

**Annual Safety report AID-ICU trial**

EudraCT number	2017-003829-15
Clinical Trial Title	Agents Intervening against Delirium in the Intensive Care Unit – AID-ICU trial
Sponsor	Lone Musaeus Poulsen, MD
Designated reporter	Nina Christine Andersen-Ranberg, MD, PhD-student
Medicines Agency Journal number	2017101527
Ethics Committee case number	SJ-646
Date of initial authorization	December 5, 2017

Period of reporting: June 13 2018 to December 31 2018

SAR in the period of reporting: 89 included patients, 0 SAR

SUSAR in the period of reporting: 89 patients included, 0 SUSAR

Conclusions in 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: 3/1/19

Signature: 