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# Data Safety Monitoring Boards (DSMBs)

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# Guidance on Data Safety Monitoring Boards (DSMB)

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## 1. Background and Scope

A need for supplementary guidance to clarify the role and function of **Data Safety Monitoring Boards (DSMBs)**, was identified following revision of the AHEC Position Statement on *Monitoring and Reporting of Safety for Clinical Trials Involving Therapeutic Goods (May 2009)*, which was re-published by the NHMRC in November 2016 as *Guidance on Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods*.<sup>1</sup>

This guidance brings together international advice from regulatory authorities, clinical trial groups and industry organisations on the use of DSMBs. It also describes alternative monitoring structures that may be utilised when a DSMB is not warranted. It has been written using terminology for investigational medicinal product (IMP) trials; however, the content is also applicable to other clinical trials. This guidance applies to both commercial and non-commercial trials. Although the *type* of DSMB (described in Section 2) may be influenced by whether the sponsor is commercial or non-commercial, the rationale for establishing a DSMB should not be influenced by the type of sponsor.

## 2. Introduction

Risks associated with clinical trials include: the risks to participant safety, the risk to data validity and, where real or perceived conflicts of interest exist, the risk to trial credibility. A DSMB is one of a range of mechanisms available to sponsors to mitigate these risks and every trial must identify the most appropriate mix of monitoring activities. *The Integrated Addendum to ICH E6 R1: Guidelines for Good Clinical Practice (ICH E6 R2)* incorporates advice for clinical trials sponsors on the development of a trial monitoring plan:

*“The plan should describe the monitoring strategy, the monitoring responsibilities of all the parties involved, the various monitoring methods to be used, and the rationale for their use.” (5.18.7)*

DSMBs are an important component of many monitoring plans, but are not required for all clinical trials. This guidance describes the typical role and function of DSMBs so that sponsors can use this information to determine whether a DSMB should be convened as part of their overall monitoring strategy.

Within this document, the term DSMB is used to describe **independent** committees that have all the characteristics and methods of operation described in Sections 4-9 of this document. Two *types* of DSMB are recognised:

1. DSMBs where members are fully independent of the product manufacturer/sponsor and all trial investigators (and their institutions). This type is most frequently used in commercial trials.

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<sup>1</sup> <https://www.nhmrc.gov.au/guidelines-publications/eh59>

2. DSMBs where members may be from (or affiliated with) the same institution as the sponsor or investigator but are not part of the trial team.<sup>2</sup> This type is most frequently used in non-commercial trials.

**Note:** The second type of DSMB has evolved in the non-commercial setting because it is usually more straightforward to establish that there are no conflicts of interest (e.g. stock ownership) between the DSMB members and the trial sponsor. However, while the most obvious conflict of interest is financial, there can also be professional, intellectual and emotional conflicts of interest (see Table 2). Non-commercial sponsors using this type of DSMB need to carefully consider the degree of separation between the DSMB members and those managing the trial. For some non-commercial trials, particularly those with a major public health impact, a fully independent DSMB will be the gold standard, for some of the reasons described in Table 1.

### 3. Definitions

Term	Definition
Clinical Trial	Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.
Commercial Trial	A trial that is funded and sponsored by a commercial company, where the company designs the protocol and owns the results and intellectual property rights arising from the trial.
Coordinating Principal Investigator (CPI)	a) In relation to a clinical trial conducted at a single trial site, the principal investigator at that site b) In relation to a clinical trial conducted at more than one trial site, the health professional, whether or not he or she is an investigator at any particular site, who takes primary responsibility for the conduct of the trial.
Data Safety Monitoring Board (DSMB)	An independent and multidisciplinary group established by the trial sponsor to review, at intervals, accumulating trial data, in order to monitor the progress of a trial and to make recommendations on whether to continue, modify or stop the trial for safety or ethical reasons.
DSMB Charter	A document that defines the primary responsibilities of the DSMB, its relationship with other trial components, its membership, and the purpose and timing of its meetings.
Monitoring	The act of overseeing the progress of a clinical trial and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).
Monitoring Plan	A document that describes the strategy, methods, responsibilities, and requirements for monitoring a trial.
Non-Commercial Trial	A trial where a non-commercial (not for profit) organisation retains control of the protocol and is the trial sponsor. Non-commercial trials are usually publically funded (e.g. by government/charities), but may also be funded/supported by a commercial company.
Pharmacovigilance	The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other product-related problem.
Principal Investigator (PI)	The person responsible, individually or as a leader of the research team at a site, for the conduct of a trial at that site. In a single centre trial, the principal investigator may also be the coordinating principal investigator.
Sponsor	An individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study.

