



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
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Medicines Agency journal number	2017021858
Ethics Committees case number	N-20170015
Date of initial authorization	June 14, 2017

Period of reporting: August 25, 2020 to December 6, 2021

Serious adverse reactions (SAR) in the period of reporting: 548 included patients, 0 SAR

Suspected unexpected serious adverse reaction (SUSAR) in the period of reporting: 548 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: 6/12-2022

Signature: 

