF plan described in **Appendix 2 – Reference documents**.

*All deviations need to be justified for their impact on the results.*

### Collected clinical data and appraisal

The PMCF via patient/user survey has been carried out to collect clinical data on safety and performance of [Device short name].

The results are appraised with a Rank 8 according to the criteria described in **Appendix 3 – Appraisal**.

The following table further describes the result obtained.

To be customized according to the design of the survey

Table 23: Results patient/user survey for subject device

| **Questions** | **Type of responses** | **Rate** | **Acceptance criteria** | **Additional patient/user comments** |
| --- | --- | --- | --- | --- |
| 1. XXX ? | * 1. Response 1 | XX% |  | * XXX |
| * 1. Response 2 | XX% |
| * 1. Response 3 | XX% |
| * 1. Response 4 | XX% |
| 1. XXX ? | * 1. Response 1 | XX% |  | * XXX |
| * 1. Response 2 | XX% |
| * 1. Response 3 | XX% |
| * 1. Response 4 | XX% |
| … |  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

### Analysis of findings

The data resulting from the patient/user survey are classified under Rank 8 per the MDCG 2020-6 (April 2020). A total of X targeted patients/users responded to the survey reaching a limit where the results can be statistically discussed.

The results obtained for the key safety and performance criteria defined to support the safety, performance and benefits claims as well as the qualitative and quantitative information related to clinical risks have been summarized in the following tables.

Table 24: Overall summary of patient/user survey

| **Key Outcome Parameters** | **Timepoint** | **Outcomes** |
| --- | --- | --- |
| N/A – no results collected on safety and performance outcome parameters.  It is not expected that the surveys will give high quality data on key outcome parameters. To be completed if applicable. | | |

Table 25: Overall summary of risks of patient/user survey

| **Clinical risks** | **Event types** | **Analysis** | |
| --- | --- | --- | --- |
| **Occurrence (n)/rate (%)** | **New or existing risks** |
| Device-related risks |  |  | new existing |
|  |  | new existing |
|  |  | new existing |
| Patient-related risks |  |  | new existing |
|  |  | new existing |
|  |  | new existing |

Other critical S&P considerations raised by the PMCF activity:

* XXX

### Impacts on Technical Documentation

Table 26: Impact assessment of patient/user survey data on subject device

| **Impact assessment** | **Conclusion on impact** | **Description / justification** |
| --- | --- | --- |
| Risk Management | Yes No |  |
| Clinical Evaluation | Yes No |  |
| PMS | Yes No |  |
| SSCP | Yes No |  |
| Need of CAPA (including FSCA) | Yes No |  |

## XXX

### Type of PMCF activity

General / specific procedure and method

### PMCF objectives

Select the appropriate objective(s)

* confirming the safety of the medical device
* confirming the performance of the medical device
* identifying previously unknown side-effects (related to the procedures or to the medical devices).
* monitoring the identified side-effects and contraindications
* identifying and analyzing emergent risks
* ensuring the continued acceptability of the benefit-risk ratio
* identifying possible systematic misuse or off-label use of the device

### Description of PMCF activity

XXX

### Deviation to the PMCF plan

No deviation to the PMCF plan described in **Appendix 2 – Reference documents**.

*All deviations need to be justified for their impact on the results.*

### Collected clinical data and appraisal

XXX

### Analysis of findings

XXX

The results obtained for the key safety and performance criteria defined to support the safety, performance and benefits claims as well as the qualitative and quantitative information related to clinical risks have been summarized in the following tables.

Table 27: Overall summary of XXX

| **Key Outcome Parameters** | **Timepoint** | **Outcomes** |
| --- | --- | --- |
|  |  |  |
|  |  |  |
|  |  |  |

Table 28: Overall summary of risks of XXX

| **Clinical risks** | **Event types** | **Analysis** | |
| --- | --- | --- | --- |
| **Occurrence (n)/rate (%)** | **New or existing risks** |
| Device-related risks |  |  | new existing |
|  |  | new existing |
|  |  | new existing |
| Patient-related risks |  |  | new existing |
|  |  | new existing |
|  |  | new existing |

Other critical S&P considerations raised by the PMCF activity:

* XXX

### Impact on Technical Documentation

Table 29: Impact assessment of XXX data on subject device

| **Impact assessment** | **Conclusion on impact** | **Description / justification** |
| --- | --- | --- |
| Risk Management | Yes No |  |
| Clinical Evaluation | Yes No |  |
| PMS | Yes No |  |
| SSCP | Yes No |  |
| Need of CAPA (including FSCA) | Yes No |  |

# Evaluation of clinical data relating to equivalent or similar devices

PMCF activities for [device short name] also include the collection and evaluation of clinical data on the equivalent and similar devices described in the next table.

