GODIF – log for site master file for new documents and/or new updated versions

Date: 30.03.2026: Annual safety report 2025 (site master file #4f), new versions of the co-enrolment list 1.7-1.8 (site master file #8a).

Date: 10.12.2025: The delegation and signature log have been added for countries preparing their own trial drug, V1.2. The change consists of revised wording in the delegation role G, reflecting that the drug preparation and blinding are made on-site. (site master file #3). Co-enrolment lists version 1.2-1.6 have been uploaded (site master file #8a).

Date: 03.02.2025: Updated protocol V2.8 (site master file #1a), front page of protocol signed by sponsor (site master file #1d), new trial information and consent forms for trial guardian, next of kin and patients for the Danish sites (site master file #7a and #7b), new sheet of patient rights in clinical research (Danish sites only) (#7c) approvals from CTIS (site master file #4g), procedure for obtaining consent for Danish sites (site master file #9dii), annual safety report for 2024 (site master file #4f), co-enrolment list V1.4 (site master file #8a), SOP for follow-up (site master file #17a).

Date: 14.08.2024: A new template for reporting SAE/SAR version 1.0 (site master file #14b)

Date: 27.09.2023: New version of the co-enrolment list version 1.1 (site master file #8a)

Date: 15.05.2023: New amendment to the protocol version 2.7: “Trial drug for the GODIF trial” (site master file #1b). Approval for the new amendment from The Danish Medicine Agency (site master file #4a) and The Committees on Health Research Ethics (site master file #4c)

Date: 31.03.2023: New version of "The rights of the patients in clinical research" (document in Danish) (site master file #7c).

Date: 11.01.2023: Annual safety report for the GODIF trial 2023 (site master file #4f). Updated Trial synopsis (site master file #1c).

Date: 13.09.2022: Updated document on case money (site master file #6a).

Date: 20.06.2022: MoCA 5 min test and instructions for Norwegian sites (site master file #17b+c)

Date: 15.06.2022: Added a new approved protocol version 2.7 (site master file #1a), the frontpage of the protocol signed by Sponsor (site master file #1d), approval from the Danish Medicine Agency and The Committee on Health Research Ethics of the new protocol (site master file #4a+c), new trial information and consent forms for Danish sites (site master file #7a+b).

Date: 10.06.2022: Added an updated EudraCT file.

Date: 11.05.2022: Added an updated EudraCT file.

Date: 21.04.2022: Added a revised GODIF algorithms with minor changes in the choice of words.

Date: 10.03.2022: Added an updated EudraCT file.

Date: 10.01.2022: Added the annual safety report for the GODIF trial (site master file #4f).

Date: 14.12.2021: Added: a revised document for case-money (site master file #6a), a revised document for trial medication dispensing system (site master file #9aiii) and a revised PowerPoint show for trial medication and dispensing (site master file #9ciii).

Date: 29.11.2021: Added a new document from The Capital Region Knowledge Center for Data Compliance. (site master file #4c).

Date: **27.10.2021**: Added an updated Trial synopsis (site master files #1c and #9biii).

Date: 02.09.2021: Added an updated document of "The rights of the patient in clinical research" (site master file #7c), former GODIF newsletters are up-loaded (site master file #13f), SOP for follow-up and MoCA mini test and instructions are updated (site master file #17a and #17c).

Date: 27.05.2021: Added a new slide show for initiation for investigators and for primary personnel (site master file #9ci).

Date: 25.05.2021: Added an updated eCRF overview for screening, baseline and day form (site master file #2), an updated document of primary data source template and for Sundhedsplatformen (site master file #12) and finally an updated plan for data-verification (site master file #15d).

Date: 10.05.2021: Added an approved GODIF protocol version 2.6 (site master file #1a), approval from The Committees on Health Research Ethics (#4c) and the Danish Medicine Agency (#4a), new EudraCT (#4b), consent forms (#7b) and trial information with up-dated protocol version (#7a), updated SOP for trial medication (#9avi), pocket cards (#9biv), leaflet for clinical staff (#9bv), and eligibility (#9ai), GODIF algorithms (#9avii), GODIF trial medication for notice board (#9bi). Table for ideal body weight and 5% fluid overload according to height (#9bviii) - has changed the name to "Table for minimum fluid overload on inclusion and goal for fluid removal" - an updated document has been added. The bedside worksheet is withdrawn/obsolete (#9bvii).

Date: 21.01.2021: Added: annual safety report 2020.

Date: 08.01.2021: Added: updated Trial medication dispensing system (site master file #9aiii).

Date: 05.01.2021: Added: data verification plan (site master file #15d) and Front page of protocol signed (site master file #1d).

Date: 04.01.2021: Added: protocol 2,5 (site master file #1a), Approval from The Danish Medicine Agency (site master file #4a), EudraCT (site master file 4b), Approval from The Committees on Health Research Ethics (site master file #4c), Trial information (site master file #7a), Consent forms (site master file #7b), Eligibility (site master file #9ai), SAE, SAR, SUSAR and unblinding (site master file #9av), SOP for trial medication (site master file #9avi), Algorithms for trial medication and resuscitation (site master file #9avii), Inclusion and exclusion criteria for notice board (site master file #9bii), Pocket cards (Danish) (site master file #9biv), Leaflet for clinical staff (Danish) (site

master file #9bv), Initiation for investigators and primary trial personnel (slides) (site master file #9ci), Primary data source (template and for Sundhedsplatformen) (site master file #12).

Date: 10.12.2020: Added: updated co-enrolment list (site master file #8a).

Date: 13.10.2020: Added a new plan for data verification from the GCP-unit and a new template for the day form to the eCRF. (site master file #15d and #2).

Date: 28.09.2020: Added SOP for trial medication, SOP for escape procedures, and GODIF algorithms in Danish (site master file #9vi and 9vii).

Date: 15.09.2020: Added an updated co-enrolment list (site master file #8a)

Date: 27.08.2020: Added: new EudraCT file and updated approvals and correspondence from The Danish Medicine Agency and The Committees on Health Research Ethics (site master file #4b, #4a, #4c).

Date: 19.08.2020: Added: Instructions in the eCRF (site master file #9aiv).

Date: 04.01.2021: Added: protocol 2,5 (#1a), Approval from The Danish Medicine Agency (#4a), EudraCT (#4b), approval from The Committees on Health Research Ethics (#4c), Trial information (#7a), Consent forms (#7b).