

# 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 and 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**