

Modified: September 4, 2019 at 9:19 am

HOT-ICU Log for new documents and/or new versions updated:

Print version – please notice the “download” feature is situated underneath the pdf.

Date 2019.09.04 at 09:19 am

Co-enrolment list #8a (go to 8.a Co-enrolment Form and find a link to the list in the text)

Date 2019.14.08 at 1.05 pm

HOT-ICU Steering Committee (appendix 1 from Protocol)

Contact details #13.a, (print and place in your Site Master File)

Annual Safety Report #4, (print and place in your Site Master File)

Date 2019.11.07 at 8.35 am

Co-enrolment list #8a (go to 8.a Co-enrolment Form and find a link to the list in the text)

Date: 2019.01.07 at 1.35 pm

HOT-ICU_monitoreringsplan version 2 (Danish only) #15.d, (print and place in your Site Master File)

Date: 2019.18.06 at 11.15 am

News letter 13.f, (print and place in your Site Master File)

HOT-ICU_monitorerings- og dataverifikationsplan (Danish only) #15.d, (print and place in your Site Master File)

Date: 2019.06.06 at 3.49pm

Updated #6a Case-money

Date: 2019.05.22 at 10.35 am

Protocol #1.a, The Danish Medicines Agency (in Danish) #4.a, EudraCT #4.b, Approval Ethics Committee (in Danish) #4.c and News letter #13.f, (print and place in your Site Master File)

Date: 2019.04.10 at 03:50 pm

Contact details #13.a, (print and place in your Site Master File)

Date: 2019.04.02 at 02:59 pm

Forsøgspersoners rettigheder (in Danish) #7.a, and News letter #13.f, (print and place in your Site Master File)

Date: 2019.03.20 at 12.50 pm

News letters #13.f, (print and place in your Site Master File)

Date: 2019.02.01 at 09.50 am

Tillæg til Monitoreringsplan (in Danish) #15.d

Date: 2018.12.19 at 02.20 pm

**Protocol #1.a, The Danish Medicines Agency (in Danish)
#4.a, EudraCT #4.b, Approval Ethics Committee (in Danish)
#4.c**

Date: 2018.11.22 at 02.00 pm

**Co-enrolment list #8.a (go to 8.a Co-enrolment Form and find
a link to the list in the text)**

Date: 2018.11.16 at 01.30 pm

**HOT-ICU CRF 1 year follow-up #2, HOT-ICU CRF all in one
document #2 and HOT-ICU CRF all in one document (Swiss
version) #2, (print and place in your Site Master File)**

Date: 2018.11.07 at 09.30 am

**Forsøgspersoners rettigheder (in Danish) #7.a,
and News letters #13.f, (print and place in your Site Master
File)**

Date: 2018.11.01 at 11.10 am

**Co-enrolment list #8.a (go to 8.a Co-enrolment Form and find
a link to the list in the text)**

Date: 2018.10.22 at 1.30 pm

Letter of acknowledgement of notification (in Danish) #4,
(print and place in your Site Master File)

Date: 2018.10.05 at 1.50 pm

Patient information (template) (English version) #7.a,
Samtykke patienten, pårørende og anden forsøgsværge, første
forsøgsværge #7.b (in Danish), and News letters #13.f, (print
and place in your Site Master File)

Date: 2018.09.26 at 12.15 am

Annual Safety Report #4, (print and place in your Site Master
File)

Date: 2018.09.12 at 1.15 pm

Protocol #1.a, Approval Ethic committee (in Danish) #4.c,
Patient information til patient, pårørende og forsøgsværge
#7.a (in Danish), (print and place in your Site Master File)

Date: 2018.09.04 at 9.15 am

News letters #13.f, (print and place in your Site Master File)

Date: 2018.08.29 at 3.15 pm

HOT-ICU Monitoring and data verification plan #15.d, (print
and place in your Site Master File)

Date: 2018.08.21 at 10.45 am

HOT-ICU Monitorerings og dataverificationsplan (Danish only) #15.d, (print and place in your Site Master File)

Date: 2018.07.03 at 8.45 am

News letters #13.f, (print and place in your Site Master File)

Date: 2018.06.13 at 4.10 pm

Co-enrolment list #8.a (go to 8.a Co-enrolment Form and find a link to the list in the text), News letters #13.f (print and place in your Site Master File)

