

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

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

Date: 2018.06.13 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, [Präsentation 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)