

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

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

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, 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 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)