BASG / AGES MEA

Institute Surveillance

Department Clinical Trials

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

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

Hereby it is confirmed that notifications of Suspected Unexpected Serious Adverse Reactions (SUSARs) according to § 41 AMG (Austrian Medicinal Product Act), BGBI No. 185/1983 (in the version prior to the coming into force of amendment BGBl. I No. 8/2022) must be transmitted to the EudraVigilance database of the European Medicines Agency (EMA) in ICH E2B (R3) format within the legally defined reporting timeline (7/15 days).

This form of electronic notification is deemed equivalent to the legal obligations according to § 41 AMG for submitting SUSARs to 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 SUSAR reporting to the EudraVigilance database, SUSAR notification should be transmitted to EMA and BASG, as instructed by [EMA](https://www.ema.europa.eu/en/human-regulatory-overview/research-development/pharmacovigilance-research-development/eudravigilance/eudravigilance-system-overview#data-submission-and-collection-7041) and [BASG](https://www.basg.gv.at/fileadmin/redakteure/01_Formulare_Listen/I/L_I209_Guidance_CT_submission_en.pdf).

For correct administration of SUSARs the following points should be considered:

* There will be no letter of acknowledgment transferred by BASG for electronic SUSARs. This will be forwarded by EMA, as the electronic message is sent directly to the Eduravigilance database.
* Double reporting via different sources must be avoided.
* Regarding „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. Enter the company or sponsor abbreviated name followed by „SUSAR Meldung BASG“. The text of the e-mail must contain the full name and address of the sponsor. To receive an acknowledgement of receipt by BASG, please use the “read confirmation” function 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)