**Post market clinical follow-up plan**

**Product Name:** **{产品名称}**

***【本处填写产品名称，需要确保全篇技术文档及报告等的名称一致】***

**Model:** **{产品型号1}、{产品型号2}、{产品型号N}**

***【需要罗列本次认证的所有产品型号清单，如型号很多，可以采用另外附件文档的方式给出】***

**Document No.:** **{文件编号}**

***【本处填写本文件的编号】***

**Edition: {文件版本}**

***【本处填写本文件的版本】***

Drafted by : {XX名字} Date： {年-月-日}

Checked by: {XX名字} Date： {年-月-日}

Approved by: {XX名字} Date： {年-月-日}

***【以上分别由负责本文档的编写、审核、批准的人员进行签字和日期，需要注意文件的签署人员和日期等信息与相关体系文档的符合性及逻辑性】***

{XXXX公司}

**Revision records:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Edition** | **Effective Date** | **Summary of revision** | **Drafted by** | **Checked by** | **Approved by** |
| {文件版本1} | {年-月-日} | First release | {XX名字} | {XX名字} | {XX名字} |
| {文件版本2} | {年-月-日} | {本版本相对上一版本版本更新了\*\*\*\*，主要原因是\*\*\*\*, 涉及到修改的小节是\*\*\*\*\*}*【填写本技术文档的版本相对于上一版本更新了哪些内容？为什么更新？以及更新内容具体的地方及小节编号？】* | {XX名字} | {XX名字} | {XX名字} |
| {文件版本N} | {年-月-日} | {本版本相对上一版本版本更新了\*\*\*\*，主要原因是\*\*\*\*, 涉及到修改的小节是\*\*\*\*\*}*【填写本技术文档的版本相对于上一版本更新了哪些内容？为什么更新？以及更新内容具体的地方及小节编号？】* | {XX名字} | {XX名字} | {XX名字} |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

**Table of Contents**

1. The document aim 4

2. The contents 4

3. Summary Table 6

Appendix 1 PMCF study protocol 13

# The document aim

*{填写本文档的目的}*

*（参考示例：The PMCF plan is aim to specify the methods and procedures for proactively collecting and evaluating clinical data with the aim of:*

*(a)confirming the safety and performance of the device throughout its expected lifetime,*

*(b)identifying previously unknown side-effects and monitoring the identified side-effects and contraindications,*

*(c)identifying and analysing emergent risks on the basis of factual evidence,*

*(d)ensuring the continued acceptability of the benefit-risk ratio referred to in Sections 1 and 9 of Annex I, and*

*(e)identifying possible systematic misuse or off-label use of the device, with a view to verifying that the intended purpose is correct.　）*

1. **The contents**
	1. **the general methods and procedures of the PMCF to be applied,** **such as gathering of clinical experience gained, feedback from users, screening of scientific literature and of other sources of clinical data**
		1. the general methods and procedures for gathering of clinical experience gained

*{对收集临床经验数据的一般方法和程序进行描述} 【也可以链接到本整套技术文档的其他地方】 （参考示例：Please refer to \*\*\* Post-market surveillance Plan, \*\*\* Clinical evaluation(\*\*\* Literature search protocol and report )）*

* + 1. the general methods and procedures for gathering of feedback from users

*{对收集用户反馈的方法和程序进行描述}*

*（参考示例：Customer complaints, sales feedback and other procedures, the detail document can be refer to the company internal quality system procedures document.）*

* + 1. the general methods and procedures for screening of scientific literature

*{对科学文献筛选的方法和程序进行描述}*

*【也可以链接到本整套技术文档的其他地方】*

*（参考示例：Please refer to \*\*\* Clinical evaluation(\*\*\* Literature search protocol and report ).）*

* + 1. the general methods and procedures for screening of other sources of clinical data

*{对筛选其他临床资料来源的方法和程序进行描述}*

**2.2 the** **specific methods and procedures of PMCF to be applied, such as evaluation of suitable registers or PMCF studies**

