

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

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

Date 2020.07.07 at 10:38 pm

[The Danish Medicines Agency](#) (in Danish) #4.a

Date 2020.07.07 at 08:30 am

[News letter](#) (#30) 13.f (print and place in your Site Master File)

Date 2020.06.22 at 01:03 pm

[Approval Ethics Committee](#) (in Danish) #4.c

Date 2020.06.18 at 02:48 pm

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

Date 2020.06.16 at 12:52 am

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

Date 2020.06.12 at 08:46 am

[News letters](#) (#27-29) 13.f (print and place in your Site Master File)

Date 2020.06.08 at 09:10 am

[Approval Ethics Committee](#) (in Danish) #4.c

Date 2020.05.25 at 11:50 am

[Approval Ethics Committee](#) (in Danish) #4.c

Date 2020.04.15 at 10:30 am

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

Date 2020.03.25 at 08:15 am

[Approval Ethics Committee](#) (in Danish) #4.c

Date 2020.03.24 at 02:42 pm

[The Danish Medicines Agency](#) (in Danish) #4.a

Date 2020.03.06 at 02:45 pm

[News letters](#) (#25+26) 13.f (print and place in your Site Master File)

Date 2020.01.09 at 12:06 am

HOT-ICU Monitoring and Dataverification Plan
([English](#)) (version 3.1)

Date 2020.01.08 at 12:17 am

HOT-ICU Monitoring and Dataverification Plan
([Danish](#) and [English](#)) (no new files added), **[News letters](#)** (23+24) 13.f

Date 2020.01.07 at 08:03 am

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

Date 2020.01.06 at 09:35 am

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

Date 2019.12.18 at 02:49 pm

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

Date 2019.12.17 at 09:22 am

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

Date 2019.12.06 at 10:30 am

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

Date 2019.11.19 at 10:14 am

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

[HOT-ICU monitorerings- og dataverifikationsplan](#) , Monitoreringsplan version 2, 1. Tillæg til Monitorerings plan verison 2 and Plan for dataverifikation version 7 (Danish only) #15.d

[News letters](#) (#19-22) 13.f

Print and place all updated files in your Site Master File

Date 2019.11.07 at 10:10 am

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

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 2019.08.14 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 2019.07.11 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: 2019.07.01 at 1.35 pm

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

Date: 2019.06.18 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, [Videnskabetisk 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 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)**