**Clinical Directorate Clinical Research Governance Team**

**Trial name**

**Trial Management Group**

**Terms of Reference**

**Version X.Y - dd/mm/yyyy**

**Guidance notes [delete before finalisation of the terms of reference].**

Please take care when completing this template and ensure all text is relevant to your proposed trial.

Some sections will not be applicable to all studies and some studies will require extra sections. The template has been provided with the below;

|  |  |  |
| --- | --- | --- |
| **Text** | **Purpose** | **Action to be taken** |
| Standardised Text | Provided by the University of Liverpool for organisational compliance | Review and ensure it applies to your study. Delete if not applicable and rewrite for your study. |
| Guidance notes | Provided for specific support, and where study specific information needs to be completed/updated | Reviewed and deleted once ToR is finalised. |

Please ensure to remove guidance notes as above, any TEMPLATE watermarks and ensure the Version Number and Date is present in the footer.

If you require any assistance please contact [sponsor@liverpool.ac.uk](mailto:sponsor@liverpool.ac.uk)

|  |  |
| --- | --- |
| **Trial Specific Information** | |
| **Trial Acronym:** |  |
| **Full Trial Name:** |  |
| **Protocol registrations (ISRCTN, EudraCT etc)** |  |
| **Sponsor:** |  |
| **Chief Investigator:** |  |

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## Introduction

The purpose of this document is to describe the membership, roles, responsibilities, authority, and decision-making processes for the Trial Management Group (TMG) for the xxx trial. This includes the timing of meetings, frequency and format of meetings and relationships with other trial committees.

TMG members should formally register their agreement to join the committee by confirming (1) that they agree to be a member of the TMG and (2) that they agree with the contents of this Terms of Reference. Any potential competing interests should be declared at the same time. Members should complete and return the form in Appendix 1.

Any observers must sign a confidentiality agreement on the first occasion they attend a meeting (Appendix 2) and **PRIOR** to receiving any meeting documentation (e.g. minutes of previous meetings, reports, etc.).

## Roles And Responsibilities

The broad remit of the TMG is to oversee the management of the trial including the day-to-day clinical and practical aspects.

**Specific roles**

The TMG are responsible for;

*amend as appropriate, the list is not extensive and should be adapted to address the specific needs of the trial:*

* Contributing to the methodological design of the trial
* Inputting into and comment on the protocol, data collection tools (e.g. case report forms (CRFs) and questionnaires) and other study documents
* Supporting applications for approvals to ethics committees and applicable regulatory agencies (e.g. MHRA)
* Promoting the trial
* Developing strategies to encourage recruitment and address any issues with recruitment that may arise at each trial centre
* Being involved in the day-to-day running of the trial by supporting the Chief Investigator (CI) and Trial Manager
* Providing clinical or other expert guidance to the insert responsible organisation/person and participating sites on trial-based matters such as clinical and practical queries and interpretation of information recorded on data collection tools
* Encouraging completion of the data collection documents and monitor reported data collection document completion rates
* Inputting into the meetings of the Trial Steering Committee (TSC), if appropriate
* Inputting into the meetings of the Independent Data and Safety Monitoring Committee (IDSMC), when appropriate (open sections only)
* Providing responses to any issues or concerns raised by the TSC and/or IDSMC
* Considering the implications of any recommendations made by the IDSMC and accepted by the TSC
* Being aware of accumulating external evidence and assess its impact and relevance to the trial
* Inputting into the development of the analysis and monitoring plans
* Inputting into the interpretation and writing up of the trial results
* Commenting to the TSC on external applications to use trial data

## Membership Of The TMG

The trial name TMG membership includes representatives from the following workstreams/organisations;

*amend as appropriate, the list is not extensive and should be adapted to address the specific needs of the trial*

* Chief Investigator (CI)
* Sponsor Representative
* Trial Management team members
* Statistics team members
* Data Management team members
* One or two site Principal Investigators
* Health Economist
* Trial Pharmacist

Additional individuals may be invited to attend a TMG meeting however they will not be considered formal members of the TMG and within the meeting there may be open and closed sessions.

