

Clinical Trial Outline Form

STUDY SYNOPSIS	
APPLICANT(S)/ COORDINATING INVESTIGATOR(S)	
STATISTICIAN	
TITLE OF STUDY / ACRONYM	
CONDITION	
HYPOTHESIS/OBJECTIVE(S)	
TRIAL TYPE (DFG PROPOSAL)	Interventional trial: [] Observational trial: [] If you have chosen an observational trial, please justify your decision briefly: ----- Key elements:
STUDY TYPE (BMBF PROPOSAL)	
INTERVENTION(S)/ TREATMENT PROCEDURES(S)	<u>Experimental intervention/index test:</u> <u>Control intervention/reference test:</u> <u>Duration of intervention per patient:</u> <u>Follow-up per patient:</u>
KEY INCLUSION AND EXCLUSION CRITERIA	<u>Key inclusion criteria:</u> <u>Key exclusion criteria:</u>
OUTCOME(S)	<u>Primary efficacy endpoint:</u> <u>Key secondary endpoint(s):</u> <u>Assessment of safety:</u>
STATISTICAL ANALYSIS	<u>Efficacy/test accuracy:</u> <u>Description of the primary efficacy/test accuracy analysis and population:</u>

	<u>Safety:</u> <u>Secondary endpoint(s):</u>
SAMPLE SIZE / SAMPLE SIZE CALCULATION	<u>To be assessed for eligibility: n =</u> <u>To be allocated to trial: n =</u> <u>To be analysed: n =</u> Alpha (e.g. 0.05) = Beta (1-beta=power) = Delta (relevant clinical difference) = Variance (e.g. pooled standard deviation) =
TRIAL DURATION	<u>Time for preparation of the trial (months):</u> <u>First patient in to last patient out (months):</u> <u>Duration of the entire trial (months):</u> <u>Recruitment period (months):</u>
PARTICIPATING CENTRES	<u>No. of centres to be involved:</u> <u>Names of cities and centres:</u>

1. MEDICAL PROBLEM AND RELEVANCE

1.1 PREVALENCE, INCIDENCE, MORTALITY

1.2 BURDEN OF THE DISEASE

1.3 IMPROVEMENT OF THERAPY/IMPACT OF THE TRIAL

1.4 PATIENT INVOLVEMENT

2. EVIDENCE

2.1 SEARCH STRATEGY

3. PATIENT`S SCHEDULE (VISITS)²

Figure. Example template of recommended content for the schedule of enrolment, interventions, and assessments.*

	STUDY PERIOD							
	Enrolment	Allocation	Post-allocation				Close-out	
TIMEPOINT**	$-t_1$	0	t_1	t_2	t_3	t_4	<i>etc.</i>	t_x
ENROLMENT:								
Eligibility screen	X							
Informed consent	X							
Allocation		X						
INTERVENTIONS:								
[<i>Intervention A</i>]								

[Intervention B]								
ASSESSMENTS:								
[List baseline variables]	X	X						
[List outcome variables]				X		X	etc.	X
[List other data variables]			X	X	X	X	etc.	X

*Recommended content can be displayed using various schematic formats. See SPIRIT 2013 Explanation and Elaboration for examples from protocols.

**List specific points of time in this row.

¹ BMBF

² <http://www.spirit-statement.org/schedule-of-enrolment-interventions-and-assessments/>