Performance studies supporting documents for application-notification

Appendix of attached documents

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Documents** | **Version/Date** *At time of NCA application* | **Version/date***At time of NCA authorisation / refusal*  | **Summary of changes made** | **Name and references of documentation that contains this information** | **Amended as a result of NCA/EC assessment** |
| [ ]  **0. Cover letter** |  |  |  |  |[ ]
|  |  |  |  |  |  |
| [ ]  **1. Application-Notification Form** |  |  |  |  |[ ]
|  |  |  |  |  |  |
| [ ]  **2. Investigator’s Brochure** |  |  |  |  |[ ]
| Information to be submitted preferably as a separate document:  |  |
| * [ ]  Instructions of the Manufacturer
 |  |  |  |  | [ ]   |
| * [ ]  Instructions for use
 |  |  |  |  | [ ]   |
| * [ ]  Example of labels
 |  |  |  |  | [ ]  |
| * [ ] Analytical performance
 |  |  |  |  | [ ]  |
| * [ ]  Clincal Data
 |  |  |  |  | [ ]   |
| * [ ]  Test reports
 |  |  |  |  | [ ]   |
| * [ ]  List of general safety and performance requirements and applicable standards
 |  |  |  |  | [ ]   |
| * [ ]  Summary of the benefit-risk analysis and the risk management
 |  |  |  |  | [ ]   |
| * [ ] Other Attached documents of Investigator’s Brochure
 |  |  |  |  |  |
| [ ]  **3. Performance study plan** |  |  |  |  | [ ]  |
| Information to be submitted preferably as a separate document: |  |  |
| * [ ]  Summary of the performance study plan
 |  |  |  |  | [ ]  |
| * [ ]  Performance evaluation plan details/or references
 |  |  |  |  | [ ]  |
| * [ ]  Other Attached documents of Performance study plan
 |  |  |  |  |  |
| [ ]  **4. Other information** |
| Information to be submitted preferably as a separate document:  |  |
| * [ ]  A signed statement by the natural or legal person responsible for the manufacture of the device for performance study pursuant to what is indicate in Annex XIV Section 4.1
 |  |  |  |  | [ ]  |
| * [ ]  Copy of the opinion/single opinion of the ethics committees or coordinating ethics committee concerned
 |  |  |  |  | [ ]  |
| * [ ]  Proof of insurance cover or indemnification of subjects,
 |  |  |  |  | [ ]  |
| * [ ]  Documents to be used to obtain the informed consent, including the information sheet and the informed consent document
 |  |  |  |  | [ ]  |
| * [ ]  Description of the arrangements to comply with the applicable rules on the protection and confidentiality of personal data/ personal information
 |  |  |  |  | [ ]  |
| [ ]  **5. Documents required according to national regulations** |
| * [ ]  Declaration in lieu of the Affidavit of the the Sponsor
 |  |  |  |  | [ ]  |
| * [ ] Declaration in lieu of the Affidavit of the Responsible for the manufacture
 |  |  |  |  | [ ]  |
| * [ ]  Mandate of Sponsor to the contact person receiving all communications provided for in the IVDR
 |  |  |  |  | [ ]  |
| * [ ]  List of the clinical sites and Ethics Committees concerneds
 |  |  |  |  |  |
| * [ ]  Documents on the suitability of investigational sites and investigation site team
 |  |  |  |  | [ ]  |
| * [ ] Documents on the suitability of investigators (CVs)
 |  |  |  |  | [ ]  |
| [ ]  **6. Other Documentation**  |
| * [ ]  Opinion of expert panels
 |  |  |  |  | [ ]  |
| * [ ]  CE certificates of notified bodies
 |  |  |  |  | [ ]  |
| * [ ]  Decisions of the other competent authorities concerned
 |  |  |  |  | [ ]  |
| * [ ]  PMPF plan
 |  |  |  |  | [ ]  |
| * [ ]  Recruitment procedures and advertising material
 |  |  |  |  | [ ]  |
| * [ ]  Opinion of other Ethics Committees concerned
* [ ]  Further documentation
 |  |  |  |  | [ ]  |
|  |  |  |  |  |  |