Table of Content (1 through 16) (download)

Site specific = each site need to add their own local or national document to the Site Master File

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: New Appendix 7 - replacing Appendix 7 in the approved protocol.

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 personnell (template) (in Danish click here)

4) Approvals and correspondence

a) The Danish Health and Medicines Authority (in Danish click here, Referat fra møde med SST og VEK)

b) EudraCT

c) The Committees on Health Research Ethics (in Danish click here, Vejledning fra National Videnskabsetisk Komité)

d) The Danish Data Protection Agency (Datatilsynet)

e) National and local approvals *(site specific)*

f) Annual Safety Report

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 Samtykke skabelon, Samtykkelog, 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) 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) Background

ii) Screening and randomisation

iii) Trial Medication

iv) Data entry

v) Withdrawal

vi) SAR/SUSAR and un-blinding

vii) Information for nurses (in Danish click here)

viii) Discharge/transfer/death

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

f) Drug transfer form (template)

11) Laboratory tests (template)

12) Primary data source (in Danish click here)

13) Communication

a) Contact details - Steering Committee

b) Contact details - Denmark - Finland - Netherlands - Norway - UK - Italy - Switzerland

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 and suspected unexpected serious adverse reactions

a) SAR/SUSAR 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