

# Do I need a Data Safety Monitoring Board in my Study?

## What is a DSMB and what is its role?

- A DSMB is a multidisciplinary group established by the trial sponsor to regularly review accumulating trial data, to monitor trial progress.
- Their role is to provide advice on safety and/or trial conduct issues by making recommendations to the sponsor, or the Trial Steering Committee (TSC), on whether to continue, modify or stop a trial for safety or ethical reasons.
- DSMBs make recommendations concerning the overall conduct of the trial. The DSMB's access to de-identified unblinded and often comparative data enables it to undertake a more comprehensive review.
- DSMBs play an important role in:
  - safeguarding the interests of participants
  - ensuring that definitive and valid results are produced which will reliably inform the future treatment of patients
  - enhancing the credibility of the trial

## When is a DSMB most likely to be set up?

- There is no single rule for what types of study require a DSMB, they are used most commonly in later phase trials that address major health outcomes such as mortality or progression of a serious disease and that are designed to definitively address efficacy and safety issues.
- They may also be convened when there is a significant risk of harm, or unknown or uncertain risks, so that regular interim, comparative analyses of the accumulating safety and efficacy data can be performed.
- DSMBs are therefore most likely to be used in trials where unblinded interim data analysis is necessary to ensure the safety of research participants.

## Does the DSMB need to be independent?

- One of the most significant characteristics of a DSMB is its ability to provide independent review of clinical trial data.
- Independence is greatest when members are not involved in the design and conduct of the trial, except through their role on the DSMB, and have no connections to the sponsor that could influence (or be perceived to influence) their objectivity in reviewing trial data.
- When establishing a DSMB, the primary consideration is to ensure that members have no vested interest in the outcome of the trial and are therefore free from conflicts of interest.
- When the available pool of suitably qualified/experienced potential DSMB members is small, it may be challenging to identify individuals with no connections with the trial sponsor. In these circumstances, when conflicts of interest are minor, they may be identified and managed through disclosure.

[Adapted from, NHMRC Data Safety Monitoring Boards \(DSMBs\) 2018](#)