**Initial application of performance study – list of documents submitted**

1.

*NOTE*

*When an approval is issued this list of approved documents will be attached to the approval letter. It is thus important that the applicants keep this list of documents provided at the initial submission and* ***submit it at each change*** *(validation questions, response to RFI, etc.).* ***Please clearly indicate which documents have been updated/added by checking the box in the third column and providing a brief description of the change made.*** *Note that the last two columns are for NCA/EC assessment and do not need to be filled-out by the applicant.*

*Rows may be added and non-applicable sections/rows may be deleted in the table below.*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ***Documents*** | ***Version and/or date*** | ***Amended as a result of NCA / EC assessment*** | ***Description of change*** | ***Assessed by NCA / EC***  | ***Approved by NCA / EC*** |
| **COVER LETTER** |  |  |  |  |  |
| Ex: Cover-Letter\_20210526.pdf | 26/05/2021 | [ ]  |  |  |  |
| **APPLICATION FORM** |  |  |  |  |  |
| Ex: Application-Form\_20210526.pdf | 26/05/2021 | [ ]  |  |  |  |
| **CLINICAL PERFORMANCE STUDY PLAN (CPSP)** |  |  |  |  |  |
| Ex: CPSP\_v1.1.pdf | *V1.1 – 26/05/2021* | [ ]  |  |  |  |
|  |  | [ ]  |  |  |  |
| **CPSP SYNOPSIS** |  |  |  |  |  |
|  |  | [ ]  |  |  |  |
|  |  | [ ]  |  |  |  |
| **INVESTIGATOR’S BROCHURE (including any annexes)** |  |  |  |  |  |
|  |  | [ ]  |  |  |  |
|  |  | [ ]  |  |  |  |
| **LIST OF GENERAL SAFETY AND PERFORMANCE REQUIREMENTS** |  |  |  |  |  |
|  |  | [ ]  |  |  |  |
| **MANUFACTURER’S INSTRUCTIONS FOR USE** |  |  |  |  |  |
|  |  | [ ]  |  |  |  |
| **CE CERTIFICATES** |  |  |  |  |  |
|  |  | [ ]  |  |  |  |
| **PERFORMACE EVALUATION PLAN (PEP)** |  |  |  |  |  |
|  |  | [ ]  |  |  |  |
| **PMPF PLAN** |  |  |  |  |  |
|  |  | [ ]  |  |  |  |
| **COMPARATOR** |  |  |  |  |  |
|  |  | [ ]  |  |  |  |
| **DECISIONS FROM OTHER COUNTRIES** |  |  |  |  |  |
|  |  | [ ]  |  |  |  |
| **EXAMPLE OF LABELS** |  |  |  |  |  |
|  |  | [ ]  |  |  |  |
| **RECRUITMENT AND ADVERTISING** |  |  |  |  |  |
|  |  | [ ]  |  |  |  |
|  |  | [ ]  |  |  |  |
| **PATIENT INFO, ICF AND ICF PROCEDURE** |  |  |  |  |  |
|  |  | [ ]  |  |  |  |
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| **SUITABILITY OF INVESTIGATOR(S)** |  |  |  |  |  |
|  |  | [ ]  |  |  |  |
|  |  | [ ]  |  |  |  |
| **SUITABILITY OF SITE(S)** |  |  |  |  |  |
|  |  | [ ]  |  |  |  |
| **PROOF OF INSURANCE** |  |  |  |  |  |
|  |  | [ ]  |  |  |  |
| **FINANCIAL AND OTHER ARRANGEMENTS** |  |  |  |  |  |
|  |  | [ ]  |  |  |  |
| **STATEMENT ON DATA PROTECTION** |  |  |  |  |  |
|  |  | [ ]  |  |  |  |
| **OTHER DOCUMENTS** |  |  |  |  |  |
|  |  | [ ]  |  |  |  |