

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

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

**Date: 2021.03.24 18:31 pm**

**Uploaded updated Protocol ver. 4.3, Danish protocol ammendment version 5.0, approval of protocol 4.3 from Danish Medicines Agency and Comittee on Health Research Ethics, Updated EudraCT form, Updated version of 'Forsøgspersoners rettighsheder'.**

**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 videnskabsetiske 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](mailto:contact@cric.nu) to get password) (print document(s) and place in your Site Master File)**