

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

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

**Date 2019.12.06 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)**