Annual Safety report SUP-ICU Trial

EudraCT number	**2015-000318-24**
Clinical Trial Title	**Stress Ulcer Prophylaxis in the Intensive Care Unit – SUP-ICU Trial**
Sponsor	**Morten Hylander Møller, MD, PhD**
Designated reporter	**Søren Marker Jensen, MD, PhD-student**
Medicines Agency journal number	**2015110369**
Ethics Committees case number	**H-15003141**
Date of initial authorization	**June 8th 2015**

Period of reporting: July 5th 2016 to June 2nd 2017
(Initiation of trial awaited GCP-approval: January 1st 2016)

SAR in the period of reporting: 2620 included patients, 0 SAR.
SUSAR in the period of reporting: 2620 included patients, 0 SUSAR.

Conclusions on observed SAR/SUSAR:
None

Benefit-risk evaluation:
Based on the above reported, the risk and benefits for the patients are considered unchanged.

Implication for the clinical trial population:

Change in / amendment to protocol	☐ **yes**	**X no**
Change in study procedures	☐ **yes**	**X no**
Change in patient information	☐ **yes**	**X no**
Change in informed consent form	☐ **yes**	**X no**

Date: 2/6/2017 **Signature:**

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