The PMCF methods and procedures applied for the collection of clinical data on equivalent/similar devices, are the same as the general procedures and methods C.1 and C.2 for [device short name]:

* Screening of scientific literature (See **Section D.1**)
* Screening of vigilance and recalls in publicly available databases (See **Section D.2**)

In addition, clinical data described in the current summary of safety and clinical performance (SSCP) for equivalent/similar devices have been evaluated in this PMCF evaluation report (See **Section D.3**)Applicable to class III and implantable devices only

Table 30: Data on equivalent and similar devices

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Product Name**  **Manufacturer Name** | **Equivalent or similar device** | **Intended purpose** | **Intended users** | **Intended patient population** | **Medical condition** | **Indication** | **Reference to CER** |
|  |  |  |  |  |  |  | XXXX rev.Y, section Z |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

## Screening of scientific literature for equivalent or similar devices

### Description of PMCF activity

A literature search has been implemented for the period from DD/MM/YYYY to DD/MM/YYYY to detect the published and unpublished articles related to devices similar with or equivalent to [device short name].

The literature search methodology has been carried out in compliance with Section A5 of MEDDEV 2.7/1 rev.4 and in alignment with the last clinical evaluation report (see **Appendix 2 – Reference documents**). Research questions have been constructed using a PICO (Populations, Interventions, Comparators, Outcomes) process to justify the selection of relevant keywords.

The literature search has been defined in a literature search protocol (see **Appendix 4 – Clinical data search protocol**) using the following databases:

* Embase
* PubMed
* Cochrane Library
* EU Clinical Trials Register
* Clinicaltrials.gov
* XXXX

The search queries have been defined using the selected keywords in a way to match with the language of each database used and the relevant search limitations (e.g., article type, language, as applicable).

The implementation of literature search has been documented in the literature search report (See **Appendix 7 – Literature search report for AC**) and resulted a list of articles that have been screened in two stages:

* Level-1 screening is based on the titles and abstracts
* Level-2 screening is based on the full articles

The screening process consisted of the review of each collected article to confirm if it should be included or excluded based on the inclusion/exclusion criteria.

### Collected clinical data, appraisal and analysis

As described in **Appendix 7 – Literature search report for AC** for similar devicesand in **Appendix 5 – Literature search report for S&P** for equivalent devices, the implementation of literature searches resulted in the inclusion of XX published articles on similar devices and XX articles on equivalent device with the objective to establish their safety and performance profiles.

Figure 2: Literature search results for similar devices

Total Number of results

n=

Number of results without duplicates

n=

Number of results after Level I screening:

n=

Number of results after Level II screening:

n=

Figure to be completed as necessary.

The list of articles included after Level II screening is described in **Appendix 8 – List of articles**.

Figure 3: Literature search results for equivalent devices

Total Number of results

n=

Number of results without duplicates

n=

Number of results after Level I screening:

n=

Number of results after Level II screening:

n=

Figure to be completed as necessary.

The following table describes the study information, device and demographic characteristics for the articles specific to similar /equivalent devices for the purpose of establishing their safety and performance profile.

Table 31: Summary of published clinical literature on similar /equivalent devices

| **Article** | **Study type** | **Device characteristics** | | **Indication** | **Number of patients** | **Demographic characteristics** | | **Follow-up** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Device Name** | **Size** | **Age** | **Sex** |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

All articles have been appraised per the requirements described in **Appendix 3 – Appraisal**. The following table describes the results of appraisal process:

Table 32: Appraisal of articles on similar /equivalent devices

| **Article ref** | **MDCG 2020-6** | **Oxford LoE** | **Suitability** | | | | **Contribution** | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **D** | **A** | **P** | **R** | **T** | **O** | **F** | **S** | **C** |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |

Safety outcome parameters related to similar /equivalent devices

The safety outcome parameters and specifications as discussed in the literature on similar /equivalent devices are described in the following table.

