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ASR-2025-00322

Nordsjaellands Hospital

IMP: Furosemide
Submitted: 28/01/2025

MSC	saMS	ASR reporting period	Submitted
DK, NL, SE		01/01/2024 - 31/12/2024	28/01/2025

ASR Submission () Assessment ()

SPONSOR DETAILS

ORGANISATION DETAILS FOR SPONSOR

Nordsjaellands Hospital
Dyrehavevej 29, 3400, Hilleroed, Denmark

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The sponsor or co-sponsors **are not** commercial.

This ASR **is not** a consolidated report following a co-development agreement.

CLINICAL TRIAL DETAILS

Expand all

Goal directed fluid removal with furosemide in intensive care patients with fluid overload: a randomised, blinded, placebo-controlled trial (GODIF)

2024-512186-14-00

IMP1: Furosemide / Role: Test ()

Annual safety report details

This is the first sponsor's ASR for any of the IMP(s) selected	No
If yes, indicate which IMPs	
Data lock point	01/01/2025
ASR reporting period	01/01/2024 - 31/12/2024
RSI Updated during the reporting period	No
Substantial modification on RSI submitted and approved during the reporting period	No
During the reporting period ASR includes	None

Submission documents

Annual safety report GODIF trial 2024

English · ASR Document · **System version 1.00**
Submission date 28/01/2025
· **Version 1** · 28/01/2025

Comment This trial was initiated in 2020 and annual safety reports have been sent to the Danish authorities every year. The trial was transferred to CTIS in October 2024. The last annual

safety report sent to Danish authorities covered the year 2023. For that reason, the annual safety report for the year 2024 is now reported.

I, on behalf of the sponsor, confirm that the:

1. Information provided is complete
2. Attached documents contain an accurate account of the information available
3. The Sponsor, Nordsjaellands Hospital, declares that the Annual Safety Report is prepared and hereby submitted to the Agency in accordance with Article 43 of Regulation (EU) No 536/2014 and all other applicable legal provisions.

- [x] RSI Document/.s (Old and new version where applicable)
- [x] I agree with the above statements