Data monitoring committee charter template

Author: Jonathan Jaeger

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This document is a template for a data monitoring committee charter. It contains the backbone structures and instructions to fill out the sections. This template is designed to cover, at minimum, the needs for a generic data monitoring committee charter. It can be adapted to cover safety review committee, data safety monitoring board and (independent) data monitoring committee. Instructions are in italic blue and hidden when document is printed out. Remove this front page before finalizing the document.

Company logo

Data monitoring committee charter

Instructions: Adapt title as relevant for safety review committee, data safety monitoring board or (independent) data monitoring committee).

|  |  |
| --- | --- |
| **Protocol title:** |  |
| **Protocol number:** |  |
| **Charter Version (date):** |  |
| **Sponsor:** | Company name  Address |
| **Emergency contact:** | Email: [xxx@companyname.com](mailto:xxx@companyname.com)  Telephone: +xx.xx.xxx.xx.xx |
| **EudraCT number:** |  |
| **IND number:** |  |

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Signature page

Instructions: Update signature page as relevant.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Signature 1** | | | | |
|  |  |  |  |  |
| **Name, Degree(s)**  **Title** |  | **Date** |  | **Signature** |
| **Signature 2** | | | | |
|  |  |  |  |  |
| **Name, Degree(s)**  **Title** |  | **Date** |  | **Signature** |
| **Signature 3** | | | | |
|  |  |  |  |  |
| **Name, Degree(s)**  **Title** |  | **Date** |  | **Signature** |

Charter amendment history

Instructions: Update document history as relevant.

Document history

|  |  |
| --- | --- |
| **Charter version** | **Date** |
| Amendment N | DD-Mmm-YYYY |
| Amendment N-1 | DD-Mmm-YYYY |
| … | DD-Mmm-YYYY |
| Amendment 1 | DD-Mmm-YYYY |
| Original | DD-Mmm-YYYY |

Amendment N (DD-Mmm-YYYY)

Amendment rationale

Changes to the previous version of the charter

Amendment N-1 (DD-Mmm-YYYY)

Amendment rationale

Changes to the previous version of the charter

Amendment 1 (DD-Mmm-YYYY)

Amendment rationale

Changes to the previous version of the charter

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List of abbreviations

Instructions: Update list of acronyms/abbreviations as relevant.

| **Acronym** | **Definition** |
| --- | --- |
|  |  |
|  |  |
|  |  |
|  |  |

# Introduction

This document is the charter for the {Instructions: Specify the type of committee} of the study {Instructions: Provide study code}, {Instructions: Provide study title}.

This committee is implemented to {Instruction: Specify the primary reasons for implementing this committee. For a standard data monitoring committee, the following text can be implemented: “assess the risk and potential benefit for the study participants during the study conduct, as well as ensuring the validity and credibility of the clinical study results”}.

This charter defines {Instructions: Update as relevant to be aligned with the type of committee}:

* the membership,
* the primary responsibilities of the committee,
* the relationship of the committee with other trial components,
* the purpose and timing of its meetings,
* the procedures for ensuring confidentiality and proper communication,
* the statistical monitoring guidelines to be implemented by the committee, and
* an outline of the content of the reports to be provided to/by the committee and of the recommendations to be provided by the committee.

# Membership of the committee

## Committee members

The committee members are {Instructions: Provide a generic description for the committee members. For (independent) data monitoring committee, the following text can be used: “experts independent from the sponsor, the steering committee, the contract research organization and other vendors involved in the study conduct”}.

The committee members are listed in Table 1.