Table 33: Summary of safety outcome parameters on similar /equivalent devices

| **Article ref.** | **Safety outcome parameters** | **Results** | | | **Comments** |
| --- | --- | --- | --- | --- | --- |
| **Device** | **Timepoint** | **Specification** |
|  |  |  |  |  | Indicate when the parameter is a key outcome parameter. Conclude on the result obtained as compared to last CER. |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |  |

Performance outcome parameters related to similar/equivalent devices

The performance outcome parameters and specifications as discussed in the literature on similar /equivalent devices are described in the following table.

Table 34: Summary of performance outcome parameters on similar /equivalent devices

| **Article ref.** | **Performance outcome parameters** | **Results** | | | **Comments** |
| --- | --- | --- | --- | --- | --- |
| **Device** | **Timepoint** | **Specification** |
|  |  |  |  |  | Indicate when the parameter is a key outcome parameter. Conclude on the result obtained as compared to last CER. |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |  |

Clinical risks reported with similar/equivalent devices

The following table describes the clinical risks identified in the articles collected on similar /equivalent devices.

Table 35: Summary of clinical risks on similar /equivalent devices

| **Article ref.** | **Clinical risks** | **Results** | | | **Comments** |
| --- | --- | --- | --- | --- | --- |
| **Device** | **Timepoint** | **Rate** |
|  |  |  |  |  | Indicate when the clinical risk is new or when the rate may affect the results identified in the last CER. |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |  |

### Impact on Technical Documentation

Table 36: Impact assessment of literature on similar/equivalent device

| **Impact assessment** | **Conclusion on impact** | **Description / justification** |
| --- | --- | --- |
| Risk Management | Yes No |  |
| Clinical Evaluation | Yes No |  |
| PMS | Yes No |  |

## Screening of vigilance and recalls in publicly available database for equivalent or similar devices

### Description of PMCF activity

A search in vigilance and recall databases has been conducted to retrieve the clinical risks related to devices similar / equivalent to [Device Short Name]. For the period from DD-MM-YYYY to DD-MM-YYYY, a total of XX vigilance and XX FSCA have been retrieved for similar devices and XX vigilance and XX FSCA for the equivalent device.

The protocol is available in **Appendix 4 – Clinical data search protocol**, and the report in **Appendix 6 – Vigilance & Recall search report.**

### Collected clinical data, appraisal and analysis

The results are appraised with a Rank 7 according to the criteria described in **Appendix 3 – Appraisal**

The following table presents the number of relevant events retrieved for all databases consulted.

Table 37: Results of vigilance/recall search implementation of similar /equivalent devices

| **Database** | **Devices** | **Number of results:** | | | | **Event type** | | | **FSCA** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Total** | **Excluded** | **Duplicate** | **Included** | **Device-related** | **Patient-related** | **Death** |
| FDA MAUDE |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| FDA Medical Device Recalls |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| FDA TPLC |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| ANSM safety information |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| Bfarm Field Corrective Actions |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| MHRA Alerts, recalls and safety information: drugs and medical devices |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| SwissMedic – FSCA and recall |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| DAEN (Database of Adverse Event Notifications) - medical devices |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| SARA (System for Australian Recall Actions) |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| Canadian recalls and safety alerts |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

The PMS review identified clinical risks and undesirable side-effects related to devices similar / equivalent to [Device Short Name] as reported in the following table.

Table 38: Risks from public vigilance / recall databases on similar /equivalent devices

| **Events Reported** | **Event types** | **Occurrence** | | |
| --- | --- | --- | --- | --- |
| **Similar device 1** | **Similar device 2** | **Equivalent device** |
| Device-related risks |  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| Patient-related risks (including undesirable Side-Effect) |  |  |  |  |
|  |  |  |  |
|  |  |  |  |

### Impact on Technical Documentation

Table 39: Impact assessment of literature on similar/equivalent device

| **Impact assessment** | **Conclusion on impact** | **Description / justification** |
| --- | --- | --- |
| Risk Management | Yes No |  |
| Clinical Evaluation | Yes No |  |
| PMS | Yes No |  |

## Screening of summary of safety and clinical performance in EUDAMED

### Description of PMCF activity

Only applicable to class III and implantable devices

For MDR class III and implantable devices, manufacturers are required to make publicly available the summary of safety and clinical performance (SSCP) via EUDAMED. Until EUDAMED becomes fully functional, SSCPs may be found on the websites of manufacturers or in other public locations.

A search has been implemented to find the SSCPs of MDR devices similar or equivalent to [device short name] starting from EUDAMED and manufacturer websites.

The result of the search has been extracted to ensure the characterization of safety and performance of similar and equivalent devices with the objective to perform a comparison with the safety and performance of [device short name].