Members of the TMG are detailed in the trial name Oversight Committee Membership Log.

**TMG Chair**

The Chief Investigator of the trial name trial will act as Chair. A vice-Chair will be appointed by the TMG to assume the responsibilities of the Chair when the Chair is not available.

## Organisation Of TMG Meetings

**Attendance**

Members should send apologies in advance of any meeting they cannot attend and provide any applicable updates/comments to the Trial Manager for consideration during the discussions.

If a member does not attend nor send a delegate or apologies for a meeting, every effort will be made to ensure their availability for the next meeting. If a member does not attend nor send a delegate or apologies for the following meeting and/or do not engage in discussions outside of the TMG meetings, they may be asked if they wish to remain part of the TMG.

Reasons for non-attendance will be discussed and additional meetings scheduled where required. If a member knows in advance that they are unlikely to be able to attend most meetings, replacement representation should be discussed and agreed with the TMG. This should be documented in the meeting minutes.

**Frequency of Meetings**

The frequency of the TMG meetings will be agreed by the TMG and documented within the ratified meeting minutes.

The frequency will depend on the demands of the different stages of the trial, for example the TMG may meet monthly in the first instance reducing to three monthly for the duration of the trial.

Other meetings may be arranged with TMG members and not termed as a TMG meeting.

**Format of Meetings**

Meetings will be held face-to-face or remotely such as videoconference or teleconference, whichever is more appropriate. The meetings will be organised by the Trial Manager or agreed delegate.

**Open versus closed sessions**

If any individuals who are not formal members of the TMG attend, the TMG meeting may be split into open and closed sessions.

Individuals who are not formal members of the TMG should not normally attend closed sessions. However, where this is agreed by the CI and Sponsor Representative, these individuals are required to sign a confidentiality agreement (see Appendix 2) **BEFORE** they attend any closed sessions, or receive any meeting documentation (e.g. meeting minutes from previous sessions, meeting reports, etc.).

## TMG Documentation

**Agenda & Minutes**

The TMG agenda and relevant supporting documents, including minutes of the previous meeting, will be circulated before the meeting to allow time for the review. The TMG Chair will decide how far in advance of meetings they wish to receive papers.

The Trial Manager or delegated other will be responsible for taking minutes of the meetings. The TMG Chair will be responsible for ratifying draft minutes.

**Reports**

The TMG will be provided with regular updates to include details of accrual, serious adverse events, CRF return rates, etc. The TMG members will not be privy to accumulating outcome measure data by trial arm; this will be reviewed by the Independent Data Safety Monitoring Committee (IDSMC) only.

The TMG Chair will decide the content of any reports and how far in advance of meetings they wish to receive papers. This may vary from meeting to meeting depending upon the stage of the trial and should be documented in meeting minutes.

**Confidentiality of Meeting Documentation**

TMG members and observers are required to securely store copies of the TMG reports, agendas and minutes, as well as copies of communications between meetings. All documentation should be considered confidential to those unconnected with the trial.

The insert responsible organisation/person will keep a central record of all agendas, minutes, reports and correspondence by trial committees in the Trial Master File (TMF).

## Decision Making

The TMG is responsible for overseeing the day-to-day running of the trial and can make decisions appropriate to this role. However, the TSC is the independent oversight body for the trial.

In some instances, it will be necessary for the TMG to refer to the TSC for example:

* Requests for additional interim analyses owing to concerns raised by external evidence;
* Stopping recruitment due to slow recruitment;
* Modifying target recruitment, or pre-analysis follow-up, based on any change to the assumptions underlying the original trial sample size calculation (but not on any emerging differences);
* Proposing substantial changes to the protocol, patient information sheet, eligibility criteria and other trial documentation;
* Request for endorsement for the early presentation of results;
* Request for endorsement for external data requests after the trial/study has closed;
* Request for sharing of trial/study samples.

The TMG may make decisions alone without referral to other committees in the following circumstances:

* Review of trial specific documents;
* Review of translated documents;
* Proposal of strategies for dealing with poor recruitment rates, data quality or compliance with CRFs and/or follow-up schedules according to consistency checks or site monitoring reports.

