BASG / AGES MEA

Institute Surveillance

Traisengasse 5, 1200 Vienna, Austria

**Application for exemption from reporting requirements of SUSARs according to § 41e AMG to the Federal Office for Safety in Health Care (Bundesamt für Sicherheit im Gesundheitswesen [BASG])**

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| --- | --- |
| Name and address of the Sponsor: |  |
| EudraCT Number[[1]](#footnote-1): |  |
| Valid from date: |  |
| Others[[2]](#footnote-2): |  |

Hereby it is confirmed that notifications of Suspected Unexpected Serious Adverse Reactions (SUSAR) according to § 41 AMG (Austrian Medicinal Product Act), BGBI No. 185/1983 (in the current version) have to be transmitted to the EudraVigilance Database of European Medicines Agency (EMA) in E2B-format within the statutory timescale (7 / 15 days).

This form of electronic notification is deemed equivalent to the statutory obligations according to § 41e AMG for submitting SUSARs to the BASG.

Reporting obligations relating to the ethics committees and other competent authorities of the European Economic Area will remain unaffected.

In case of technical problems with E2B SUSAR Reporting to the EMA, SUSAR notification will be transmitted to the EMA and to the BASG, as instructed by the EMA ([http://eudravigilance.ema.europa.eu/human/ SystemFailureSteps.asp](http://eudravigilance.ema.europa.eu/human/%20SystemFailureSteps.asp)) and the BASG (Guidance document for submission of Clinical trial applications on [www.basg.gv.at](http://www.basg.gv.at/)).

For correct administration of SUSARs the following points have to be considered:

* There will be no letter of acknowledgment transferred by BASG for electronic SUSARs. This will be forwarded by the EMA, as the electronic message is sent directly to the EV database.
* Each SUSAR report should specify the EudraCT Nr. (ICH E2B(R2) data element A.2.3.1 ‘Study name’).
* Prevent double reporting.
* Ad „valid from date“: For new clinical trial applications the date of submission is applicable. Otherwise the date of switching the SUSAR process to electronic reporting.
* The obligation to submit SUSARs to the concerned ethics committee remains unaffected. More detailed information is presented in the „Guideline – Safety Reports“ (see <http://www.ethikkommissionen.at/>).

Please transmit the signed application as scanned document per e-mail to following address: [Susar@basg.gv.at](mailto:Susar@basg.gv.at). Enter the company or sponsor short name followed by „SUSAR Meldung BASG“. The text of the e-mail has to contain the full name and address. In order to receive confirmation of the document by AGES MEA please use the acknowledgment operation of your e-mail system.

Place, Date, Name:

Signature:

1. Enter study specific EudraCT Numbers or – if applicable - „future studies“ [↑](#footnote-ref-1)
2. Further Information with relevance for SUSAR reporting [↑](#footnote-ref-2)