2.2.1 the specific methods and procedures of evaluation of suitable registers

*{对适合登记评价的具体方法和程序进行描述}*

2.2.2 the specific methods and procedures of evaluation of PMCF studies

*{对适合PMCF研究的评价的具体方法和程序进行描述}*

**2.3 a rationale for the appropriateness of the methods and procedures referred to in section 2.1 and 2.2**

2.3.1 a rationale for the appropriateness of the methods and procedures referred to in section 2.1

*{对第2.1节所述的方法和程序适当性进行理由说明}*

2.3.2 a rationale for the appropriateness of the methods and procedures referred to in section 2.2

*{对第2.2节所述的方法和程序适当性进行理由说明}*

**2.4** **the specific objectives to be addressed by the PMCF**

*{填写通过PMCF要处理的具体问题}*

**2.6 an evaluation of the clinical data relating to equivalent or similar devices**

*{对等同器械或是相似器械的临床数据进行评价}*

**2.7 reference to any relevant CS, harmonised standards when used by the manufacturer, and relevant guidance on PMCF; and**

*{填写在PMCF中所参考的如CS、协调标准、指南}*

**2.8 a detailed and adequately justified time schedule for PMCF activities (e.g. analysis of PMCF data and reporting) to be undertaken by the manufacturer**

*{详细的列出PMCF活动的时间表}*

**2.9 other**

*{若有其他与PMCF相关的内容请填写}*

1. **Summary Table**

|  |
| --- |
| Section A. Manufacturer contact details 　 |
| Legal manufacturer name: *{填写制造商的名称}* |
| Address: *{填写制造商的地址}* |
| SRN:*{填写SRN号}*  |
| Person responsible for regulatory compliance: *{填写法规符合人员名单}* |
| E-mail: *{填写邮箱地址}* |
| Phone: *{填写联系方式}* |
| Fax: *{填写传真方式}* |
| Authorised representative (if applicable): *{填写授权代表名称}* |
| Address:*{填写授权代表地址}* |
| Contact person:*{填写授权代表联系人}* |
| E-mail: /:*{填写授权代表邮箱方式}* |
| Phone:*{填写授权代表联系方式}* |
| Fax: :*{填写授权代表传真方式}* |

|  |
| --- |
| Section B. Medical Device description and specification 　 |
| Product or trade name:*{填写申报产品名称}* |
| Model and type: *{填写申报产品型号}* |
| General description of the device: *{对申报产品进行简要描述} （参考示例：Refer to* *\*\*\* Device description and specification of Technical Document）* |
| Intended purpose: *{填写申报产品的预期用途}* |
| Intended users：*{填写申报产品的预期使用者}* |
| Basic UDI-DI: *{填写申报产品的基本UDI-DI}* |
| Intended patient population: *{填写申报产品的预期患者人群}* |
| Medical condition(s): *{填写申报产品医疗条件}* |
| Indications：*{填写申报产品适应症 }* |
| Contraindications: *{填写申报产品禁忌症}* |
| Warnings: *{填写申报产品警告}* |
| List and description of any variants and/or configurations covered by this plan: *{本计划覆盖的产品型号/变体，及描述}* |
| List of any accessories covered by this plan: *{本计划覆盖的产品附件}* |
| Certificate number (if available): *{填写证书编号}* |
| CND code(s):*{填写CND号}* |
| Class: *{填写申报产品的风险等级}* |
| Classification rule: *{填写申报产品的风险等级分类依据}* |
| Expected lifetime: *{填写申报产品的寿命}* |
| Novel product: ☐ yes □ no  |
| Novel related clinical procedure: ☐ yes □ no  |
| Explanation of any novel features: *{填写申报产品是否有新的特征}* |

