

Clinical Trial PROTOCOL REVIEW Checklist - BIOSTATISTICS

Study no, abbreviation	
Protocol title	
Version no. and date	
Sponsor-Investigator (PI)	
Sponsor	
Study Statistician	

Required Elements		Yes	No	NA	If No, specify action taken or comment
1.	Title is clear and descriptive	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2.	A trial schema is included and is clear and concise	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.	The schedule of assessments table contains all required baseline, treatment/intervention, safety and endpoint data (and nothing else)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.	The hypotheses of the trial are clear and concise, if applicable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5.	The objectives of the trial are clear, concise and measurable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6.	The endpoints/outcomes of the trial are clear, appropriate and measurable (and a time point is specified)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
7.	The eligibility criteria are internally consistent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8.	Recruitment strategy/sampling details are provided (e.g. number of study sites)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
9.	Detail is provided on how informed consent will be obtained	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
10.	The number of study arms is clearly specified	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
11.	The treatment/intervention details (what and when) are clear for all arms of the trial (including the control arm)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
12.	There is a clear description of the study design (e.g. parallel arm, crossover, etc.) and the study design is appropriate to address the objectives	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
13.	Randomisation details are clear and appropriate (allocation ratio, how sequence is generated, stratification, minimisation, blocked randomisation, level of randomisation)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Required Elements		Yes	No	NA	If No, specify action taken or comment
	[individual/ cluster]). If the trial is not randomised the decision is justified				
14.	The blinding and unblinding details are clear and appropriate, including how to deal with data collected during the trial that may have the potential to unblind (e.g. concentration of lab parameters). If the trial is not blinded the decision is justified	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
15.	Timing of follow-up assessments and the data collected at each assessment is clear	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
16.	The protocol states that participants are to be followed to the end of trial if off study intervention (and if not, it is justified and appropriate). The plans for handling treatment discontinuation and withdrawal are clear and appropriate.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
17.	Study duration per participant is clear (screening and follow up)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
18.	The sample size is clear, appropriate and justified; including justification for assumptions and enough details on calculation of sample size to repeat the calculation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
19.	The analysis populations for each of the objectives (e.g. all randomised participants, all treated participants, all eligible participants) is stated. If a per protocol analysis is included, specify what steps are taken to reduce bias in this analysis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
20.	Analyses are specified for each of the study objectives, and the statistical methods to be employed are appropriate. If an interim analysis is planned details are provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
21.	Replacement of participants is covered in the protocol and is appropriate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
22.	Procedure for accounting for missing data is stated and appropriate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
23.	Procedure for reporting any deviations from the original statistical plan or protocol is stated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
24.	Study stopping rules (early termination criteria) are clear and appropriate (including the role of a data and safety monitoring board in relation to these rules)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
25.	Pre-specification of any subgroup analyses or a statement that there are no planned subgroup analyses	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Required Elements		Yes	No	NA	If No, specify action taken or comment
26.	Information about safety monitoring e.g. a data and safety monitoring board is provided, or if not there is a justification for why this is not needed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
27.	Information is provided about data storage (who has access, where and how long data are stored)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
28.	Procedure for accounting for inflation of the Type I error as a result of multiple testing is stated and appropriate (if applicable)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	