

AID-ICU LOG for new documents and/or new versions updated

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

Date: 2020.12.10 13:01 pm

Uploaded Presentation For Interim Meeting

Revised Trial Documents Layout

Uploaded Danish Version Of Information Til Sygeplejersker

Uploaded SAR/SUSAR Instructions Ver. 3

Date: 2020.11.11 At 11:15 Am

Uploaded Newsletters May/June/July And August/September/October

Date: 2020.03.10 at 12:57 pm

Uploaded Newsletter November/December 2019, Newsletter

January/February 2020 and Safety Report for 2019.

(print document(s) and place in your Site Master File)

Date: 2019.12.20 at 13:22 pm

Uploaded SOP Obtaining EQ-5D-5L #9avi

(print document(s) and place in your Site Master File)

Date: 2019.11.04 at 14:06 pm

Uploaded newsletter no. 7 #13f (print document(s) and place in your Site Master File)

Date: 2019.09.03 at 14.00 pm

Uploaded [Approval from Danish Ethics Committee #4b](#), [SOP Acute Hepatic Failure #9avi](#), [Newsletter no. 6 #13f](#) (print document(s) and place in your Site Master File)

Date: 2019.08.16 at 13.00 pm

Uploaded [Newsletter 4 and Newsletter 5 #13e](#)

Date: 2019.07.17 at 07.40 am

Updated [Protocol version 4.2 dated 7 June 2019](#) and #1a, [Approval from Danish Medicines Agency #4d](#)

Date: 2019.05.10 at 14.40 pm

Receipt of received safety report from [Danish Medicines Agency and Health Research Ethics #4d](#), Approval of 1. amendment Danish Dataprotection Agency (danish) #4c (print document(s) and place in your Site Master File)

Date: 2019.04.12 at 13.18 pm

Updated versions of [Pocket cards Læger ver. 5](#), [Pocket Cards Sygeplejersker ver. 4](#) (danish) #9bv and updated [Folder Læger ver. 2.0 \(danish\)](#), [Folder sygeplejerske ver. 2.0 \(danish\)](#) #9bv

Updated version of educational material on [Trial medication dispensation](#) #9ciii

(print document and place in your Site Master File)

Date: 2019.03.19 at 1.08 pm

1-year follow-up protocol cognitive function #1b and Newsletter_2 #13e and Newsletter_3 #13e

(print document and place in your Site Master File)

Date: 2019.03.19 at 1.08 pm

[1-year follow-up protocol cognitive function](#) #1b and [Newsletter 2](#) #13e and [Newsletter 3](#) #13e

(print document and place in your Site Master File)

Date: 2019.03.05 at 3.12 pm

Revised #13a [AID-ICU Steering Committee](#) (print document and place in your Site Master File)

Date: 2019.03.05 at 1.47 pm

Edit #13b [contact details of national investigators](#) (print document and place in your Site Master File)

Date: 2019.03.05 at 1.47 pm

Edit #13b [contact details of national investigators](#) (print document(s) and place in your Site Master File)

Date: 2019.01.24 at 12.54 am

[AID-ICU Case Money \(DKK\)](#) #6a

Date: 2019.01.08 at 14.05 pm

[Annual Safety Report 2018 #4f](#) (print document(s) and place in your Site Master File)

Date: 2018.12.12 at 10.31 am

**[Revideret Godkendelse fra Datatilsynet #4c](#) and [Lommekort Læger v4 #9b](#)
(print document(s) and place in your Site Master File)**

Date: 2018.12.11 at 12.55 pm

[AID-ICU Protocol 4.1 #1b](#) and Approval of Protocol 4.1 from [Danish Medicine Agency #4a](#) and [Danish Committee on Health Research Ethics #4b](#) (print document(s) and place in your Site Master File)

Date: 2018.11.30 at 14.20 pm

[AID-ICU Trial Medication #9a](#) and [1 Newsletter #13e](#) (print document(s) and place in your Site Master File)

Date: 2018.11.27 at 16.10 pm

**[Delegation- and signature-log v.1.2 #3a](#) and [Opgavefordelingsliste v.1.2 #3a](#)
and [Forsøgspersoners Rettigheder 2018 #7a](#)**

(print document(s) and place in your Site Master File)

Date: 2018.11.30 at 14.20 pm

[AID-ICU Trial Medication #9a](#) and [1 Newsletter #13e](#) (print document(s) and place in your Site Master File)

Date: 2018.11.27 at 16.10 pm

**[Delegation- and signature-log v.1.2 #3a](#) and [Opgavefordelingsliste v.1.2 #3a](#)
and [Forsøgspersoners Rettigheder 2018 #7a](#)**

(print document(s) and place in your Site Master File)

