



Annual Safety Report HOT-COVID trial

EudraCT number	2017-000632-34
Clinical Trial Title	Handling Oxygenation Targets in COVID-19 – HOT-COVID 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: December 6, 2021 to August 16, 2022

Serious adverse reactions (SAR) in the period of reporting: 148 included patients, 0 SAR
Suspected unexpected serious adverse reaction (SUSAR) in the period of reporting: 148 included patients, 0 SUSAR

Conclusions on observed SAR/SUSAR:

None

Benefit-risk evaluation:

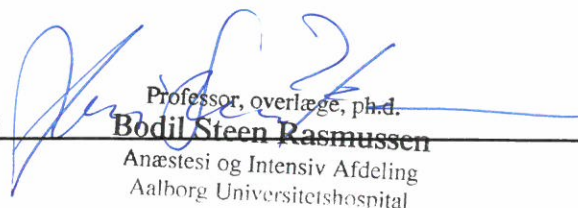
Based on the above reported, the risk and benefits for the patients are considered unchanged

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: 16TH OF AUGUST 2022

Signature: _____


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