MREC Stichting BEBO

Weiersstraat 1C

9401 ET ASSEN

\*Place\*, Click or tap to enter a date.

Ref.: Cover letter for study – \*study code\* (\*NL-number\*)

\*Periodic SUSAR/SAE Line Listings / Development Safety Update Report (DSUR) / Early Termination / Study on Hold / Dear Investigator Letter / End of Trial (EoT) Notification / etc\*

Dear members of the MREC,

Please find the documents uploaded digitally *[or via another medium]* (see Appendix I).

We send you this letter because \*elaborate description\*.

The undersigned declares that all relevant documents from the aforementioned research file are signed by the authorized persons. The original, signed documents, are in the possession of the sponsor.

Please add these documents to the study file.

Yours sincerely,

\*Name\*

\*Signature\*

\*Submitter / contact person\*

E-Mail: \*E-mail\* and telephone number: \*telephone number\*

|  |
| --- |
| Appendix I |
|  | Document | Format document name | Date |
| B. Forms |
| B5 | EudraCT notification of amendment form | B5. EudraCT\_NoA\_form\_Amdt\_[*nr*]\_[*study code*]\_ddMmmyy |  |
| B7  | EudraCT end of trial form | B7. EudraCT\_EoT\_form\_[*study code*]\_ddMmmyy |  |
| L. Safety information |  |
| L2 | Periodic SUSAR line listings | L2. Periodic\_SUSAR\_LL\_[*study code*]\_[*period ddMmyy-ddMmmyy*]\_ddMmmyy |  |
| L3  | Development Safety Update Report (DSUR) | L3. DSUR\_[*study code*]\_ddMmmyy |  |
| L5 | Periodic SAE line listings | L5. Periodic\_SAE\_LL\_[*study code*]\_[*period ddMmyy-ddMmmyy*]\_ddMmmyy |  |
| L6 | Other relevant safety information | L6. [*type of document*]\_[*study code*]\_ddMmmyy |  |

**Instructions for completing the submission overview:**

* Fill out the table and match documents in terms of names. The submitted documents must correspond in terms of names to the file names in the overview.
* Is the type of document not in the table? Then add it manually. Keep the same style.
	+ You do **not** need a BEBO cover letter for L1 (SUSARs) en L4 (SAEs)!
* Keep the length of the file name as short as possible, specific and including the version number and date (in the style ddMmmyy). The date is the date of the file or the date of the last signature.
* Multiple documents? Place these below the other in the same cell in the third column. The information in the first two columns does not need to be repeated.
* If there are several D4 documents with the same manufacturer, city name and country code, please complete the file name with the street name.
* If documents are not applicable, remove them from the overview.
* Keep the table in landscape orientation.
* Remove this text before submitting.