

Modified: June 6, 2019 at 3.49pm

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

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, [Videnskabetisk 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 forsøgsværgen](#) #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)