

Log for new documents and/or new versions updated:

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

Date: 2018.06.19 at 12.20 am

[Annual Safety Report 2018](#), #Fane 4.f, (print and place in your Site Master File)

Date: 2018.02.28 at 5.45 pm

[Trial completion](#) (in Danish) #Fane 16, [Table of content](#), and [News letter](#) , #Fane 13.f, 22'nd News letter (print and place in your Site Master File)

Date: 2018.01.24 at 4.30 pm

[Anmeldelse og sikkerhedsdokument](#) (in Danish) #Fane 4.d, (print and place in your Site Master File)

Date: 2018.01.11 at 2.50 pm

[EudraCT](#) #Fane 4.b, [Sikkerhedsdokument](#) (in Danish) #Fane 4.d, (print and place in your Site Master File)

Date: 2017.11.24 at 8.30 am

[News letter](#) , #Fane 13.f, 21'st News letter (print and place in your Site Master File)

Date: 2017.11.23 at 1.00 pm

[Drug Disposal Form](#), #Fane 10.c (print and place in your Site Master File)

Date: 2017.10.30 at 1.00 pm

[News letter](#) , #Fane 13.f, 20'th News letter (print and place in your Site Master File)

Date: 2017.09.22 at 3.30 pm

[News letter](#) , #Fane 13.f, 19'th News letter (print and place in your Site Master File)

Date: 2017.08.24 at 3.00 pm

[News letter](#) , #Fane 13.f, 18'th News letter (print and place in your Site Master File)

Date: 2017.08.24 at 1.30 pm

Amendment to protocol [Appendix 3](#) #Fane 1.b, amendment to [Danish Medicine Agency](#) approval (in Danish) #Fane 4.a, amendment to [Ethic Committee](#) approval (in Danish)#Fane 4.c, [Table of content](#) (print and place in your Site Master File)

Date: 2017.07.17 at 3.00 pm

[News letter](#) , #Fane 13.f, 17'th News letter (print and place in your Site Master File)

Date: 2017.06.14 at 4.50 pm

[News letter](#) , #Fane 13.f, 16'th News letter, [Annual Safety Report](#), #Fane 4.f (print and place in your Site Master File)

Date: 2017.06.06 at 12.00 am

[Drug transfer form](#), #Fane 10.f is updated and [Drug transfer procedure](#) is added to #10.f, and as a consequence [Table of content](#) has changed (print and place in your Site Master File)

Date: 2017.05.19 at 3.30 pm

[News letter](#) , #Fane 13.f, 15'th News letter, [Drug transfer form](#), #Fane 10.f is added and as a consequence [Table of content](#) has changed (print and place in your Site Master File)

Date: 2017.04.11 at 11.50 am

[News letter](#) , #Fane 13.f, 14'th News letter (print and place in your Site Master File)

Date: 2017.03.20 at 3.40 pm

[SUP-ICU Samtykkelog \(skabelon\)](#) , #Fane 7.b (print and place in your Site Master File)

Date: 2017.03.10 at 4.00 pm

REMINDER: [Annual Safety report](#) , #Fane 4 (print and place in your Site Master File)

Date: 2017.03.10 at 3.00 pm

[News letter](#) , #Fane 13.f, 13'th News letter (print and place in your Site Master File)

Date: 2017.02.10 at 11.00 am

[News letter](#) , #Fane 13.f, 12'th News letter (print and place in your Site Master File)

Date: 2017.01.10 at 10.30 am

News letter , #Fane 13.f, 11'th News letter (print and place in your Site Master File)

Date: 2017.01.05 at 8.30 am

For Danish sites only:

Table of content for Site Master File

Nyt **Appendix 7** (7.2), #Fane 1.b

Korrigeret godkendelse VEK, #Fane 4.c

Deltager information **forsøgsværgeren, pårørende, patienten,**
Procedure for videregivelse af mundtlig deltagerinformation,
#Fane 7.a,

