

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

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

**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 [forsøgsværgen](#), [pårørende](#), [patienten](#),  
[Procedure for videregivelse af mundtlig deltagerinformation](#),  
#Fane 7.a,**

**[Samtykke patienten](#), [Samtykke pårørende](#), [Samtykke forsøgsværge](#), [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 forsøgsværgen, 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\*](#)**