

Annual Safety report HOT-ICU Trial

EudraCT number	2017-000632-34
Clinical Trial Title	Handling Oxygenation Targets in the Intensive Care Unit – HOT-ICU Trial
Sponsor	Bodil Steen Rasmussen, MD, PhD
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Medicines Agency journal number	2017021858
Ethics Committees case number	N-20170015
Date of initial authorization	June 14 th 2017

Period of reporting: June 20th 2017 to September 10th 2018

SAR in the period of reporting: 890 included patients, 0 SAR

SUSAR in the period of reporting: 890 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: SEPT. 10, 2018 Signature: 