Date: 2018.04.17 at 12.15 pm

News letters #13.f, Standard operating procedure (SOP) for EuroQol follow-up (in Danish) #17.a, Table of content (print and place in your Site Master File)

Date: 2018.02.09 at 6.45 pm

News letters #13.f, (print and place in your Site Master File)

Date: 2018.02.02 at 2.00 pm

Monitoring plan in English #15.d., Daily form and Baseline, and for Swiss only Screening form #2, (print and replace in your Site Master File)

IF you want to print at whole new set of all CRF documents then your find them here:

- 1. For all but Swiss: CRF – all in one document**
- 2. For Swiss: Swiss CRF – all in one document**

Date: 2018.01.05 at 5.15 pm

Tillæg til Monitoreringsplan (in Danish) #15.d., News letters #13.f, (print and place in your Site Master File)

Date: 2017.12.06 at 4.40 pm

Table of content (print and place in your Site Master File)

Date: 2017.11.17 at 4.15 pm

News letters #13.f, (print and place in your Site Master File)

Date: 2017.11.16 at 12.00 am

The Co-enrolment list is no longer part of the Site Master File – to get access to the list a link is to be found in the Co-enrolment Form document #8.a (remove Co-enrolment list from the Site Master File), Table of content (print and place in your Site Master File)

Date: 2017.11.08 at 3.30 pm

The Danish Medicine Agency #4.a, EudraCT #4.b, Table of content (print and place in your Site Master File)

Date: 2017.11.08 at 8.30 am

Protocol #1.a, EudraCT #4.b, Videnskabsetisk komité #4.c (in Danish), Datatilsynet #4.d (in Danish), Table of content (print and place in your Site Master File)

Date: 2017.11.02 at 11.30 am

Co-enrolment list #8a, Information to patient (in Danish) #7a, (print and place in your Site Master File)

Date: 2017.10.24 at 1.00 pm

Co-enrolment list #8a (print and place in your Site Master File)

Date: 2017.10.17 at 8.00 pm

Case money #6 (print and place in your Site Master File)

Date: 2017.10.03 at 3.45 pm

Implemented in eCRF September 18, 2017: CRF – all in one document #2(1), Screening form #2 (2), Baseline form #2(2), Daily form #2(2), Withdrawal #2(2), Discharge and readmission #2(2), 90 days follow-up #2(2), 1 year follow-up #2(2), and News letter #13.f, (print and place in your Site Master File)

Date: 2017.09.20 at 0.15 am

News letters #13.f, (print and place in your Site Master File)

Date: 2017.09.08 at 3.45 pm

Co-enrolment Form #8.a, Co-enrolment list #8.a, Table of content (print and place in your Site Master File)

Date: 2017.08.31 at 12.30

Trial initiation #9.a.i, Præsentation plejepersonale #9.c.ii, Contact details #13.a, Monitoring visits #15.b, Table of content (print and place in your Site Master File)

Date: 2017.08.28 at 3.00 pm

Samtykke patienten (dansk)#13.f, Videnskabsetisk komité (dansk) #4.c, Monitoring plan (English) #15.d, Table of content (print and place in your Site Master File)

Date: 2017.08.21 at 4.15 pm

Patient information (template), #7.a, Table of content (print and place in your Site Master File)

Date: 2017.08.16 at 11.15 am

Samtykke patienten, Samtykke pårørende, Samtykke forsøgsværgeren #7.b, News letters #13.f, Table of content (print and place in your Site Master File)

Date: 2017.08.14 at 2.00 pm

CRF – all in one document (**Swiss** version) #2(1), Screening form (**Swiss** Screening form) #2 (2), **Baseline form** #2(2), **Daily form** #2(2), **Table of content** (print and place in your Site Master File)

Date: 2017.08.11 at 12.00 am

Remove: Collaboration agreement between Sponsor and site,#5.a (remove from Site Master File)

Date: 2017.07.18 at 9.00 pm

Receipt of notification #4.a (print and place in your Site Master File)

Date: 2017.07.03 at 18.00 pm

Primary data source and **Kildedataliste** #12 (print and place in your Site Master File)

Date: 2017.06.19 at 8.00 am

HOT-ICU Site Master File released (print and place in your Site Master File)