

# **CLASSIC Log for new documents and/or new versions updated:**

[Print version](#) - please notice the "download" feature is situated *underneath* the pdf.

**Date 13.04.21 at 15.33 Updated [EudraCT](#) and [EudraCT xml](#) and added [annual safety report 2021](#)**

**Date 23.03.21 at 14.20 Updated [co-enrolment list](#)**

**Date 01.03.21 at 10.16 Updated [EudraCT](#), [EudraCT xml](#) and [Danish ethics committee amendments](#).**

**Date 25.01.21 at 16.25 uploaded [EudraCT](#) and [EudraCT xml](#)**

**Date 13.01.21 at 16.45 pm added ethics committee [approved amendment](#) and updated [co-enrolment](#) list**

Date 27.11.20 at 07.25 Added [newsletters](#)

**Date 04.11.20 at 09.55**

**Added updated [screening form](#) and [discharge form](#)**

**Date 29.06.20 at 11.27**

**Added approved [amendments](#) from Ethics Committee to site master file #4c**

**Date 24.06.2020 at 12.45 pm**

**Added [Annual Safety report](#) and updated [CLASSIC newsletters](#)**

**Date 01.05.2020 at 10.06 am**

**Added eCRF [Consent form](#) to site master file #2**

**Date 20.01.2020 at 14.07 pm**  
**Updated [CLASSIC newsletter](#)**

**Date 06.12.2019 at 10.00 am**

**Updated [EudraCT \(pdf\)](#) and XML versions (for national investigators)**

**Date 28.11.2019 at 11.52 am**

**New documents for 1-year follow-up available in [Site Master File #17 Appendices](#) and updated [#4c amendment from Danish Ethics Committee](#)**

**Date 22.11.2019 at 10.37pm**

**Updated #6a [CLASSIC case-money form \(Danish\)](#)**

**Date 11.11.2019 at 12.46pm**

**Updated #9c [CLASSIC Initiation](#) (power point)**

**Date 25.09.2019 at 10.24am**

**Updated #6a [CLASSIC Case-money Form](#)**

**Date 29.08.2019 at 18:47 pm**

**[Protocol](#) version 2.3 updated in Site Master File #1 (Print and place in your Site Master File)**

**[Medicines agency approval](#) and [Ethics committee approval](#) updated in Site Master File #4 (Print and place in your Site Master File)**

**[Adverse event reporting form](#) updated in Site Master File #14 (Print and place in your Site Master File)**

**Date 2019.07.23 at 9.58pm**

**Primary data source (English) updated in Site Master File #12  
(Print and place in your Site Master File)**

**Co-enrolment list updated in Site Master File #8**

**Contact details updated in Site Master File # 13 (Print and  
place in your Site Master File)**

**Date 2019.06.06 at 3.24pm**

**Updated #6 CLASSIC Case-money Form**

**Date 2019.06.06 at 9.45am**

**Updated #13a Contact details - Steering Committee**

**Date 2019.31.05.2019 at 11.50am**

**Annual Safety Report #4 f) added to Site Master File (Print  
and place in your Site Master File).**

**Data verification plan (English) added to National investigator  
documents.**

**Date 2019.05.23 at 10.49 pm**

**Updated Co-enrolment list**

**Date 2019.05.07 at 14.35 pm**

**Updated EudraCT (including xml file for international sites)  
(print and place in your Site Master File #4b), eCRF  
baselineform (print and place in your Site Master File #2), and  
CLASSIC newsletter May 2019 (print and place in your Site  
Master File #13f)**

**Date 2019.03.26 at 09.00am**

**Updated [kildedataliste](#) (Danish) (print and place in your Site Master File #12)**

**Date 2019.03.25 at 10.45 am**

**Updated "[forsøgspersoners rettigheder](#)" (print and place in your Site Master File #7)**

**Date 2019.03.01 at 13.02 pm**

**Updated [monitoring plan \(danish\)](#) and [monitoring plan \(english\)](#) (print and place in your Site Master File #15d)**

**[Newsletters](#) posted (print and place in your Site Master File #13f)**

**Date 2019.02.18 at 12.54 pm**

**Updated version of CLASSIC [classic-contact-details/](#) #13b**

**Date 2019.02.15 at 13.24 am**

**Updated [EudraCT](#) (print and place in your Site Master File #4b) and EudraCT [xml](#) (for national investigators). Updated [Dayform](#) in the eCRF (print and place in your Site Master File #2)**

**Date 2019.02.07 at 11.22 am**

**Updated version of CLASSIC [contact details - Steering Committee](#)**

**Date 2019.01.24 at 10.30 am**

**Leaflet for clinicians/nurses (English) #9b v) added to Site Master File (Print and place in your Site Master File at international sites)**

**Date 2019.01.10 at 10.00am**

**Letter of acknowledgement of notification, The Danish Medicines Agency (Danish) #4a added to Site Master File (Print and place in your Site Master File)**

**Date 2019.01.08 at 09.40 am**

**Approved amendment from Danish Ethics Committee #4c added to Site Master File (Print and place in your Site Master File)**

**Date 2019.01.04 at 11.50 am**

**Approved protocol v.2.2 #1 added to Site Master File (Print and place in your Site Master File)**

**Danish trial information for relatives and patients v 1.3 #7 added to Site Master File (Print and place in your Site Master File)**

**Danish consent forms for relatives and patients v. 1.1 #7 added to Site Master File (Print and place in your Site Master File)**

**Danish curriculum vitae template v.1.1 #3 added to Site Master File (Print and place in your Site Master File)**

**eCRF dayform and withdrawal form updated #2 added to Site Master File (Print and place in your Site Master File)**

**Danish delegation log updated v 1.3 #3 added to Site Master File (Print and place in your Site Master File)**

Consent '[samtykke drejebog](#)' added to Site Master File (Print and place in your Site Master File)

Date: 2018.12.18 at 10.30 am

[Curriculum vitae \(Danish\)](#) v.1.1 #3 added to Site Master File (Print and place in your Site Master File)

Date: 2018.12.13 at 10.30 am

[Primary data source](#) (blank) #12 added to Site Master File

Date: 2018.12.11 at 10.50 am

[CLASSIC pocket cards](#) #9, [CLASSIC pocket cards \(Danish\)](#) #9 , (print and place in your Site Master File)

Date: 2018.12.04 at 11.06 am

[CLASSIC initiation power point](#) #9, [CLASSIC initiation power point for nurses](#) #9 , (print and place in your Site Master File)