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

<u>Print version</u> - please notice the "download" feature is situated <u>underneath</u> the pdf.

Date 24.06.2020 at 12.45 pm Added <u>Annual Safety report</u> and updated <u>CLASSIC</u> 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 <u>CLASSIC newsletter</u>

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 <u>Site Master File #17 Appendices</u> and updated <u>#4c amendment from Danish Ethics Committee</u>

Date 22.11.2019 at 10.37pm

Updated #6a CLASSIC case-money form (Danish)

Date 11.11.2019 at 12.46pm

Updated #9c <u>CLASSIC Initiation</u> (power point)

Date 25.09.2019 at 10.24am

Updated #6a <u>CLASSIC Case-money Form</u>

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

<u>Primary data source (English)</u> 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 <u>CLASSIC Case-money Form</u>

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).

<u>Data verification plan</u> (English) added to <u>National</u> investigator documents.

Date 2019.05.23 at 10.49 pm

Updated <u>Co-enrolment list</u>

Date 2019.05.07 at 14.35 pm

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

Date 2019.03.26 at 09.00am

Updated <u>kildedataliste</u> (Danish) (print and place in your Site Master File #12)

Date 2019.03.25 at 10.45 am

Updated <u>"forsøgspersoners rettigheder"</u> (print and place in your Site Master File #7)

Date 2019.03.01 at 13.02 pm

Updated <u>monitoring plan (danish)</u> and <u>monitoring plan (english)</u> (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 <u>classic-contact-details/</u> #13b

Date 2019.02.15 at 13.24 am

Updated <u>EudraCT</u> (print and place in your Site Master File #4b) and EudraCT <u>xml</u> (for national investigators). Updated <u>Dayform</u> in the eCRF (print and place in your Site Master File #2)

Date 2019.02.07 at 11.22 am

Updated version of CLASSIC <u>contact details -</u> Steering Committee

Date 2019.01.24 at 10.30 am

<u>Leaflet for clinicians/nurses (English)</u> #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

<u>Letter of acknowledgement of notification, The</u>
<u>Danish Medicines Agency (Danish)</u> #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 <u>relatives</u> and <u>patients</u> v 1.3 #7 added to Site Master File (Print and place in your Site Master File)

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

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

eCRF <u>dayform</u> and <u>withdrawal</u> form updated #2 added to Site Master File (Print and place in your Site Master File)

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

Consent '<u>samtykke drejebog</u>' added to Site Master File (Print and place in your Site Master File)

Date: 2018.12.18 at 10.30 am

<u>Curriculum vitae (Danish)</u> 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

<u>Primary data source</u> (blank) #12 added to Site Master File

Date: 2018.12.11 at 10.50 am

<u>CLASSIC pocket cards</u> #9, <u>CLASSIC pocket cards</u> (<u>Danish</u>) #9, (print and place in your Site Master File)

Date: 2018.12.04 at 11.06 am

<u>CLASSIC initiation power point</u> #9, <u>CLASSIC</u> <u>initiation power point for nurses</u> #9, (print and place in your Site Master File)