

Log for new documents and/or new versions updated:

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

Date 2023.03.06 at 09.31 am.

[Approval Ethics Committee](#) (Protocol version 2.4)

[HOT-ICU protocol v. 2.4](#)

[Eudract HOT-ICU protocol v. 2.4](#)

Date 2023.02.21 at 11.50 am.

[News letters](#) (#21) 13.f

[Annual Safety Report](#) #1 & #5, (print and place in your Site Master File)

Date 2022.01.12 at 09.20 am.

[News letters](#) (#18 & #19 & #20) 13.f

Date 2022.05.07 at 09.20 am.

[News letters](#) (#16 & #17) 13.f

Date 2022.04.05 at 01.15 pm.

[News letters](#) (#14 & #15) 13.f

[Updated approval from the Danish Medicines Agency](#) (in Danish) #4.a

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

[Approval Ethics Committee](#) (Protocol version 2.3) (in Danish) #4.c

[HOT-ICU protocol v. 2.3](#) #1.a,

Date 2022.01.21 at 10.58 am.

[News letters](#) (#12 & 13) 13.f

[Trial information for patients and next of kin](#) (updated: English)

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

Date 2021.11.04 at 10.36 am.

[News letters](#) (#7 & #8 #9 & #10 & #11) 13.f

Date 2021.05.12 at 11.38 am.

[News letters](#) (#5 & #6) 13.f

[Trial information for patients and next of kin](#) (Turkish, Polish, Spanish)

Date 2021.03.10 at 09.34 am.

[Forsøgspersoners rettigheder](#)

[News letter](#) (#2) 13.f

[Trial information for patients and next of kin](#) (Arabic, Romanian, Russian)

Date 2021.02.01 at 02.19 pm.

Plan for Monitoring version 1 (in English), Data Verification Plan version 1 (in English)

Date 2021.01.15 at 11:00 am

[News letter](#) (#33) 13.f

Print and place all updated files in your Site Master File

Date 2020.12.18 at 07.39 am.

[Plan for Monitoring](#) version 4 (in Danish)

Date 2020.12.10 at 05.45 pm.

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

[Primary data source list](#) version 1.1 (Danish version)

Date 2020.12.07 at 01.05 pm.

[HOT-ICU protocol v. 2.2](#) #1.a,

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

Date 2020.08.13 at 09:24 am

[News letter](#) (#32 HOT-ICU & #1 HOT-COVID) 13.f

Date 2020.11.16 at 02:35 pm

HOT-COVID [Monitoring and Data Verification Plan](#) (Danish)

Date 2020.11.04 at 09:05 am

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

Date 2020.10.08 at 09:30 am

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

Date 2020.08.25 at 11:43 am

[Approval Ethics Committee](#) (in Danish) #4.c, [Datatilsynet](#) #4.d (in Danish), #17.a, [Table of content](#) (print and place in your Site Master File)

Date 2020.08.13 at 09:24 am

[News letter](#) (#31) 13.f

Print and place all updated files in your Site Master File

Date 2020.08.12 at 11:09 am.

Update with HOT-COVID related documents:

HOT-COVID protocol 1.2 (approved), EudraCT, Delagation log (English and Danish version), CV (English and Danish versions), Approval from head of department template (English and Danish versions), Case money template, Patient information template (HOT-COVID) English version, Patient Information til [patient](#), [pårørende](#) og [forsøgsværge](#) #7.a (in Danish), Samtykke (HOT-COVID) [patienten](#), [pårørende og anden forsøgsværge](#), [første forsøgsværge](#) #7.b (in Danish), Samtykke drejebog (in Danish), Co-enrolment form, HOT-COVID substudy proposal template, HOT-COVID eligibility criteria, Instructions for SUSAR reporting, Sign for bed (in Danish), Sign for board (in Danish), FiO2 conversion table for open systems, HOT-COVID pocket cards (English and Danish versions), HOT-COVID leaflet for clinicians (English and Danish versions), HOT-COVID Laboratory test template, HOT-COVID Primary data source list (English and Danish versions), HOT-COVID contact details, Note to file template, HOT-COVID monitoring visit template

Date 2020.07.07 at 10:38 am

[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 am

[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 2020.03.24 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
version 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 2019.14.08 at 1.05 pm

[HOT-ICU Steering Commitee](#) (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 2019.11.07 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: 2019.01.07 at 1.35 pm

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

Date: 2019.18.06 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, 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, [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)