Table - List of committee members

|  |  |  |
| --- | --- | --- |
| **Name, Degree(s)** | **Institution**  **City**  **Country** | **Phone**  **Email address** |
| **Committee chair** | | |
|  |  |  |
| **Member 1** | | |
|  |  |  |
| **Member 2** | | |
|  |  |  |
| **Statistician** | | |
|  |  |  |

## Conflict of interest

{Instructions: Adapt the section (or deleted) as necessary. For (independent) data monitoring committee, the following text can be used: “The committee membership has been restricted to individuals free of apparent (actual or potential) significant conflicts of interest. Conflict of interest includes without limitations:

* any financial relationship with the sponsor, including without limitation research grants, fees for services rendered and retainers for consulting services, but not including payments for participating to the committee,
* any financial relationship or scientific role with sponsors for any products that are being evaluated or that are competitive with those being evaluated,
* any financial arrangements that could be affected by the outcome of the clinical trial, or any other financial interest in the outcome of the clinical trial,
* potential to be providing clinical care for participants of the clinical trial, or
* potential to have regulatory responsibilities for the clinical trial product(s).

Certain other activities are not necessarily viewed as constituting unacceptable conflicts of interest, but have to be reported annually to the committee chair. Committee members have to disclose any consulting agreements or financial interests existing with the sponsor, the independent statistical data analysis, other vendor involved, or other sponsors having products that are being evaluated or having products that are competitive with those being evaluated in the clinical trial. Any committee members who develop significant conflicts of interest during the course of the clinical trial should resign from the committee.”}

# Responsibilities

## Responsibilities of the committee

{Instructions: Adapt the section as necessary. For (independent) data monitoring committee, the following text can be used: “The committee is established to provide an independent review and assessment of the accumulating safety and clinical activity data, and to safeguard the interests and safety of the clinical trial participants. The primary role of the committee is to provide recommendation to the sponsor about the continuation of the clinical trial based on the analysis of the available clinical trial data. In particular, the committee is responsible for:

* Contributing to the development of the charter and approving the charter,
* Reviewing the clinical trial protocol with specific attention to the safety and clinical activity monitoring procedures, the overall data collection methods, and making recommendation for additions or adjustments to the clinical trial conduct to the sponsor,
* Defining the safety and clinical activity parameters to be monitored, frequency of committee monitoring reviews, and methods for review,
* Reviewing in a timely and comprehensive manner the safety and clinical activity data report,
* Monitoring the clinical trial integrity and scientific credibility and advise the sponsor of potential concerns,
* Providing recommendations to the sponsor based on protocol-defined rules, including whether the trial should be terminated or continued, possibly with modifications. These modifications may include, but are not limited to, eligibility criteria, visit and assessment schedule, frequency of data monitoring, or other modification in the management of clinical trial participants.

In addition to the above-mentioned responsibilities, the committee chair will sign the charter, lead the open and closed session, organize the writing/review of and approve the minutes for the open and the closed session, and communicate to the sponsor the committee recommendations. In case of a replacement needed for a committee member, the committee chair will provide access to the minutes of all preview committee meeting.

In addition to the above-mentioned responsibilities, the statistician will provide statistical guidance to the other committee members in reviewing the safety and clinical activity reports.”}

## Responsibilities of the sponsor

{Instruction: Adapt as necessary. For independent data monitoring committee, the following text can be used: “ The sponsor is responsible for the following:

* Ensuring the completeness and the accuracy of all clinical trial data to be used for the safety and clinical activity monitoring,
* Making resources available to the committee as required to carry out its designated role,
* Creating and maintaining an independent statistical data analysis service provider, adequately separated from the sponsor and any other parties involved in the conduct of the clinical trial,
* Ensuring availability of material necessary for creating open and closed session report to the independent statistical data analysis service provider,
* Promptly informing the committee in writing of any new potential safety concerns that have become known, either from the study being monitored or from external data that have become available,
* Notifying the committee of any substantial amendment to the clinical trial protocol,
* Drafting, distributing for review, revising and archiving in the trial master file the open session minutes,
* Archiving in the trial master file the open session committee report,
* At the end of the clinical trial, ensuring the archive in the clinical trial master file of the closed session committee report and closed session minutes,
* Promptly reviewing the committee recommendations, sharing it with the steering committee and deciding whether to implement the committee recommendations.”}

## Responsibilities of the independent statistical data analysis service provider

{Instructions: Independent statistical data analysis service provider are only required for (independent data monitoring committee. Delete this section if not required.}

The independent statistical data analysis service provider is an entity independent of the sponsor or any other parties involved in the conduct of the clinical trial. It is composed by at least one statistician and one programmer, all free of conflict of interest. The independent statistical data analysis service provider is responsible for the following:

* Generating the open and closed session report,
* Attending (statistician only) and presenting data at the open and closed sessions,
* Addressing questions from the committee regarding the content of the open and closed session reports, and
* Providing ad hoc analysis as required.

