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 |  |  |  |  |  |
|  |  |  |  |  |  |