*Guidelines for preparing a Committee Charter:*

*All fields highlighted in yellow must be completed by the Trial Coordinator*

*All fields highlighted in green need to be amended for open-label or blinded studies.*

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| **STUDY TITLE**  **XXXXXXXXX Committee Charter** | |
| |  |  | | --- | --- | | Chief Investigator: | Insert | | Sponsor: | Insert | | Sponsor Reference: | Insert | | EudraCT Number: | Insert | | REC Reference: | Insert | | |
| *Property of XXXXXXXX,   May not be used, divulged, published, or otherwise disclosed without the consent of the Chief investigator* | |
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**Outline of scope of charter:**

The purpose of this document is to describe the roles and responsibilities of the DMC for the <<Insert Trial Name>> including the timing of meetings, methods of providing information to and from the XXC, frequency and format of meetings, statistical issues, and relationships with other committees.

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| **1. Introduction** | |
| Objectives of trial, including interventions being investigated | The primary objectives of this study are:  <<List objectives>>  The trial scheme is given in *Figure 1.* |
| Outline of scope of charter | The purpose of this document is to describe the roles and responsibilities of the XXC for the above trial. |
| **2. Roles and responsibilities** | |
| A broad statement of the aims of the committee | To safeguard the interests of trial participants, assess the safety and efficacy of the interventions during the trial, and monitor the overall conduct of the clinical trial.  Make recommendations to the <<Trial Management Group/CI >>.  The XXX is independent of, but reports to, the TMG |
| Terms of reference | The DMC should receive and review the progress of and accrual of data for this trial and provide advice on the conduct of the trial to the Trial Management Group.  The XXX should inform the Chair of the Management Group if, in their view:   * There are concerns about the safety of one or more of the treatment arms * The results show a benefit of one treatment arm over another that is so large, and statistically significant, that it is likely to convince a broad range of clinicians to change practice * It is evident that if the trial continued it would fail to show a clear benefit for any treatment arm * Accrual is so low that it is unlikely that a sufficient number of patients would be recruited to provide meaningful results |
| Documentation | Each XXX Member should provide to the Clinical Trial Coordinator:   * Signed confidentiality agreement * Signed competing interests form * Signed copy of this charter |
| Specific roles of XXX | Interim review of the trial’s progress to:   * Monitor evidence for treatment harm (e.g., toxicity data, SAEs, deaths) * Suggest additional data analyses (using blinded data where possible), for example, of main outcome measures, but only where this is relevant to the trial continuing or stopping early * Advise whether to recommend that the trial continues to recruit participants or whether recruitment should be terminated either for everyone or for some treatment groups and/or some participant subgroups * Monitor planned sample size assumptions and recommend amendment if appropriate * Monitor recruitment figures and losses to follow-up * Advise on major protocol modifications suggested by investigators or sponsors such as changing the main endpoints * Assessment of data quality, including completeness * Monitor compliance with the protocol by participants and investigators * Monitor continuing appropriateness of patient information * Consider the ethical implications of any recommendations made by the DMC * Assess the impact and relevance of external evidence |
| **3. Before or early in the trial** | |
| Input to the trial protocol | All potential XXX members will have sight of the protocol/outline before agreeing to join the committee. |
| Timing of first meeting | The XXX will meet either before the trial starts or within one year of recruitment commencing, to discuss the protocol, XXX Charter, analysis plan, and future meetings. |
| Regulatory implications | The XXX should be aware of any regulatory implications of their recommendations. |
| **4. Composition** | |
| List of DMC members | The members of the XXX for this trial are:   * List members   ***For open label studies:***  The Clinical Trial Coordinator will minute XXX meetings and file all XXX documentation in the TMF.  ***For blinded studies:***  The CI has appointed <<Insert Name>> to minute XXX closed meetings. |
| Choice of chair | The Chair for this XXX is: Insert Name |
| The responsibilities of the trial statistician | The trial statistician will produce (or oversee the production of) the report to the XXX and will participate in XXX meetings, guiding the XXX through the report, and participating in XXX discussions. In case of blinded studies, the closed section of the report will be produced by another statistician other than the trial statistician, if possible. The statistician producing the report will be attending the closed section of the XXX meeting instead of the trial statistician. |
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| The responsibilities of the Chief Investigator (CI) and other members of the Trial Management Group (TMG) | The CI may be asked to attend open sessions of the XXX meeting. Other TMG members will not usually attend but may attend open sessions when necessary. |
| **5. Organisation of** XXX **meetings** | |
| Expected frequency of XXX meetings | The frequency of meetings will depend upon the XXX and the progress of the trial. It is recommended that the XXX meet at least yearly, either face-to-face, or online. |
| Emergency meetings | An *ad hoc* emergency meeting may be arranged if important safety data comes to light that could have significant implications on the safety of trial participants. The Chair will call the meeting as normal, and the committee must still be quorate in order to make binding decisions. Committee members should exercise flexibility in ensuring that they can attend the urgent meeting. |
| How XXX meetings will be organised, especially regarding open and closed sessions, including who will be present in each session | ***For open label studies:***  All XXX meetings will be open and will be attended by theMembers of the XXX and the trial statistician, Chief Investigator, Principal Investigators and Clinical Trial Co-ordinator.  ***For blinded studies:***  Closed sessions: Members of the XXX.Open sessions: Members of the DMC and the trial statistician, Chief Investigator, Principal Investigators and Clinical Trial Co-ordinator.The format of the meetings will be:  1. Open session: Introduction and any “open” parts of the report  2. Closed session: XXX discussion of “closed” parts of the report  3. If necessary, further discussion with other attendees on any matters arising from the previous session(s). |
| Payments to XXX members | Members will be reimbursed for travel and accommodation if appropriate. |