## Responsibilities of other parties involved

{Instructions: Adapt as relevant. The following text can be used for (independent) data monitoring committee: “The clinical contract research organization is responsible for the following:

* Ensuring collection and monitoring of case report forms,
* Ensuring the completeness and the accuracy of all clinical trial data to be used for the safety and clinical activity monitoring, and
* Providing relevant programs for analysis datasets and output generation and access, when relevant, to unblinding elements.”}

# Procedure of the committee

## Trial integrity

{Instructions: This section is adapted for independent data monitoring committee. Delete as require.}

Any unblinded subject-level data and aggregate data will be generated by the independent statistical data analysis service provider. Access will remain restricted to the committee members until the last interim analysis potentially affecting the trial integrity.

## Committee report

{Instructions: This section is adapted for independent data monitoring committee. In case of other committee, closed session might not be required. Adapt the subsections accordingly to the type of committee.}

### Open session report

The open report will contain blinded information on recruitment, eligibility, protocol deviations/violations, baseline characteristics, disease characteristics, data completeness, and other study management related information. Unless any relevant safety signal is observed by the sponsor requiring the need to call for an unscheduled committee meeting, pooled safety or clinical activity information will not be part of the open report.

The committee members and the sponsor will receive the open report from the independent statistical data analysis service provider.

### Closed session report

The closed report will contain unblinded information on safety endpoints and, if applicable, selected clinical activity/efficacy endpoints. Content of the open report will also be provided by treatment group in the closed report.

Access to the closed report will be granted to the committee members only. The sponsor or other parties involved in the clinical trial conduct will not have access to the closed report until the clinical trial end.

## Schedule and purpose of the committee meetings

{Instructions: The section below is adapted for an independent data monitoring committee. Adapt accordingly. At least an organizational meeting, regular meeting and unscheduled meeting have to be set up.}

### Organizational meeting

All committee members, the statistician from the independent statistical data analysis service provider, and the sponsor representatives should attend the organizational meeting. The committee will be provided with the clinical trial protocol, the statistical analysis plan, the shells for the open and closed reports, the DMC charter, and any other relevant clinical trial document.

The organizational meeting will be held during the final stages of the protocol development with the following objectives:

* Gather advisory review of scientific and ethical issues related to study design and conduct,
* Discuss the roles and responsibilities of the committee, the independent statistical data analysis service provider, the sponsor, and other parties that will be involved in the clinical trial conduct, and
* Finalize the committee charter, the content of the open and closed session reports.

### Regular review meeting

Regular safety and trial integrity review meetings will be held every quarter. Open and closed report will be provided 7 days before the regular review meeting based on all available data. Only preserved data extract will be done for regular review meeting.

### Interim analysis review meeting

Interim analysis review meeting will be triggered based on the following conditions {Instructions: Describe the conditions for triggering an interim analysis review meeting. If needed, tabular formatting can be used.}.

Open and closed reports for interim analysis will be provided 7 days before the regular review meeting based on the totality of a locked database extract. Duration between the extract of the locked data and the production of the reports should not exceed 14 days.

### Unscheduled meeting

Unscheduled meeting might be organized in the following situation:

* At a scheduled meeting, the committee determines the need of a follow-up meeting. Such meeting may be scheduled without involvement of the sponsor, and
* Safety signals or external information would require the committee to evaluate the impact on the risk and potential benefit for clinical trial participants.

## Committee meetings and documentation

### Open session

an open session will be held between the closed session.

Content of the open report is specified in XXX. As the sponsor will be present during the open session, no unblinded information should be presented or discussed.