<sup>2</sup> That is, members do not have a role with the trial they monitor, including not having a supervisory relationship with members of the trial team.

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

A DSMB is a multidisciplinary group established by the trial sponsor to review, at regular intervals, accumulating trial data, in order to monitor the progress of a clinical trial.<sup>3</sup> 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<sup>4</sup> a trial for safety or ethical reasons [1]. DSMBs go by a variety of names including Data Monitoring Committee (DMC) and Data Monitoring and Ethics Committee (DMEC). These entities will be referred to as DSMBs within this document.

While investigators and sponsors monitor the day-to-day conduct of the trial, DSMBs make recommendations concerning the overall conduct of the trial. The DSMB's access to unblinded and often comparative data enables it to undertake a more comprehensive and integrated review [2]. DSMBs play an important role in:

- safeguarding the interests of study participants
- ensuring that definitive and valid results are produced which will reliably inform the future treatment of patients
- enhancing the credibility of the trial.

**Table 1: Areas where risks may be mitigated by the presence of a DSMB**

Risk	DSMB role	How risk is mitigated
Participant interests	Identify, through regular monitoring, serious emerging safety concerns as rapidly as possible, so as to minimise the time that participants may be placed at excess risk of harm.	Through monitoring of interim, unblinded, comparative data, (available only to the DSMB) the DSMB is able to develop a clear picture of the emerging balance of risks and benefits.
Data validity	Maintain confidentiality of unblinded interim results and provide an objective and unbiased assessment of those results.	By keeping the sponsors and trial investigators blinded to emerging trends that may impact on their ongoing decision making, the risk of bias is substantially diminished. <sup>5</sup>
	Contribute to the successful completion of a trial by periodically reviewing accumulating trial data, to inform trial conduct decisions.	By reviewing aspects of trial conduct (e.g. recruitment rates, protocol compliance, the accuracy and completeness of data capture, including missing data and rates of loss to follow-up), to identify problems and recommend action.

3 Sponsors may delegate their functions to third parties (e.g. a Contract Research Organisation, Coordinating Principal Investigator or coordinating centre). The term sponsor in this document means sponsor or their delegate.

4 Some trials plan for a series of interim analyses of the accumulating trial data, with stopping rules based on the findings. The DSMB may recommend stopping a trial based on:

- **Safety:** If the trial treatment harms participants, and this harm outweighs any benefit from the treatment, then the trial may be stopped to prevent participants from continuing to receive a treatment that already appears to be unsafe.
- **Efficacy:** In rare situations, the data may show that a treatment is vastly superior to the alternatives sooner than expected and stopping may allow a successful treatment to become generally available as soon as sufficient evidence of its advantages has been collected.
- **Futility:** If there is clearly no difference between the treatment arms part way through the trial and there is sufficient data to indicate that, even if the trial were to continue to its conclusion, it is extremely unlikely that the new treatment would show a statistically significant benefit.

5 Blinding the sponsor/investigator to interim outcome data reduces the risk that they will be influenced by any interim data indicating emerging trends that could be attributable to chance and could lead to false conclusions. Blinding of the sponsor/investigator to interim outcome data also preserves their ability to make certain modifications to a trial in response to new external information without introducing bias [4].

