CHARTER FOR THE

INDEPENDENT DATA MONITORING COMMITTEE (IDMC)

Version [insert version number]

Protocol: [insert protocol number]

Title: [insert protocol name]

Charter approved by [insert sponsor name]:

| Full Name**:** | Signature:  | Date: |
| --- | --- | --- |
| [insert name of Sponsor representative][insert role of Sponsor representative]  |  |  |

IDMC Approved:

| Full Name**:** | Signature:  | Date: |
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# Purpose

The purpose of this charter is to describe the procedures that the IDMC will follow during its review of safety and tolerability *[and insert other protocol relevant outcomes as needed]* data for Study *[insert protocol number].* This study aims to establish the safety and tolerability [and *insert protocol relevant information]* in *[insert patient population information as described by protocol e.g. healthy volunteers or subjects with a particular condition]*.

# Responsibilities

The overall responsibility of the IDMC is to protect the ethical and safety interests of *[insert patient population information as described by protocol]* recruited into *[insert protocol number]* while protecting as far as possible the scientific validity of the data.

The IDMC will review the safety and tolerability *[and insert other protocol relevant outcomes as needed]* findings from *[insert patient population information as described by protocol]* recruited into *[insert protocol number]* study. *[Describe data analyses to be conducted]*.

A summary of IDMC responsibilities is as follows:

1. Review the IDMC Charter supplied by the Sponsor, make any recommendations for changes to the Sponsor, and agree and sign the Charter.
2. Review the current *[insert protocol number]* Investigator’s Brochure or *package insert/summary of product characteristics [if applicable]****.***
3. Agree the type of information needed for review during the study and the presentation format of those data.
4. Review the protocol to ensure that it adequately fulfils the needs for the IDMC data review.
5. Assess the *[relevant analyses]*
6. Identify and evaluate any emergent safety information.
7. Identify and alert the Sponsor of any emergent ethical issues.
8. Recommend continuation, modification or discontinuation of the study based on study data review. The IDMC members should evaluate safety (Appendix B) and *[insert study specific information]*, at the open session of the IDMC meeting; however, IDMC data evaluations and recommendations should not be limited by those predefined criteria.
9. Communicate and discuss the IDMC findings and recommendations with the Sponsor and Investigators in a manner that maintains the study blinding.

# Composition of the IDMC and quorum

The composition of the IDMC (names and affiliations of the committee members) is shown in Appendix A.

The IDMC should consist of at least 4 independent members (i.e. external to the study team and Sponsor): a physician who has participated in the design or monitoring of *[insert relevant phase of study]* safety studies, one or more physicians with local experience in the fields of *[insert study relevant fields]* who have preferably participated previously in *[insert relevant Phase of study where experience is needed]*, and a *[analysis relevant expert. e.g. statistician, pharmacometrician]*. A quorum of 3 committee members is required at scheduled meetings or at phone conferences, and must reach a consensus recommendation, usually by teleconference (i.e. each member must be able to live with the decision made and must be able to support it).

The IDMC also may convene an *ad-hoc* Advisory Committee should it deem it necessary for review of specific cases/safety concerns. In this case, the Sponsor must be notified prior to the next scheduled meeting and all *ad-hoc* members must sign a Sponsor confidentiality agreement prior to the meeting. *Ad-hoc* members would act as consultants with the particular expertise required by the presenting situation, but would not participate in the consensus decision.  *Ad-hoc* members cannot be principal / sub-investigators, nor can they knowingly administer medical care to a study *[insert patient population information as described by protocol e.g. volunteers].*

# CONDUCT OF IDMC MEETINGS

## Meeting format

The IDMC will convene for set-up, and *[define study relevant meeting timeline]*. Additional meetings may be scheduled if needed.

Meetings will consist of open and closed portions. During the initial open portion of a meeting, the Investigator(s) and Sponsor will be invited to provide an overview of the study results to date and be available for questions and for discussion.

The Sponsors and investigators will not attend closed portions of any meeting, unless agreed by the IDMC chair. Data review will generally be *[insert study relevant parameters e.g. blinded]*; if required, *[detail procedures when defined parameters may need to change and why]*.

## Data to be reviewed

The IDMC will review the following data in a *[define parameters e.g. blinded fashion]:*

* *[List important data that needs to be reviewed in order to adequately assess safety]*

The Sponsor will circulate the data (*[define data i.e. number of participants]*), to be reviewed to the IDMC members at least [timeframe] in advance of the meeting date.

