

DATA MONITORING AND ETHICS COMMITTEE (DMEC)

The main features of the DMEC are as follows:

- It is the only body involved in a trial that has access to the unblinded comparative data.
- The role of its members is to monitor these data and make recommendations to the TSC on whether there any ethical or safety reasons why the trial should not continue.
- The safety, rights and well-being of the trial participants are paramount.
- The DMEC considers the need for any interim analysis advising the TSC regarding the release of data and/or information.
- The DMEC may be asked by the TSC, Trial Sponsor or Trial Funder to consider data emerging from other related studies.
- If funding is required above the level originally requested, the DMEC may be asked by the Chief Investigator, TSC, Trial Sponsor or Trial Funder to provide advice and, where appropriate, information on the data gathered to date in a way that will not compromise the trial.
- Membership of the DMEC should be completely independent¹, small (3 – 4 members) and comprise experts in the field, eg, a clinician with experience in the relevant area and an expert trial statistician.
- Responsibility for calling and organising DMEC meetings lies with the Chief Investigator, in association with the Chair of the DMEC. The project team should provide the DMEC with a comprehensive report, the content of which should be agreed in advance by the Chair of the DMEC.
- The DMEC should meet at least annually, or more often as appropriate, and meetings should be timed so that reports can be fed into the TSC.

¹ Independence, in respect of the DMEC, is defined as independent from the Chief Investigator, TSC and Host Institution.