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: January 1th 2019 to December 31 2019

SAR in the period of reporting: 307 included patients, 3 SARs

SUSAR in the period of reporting: 307 patients included, 0 SUSAR

Conclusions in observed SAR/SUSAR:

Three cases of Ventricular Tachycardia (VT) have been reported among trial participants in 2019. Patients that experienced VT were immediately discontinued from trial medication and treated according to local guidelines. Two of these cases of VT were non-stained and thereby self-limiting and no further management were needed other than cardiac monitoring. One patient was converted to sinus rhythm by cordarone (amiodaron) –loading and defibrillation. All patients survived their VT and treated until VT abated. VT is prevalent in a critically ill population and causality to haloperidol intervention was not proven. The reported cases did not give rise to any new safety concerns as all patients are closely monitored in the Intensive Care department.

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	☒ no
Change in study procedures	☐ yes	☒ no
Change in patient information	☐ yes	☒ no
Change in informed consent form	☐ yes	☒ no

Date: 21/1/20 **Signature:**