

<insert trial title>

Data Safety Monitoring Board (DSMB)

MEETING AGENDA

<insert MEETING DATE, TIME & VENUE>

Attendees:

- Voting members
- Non-Voting members
- Quorum - Determine whether DSMB member attendance meets quorum

Apologies:

1) Agenda for Open Meeting

1. DSMB member Conflicts of Interest (Col):

- a. Board Members to verbally confirm whether they have a financial or scientific conflict of interest which would affect their participation on the DSMB (this should be minuted; any declared Col should be actioned appropriately).

2. Review of minutes and recommendations from [insert last meeting date]

3. Discussion of open report

a. Summary of trial progress:

- i. Updates from the Sponsor-Investigator - include general statements about the progress of the trial (e.g., new sites, protocol changes), trial challenges, and scientific or therapeutic developments in the field that affect the research.
- ii. Participant recruitment, accrual and retention rates
- iii. Adherence to eligibility and exclusion criteria
- iv. Key protocol deviations
 1. Protocol deviations that exclude a participant from the per-protocol analysis*
 2. Serious breaches** (i.e. significantly affect or have the potential to significantly affect participant protection or the reliability of trial results)

** Researchers should indicate in the analysis plan section of the protocol which protocol deviations would exclude a participant from the per-protocol analysis (PPA). Examples of these could be: participant deemed ineligible, investigational product non-compliance (e.g. 'x' missed doses or % of missed dose), participant dispensed incorrect treatment arm, use of certain prohibited medications, 'x' visits outside permissible visit windows). During the trial, there may be uncertainty regarding the inclusion in the PPA of other deviations not already specified in the protocol; in such cases the decision to include/exclude the participant from the*

analysis must be made (and documented) before any analyses are commenced. Ideally, the decision around exclusion from the PPA is made by an independent committee.

Note that protocol deviations requiring exclusion from the PPA do not need to be reported to HREC unless they fit the definition of a Serious Breach.

*** In 2018, NHMRC adopted ICH GCP guidance aimed at streamline the reporting of deviations to reviewing bodies. The term 'deviation' is now used to describe any breach, divergence or departure from the requirements of Good Clinical Practice or the clinical trial protocol, whether minor or major (note that the term 'violation' has been widely to indicate major deviations but this term is no longer recommended). Although all protocol deviations should be captured in the database, only a small sub-set of these deviations should now be reported to reviewing bodes (i.e. those significantly affect or have the potential to significantly affect human subject protection or reliability of trial results). These deviations are termed these Serious Breaches. "Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods" (EH59, November 2018) available at <https://nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods#block-views-block-file-attachments-content-block-1>*

- b. Efficacy data (where appropriate)**
- c. Safety events**

2) Agenda for Closed Meeting *(where applicable)*

Attendees: *List*

- 1. Review of minutes and recommendations from** *[insert last meeting date]*
- 2. Discussion of closed report**
- 3. Discussion of Risk/Benefit ratio (where appropriate)**
- 4. DSMB Recommendations**
- 5. Timing of the next DSMB meeting(s)**