|  |
| --- |
| Section C. Activities related to PMCF: general and specific methods and procedures  |
| *{填写PMCF活动的通用和具体方法及程序}**（参考示例：**In this section it is expected to describe the different activities that will be conducted in post-market, including general and specific methods / procedures to conduct in relation to the product covered by the scope of PMCF, also the aim of each activity described and the rational for the appropriateness of the chosen general and specific methods to achieve those objectives as well as the known limitations of the planned activities such as for example incomplete follow up, missing data and so on. The timelines of those activities shall be also defined quarterly or at least yearly.* *A summary table of the different PMCF activities foreseen by the manufacturer is provided below:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| *Number* *of* *activity*  | *Description of activity*  | *Aim of the activity*  | *Rationale and known* *limitations of the activity* | *Timelines of the activity*  |
| *1* | *{对PMCF的活动进行描述}**（参考示例：Adverse event collection）* | *{对PMCF的活动目的进行描述}**（参考示例：Identify device problems in adverse events）* | *{对PMCF的活动基本原理和限制和进行描述}**（参考示例：Conduct risk analysis and risk management to ensure equipment safety and effectiveness）* | *{活动的时间表进行描述}**（参考示例：According to the frequency specified in the SOP of quality system document）* |
| *2* | *{对PMCF的活动进行描述}**（参考示例：customer complaints and warranty claims）* | *{对PMCF的活动目的进行描述}**（参考示例：Identify device problems in customer complaints）* | *{对PMCF的活动基本原理和限制和进行描述}**（参考示例：Conduct risk analysis and risk management to ensure equipment safety and effectiveness）* | *{活动的时间表进行描述}**（参考示例：According to the frequency specified in the SOP of quality system document）* |
| *3* | *{对PMCF的活动进行描述}**（参考示例：User feed-back other than complaints）* | *{对PMCF的活动目的进行描述}**（参考示例：Identify device problems in user feed-back ）* | *{对PMCF的活动基本原理和限制和进行描述}**（参考示例：Conduct risk analysis and risk management to ensure equipment safety and effectiveness）* | *{活动的时间表进行描述}**（参考示例：According to the frequency specified in the SOP of quality system document）* |
| *4* | *{对PMCF的活动进行描述}**（参考示例：literature reviews）* | *{对PMCF的活动目的进行描述}**（参考示例：Identify device problems in literature reviews ）* | *{对PMCF的活动基本原理和限制和进行描述}**（参考示例：Conduct risk analysis and risk management to ensure equipment safety and effectiveness）* | *{活动的时间表进行描述}**（参考示例：According to the frequency specified in the SOP of quality system document）* |
| *\*\*\*\** | *\*\*\*\** | *\*\*\*\** | *\*\*\*\*\** | *\*\*\*\** |

 |

|  |
| --- |
| **Section D. Reference to the relevant parts of the technical documentation**  |
| *{对PMCF过程中参考的技术文档进行描述}**（参考示例：In this section the manufacturer is required to include references to the relevant information from the clinical evaluation report and from the risk management file, which need to be analysed, followed up, and evaluated in this plan. As an alternative, the manufacturer is required to state that there is no relevant information from the clinical evaluation report and/or from the risk management file to be considered in this plan.* *Clinical Evaluation Report (date and version)* *Relevant information to be further analysed and monitored:* *- Clinical Evaluation Report（V1.0）**-Please refer to\*\*\*Clinical Evaluation Report**Risk Management File (date and version)* *Relevant information to be further analysed and monitored:* *- Risk Management File (V1.0)* *Please refer to \*\*\* Risk Analysis Report and \*\*\*\* Risk Evaluation Report.**No relevant information from the clinical evaluation report to be considered in this plan*  *No relevant information from the risk management file to be considered in this plan ）* |

|  |
| --- |
| **Section E. Evaluation of clinical data relating to equivalent or similar devices**  |
| *{对等同或相似器械的临床数据进行评价}**（参考示例：The manufacturer shall gather in this section information regarding equivalent / similar devices for which clinical data will be further evaluated and presented in the PMCF report.* *Please note that PMCF data intended to demonstrate continuing safety and performance should be sourced from the device under evaluation.* *Data from equivalent or similar devices may be used, for example to update the information relating to the state of the art, to identify and further assess relevant safety outcomes etc.* *The selected devices shall be consistent throughout the technical documentation. Indicate whether the selected device is demonstrated to be equivalent or is a similar device. For each device listed, a clear reference to the pertinent parts of the CER can be made.* *The following items of each equivalent and/or similar devices would be at least provided, in a table format:*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Product name of equivalent / similar device  | Intended purpose  | Intended users | Intended patient population | Medical condition | Indication | Reference to clinical data evaluation in the CER (date, version and location in the text) |
| *{等同产品或相似产品名称}* | *{预期目的}* | *{目标用户}* | *{预期患者人群}* | *{产品医疗状况}* | *{适应症}* | *{参考临床评价报告中的临床数据}* |
| *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** |