| **6. Trial documentation and procedures to ensure confidentiality and proper communication** | |
| Intended content of material to be available in open sessions | Open sessions: Accumulating information relating to recruitment and data quality (e.g., data return rates, treatment compliance) will be presented. |
| Safety reporting requirements | *[Delete as appropriate]* All serious adverse events [and device deficiencies] will be reported to the DMC for their review *OR* the following safety data will be reported to the DMC for their review: (specify)  *[Delete as appropriate]* Individual safety events will be reported to the DMC as they are received OR tabulated safety data will be presented for review at committee meetings. |
| ***For blinded studies only:***  Intended content of material to be available in closed sessions | Closed sessions: In addition to all the material available in the open session, the closed session material will include safety data by treatment group. It may include efficacy data by treatment group, depending on the planned interim analysis. |
| ***For blinded studies only:***  XXX Blinding | Data reported by treatment group should be blinded where possible, unless the XXX requests otherwise. |
| Who will see the accumulating data and interim analysis? | ***For open label studies:***  All XXXMembers, the trial statistician, Chief Investigator, Principal Investigators and Clinical Trial Co-ordinator will have access to the accumulating data and interim analysis associated with safety and efficacy.  There may sometimes be a case for other members of the trial team to see the data on safety by treatment group.  ***For blinded studies:***  The only people who should see the accumulating data and interim analysis associated with safety and efficacy will be the members of the XXX and the Trial Statistician.  There may sometimes be a case for other members of the trial team to see the data on safety by treatment group.  XXX members including the CI do **not** have the right to share confidential information with anyone outside the XXX. |
| Who will be responsible for identifying and circulating external evidence (e.g., from other trials/ systematic reviews)? | Identification and circulation of external evidence (e.g., from other trials/ systematic reviews) will be collated by the CI and the Clinical Trial Coordinator. |
| To whom the XXX will communicate its report? | The XXX will report its recommendations in writing to the Trial Management Group, via the Trial Statistician or Clinical Trial Coordinator. |
| Whether reports to the XXX be available before the meeting | The XXX should receive the report from the Trial Statistician at least one week prior to the scheduled meeting. |
| What will happen to the papers after the meeting? | For open label studies:  The Clinical Trial Coordinator will be responsible for filing the papers in the TMF.  For blinded studies:  The XXX members should store the papers safely after each meeting so they can check the next report against them. After the trial is reported, the XXX members should destroy all interim reports. |
| **7. Decision making** | |
| What recommendations will be open to the XXX? | • No action needed; trial continues as planned  • Early stopping due, for example, to a clear benefit or harm of a treatment, futility, or external evidence  • Stopping recruitment within a subgroup  • Increasing the target sample size or extending follow-up  • Stopping a single arm of a multi-arm trial• Sanctioning and/or proposing protocol changes  • To review and agree any interim analysis plan |
| How decisions or recommendations will be reached within the XXX? | Every effort should be made for the XXX to reach a unanimous decision. If the XXX cannot achieve this, a vote may be taken. |
| When the XXX is quorate for decision-making? | All members should attend if possible. Members who cannot attend in person should be encouraged to attend by teleconference. If, at short notice, any XXX members cannot attend at all then the XXX may still meet if at least two members are present. It is important for the XXX statistician to be present at all meetings. The subsequent report, including any recommended major actions, should be reviewed, and approved by all members. |
| Input from XXX members who cannot attend the meeting | As the report is circulated one week before the meeting, XXX members who will not be able to attend the meeting may pass comments to the XXX Chair for consideration during the discussions. |
| What happens if members do not attend meetings? | If a member does not attend a meeting, it should be ensured that the member is available for the next meeting. If a member does not attend a second meeting, they should be asked if they wish to remain part of the XXX. If a member does not attend a third meeting, they should be replaced. |
| **8. Reporting** | |
| To whom will the XXX report their recommendations and in what form? | By letter or email to the Trial Management Group within 3 weeks. A copy of this will be lodged with the Clinical Trial Coordinator. |
| What will be done if there is disagreement between the XXX and the body to which it reports? | If there is a serious disagreement between the XXX and the body to which it reports, a meeting of these groups should be held. The information to be shown would depend upon the action proposed and the XXX’s concerns. Depending on the reason for the disagreement some confidential data might have to be revealed to all those attending such a meeting. The meeting should be chaired by an external expert who is not directly involved with the trial. |
| **9. After the trial** | |
| Publication of results | At the end of the trial, the XXX may request to examine the final data, and comment on data interpretation |
| The information about the XXX **(Applies to IDMC only)** that will be included in published trial reports | In case of confirmatory trials, IDMC members may be named, and their affiliations listed in the main report, unless they explicitly request otherwise |
| Any constraints on XXX members divulging information about their deliberations after the trial has been published | The XXX may not discuss issues arising from their involvement in the trial until at least 12 months after the primary trial results have been published. |

**Figure 1:**

**Trial Schema**

<<Insert Trial Schema>>

**Contacts:**

**Chief Investigator:**

Insert

**Clinical Trial Coordinator:**

Insert

**Trial Statistician:**

Insert

XXX **Members:**

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| --- | --- | --- | --- |
| **Expert** | **Role** | **Institution, City, Country** | **Contact Details** |
| (chair) |  |  |  |
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**Signature:**

I confirm that I am happy to sit on the XX Committee for the <<insert title>> trial and agree to abide by this charter whilst sitting on the committee.

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Name Signature Date

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Name Signature Date

*Insert as needed*