Date: 2018.11.15 at 12.45 pm

**Patient information template (english)_v2 #7a and Table of Content updated
(print document(s) and place in your Site Master File)**

Date: 2018.11.09 at 13.45 pm

[Samtykke-log template v2.0_09Nov2018.xlsx #7b](#) (print document(s) and place in your Site Master File)

Date: 2018.11.09 at 11.34 pm

[Approved amendment 'Protocol follow-up EQ-5D-5L #1.b](#) (print document(s) and place in your Site Master File)

Date: 2018.10.31 at 4.00 pm

[Protocol version 4.0 #1.a](#), **[SOPs #9.vi](#)** and **[Table of Content](#)** (print document(s) and place in your Site Master File)

Date: 2018.09.28 at 1.30 pm

[Drug disposal form #10.c](#) (print document(s) and place in your Site Master File)

Date: 2018.09.26 at 5.00 pm

Deltager information **[patienten, pårørende, forsøgsværge #7.a](#)**, **[Co-enrolment list #8.a](#)**, Lommekort for **[læger og sygeplejersker](#)** (for Danes only) #9.b.iv, and **[Sign for bed #9.b.vi](#)** (print document(s) and place in your Site Master File)

Date: 2018.09.20 at 8.45 am

[eCRF Baseline #2](#) (print document(s) and place in your Site Master File)

Date: 2018.09.14 at 5.20 pm

[eCRF Discharge form #2](#), **[SAR/SUSAR #9.a.v](#)**, and **[SAR/SUSAR report form #14](#)** (print document(s) and place in your Site Master File)

Date: 2018.09.12 at 5.15 pm

[Guideline to notes and discrepancies in OpenClinica](#) (in Danish click **[here](#)**) #2, **[CV template](#)** (Danish only), #3.c (print document(s) and place in your Site Master File)

Date: 2018.09.11 at 1.45 pm

[Protocol amendment](#) (for Danes only) #1.b., **[Collaboration agreement between Sponsor and site #5.a](#)**, Lommekort for **[læger og sygeplejersker](#)** (for Danes only) #9.b.iv, **[Contact information for GCP](#)** (for Danes only) #15.d, **[Table of content](#)** (print document(s) and place in your Site Master File)

Date: 2018.09.06 at 11.15 am

[The Danish Medicine Agency](#) (in Danish, the top three documents are new) #4.a, **[Videnskabsetisk komité](#)** (in Danish, the top two documents are new) #4.c. (print document(s) and place in your Site Master File)

Date: 2018.08.30 at 12.00 am

Approval of amendments from ethic committee has mistakenly been misplaced as amendments for the protocol - **There are no amendments for the protocol #1.b.**, and the amendments - [The committees on health research ethics](#) and [Den videnskabetiske komité](#) (in Danish) are moved to their right environment # 4.c. - apologize for the inconvenience.

Deltagerinformation [forsøgsværge](#), [pårørende](#) og [patienten](#) (in Danish) #7.a., [Samtykke drejebog](#) (in Danish) #7.b. (print document(s) and place in your Site Master File)

Date: 2018.07.26 at 2.45 pm

[Samtykke patienten](#), [Samtykke 1. forsøgsværge](#), [Samtykke 2. forsøgsværge](#), og [Samtykke pårørende](#) (all in Danish) #7.b and for national investigators only the .xml file for EudraCT is now available in "National Investigator Documents" (print document(s) and place in your Site Master File)

Date: 2018.07.02 at 9.15 am

[Lommekort](#) (in Danish) #9.b.iv (print document(s) and place in your Site Master File)

Date: 2018.06.20 at 1.00 pm

[Table of content](#), [Monitoring plan](#) (in English) and [Plan for data-verification](#) (in English) #15.d (print document(s) and place in your Site Master File)

Date: 2018.05.04 at 4.00 pm

[Table of content](#), CRF ([Screening](#), [Baseline](#), [Day form](#), [90 days follow-up](#), [1 year follow-up](#), [Discharge and readmission](#), [Withdrawal](#)) #2, [EudraCT](#) #4b, [Etisk komite](#) (Danish), #4.c, [Approval head of department](#) (in Danish [Tilladelse afdelingsledelsen](#)) #5.b, [Primay data source](#) (in Danish [Kildedata](#)) #12, [Contact details](#) #13.b, [Monitoreringsplan](#) (Danish) #15.d (print document(s) and place in your Site Master File)

Date: 2018.04.24 at 3.40 pm

[Godkendelse af tillægsprotokol VEK](#), #4.c (in Danish) (print document(s) and place in your Site Master File)

Date: 2018.04.23 at 12.30 pm

AID-ICU trial documents are now accessible at the [homepage](#). Access to "Documents for National investigator" will still require a password to get

access (you may e-mail to contact@cric.nu to get password) (print document(s) and place in your Site Master File)