Clinical investigation supporting documents

**Appendix of documents to attach**

**Version 1.0**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Document** | **Version/Date [DD-MM-YY]****At time of NCA application** | **Version / Date [DD-MM-YY]****At time of NCA authorisation / refusal** | **Summary of changes made** | **Amended as a result of NCA / REC assessment** |
| **Mandatory** |
| **Cover letter** |  |  |  | [ ]  |
| **Application form** |  |  |  |  |
| **Investigator’s Brochure (including any annexes) (if applicable)** |  |  |  | [ ]  |
| **Clinical investigation plan** |  |  |  | [ ]  |
| **Clinical evaluation plan** |  |  |  | [ ]  |
| **CIP synopsis** |  |  |  | [ ]  |
| **Statement of conformity** |  |  |  | [ ]  |
| **Example of labels** |  |  |  | [ ]  |
| **Description of the arrangements to comply with the applicable rules on the protection and confidentiality of personal data/ personal information** |  |  |  | [ ]  |
| **List of General Safety and Performance Requirements** |  |  |  | [ ]  |
| **As applicable** |
| **Description of the arrangements to comply with the applicable rules on the protection and confidentiality of personal data/ personal information** |  |  |  | [ ]  |
| **Risk management documentation** |  |  |  | [ ]  |
| **Test reports** |  |  |  | [ ]  |
| **Proof of Clinical Investigation Insurance** |  |  |  | [ ]  |
| **Suitability of investigational sites and investigation site team** |  |  |  | [ ]  |
| **Manufacturer’s Instructions for Use** |  |  |  | [ ]  |
| **Suitability of the investigators** |  |  |  | [ ]  |
| **Recruitment procedures and advertising materials** |  |  |  | [ ]  |
| **Documents to obtain informed consent, informed consent procedure, all written information to participants, payments and compensation of participants** |  |  |  | [ ]  |
| **Notified Body Certificates** |  |  |  | [ ]  |
| **Decisions form other countries** |  |  |  | [ ]  |
| **PMCF plan** |  |  |  | [ ]  |
| **Expert panel opinion**  |  |  |  | [ ]  |
| **Other documents** |  |  |  | [ ]  |

**Notes**

This template has been prepare by the Clinical Investigation and Evaluation Working Group of the European Commission to support document traceability in the absence of EUDAMED.

This template should be used in conjunction with the document ‘Clinical investigation – application form under Medical Device Regulation’. The use of this template is not mandatory, and it is advisable to check with the relevant NCA regarding expectations for the use and completion of the template.

Fields marked as ‘mandatory’ are required to support a submission with respect to Regulation 745/2017, ‘optional’ fields may or may not be required, depending on the clinical investigation.

With respect to the ‘summary of changes made’ please include a short description of the sections amended and the type of change.

**Acronyms**

NCA National Competent Authority

REC Research ethics committee

PMCF Post-market clinical follow-up