**Templaatti mononationaalisen akateemisen, tutkijalähtöisen tutkimuksen vuosiraportille, kun tutkimusvalmiste on myyntiluvallinen**

# **Annual Safety Report (ASR)**

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| **Information of Clinical Trial:** |
| **EU CT number** |  |
| **Clinical Trial Title** |  |
| **Investigational Medicinal Product (IMP) (Active substance and Trade name)** |  |
| **Sponsor** |  |
| **Designated reporter** |  |
| **Date of initial authorization** |  |

## Period of reporting:

Reference document during the period of reporting: (Poista esimerkkiteksti raportista/remove text example from the template)

Specify the Reference Safety Information (RSI) which is used for the assessment of the expectedness of all ‘suspected’ SARs (Serious Adverse Reactions) that occur in clinical trials. At initial submission in CTIS the RSI has been declared in the cover letter. For IMP’s with a market authorization the RSI is often section 4.8 in the Summary of Product Characteristics (SmPC).

Risk-adapted measures: Describe if the protocol proposes an adaption of procedures for recording and reporting adverse events or serious adverse events in accordance with Regulation (EU) no. 536/2014. See EU guidance [Risk proportionate approaches in clinical trials.](https://health.ec.europa.eu/document/download/be80ee91-f7b8-4100-be72-42efd8362d71_en?filename=2017_04_25_risk_proportionate_approaches_in_ct.pdf)

If this is not relevant (no Risk-adapted measures) write “None”.

SARs (Serious Adverse Reactions) in the period of reporting:See Annex 1, Line listing

(See definitions of SAE, SAR and SUSAR in page 2.)

## Conclusions on observed SAEs: (Serious Adverse Events) /SARs (Serious Adverse Reactions)

Esimerkkiteksti/For example*:* A total of XX SAE were reported, XX of these with fatal outcome.
Tai/Or*:* None of the SAE were considered to be related to study medication. Thus no SAR or SUSAR (Suspected Unexpected Serious Adverse Reactions) were reported.

Tai/Or*:*A total of XX SAE were reported. XX of the SAE were considered to be **related** to study medication (SAR/SUSAR) – **see the list attached** (raportoi nämä liitteessä 1/list these in Appendix 1). Please indicate whether possible SUSARs were reported in an expedited manner directly to EudraVigilance or via Fimea.

## Benefit-risk evaluation:

Esimerkkiteksti/For example:Based on the reported SAE/SAR and updated knowledge of the investigational products, the risk and benefits for the patients are considered unchanged.

Tai/Or: Based on the amount of SAE/SAR we have decided to make following changes in the study: Kuvaile muutoksia/Describe the changes in the study protocol.

## Implication for the clinical trial population:

**Change in / amendment to protocol** [ ]  **yes** [ ]  **no**

**Change in study procedures** [ ]   **yes** [ ]  **no**

**Change in patient information** [ ]  **yes** [ ]  **no**

**Change in informed consent form** [ ]  **yes** [ ]  **no**

Date: XX/XX/20XX

Author of the report:

## Appendix to Annual Safety Report:

Annex 1: Line Listings of SARs, information of subjects who died during the reporting period and information of subjects who dropped out of clinical trial in association with an AE

## Definitions:

SAE (Serious Adverse Event): An adverse event is a serious adverse event (SAE) when it requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, results in a congenital anomaly or birth defect, is life-threatening, or results in death.

SAR (Serious Adverse Reaction): a reasonable causal relationship can be established between the adverse event and the investigational medicinal product.

SUSAR (Suspected Unexpected Serious Adverse Reaction): S[erious adverse reaction](https://toolbox.eupati.eu/glossary/serious-adverse-reaction/) ([SAR](https://toolbox.eupati.eu/glossary/serious-adverse-reaction/)) for which a reasonable [causal relationship](https://toolbox.eupati.eu/glossary/causal-relationship/) with the IMP use is suspected. Unexpected in this context means not consistent with the applicable product information ([Summary of Product Characteristics](https://toolbox.eupati.eu/glossary/summary-of-product-characteristics/), [SmPC](https://toolbox.eupati.eu/glossary/summary-of-product-characteristics/)). **Please note SUSARs should be reported in an expedited manner to EudraVigilance directly or via Fimea.**

Annex 1: Line listing of all SARs (including SUSARs) that had occurred from XX/XX/20XX to XX/XX/20XX in the trial: EU CT no: XXXX-XXXXXX-XX-XX

Please also include:

* Information of subjects who died during the reporting period. Cases where the death is caused by the disease/condition under investigation need not to be included.
* Information of subjects who dropped out of clinical trial in association with an AE during the reporting period (Discontinuation).

| **ID.nr1** | **Age2** | **Gender3** | **Suspected IMP4** | **Dose and route5** | **Date6** | **SAR term7** | **Seriousness criterion8** | **Treatment****group9** | **Onset date10** | **Outcome11** | **Discontinuation12** | **SUSAR13** | **Comments** |
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1. Subject clinical trial identification number
2. Age in years
3. Male/Female
4. Suspected Investigational Medicinal Product
5. Dose and route of administration
6. Last study medication given
7. Precise coding (related to the coding method decided by sponsor for example CTCAE or MEDRA). Coding should be done on a Preferred term (PT)-level and should describe a specific medical event, for instance pneumonia or sepsis
8. A: Death

B: Life-threatening

C: Hospitalisation/prolongation of existing hospitalisation

D: Results in persistent or significant disability or incapacity

E: Congenital anomaly or birth defect

1. If the blind has not been broken, treatment group is identified as “blinded”. If the blind has been broken or not blinding takes place, describe the treatment in the relevant arm.
2. Date of onset of the adverse reaction
3. Outcome

1: resolved

2: resolved w. sequelae

3: improved

4: fatal

5: unknown

1. The adverse event led to discontinuation of the subject in this trial. Yes/No
2. Has the SAR been evaluated as a SUSAR and reported as such to EudraVigilande directly or via Fimea. Yes/No.