Risk	DSMB role	How risk is mitigated
Trial credibility	<p>Enhance trial credibility particularly:</p> <p>Trials designed to provide definitive information about effectiveness and/or safety of an intervention and, therefore, have significant public health impact.</p> <p>Trials where there is a significant perception (fair or not) that financial or professional goals might unduly influence the sponsor/investigator.</p>	<p>By involving experts that are widely recognised for their expertise in the area being studied, the uptake/acceptance of trial results by the medical community may be enhanced [2].</p> <p>Through enhancement of objectivity. The perception of a conflict of interest could harm the ultimate credibility of a trial.</p> <p>Each increment of independence will add to perceived objectivity, with a fully independent DSMB maximizing that perception [3].</p>

## 5. 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 have no involvement in the design and conduct of the trial, except through their role on the DSMB, and have no financial or other connections to the sponsor or other trial organisers that could influence (or be perceived to influence) their objectivity in evaluating trial data [4]. 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 material conflicts of interest. It should be recognised, however, that 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.

**Table 2: Examples of potential conflicts of interest**

Examples of potential conflicts of interest
Stock ownership in any commercial companies involved
Stock transaction in any commercial company involved (if previously holding stock)
Consulting arrangements with the sponsor
Frequent speaking engagements on behalf of the intervention
Career tied up in a product or technique assessed by trial
Hands-on participation in the trial
Involvement in the running of the trial
Emotional involvement in the trial
Intellectual conflict, e.g. strong prior belief in the trial's experimental arm
Investment (financial or intellectual) in competing products
Involvement in the publication (in the form of authorship)

Adapted from the Damocles Charter [8]

## 6. How is a DSMB established?

The sponsor and/or their Trial Steering Committee generally appoint members of a DSMB. In addition to one or more statisticians, DSMBs usually include members with scientific expertise in the clinical aspects of the disease/patient population being studied, and members with practical experience and expertise in current clinical trial conduct and methodology.

The size of a DSMB depends on the type of trial and the expertise needed. A DSMB usually comprises three or more members (with an odd number allowing for a definitive decision in case a vote is required). The optimal size needs to balance the advantages of larger groups (full range of skills, wide range of opinions, low risk of dominance) with the advantages of smaller groups (availability of members, convenience and cost of meetings, less reluctance to express views, less risk of conflict, less potential for bias towards riskier decisions) [5].

## 7. What training and experience should DSMB members have?

To facilitate the work of a DSMB, it is helpful that some of the members, particularly the DSMB chair, have previous experience serving on a DSMB [6]. In their guidance, the US based group, the Clinical Trials Transformation Initiative (CTTI), comment on the dearth of suitably qualified DSMB candidates and recommend the following actions to ensure all trial sponsors have access to appropriately trained and experienced members [7]:

*“Preparation [of the DSMB] requires a combination of training and experience. Sole reliance on on-the-job training is not feasible due to the complexity of the role and size of the currently available pool of candidates.*

1. *Training should include:*
  - a. *review of the fundamentals of the [DSMB] (e.g., via books, courses at professional meetings, and/or on-line content)*
  - b. *review of published case studies.*
2. *The inclusion of one or more members without prior [DSMB] service on each [DSMB] (including closed sessions) is encouraged, such that continued development of new [DSMB] members can occur through apprenticeship and mentoring.*
3. *Professional societies/organisations with an interest in the role and function of [DSMBs] should develop and maintain databases of experienced [DSMB] members and their relevant expertise.*
4. *[DSMB] members should submit interesting and instructive [DSMB] case studies to peer-reviewed journals in compliance with confidentiality provisions described in the [DSMB] Charter. This will increase awareness of issues and challenges that can arise during the conduct of a clinical trial”.*

**Note:** It is recognised that the existence of professional societies/organisations is limited in Australia and that DSMBs are generally reliant on stewardship provided by the trial sponsor.

## 8. How is the role and function of the DSMB documented?

It is common practice for the role and function of the DSMB to be described in a **Charter**. The Charter should generally provide details of the DSMB’s operational procedures including: membership, the roles and remit of the DSMB, what recommendations are permissible, the minimum number of attendees before the DSMB is quorate for decision making, how often the DSMB meets, to whom they report and how decisions are made.

