

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

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

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 EurdraCT [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 Committe 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)**