Clinical study guidelines (interventional study)

Please provide a brief description of your interventional clinical study, based on the headings below:

1. Study design
Describe the study design including methods of randomisation, allocation concealment, masking, types of analysis (intention to treat, per protocol).

2. Study population
Describe the inclusion and exclusion criteria.

3. Proposed interventions
Include both experimental and control/comparator interventions.

4. Duration of treatment

5. Outcome measures
Describe primary and secondary outcomes measures. Explain how the outcomes will be measured.

6. Follow up
Provide details of frequency and duration of follow up.

7. Proposed sample size
Specify the number of participants and centres (including both control and treatment groups).

8. Power calculations
Give details of the estimated effect size, power and/or precision employed in the calculation. Justify the estimated effect size and the assumptions underlying the sample size calculations.

9. Compliance and loss to follow up
Provide details of any anticipated problems with compliance and explain how these will be dealt with.

10. Planned subgroup analysis
Describe any planned subgroup analysis.

11. Bias
Identify potential sources of bias and explain the methods used for protecting against such bias.

12. Statistical analysis
State the purpose, proposed type and frequency of any statistical analyses, including the selection of participants to be included in the analyses.

13. Potential risks and hazards

Outline the potential risks to participants and how they are being minimised.

14. Early stopping

Outline the plans in place for early stopping of the trial.

15. Flow diagram

Please include a flow diagram (single-side of A4) for submission with your application form. This should illustrate the study design and the flow of participants. Applicants should describe complex interventions and controls accurately and in full within their diagram. If proposing a randomised control trial (RCT), we advise that you refer to the CONSORT statement website for guidance.

16. Project timetable including recruitment rate

- Describe how recruitment will be organised and the time period over which it will take place.

- Provide evidence that the planned recruitment rate is achievable. Please include the following information:
    - the process for identifying potentially eligible participants
    - the proportion of potentially eligible participants who will fulfil the inclusion/exclusion criteria
    - estimated consent rates
    - details of ongoing studies that are competing for the same group of participants or whose results may affect recruitment
    - results of any pilot study indicating that planned recruitment targets can be achieved.

- Provide a timeline for the study.

17. Trial logistics and management

- Describe the roles of the study team members: outline the contribution each team member will make towards the project, including the role of any CTU member.

- Trial Steering Committee (TSC): a TSC should be set up for all multicentre studies. The membership should include an **independent** chairperson (not involved directly with the study other than as a member of the Steering Committee) and a BHF representative as an observer. Please list the proposed members of the TSC and their job titles.

- Data Monitoring Committee (DMC) members. The Sponsor should complete a risk assessment to determine the need for a DMC; if required this should be constituted. Please list the proposed members of the DMC and their job titles.