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, notice boards etc.
- Educational materials

1) Protocol and trial synopsis

a) Approved protocol

b) Approved amendments (no amendments at present)

c) Trial synopsis

2) CRF (for instruction, please see 9.a.iv.)

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 Medicine 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)*

5) Collaboration agreement

a) Collaboration agreement between Sponsor and site (template)

b) Approval from head of department (template)(in Danish click here)

c) Other relevant contracts *(site specific)*

6) Financial affairs

a) Case money

b) Patient insurances *(site specific)*

7) Information to participants

a) Patient information (template) (in Danish click here)

b) Consent form *(site specific)* (in Danish click here)

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) Trial medication

iv) eCRF

v) SAR/SUSAR

b) Pocket cards, documents for a notice board in the department

i) Trial medication for notice board (in Danish click here)

ii) Inclusion and exclusion criteria for notice board (in Danish click here)

iii) Trial synopsis for notice board

iv) Pocket cards (in Danish click here)

v) Leaflet for clinicians/nurses (in Danish læger/plejepersonale)

vi) Sign for bed

vii) Identification log (in Danish click here)

c) Educational material (power point presentations)

i) Initiation

ii) Screening and randomisation

iii) Trial medication dispensing (in Danish click here)

iv) Data entry

v) Withdrawal

vi) SAR/SUSAR and un-blinding

vii) Information for nurses (in Danish click here)

10) Trial Medication

a) Labels

b) Summary of product characteristics (in Danish click here)

c) Drug disposal form

d) Receipt of trial medication

e) Instruction for temperature logger

11) Laboratory tests (template)

12) Primary data source (in Danish click here)

13) Communication

a) Contact details - Steering Committee

b) Contact details - Denmark - Finland - Norway - UK - Italy - Spain - Germany

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) Serious adverse reactions ans suspected unexpected serious adverse reactions

a) SAR/SUSAR report form

b) Documentation for reporting of SAR/SUSAR *(site specific)*

15) GCP unit

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

b) Monitoring visits (template) (in Danish click here)

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