Clinical study guidelines (observational study)

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

1. Study design
Describe the study design proposed.

2. Study population
Describe the inclusion and exclusion criteria. Include details of the source of the study population – for example, is the population a random sample from the larger population or are study participants obtained from a disease register?

3. Measures of exposure
Describe the main exposures of interest and how they will be assessed if appropriate.

4. Confounding factors
Describe the main anticipated confounding factors, how they will be measured and any proposed adjustment for confounders.

5. Outcome measures
Describe primary and secondary outcomes measures. Explain how 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 in the case of multi-centre studies.

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. Loss to follow up
Provide details of any anticipated loss to follow up 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. Data access
Describe the data access arrangements.

14. Data and sample storage
Describe the processes for data and sample storage and archiving.

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.

16. Project timetable including recruitment rate
- Describe how recruitment will be organised, the time period over which it will take place, and 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. Describe the roles of the study team members
Outline the contribution each team member will make towards the project.