

Site Master File CLASSIC Table of content

1.	Protocol and trial synopsis
	a) Approved protocol
	b) Approved amendments
	c) Trial synopsis
2.	eCRF
3.	Trial participants
	a) Delegation-and signature log
	b) Training log
	c) Curriculum Vitae for all personnel
4.	Approvals and correspondence
	a) The Danish Medicine Agency
	b) EudraCT
	c) The Committees on Health Research Ethics
	d) The Danish Data Protection Agency
	e) National and local approvals
5.	Collaboration agreement
	a) Collaboration agreement between Sponsor and site
	b) Approval from head of department
	c) Other relevant contracts
6.	Financial affairs
	a) Case money
	b) Patient insurances
7.	Information to participants
	a) Trial information to patients and relatives
	b) Consent forms
8.	Co-enrolment and substudies
	a) Co-enrolment Form
	b) Quality criteria for substudies
	c) Substudy proposal form
9.	Trial documents
	a) Trial instructions
	i) Eligibility
	ii) Screening and randomisation
	iii) Trial medication, co-interventions and concomitant interventions
	iv) eCRF
	v) SAR/SUSAR

	b) Pocket cards, documents for a notice board in the department
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	i) Trial medication for notice board
	ii) Inclusion and exclusion criteria for notice board
	iii) Trial synopsis for notice board
	iv) Pocket cards
	v) Leaflet for clinicians/nurses
	vi) Sign for bed
	vii) Identification log
	c) Educational material (power point presentations)
	i) Initiation
	ii) Screening and randomisation
	iii) Trial medication dispensing [not applicable in CLASSIC]
	iv) Data entry
	v) Withdrawal
	vi) SAR/SUSAR and un-blinding
	vii) Information for nurses
10.	Trial Medication
	a) Labels [not applicable in CLASSIC]
	b) Summary of product characteristics
	c) Drug disposal form [not applicable in CLASSIC]
	d) Receipt of trial medication [not applicable in CLASSIC]
	e) Instruction for temperature logger [not applicable in CLASSIC]
11.	Laboratory tests [not applicable in CLASSIC]
12.	Primary data source
13.	Communication
	a) Contact details – Steering Committee
	b) Contact details – participating countries
	c) Note to file send to Sponsor
	d) Note to file received from Sponsor (template)
	e) Other correspondences between Sponsor and site(s) (site specific)
	f) News letters
	g) Investigator meeting
	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
15.	GCP unit
	a) Contacts (monitors/GCP units) (site specific)
	b) Monitoring visits
	c) Monitoring reports (site specific)
	d) Monitoring plan
	e) Approval of trial initiation (site specific)
	f) Correspondence with the monitor (e.g. GCP unit) (site specific)
16.	Trial completion
17.	Appendices
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