Samtykke patienten, Samtykke pårørende, Samtykke
forsøgsværger, Samtykke drejebog #Fane 7.b

(print and place in your Site Master File)

Date: 2016.12.06 at 11.10 am

News letter , #Fane 13.f, tenth News letter (print and place in your Site Master File)

Date: 2016.11.09 at 3.15 pm

News letter , #Fane 13.f, ninth News letter (print and place in your Site Master File)

Date: 2016.10.10 at 11.15 am

News letter , #Fane 13.f, eight News letter (print and place in your Site Master File)

Date: 2016.09.29 at 3.15 pm

Background, Screening and randomisation, Trial medication, Data entry, Withdrawal, SAR/SUSAR and unblinding, Information for nurses (in Danish), Discharge/transfer/death (*new paragraph*), #Fane 9.c.i-viii, and Table of contents, (print and place in site master file).

Date: 2016.09.23 at 12.45 am

Lommekort, #Fane 9.b.iv, and Folder for Læger, Plejepersonale, #Fane 9.b.v (Danish sites only), Leaflet for Clinicians, Nurses #Fane 9.b.v (print and place in Site Master File)

Date: 2016.09.14 at 1.15 pm

Appendix 7, #Fane 1.b (amendment)

Procedure for videregivelse...., Deltager-information forsøgsværger, Deltager-information pårørende, Deltager-information patienten, #Fane 7.a, (Danish sites only, print and place in Site Master File)

Samtykke patienten, Samtykke pårørende, Samtykke forsøgsværge, Samtykkelog (*new document*), Samtykke drejebog (*new document*), #Fane 7.b, (Danish sites only, print and place in Site Master File)

Approval from SST, Approval from VEK, Minutes from meeting with SST and VEK, #Fane 4.a and 4.c, (Danish sites only, print and place in Site Master File)

Date: 2016.09.12 at 12.30 am

News letter , #Fane 13.f, eight News letter (print and place in your Site Master File)

Date: 2016.08.30 at 2.30 pm

Contact list, #Fane 15.a, Contact list for GCP-units in DK (Danish sites only, print and place in Site Master File)

Date: 2016.08.17 at 12.00 am

News letter , #Fane 13.f, seventh News letter (print and place in your Site Master File)

Date: 2016.08.09 at 10.40 am

[Annual Safety Report](#), #Fane 4.f (new), [Table of Content](#) updated, # at top of Site Master File (print and place in your Site Master File)

Date: 2016.07.11 at 11.15 am

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

Date: 2016.06.20 at 3.10 pm

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

Date: 2016.05.10 at 2.40 pm

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

Date: 2016.04.15 at 1.40 pm

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

Date: 2016.03.08 at 10.45 am

Trial medication to notice board (English), website address corrected, #Fane 9.b (print and place in your Site Master File) [New version](#)

Date: 2016.03.07 at 1.45 pm

Danish Data Protection Agency , update, #Fane 4.d (in Danish only, print and place in your Site Master File) [New version](#)

Date: 2016.03.03 at 3.40 pm

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

Date: 2016.02.09 at 8.40

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

Date: 2016.01.19 at 11.30 am to 12.30 pm

Please notice, in the files below you need to replace the contact information at the end of the document with the contact information at your location (local site).

1. Information for Participant (#Fane 7.a. in Danish) has been changed from pdf- to word-format.

1. Deltager-information forsøgsværgen [New version](#)

2. Deltager-information pårørende [New version](#)

3. Deltager-information patienten [New version](#)

Date: 2016.01.07

1. CRF (#Fane 2) [New version](#)

2. SUP-ICU medication dispensing system in Danish (#Fane 9.b.i) [New version](#)

3. Educational materials (#Fane 9.c.iii) [New version](#)

4. Educational materials (#Fane 9.c.vii) in English [New](#)

5. Educational materials (#Fane 9.c.vii) in Danish [New version](#)