**Associated Document 1: Further guidance for Trial Committees**

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# **Data Monitoring Committee:**

An Independent Data Monitoring Committee (DMC) -group also referred to as Data Monitoring and Ethics Committee (DMEC), Data Safety and Monitoring Committee (DSMC), or Data Safety and Monitoring Board (DSMB) - is a group of experts independent of the study team who review accumulating data from an on-going clinical trial. Definitions of what constitutes independence vary, but members should not be hold a position where they could be seen to be exposed to undue influence of the trial team. The broad remit of a DMC is to safeguard the interests of the study participants, as well as future patients whose care may be influenced by the trial findings. The DMC will monitor the safety and the treatment efficacy of the interventions during the study. The DMC is not necessary for all studies, it is the TSC decision. may also assess other aspects of a clinical trial such as efficacy, study integrity, design aspects, recruitment and some ethical considerations (such as early analysis and publication). In general a DMC is required when a trial is randomised, and the trial team should not access data which gives any insight into the potential findings until the trial is complete. In addition to providing independent advice on safety and efficacy, the DMC ensures the blinding of the research team to the interim trial findings. Rather than making decisions, the DMC makes recommendations to the Trial Steering Committee, which may include recommending the termination of a study for safety reasons, due to evidence of the studies futility, or the studies overwhelming statically proven benefit. The DMC usually includes at least one clinician with relevant expertise and at least one statistician.

# **Trial Steering Committee:**

A TSC provides overall study supervision and advice through its Independent Chair (see note above on independence), on behalf of the trial sponsor and/or the funder. Its role is to ensure that the study is conducted in accordance with the protocol, Good Clinical Practice (GCP), and relevant regulations. The TSC should include members who are independent of the study investigators, their employing organisations, funders, and sponsor. Rules on TSC membership vary but in general, it is helpful for the majority of voting members to be independent. The TSC concentrates on the progress of the study, adherence to the protocol, patient welfare, and considers new information of relevance to the research question. The TSC may meet at the beginning of the study to approve the final protocol and, once active, considers any new relevant information, including recommendations from the DMC or results from other studies. Based on any such information, the TSC may make recommendations to change the trial documents (i.e. the protocol or patient documents) or to stop or extend the trial. Where the sponsor and protocol permit, the TSC may consider requests to publish data before the end of study. All studies require a TSC.

# **Independent:**

The Chair should not be an employee of Barts Health or Queen Mary. They should not be named on any funding application associated with the study and should not have been involved in the study design or study planning stages. They should not be colleagues or close research collaborators of the trial team. See guidance for more

# **Independent (in relation to the statistician for TSC and DMC):**

For selected studies, it may be considered acceptable for the independent statistician to be an employee of Queen Mary or Barts Health, but they should not be directly related or involved with the study design or funding application, the day to day running of the study, or its final analysis, and so cannot be the named study statistician. It is acceptable to contract a suitably qualified statistician to perform this role.

# **Charter:**

A document which describes the role and function of the committee. The charter (also referred to as the “Terms of Reference”) should also cover the committee’s membership and quorum, how often it meets, how decisions are reached and whether they are “advisory” (which is the norm) or “executive”. The charter will make clear the need for confidentiality, the liability of the committee members, and the obligation to declare any conflicts of interests. The members of the committee will formally register their assent by confirming that they agree to be on the committee, and that they agree with the contents of the charter.

# **Trial Management Group Remit**

**Study Title:**

**Chief Investigator:**

**Study Sponsor:**

**Sponsor Reference:**

TMG Members:

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Role | Institution | Contact Details |
| (Chair) | CI |  |  |
|  | Trial Statistician |  |  |
| *Add more rows as applicable* |

TMG Role:

For this study the TMG will:

* Oversee the day to day running of the trial, ensuring that the trial is running to timelines and budget
* Ensure all trial procedures are adhered to at sites
* Ensure all trial management activities are adhered to at the coordinating centre (including, but not limited to: documentation, monitoring, data management, statistical analysis etc)
* Insert any study specific roles

TMG Meetings:

The TMG will meet every <<insert>> months at a minimum.

The TMG may be convened in the event of any safety concerns raised by the trial.

TMG Meetings will be by teleconference of face-to-face.

The following information will be provided in advance of each TMG Meeting:

* Participating sites update (in set-up, open, closed)
* Recruitment update (screened, enrolled, withdrawn, completed, deaths)
* Safety (SAE and SUSAR line listings)
* Updates from TSC and DMC Meetings
* Annual reports (MHRA, REC, Study Funders)
* Data (quality, missing data) and study database
* Upcoming analyses
* Monitoring (as per monitoring plan, issues)
* Study documentation (amendments)
* IMP changes/updates (updates from supplier)
* Funding (status, updates)
* Study concerns Ie resources
* Insert any other study specific updates that will be provided

TMG Meetings will be documented by the XXX.