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:

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) FiO_2 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

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