Performance study 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).[[1]](#footnote-1)  Non-exhaustive items: |  |  |  |  |
| * List of General Safety and Performance Requirements that apply to the device and the methods used to demonstrate conformity with each applicable GSPR |  |  |  |  |
| * Risk management documentation |  |  |  |  |
| * Scientific validity documentation |  |  |  |  |
| * Analytical performance documentation |  |  |  |  |
| Performance study plan |  |  |  |  |
| Performance evaluation plan |  |  |  |  |
| Performance study synopsis |  |  |  |  |
| A signed conformity statement according to Annex XIV, Chapter 1.4.1 |  |  |  |  |
| Example of labels |  |  |  |  |
| Description of clinical data management including general data protection procedures. |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
| **As applicable** | | | | |
| Test reports |  |  |  |  |
| Proof of study performance Insurance |  |  |  |  |
| Suitability of investigational sites and investigation site team |  |  |  |  |
| Manufacturer’s Instructions for Use (draft or final) |  |  |  |  |
| 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 from other countries |  |  |  |  |
| PMPF plan |  |  |  |  |
| Expert panel opinion |  |  |  |  |
| National ethics committee opinion |  |  |  |  |
| Other documents |  |  |  |  |

**Notes**

This template has been prepared 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 ‘Performance study – application form under *In Vitro* 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 2017/746, ‘optional’ fields may or may not be required, depending on the performance study.

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

PMPF Post-market performance follow-up

1. **See chapter I of annex XIV from EU 746/2017 for the content of investigator brochure** [↑](#footnote-ref-1)