On all issues, every effort should be made to achieve consensus. The role of the Chair is to summarise discussions and encourage consensus; therefore, it is usually best for the Chair to give their own opinion last. It is important that the implications (e.g. ethical, statistical, practical or financial) for the trial be considered before any decision is made.

Any members absent from the TMG meeting should be made aware of any action points and any decisions made.

## Organisational Diagram

The TSC is the independent oversight body for the trial and must be composed of independent members. In addition to the independent members, the Chief Investigator will be a non-independent voting member.

The IDSMC is the independent body responsible for maintaining oversight of data quality and participant safety and must be composed of independent members. The IDSMC will be privy to unblinded data in their closed sessions. The IDSMC are advisory to the TSC.

Membership of the committees are detailed in the trial name Trial Oversight Committee Membership Log.

The following diagram shows the flow of information between the TMG and the other committees and functional areas involved in the trial.

*<please adapt diagram as required for your study>*

**IDSMC open report & recommendations**

**Report**

**TSC**

**Feedback**

**IDSMC**

**TSC**

**TMG**

**Questions/Feedback**

**Report**

**TSC**

**Feedback**

## Declaring Conflicts Of Interest

Members of the TMG should disclose potential competing interests (other than an intellectual involvement in the trial) which may be perceived by some as preventing them from making decisions to the benefit of the trial. Potential competing interests are not restricted to financial matters – involvement in other trials could be relevant. Although members may well be able to act objectively despite such connections, complete disclosure enhances credibility. This should be confirmed before accepting the invitation to join the TMG. Changes during the trial period should be notified to the Trial Manager.

## Appendix 1: Agreement and competing interests form for TMG members

**Trial name Trial Management Group: Agreement to join the Trial Management Group and disclosure of potential competing interests**

By signing below, I agree to the following statements:

1. I have read and understood the Trial name TMG Terms of Reference (version and date as per the foot of this page);
2. I agree to join the TMG for this trial;
3. I agree to treat all information and sensitive trial data and discussions confidentially.

The avoidance of any perception that members of a TMG may be biased in some fashion is important for the credibility of the decisions made by the TMG and for the integrity of the trial.

Potential competing interests should be disclosed via the insert responsible organisation/person. In many cases simple disclosure up front should be sufficient. Otherwise, the (potential) TMG member should remove the conflict or stop participating in the TMG. Table 1 lists potential competing interests.

|  |  |
| --- | --- |
|  | No, I have no potential competing interests to declare |
|  | Yes, I have potential competing interests to declare (please detail below) |
| Please provide details of any potential competing interests: | |
|  | |
|  | |

Table 1: Potential competing interests for members

|  |
| --- |
| * Stock ownership in any commercial companies involved |
| * Stock transaction in any commercial company involved (if previously holding stock) |
| * Consulting arrangements with the Sponsor/Funder |
| * Frequent speaking engagements on behalf of the intervention |
| * Intellectual conflict e.g. strong prior belief in the trial’s experimental arm |
| * Involvement in regulatory issues relevant to the trial procedures |

|  |  |
| --- | --- |
| Name: | Name of Institution: |
| Signed\*: | Date: |

*\*Signatures may be wet-ink or electronic (e.g. ADOBE Sign)*

**Once completed, please return completed appendix to trial email address.**

## Appendix 2: Confidentiality agreement for observers

**Trial name Trial Management Group: Agreement to attend the Trial Management Group and treat all information confidentially**

By signing below, I agree to the following statements:

1. I have read and understood the Trial name TMG Terms of Reference (version and date as per the foot of this page);
2. I agree to treat as confidential all information and documentation obtained by attending the Trial name TMG unless explicitly permitted otherwise.

|  |  |
| --- | --- |
| **Name:** | **Name of Institution:** |
| **Signed\*:** | **Date:** |

*\*Signatures may be wet-ink or electronic (e.g. DocuSign or Adobe Sign)*

**Once completed, please return completed appendix to trial email address.**