### Collected clinical data, appraisal and analysis

The following SSCPs have been retrieved for similar / equivalent devices.

Table 40: Impact assessment of SSCP clinical data on similar/equivalent device

| **Similar / Equivalent device** | **Document number** | **Link to SSCP** |
| --- | --- | --- |
| XXXX (similar device) |  |  |
| XXXX (similar device) |  |  |
| XXXX (equivalent device) |  |  |

The following table describes the study information, device and demographic characteristics for SSCP clinical data specific to similar /equivalent devices for the purpose of establishing their safety and performance profile.

Table 31: Summary of published clinical SSCP clinical data on similar /equivalent devices

| **Title of clinical data** | **SSCP clinical data type** | **Device characteristics** | | **Indication** | **Number of patients** | **Demographic characteristics** | | **Follow-up** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Device Name** | **Size** | **Age** | **Sex** |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

All articles have been appraised per the requirements described in **Appendix 3 – Appraisal**. The following table describes the results of appraisal process:

Table 32: Appraisal of SSCP clinical data on similar /equivalent devices

| **Clinical data ref** | **MDCG 2020-6** | **Oxford LoE** | **Suitability** | | | | **Contribution** | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **D** | **A** | **P** | **R** | **T** | **O** | **F** | **S** | **C** |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |

Safety outcome parameters related to similar /equivalent devices

The safety outcome parameters and specifications as discussed in the SSCP clinical data on similar /equivalent devices are described in the following table.

Table 33: Summary of safety outcome parameters on similar /equivalent devices

| **Clinical data ref.** | **Safety outcome parameters** | **Results** | | | **Comments** |
| --- | --- | --- | --- | --- | --- |
| **Device** | **Timepoint** | **Specification** |
|  |  |  |  |  | Indicate when the parameter is a key outcome parameter. Conclude on the result obtained as compared to last CER. |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |  |

Performance outcome parameters related to similar/equivalent devices

The performance outcome parameters and specifications as discussed in the SSCP clinical data on similar /equivalent devices are described in the following table.

Table 34: Summary of performance outcome parameters on similar /equivalent devices

| **Article ref.** | **Performance outcome parameters** | **Results** | | | **Comments** |
| --- | --- | --- | --- | --- | --- |
| **Device** | **Timepoint** | **Specification** |
|  |  |  |  |  | Indicate when the parameter is a key outcome parameter. Conclude on the result obtained as compared to last CER. |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |  |

Clinical risks reported with similar/equivalent devices

The following table describes the clinical risks identified in the SSCP clinical data collected on similar /equivalent devices.

Table 35: Summary of clinical risks on similar /equivalent devices

| **Article ref.** | **Clinical risks** | **Results** | | | **Comments** |
| --- | --- | --- | --- | --- | --- |
| **Device** | **Timepoint** | **Rate** |
|  |  |  |  |  | Indicate when the clinical risk is new or when the rate may affect the results identified in the last CER. |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |  |

### Impact on Technical Documentation

Table 41: Impact assessment of literature on similar/equivalent device

| **Impact assessment** | **Conclusion on impact** | **Description / justification** |
| --- | --- | --- |
| Risk Management | Yes No |  |
| Clinical Evaluation | Yes No |  |
| PMS | Yes No |  |

# Impact of the results on the technical documentation

The results and findings of PMCF activities have been analyzed for their impact on the technical documentation and especially for the need to update the risk management and clinical evaluation.

When all data are aggregated, the following conclusions can be drawn-up:

## Clinical evaluation report

CER document number and revision is specified in **Appendix 2 – Reference documents**

After the aggregation of data discussed in this PMCF Evaluation Report on [device short name] and its similar / equivalent devices, the following impact on the clinical evaluation report has been identified:

No relevant information needs a specific analysis and monitoring in the clinical evaluation report.

OR

Information needs a specific analysis and monitoring in the clinical evaluation report as described in the following table.

Table 42: Relevant information for the CER

| **Information to be analyzed and monitored in the CER** | **Impact on CER** |
| --- | --- |
| **Information on [device short name]** | |
|  | S&P of the subject device |
| **Information on similar devices** | |
|  | State of the art,  Safety and performance acceptance criteria |
| **Information on equivalent device** | |
|  | State of the art,  Safety and performance acceptance criteria,  S&P of the subject device |

The data obtained and discussed in this PMCF Evaluation Report will be used to update the clinical evaluation report in addition to the specific data identified in the table above.