*）* |

|  |
| --- |
| Section F. Reference to any applicable common specification(s), harmonized standard(s) or applicable guidance document(s)  |
| *{列出参考的通用规范、标准和指南}**（参考示例：**Common specification(s) to comply with, if applicable: ：(Title, date and version)**Harmonised standards to apply, if applicable* *(Title, date and version)* *Refer to \*\*\* Standards and Reports list**Guidance on PMCF, if applicable**(Title, date and version)* *Refer to* *\*\*\* POST-MARKET CLINICAL FOLLOW-UP control Procedure**\*\*\* Post-market clinical follow-up plan）* |

|  |
| --- |
| Section G. – Estimated date of the PMCF evaluation report  |
| *{填写PMCF评估报告的预期日期}* |

1. **Appendix**

*{前面内容中涉及到的附件}*

Appendix 1 PMCF study protocol

Appendix 2 \*\*\*

Appendix 3 \*\*\*

Appendix 4 \*\*\*

**Appendix 1**

**PMCF study protocol**

**Product Name:** **{产品名称}**

***【本处填写产品名称，需要确保全篇技术文档及报告等的名称一致】***

**Model:** **{产品型号1}、{产品型号2}、{产品型号N}**

***【需要罗列本次认证的所有产品型号清单，如型号很多，可以采用另外附件文档的方式给出】***

**Document No.:** **{文件编号}**

***【本处填写本文件的编号】***

**Edition: {文件版本}**

***【本处填写本文件的版本】***

Drafted by : {XX名字} Date： {年-月-日}

Checked by: {XX名字} Date： {年-月-日}

Approved by: {XX名字} Date： {年-月-日}

***【以上分别由负责本文档的编写、审核、批准的人员进行签字和日期，需要注意文件的签署人员和日期等信息与相关体系文档的符合性及逻辑性】***

{XXXX公司}

**Revision records:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Edition** | **Effective Date** | **Summary of revision** | **Drafted by** | **Checked by** | **Approved by** |
| {文件版本1} | {年-月-日} | First release | {XX名字} | {XX名字} | {XX名字} |
| {文件版本2} | {年-月-日} | {本版本相对上一版本版本更新了\*\*\*\*，主要原因是\*\*\*\*, 涉及到修改的小节是\*\*\*\*\*}*【填写本技术文档的版本相对于上一版本更新了哪些内容？为什么更新？以及更新内容具体的地方及小节编号？】* | {XX名字} | {XX名字} | {XX名字} |
| {文件版本N} | {年-月-日} | {本版本相对上一版本版本更新了\*\*\*\*，主要原因是\*\*\*\*, 涉及到修改的小节是\*\*\*\*\*}*【填写本技术文档的版本相对于上一版本更新了哪些内容？为什么更新？以及更新内容具体的地方及小节编号？】* | {XX名字} | {XX名字} | {XX名字} |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

1. **the study population (corresponding to the CE-mark scope)**

{研究人群}

**2.inclusion/exclusion criteria**

{入选/排除标准}

**3.rational and justification of the chosen study design**

{选择的研究设计的原理和理由 }

**4.controls/control groups (where relevant; randomised or not);**

{对照组，是否随机等}

**5.the selection of sites and investigators;**

{选择的地点和研究者}

**6.study objectives and related study endpoints and statistical considerations**

{研究目的及相关的研究终点和统计考虑}

**7.the number of subjects involved**

{涉及的受试者数量}

**8.the duration of patient follow-up**

{病人跟踪的时间}

**9.the data to be collected**

{收集的数据}

**10.the analysis plan including any interim reporting where appropriate to**

{分析计划，包括适当的任何临时报告}

**11.ensure continuous risk management based on clinical data**

{确保基于临床数据进行持续的风险管理}

**12.procedures/criteria for early study termination**

{早期研究终止的程序/标准}

1. **ethical considerations**

{伦理考虑}

**14.methods of quality control of data where appropriate**

{适当的数据质量控制方法}

**15.Other**

{其他}

**16.Reference**

{参考资料或文献等}