

Example letter

Waiver request for reporting of SUSAR reports as defined in clinical trial legislation

"I hereby declare that all reports meeting the definition of Suspected Unexpected Serious Adverse Reaction (SUSAR) reports as defined in clinical trial legislation are submitted to the EMA EudraVigilance database in E2B format within the appropriate time frames (7/15 days). Our procedures are compliant with the Clinical Trials Directive 2001/20/EC and associated EU Commission guidance "Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use ('CT-3') (ref 2011/C 172/01)"

Therefore, our procedures for reporting to the EMA include:

- SUSARs arising directly from clinical trials (including SUSARs associated with active comparator or placebo);
 - Cases meeting the definition of a SUSAR obtained from Spontaneous Reports;
 - Cases meeting the definition of a SUSAR, arising from organised data collection systems other than interventional clinical trials
 - Cases meeting the definition of a SUSAR originating from EEA and non-EEA countries.
- We would like to request for a waiver to report the SUSAR reports mentioned above directly to the MEB.

In case of technical problems with E2B SUSAR reporting to the EMA, SUSAR reports will be sent to both the EMA and the MEB in an alternative way in line with the instructions given by the EMA and published on the MEB website."

NOTES:

- Please specify if this declaration is applicable to all clinical trials that fall under the responsibility of the sponsor or if this request is only applicable to a specific trial (if applicable specify Study Name, EudraCT number if available and sponsor protocol number).
- If there are relevant exemptions to the above (e.g. for a specific product, reporting source, country, 3rd party provisions, etc) please specify.
- The example text above should be printed on paper with company logo (amend text where needed) and sign the letter. The waiver request can be sent via e-mail to magmb@cbg-meb.nl
- Please be informed that SUSARs should still be reported to the assessing review committee (accredited MREC or CCMO, check www.ccmo.nl for instructions).