

Table of Content (1 through 16) ([download](#))

Site specific = each site need to add their own local or national documents to some of the Site Master File sections.

Please see [LOG](#) for latest up-loads of new documents and/or new versions of documents in Site Master File

Short cut to:

- - [Instructions](#)
 - [Pocket cards and notice boards](#)
 - [Educational materials](#)

1) Protocol and trial synopsis

- a) [Approved protocol](#)
- b) Approved amendments
- c) [Trial synopsis](#)

2) [CRF](#) (for instruction, please see 9.a.iii)

3) Trial participants

- a) [Delegation- and signature-log](#) (in Danish click [here](#))
- b) [Training log](#)
- c) [Curriculum Vitae](#) for all personnel (template) (in Danish click [here](#))

4) Approvals and correspondence

- a) [The Danish Medicines Agency](#)
- b) [EudraCT](#)
- c) [The Committees on Health Research Ethics](#) (in Danish click [here](#))
- d) The Danish Data Protection Agency ([Datatilsynet](#))
- e) National and local approvals (*site specific*)
- f) Annual Safety Report

5) Collaboration agreement

- a) (To be announced)
- b) [Approval from head of department](#) (template) (in Danish click [here](#))
- c) Other relevant contracts (*site specific*)

6) Financial affairs

- a) [Case money](#) (template)
- b) Patient insurances (*site specific*)

7) Information to participants

- a) Patient information ([template](#)) (in Danish click [here](#))
- b) Consent forms (*site specific*) (in Danish [Samtykke skabelon](#), Samtykke log, [Samtykke drejebog](#))

8) Co-enrolment and substudies

- a) [Co-enrolment Form](#) (with access to Co-enrolment List)
- b) Quality criteria for substudies
- c) [Substudy proposal form](#) (template)

9) Trial documents

- a) Trial instructions
 - i) [Eligibility](#)
 - ii) [Screening and randomisation](#)
 - iii) [eCRF](#)
 - iv) [SUSAR](#)
- b) Pocket cards, documents for a notice board in the department
 - i) Oxygenation target for notice board (in Danish click here)
 - ii) Inclusion and exclusion criteria for notice board (in Danish click here)
 - iii) [Pocket cards](#) (in Danish click [here](#))

- iv) [Leaflet for all clinicians](#) (in Danish [Folder fagpersonale](#))
- v) Sign for bed
- vi) [FiO₂ conversion tables for open systems](#)
- vii) Identification log (drawn from the eCRF-system OpenClinica)
- c) Educational material (power point presentations)
- i) [Trial Initiation](#)

Background

Design and organisation

Screening and randomization

Adherence to oxygenation target

Trial withdrawal and SUSAR

Data entry

Discharge/transfer/death

Follow-up

- ii) Information for nurses (in Danish click [here](#))

10) Trial Medication

- a) [Summary of product characteristics](#) (in Danish click here for [Summary](#))

11) [Laboratory tests](#) (template)

- 12) [Primary data source](#) (in Danish click [here](#))

13) Communication

- a) HOT-ICU [Contact details](#) - [Steering Committee](#)
- b) Contact details - eight countries
- c) [Note to file send to Sponsor](#) (template)
- d) [Note to file received from Sponsor](#) (template)

e) Other correspondences between Sponsor and site(s) (*site specific*)

f) [News letters](#)

g) Investigator meeting

14) Suspected unexpected serious adverse reactions

a) [SUSAR form](#)

b) Standard operating procedure for SUSAR reporting (in Danish click [here](#))

c) Documentation for reporting of SUSAR (*site specific*)

15) GCP unit

a) Contacts (monitors/GCP units) (*site specific*) (in Danish click here)

b) [Monitoring visits](#) (template)

c) Monitoring reports (*site specific*)

d) [Monitoring plan](#) (in Danish click [here](#))

e) Approval of trial initiation (*site specific*)

f) Correspondence with the monitor (e.g. GCP-unit) (*site specific*)

16) Trial completion