<<Insert Address>>

<<Date>>

Dear Recipient,

|  |  |
| --- | --- |
| **Title:** | <<INSERT>> |
| **Sponsor:** | <<INSERT>> |
| **CI:** | <<INSERT>> |
| **REC Ref:** | <<INSERT>> |
| **IRAS #** | <<INSERT>> |

Please find enclosed the development safety update report (DSUR) for the above study. This report covers the period from XXXXXXXX to XXXXXX.

<<Insert short summary of main points of study and IMP issues during this reporting period>>

Reference safety information can be found in section XXXXXXX << Insert name of section>> in the Investigator Brochure/SmPC/ Protocol (change as relevant) Version XXXX (dated XXXXX).

<<State if there has been any change to RSI during reporting period and if yes provide details the date / amendment reference in which the new RSI was approved >>

If you have any queries, please do not hesitate to contact me on XXXXXXX or by email XXXXXXX.

Yours sincerely,

**<<NAME>>**

**<<Title>>**