## Meeting minutes

Recommendations of the IDMC should preferably be made by consensus rather than voting, and should ideally be made verbally to the Sponsor and investigators at the open session at end of the meeting. Should consensus not be reached, the number of members voting for each alternative recommendation will be reported and if evenly split, the most conservative approach should be taken. To vote, a committee member must be present at a meeting. No member may delegate his/her participation in case of absence. Sponsor staff will not participate in any voting. No *[stipulate who is not allowed to attend]*members may attend closed or voting portions of the meeting.

After each meeting, the elected IDMC secretary will distribute summary minutes to all IDMC members within [timeframe]. All IDMC members must review and approve the minutes via email within timeframe] of their being distributed to ensure that there is no delay in sending the IDMC recommendations to both the Sponsor and the investigators. At the end of the study or upon discontinuation of the study, a copy of all meeting minutes will be forwarded to the Sponsor for archive.

# Confidentiality

All members must have signed a Confidentiality Agreement with the Sponsor. In addition, members will treat as confidential the reports, meeting discussions, minutes, and recommendations of the IDMC.

# Conflict of Interest Guidelines

Members of the IDMC must declare the extent of any financial or other interests that could be affected by the outcome of the *[insert protocol number]* study. IDMC members should also declare minor conflicts of interest that are not thought to impede objectivity to all IDMC members. The IDMC chairperson will have the final say as to whether potential conflicts of interests might impede objectivity.

Committee members may not participate in *[insert protocol number]* the study as principal or co-investigators, or as study subject care physicians, nor can they knowingly administer medical care to a study *[insert patient population information as described by protocol e.g. volunteer].*

# Reimbursement

IDMC members will *[not be reimbursed or be]* reimbursed for their time as per the standard industry consultancy rate typically paid by the Sponsor, and for their travel expenses as per the Sponsor’s travel policy should a face-to-face meeting be required.

# Procedures for Communicating Recommendations to the Sponsor and Steering Committee

The IDMC chairperson will send the IDMC recommendations to the Sponsor and investigators by email within [timeframe] of the meeting. The Sponsor and investigator will both indicate their agreement and acceptance (or disagreement and rejection) of the proposed action in writing before the action is taken (for example before the next dose is prepared and administered).

Based on its review, the IDMC may recommend one of the following actions:

1. Continue the study according to the protocol.
2. Continue the study according to any recommended amendments
3. Continue the study but suggest modifications to the study protocol. Modifications may include, but are not limited to, changes in inclusion/exclusion criteria, changes to dosing, the frequency of safety monitoring, alterations in study procedures, and follow-up period for purposes of safety as defined in the protocol.
4. Pause or stop enrollment.
5. Discontinue the study (with provisions for orderly discontinuation in accordance with good clinical practice).

# Appendix A: IDMC committee members

| **Full Name**  | **Specialty** | **Affiliation** | **E-mail** |
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# Appendix B: Planned safety evaluationS *[protocol dependent]*

The investigators will monitor the *[insert patient population information as described by protocol]* closely as summarised in Appendix C. The Sponsor, investigators and IDMC will review emerging safety data summarised below, following completion of *[define period]* - in order to select the recommended *[define parameter needed e.g. dose]*. The objective of the *[supply relevant protocol specific objectives]* was defined in section *[insert relevant section of the protocol]* of the protocol. In addition to a summary of the *[define information needed]* of the *[insert patient population information as described by protocol]*, as well as any study drug discontinuation and study withdrawals, the following will be reported :

**B1. Line listing of adverse events (AEs):**

The investigator will report all clinical and laboratory AEs, noting duration, time of onset relative to dosing, severity, the investigator’s assessment of causality, and the action taken (if any). A more detailed narrative will accompany report of any serious adverse events (SAEs).

**B2. Laboratory safety investigations**

The investigator will report summaries of [biochemistry and haematology or other study-specific parameters] results as detailed below.

**B3. *[Other relevant safety or endpoint data investigations needed]***

*[Describe in detail tests needed and parameters]*

**B4. *[Other relevant safety or endpoint investigations needed]***

*[Describe in detail tests needed and parameters]*

**B5. *[Other relevant safety or endpoint data investigations needed]***

*[Describe in detail tests needed and parameters]*

# 12. Appendix C: *[study procedures for evaluated time periods]*