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

Date: 03.02.2025: Updated protocol V2.8 (site master file #), 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 (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).