

[Supplementary file 6. Short description of the independent Data Safety and Monitoring Committee \(DSMC\)](#)

Introduction

This Charter defines the primary responsibilities for the independent Data safety and monitoring Committee (DSMC) of the randomised clinical trial DanAF. This includes the relationships with other aspects of the trial.

Primary responsibility of the DSMC

The DSMC will ensure the safety of trial participants. This will be achieved by the following tasks:

- Performing planned analyses of outcomes related to the safety of participants from the two rate control strategies during the trial.
- Continuously monitoring if the trial still holds scientific merit

Members of the DSMC

The exact composition of the DSMC will be specified later but is expected to consist of two clinicians and one person with adequate statistical knowledge to conduct the interim analysis. One member will be chosen as the committee chair.

Recommendations are recommended to be anonymous. However, in case of members not coming to an agreement, members will vote. The points of discussion will be part of the discussion of the DSMC report to the Steering Committee (SC). The members of the DSMC will be free of conflicts of interest. Assessment if members are free of conflict of interest will be decided by the SC.

Meetings

This is the initial DSMC charter. The final charter will be determined and signed as the last part of the first meeting of the DSMC (see below).

1. Meeting

The first meeting will be a finalization of the DSMC role during the trial. The following will be agreed on and finalized.

- How DSMC can request additional (unblinded) data
- How meetings will be held (virtually, physical meeting, phone)
- How many meetings are necessary.
- Decision on whether a test run is necessary.
- Finally, the charter will be finalised and signed.

2. meeting

The second meeting will take place as part of an interim analysis after 50% of the participants (n=175) have been recruited.

The DSMC will be allowed to conduct additional interim analyses independently of the SC. The following meeting may take place virtually, in person or by phone.

Communication

Different formats will be used in order to secure proper communication is established. The formats include open and closed reports as well as open and closed sessions.

Closed Sessions

These sessions will involve only DSMC members. Discussions will be based on a closed report that will be based on blinded data provided by the data manager. A single member will be in charge of preparing the report but may receive input from the other two members before finalizing the closed report.

If the DSMC deems it necessary, they may ask for unblinding of the data from the steering committee.

Data for review will be the composite outcome all-cause mortality, stroke, myocardial infarction and cardiac arrest mortality (and its individual components), serious adverse events including any serious adverse reactions.

Recommendations to the steering committee (open report)

The DSMC will report its recommendations to the SC based on safety considerations. If the DSMC recommends anything other than continuing the trial, there will be held a virtual meeting between the DSMC and the SC. The DSMC will here present the reasoning behind its recommendations.

The SC ultimately makes the decisions regarding all aspects of the trial.

Data

The DSMC will be provided with data on the following variables

1. Randomisation code (this will not reveal the allocated heart rate target)
2. The composite outcome of all-cause mortality, stroke, myocardial infarction and cardiac arrest and the individual components:
 - a. All-cause mortality
 - b. Stroke
 - c. Myocardial infarction
 - d. Cardiac arrest
3. Serious adverse events including subcategories of individual events
4. Numbers of participants lost to follow up

The DSMC will not be provided with data on site or any identifier the data is considered anonymized.

Analyses

The DSMC is recommended to use Lan-DeMets sequential monitoring boundaries.

Meta data

The DSMC will be provided with a detailed codebook that explains all the coding in the data set.