

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
Designated reporter	Olav Lilleholt Schjørring, MD, PhD
Medicines Agency journal number	2017021858
Ethics Committees case number	N-20170015
Date of initial authorization	June 14, 2017

Period of reporting: June 19, 2019 to June 18, 2020

SAR in the period of reporting: 1,060 included patients, 0 SAR

SUSAR in the period of reporting: 1,060 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	<input type="checkbox"/> yes	<input checked="" type="checkbox"/> no
Change in study procedures	<input type="checkbox"/> yes	<input checked="" type="checkbox"/> no
Change in patient information	<input type="checkbox"/> yes	<input checked="" type="checkbox"/> no
Change in informed consent form	<input type="checkbox"/> yes	<input checked="" type="checkbox"/> no

Date: 18TH JUNE, 2020

Signature: _____

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