**Substantial modification of clinical investigation – 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.)* ***with a clear indication of which documents have been updated/added.***

*Non-applicable sections/rows may be deleted in the table below.*

|  |  |
| --- | --- |
| ***Documents*** | ***Version and/or date*** |
| **COVER LETTER** |  |
| Ex: Cover-Letter\_20210526.pdf | 26/05/2021 |
| *…* |  |
| **APPLICATION FORM SUBSTANTIAL MODIFICATION** |  |
| Ex: Application-Form\_SM\_20210526.pdf | 26/05/2021 |
| *…* |  |
| **DESCRIPTION OF THE SUBSTANTIAL MODIFICATION(S)** |  |
| Ex: SM002\_CIP\_V1.2\_TC.pdf | V1.2 – 26/05/2021 |
| *…* |  |
| **SUPPORTING INFORMATION** |  |
| … |  |