## Risk management file

Risk management documents are specified in **Appendix 2 – Reference documents**

After the aggregation of data discussed in this PMCF Evaluation Report on [device short name] and its similar / equivalent devices, the following impact on the risk management file has been identified:

No relevant information needs a specific analysis and monitoring in the risk management file.

/OR

Information needs a specific analysis and monitoring in the risk management file as described in the following table.

Table 43: Relevant information for the risk management file

| **New clinical risks** | **Information on existing risk impacting the risk management file** | |
| --- | --- | --- |
| **Existing risks** | **Impact** |
|  |  | e.g., rates/occurrence/severity of risk identified may affect the risk management file |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

As a result, the risk management file does not require to be updated / will be revised.

## Other documents

The main findings of this PMCF evaluation report will feed the Period Safety Update Report of [device short name]. Not applicable for class I devices.

The Technical Documentation of [device short name] as specified in **Appendix 2 – Reference documents**, will be updated to include this PMCF Evaluation Report.

# Reference to any common specification(s), harmonized standard(s) or guidance document(s) applied

Table 44: Common specifications, harmonized standards and guidance documents

| **Reference** | **Description** |
| --- | --- |
| **Common specifications** | |
|  |  |
| **Harmonized standards** | |
|  |  |
| **Guidance documents** | |
| MDCG 2020-7 (April 2020) | Guidance on PMCF plan template |
| MDCG 2020-8 (April 2020) | Guidance on PMCF evaluation report template |
| XXXX |  |

# Conclusions

This PMCF evaluation report documents the activities implemented according to the PMCF plan specified in **Appendix 2 – Reference documents**. New /No new clinical data have been collected based on the PMCF activities conducted from DD/MM/YYYY and DD/MM/YYYY.

No information requiring a specific analysis and monitoring in the clinical evaluation report and risk management file has been identified. To be customized according to the conclusions.

The objectives of the PMCF plan have been met with the following conclusions: remove the objectives not included in the PMCF.

Table 45: Conclusions on the PMCF objectives

| **Objective** | **Conclusions and summary of findings** |
| --- | --- |
| Confirming the safety of the medical device | provide an overall conclusion of the findings for applicable PMCF objectives |
| Confirming the performance of the medical device |  |
| Identifying previously unknown side-effects (related to the procedures or to the medical devices). |  |
| Monitoring the identified side-effects and contraindications |  |
| Identifying and analyzing emergent risks |  |
| Ensuring the continued acceptability of the benefit-risk ratio |  |
| Identifying possible systematic misuse or off-label use of the device |  |

The conclusions and findings of this PMCF evaluation report will be considered in the next revisions of the clinical evaluation report and risk management file as specified in **Appendix 2 – Reference documents**. They will also be an input of next PMCF Plan for [device short name].

Throughout the analysis of PMCF activities, the need for CAPA (e.g., field safety corrective action) has been evaluated. No CAPA has been evaluated required /OR The CAPA #XXX Indicate the CAPA number has been initiated to address XXX Indicate the concern to be addressed by the CAPA.

# Appendix 1 – List of devices

Table 46: Device list

| **Model number (UDI-DI)** | **Device description** | **EMDN code** | **Lifetime** | **Class and rule** |
| --- | --- | --- | --- | --- |
|  |  |  |  | Class X / Rule Y |
|  |  |  |  | Class X / Rule Y |
|  |  |  |  | Class X / Rule Y |
|  |  |  |  | Class X / Rule Y |
|  |  |  |  | Class X / Rule Y |
|  |  |  |  | Class X / Rule Y |
|  |  |  |  | Class X / Rule Y |

# Appendix 2 – Reference documents

Table 47: Documents of reference

|  |  |
| --- | --- |
| **Documents** | **Document Number** |
| Instructions for use | Doc + Rev |
| Risk management file | - |
| * Risk management plan | Doc + Rev |
| * Risk analysis | Doc + Rev |
| * Risk management report | Doc + Rev |
| PMCF Plan | Doc + Rev |
| PMS Plan | Doc + Rev |
| Technical Documentation (TD) | Doc + Rev |

# Appendix 3 – Appraisal plan

# Appendix 4 – Clinical data search protocol

# Appendix 5 – Literature search report for S&P

# Appendix 6 – Vigilance & Recall search report

# Appendix 7 – Literature search report for AC

# Appendix 8 – List of articles

Articles on subject device

Articles on similar devices

Article on equivalent devices