The open session minutes will be distributed by the sponsor to the committee members for review and will summarise the findings during the open session and the recommendation from the closed session discussions as to whether the clinical trial should continue as planned, be modified or terminated. The open session minutes will be signed by the committee chair and archived by the sponsor no later than 7 days after the meeting. These open session minutes must be devoid of any statements having the potential to compromise the integrity of the clinical trial.

### Closed session

Closed sessions will involve only the committee members and the statistician from the independent statistical data analysis provider.

During these sessions, unblinded data from the clinical trial, including information about the safety and, as applicable, the clinical activity/efficacy will be evaluated. Content of the closed report is specified in XXX.

The committee will develop consensus on its list of recommendations, including those related to the clinical trial continuation. A quorum, defined as {Instructions: Specify any criteria to define the minimum number of members to be present at the closed session.}, must attend the meeting to make any formal recommendations.

The closed session minutes will be distributed by the statistician from the independent statistical data analysis service provider to the committee members for review and will summarise the discussion of the unblinded data and other issues the committee wishes to document. The closed session minutes will be revised accordingly, signed by the committee chair and archived by the statistician from the independent statistical data analysis service provider no later than 7 days after the meeting. All minutes of the closed sessions will be provided to the sponsor at the earliest at the last interim analysis potentially affecting the trial integrity and at the latest at the conclusion of the clinical trial.

### Committee recommendation

The committee recommendations will primarily use the guidelines defined in this charter or the statistical analysis plan, as applicable. The committee will also make recommendations, as appropriate, regarding the conduct and management of the trial.

The committee chair will communicate the recommendation within 2 days to the sponsor by phone and/or in writing. Within 7 days after the meeting, the committee chair will additionally provide the sponsor with the committee recommendations document using the template in XXX.

The committee will not communicate directly with any regulatory bodies. Communications with regulatory agencies will be done by the sponsor.

# Statistical considerations for interim monitoring

## Clinical activity/efficacy

{Instructions: Describe the relevant considerations for any interim monitoring for efficacy. For the particular case of an interim analysis for efficacy, describe the condition for evaluation of efficacy, i.e., endpoint to consider, endpoint definition, high level information on the analysis methods, boundaries for stopping for efficacy and/or futility. In case of futility, specify if it is a binding or non-binding futility rule. It is recommended to refer to the statistical analysis plan to limit duplicated or conflicting information.}

## Safety

{Instructions: Describe the condition for evaluation of safety, i.e., endpoint to consider, endpoint definition, high level information on the analysis methods. If required, provided boundaries for hypothesis testing.}

# Appendices

{Instructions: The below appendices are applicable for independent data monitoring committee. Adapt accordingly to the committee of interest.}

* 1. Open report table of content

The following summaries will be provided in the open report:

* Information on patients screening,
* Study accrual by month and by institution,
* Demographics,
* Baseline disease characteristics,
* Baseline laboratory values and other measurements,
* Prior cancer therapy,
* Protocol deviations,
* Exposure,
* Participant intervention and study status,
* Attendance at scheduled visits,
* Retention of participants,
* Data management metrics of key data,
* Data management metrics on endpoints requiring adjudication (if relevant).
  1. Closed report table of content

The following summaries will be prepared and will be presented by treatment group in the closed report:

* Repeat of the open report information by intervention group
* As relevant, analyses of primary and secondary efficacy endpoints required by the interim analysis for efficacy
* Presentation of adverse events, including overall and by severity, and serious adverse events
* Analyses of safety laboratory parameters
  1. Committee recommendation

Dear {Instructions: Insert the sponsor’s representative name}

The committee has reviewed the {Instruction: Specify if safety and/or efficacy data have been reviewed} data collected up to {Instructions: Insert the cut-off date, in a format DD-Mmm-YYYY}.

Based on the review of the data, the committee recommends the following action(s) to be taken:

Continue the clinical trial as planned

Continue the clinical trial and implement the following modification:

Modification:

Reason:

Discontinue the clinical study

Reason:

Other recommendation or request from the committee

Recommendation/request:

Reason:

Sincerely,

{Instruction: Complete with committee chair name}

On behalf of the committee members

Cc: Committee members and the statistician from the independent statistical data analysis service provider