As the DSMB may have access to unblinded treatment information, there is potential to introduce bias to future trial results. Thus, transparency is important when it comes to the procedures used to make decisions. The Charter should usually describe how and when the DSMB will interact with



external parties such as the sponsor.<sup>6</sup> For example, the Charter may document the procedure for meetings to review unblinded efficacy and safety data by treatment group, at which the sponsor and trial team will not be present (closed meetings); and meetings to discuss its conclusions and recommendations with the sponsor (open meetings).

**Note:** There is considerable debate amongst the trial community on whether the statistician conducting the interim analysis should also be the primary statistician involved in the design and management of the trial. On one hand, the trial statistician's knowledge of the interim analysis results could potentially affect their trial management decisions but, on the other, their familiarity with the trial is advantageous in interpreting the data. In their guidance [4], the FDA suggest that it is optimal for a statistician independent of the sponsor to perform the unblinded interim analysis despite the fact that this is not common practice, particularly in non-commercial trials. If the trial statistician does perform the analysis, any working procedures should clearly describe the measures that will be taken to prevent dissemination (directly or indirectly) of unblinded study information to individuals responsible for the further conduct of the study or future analyses.

It is the sponsor's responsibility to ensure that the Charter is in place for the DSMB when it is established. A Charter template has been developed by the DAMOCLES study group — <http://bcsrc.jhmi.edu/courses/c34066001/DAMOCLES%20article%20Lancet%202005.pdf>

## 9. When is a DSMB most likely to be convened?

Although there is no single rule for what types of study require a DSMB, they are used most commonly in later phase (IIb to IV<sup>7</sup>) 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 [2]. 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.

## 10. Alternatives to DSMBs

When the risk assessment indicates that a DSMB is not warranted, alternative monitoring structures may be used to manage potential risks [2-6].<sup>8</sup> In many trials where a DSMB is not convened, a trial group or committee, often with multidisciplinary representation, may be convened to provide some level of structured oversight. The algorithms for determining the type and nature of data and safety monitoring will vary substantially depending on the trial sponsor, as will the terminology to describe the individuals, groups or committees utilised. The type of oversight provided by 'non-DSMB committees' may include regular meetings to review individual safety reports, aggregate event rates, data relating to the quality, protocol adherence and patient retention rates.

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6 Sponsor and investigator involvement in DSMB deliberations is often warranted as they contribute valuable perspectives and insights regarding the trial (e.g. updating the DSMB on trial progress and answering any questions that members may have).

7 It should be noted that most Phase IV post-marketing observational studies, post-marketing surveillance studies or registries rarely require a DSMB, as these studies are non-randomised and have no interim analyses.

8 For non-commercial trials, investigators delegated sponsor duties should also take account of sponsor or funder policies relating to the establishment of DSMBs.

Non-DSMB committees may be entirely internal to the study team or, depending on the outcome of the sponsor's risk assessment,<sup>9</sup> may include one or more expert members that are external to the sponsor or study team.

The following are examples of individuals, groups or committees that are utilised to provide monitoring and/or oversight for clinical trials. These examples are not intended to be exhaustive of the types of entities that may be utilised for trial monitoring and/or oversight.

#### **a) Safety Review/Dose Escalation Committee**

These types of non-DSMB committee are commonly utilised in early phase trials to perform assessments of safety and pharmacokinetic data prior to dose escalation. Commercial trial safety review committees often include a medical monitor, sponsor staff and the trial investigator and, where indicated by the risk assessment, one or more external members. Dose escalation meetings form part of the safety review process overseen by this type of committee. In a non-commercial trial, these activities may be conducted by the Trial Management Group.

#### **b) Trial Management Group (TMG)**

Non-commercial trials should have a TMG (also known by other names such as Trial Management Committee) although, in very small simple trials, the Coordinating Principal Investigator (CPI) may perform the functions of the TMG. The TMG should include those individuals responsible for the day-to-day running of the trial, such as the CPI, statistician, trial coordinator/research nurse and data manager. The TMG oversees all aspects of the conduct of the trial; performing safety oversight activities and/or acting on advice from other individual(s) or group(s) providing safety oversight. For many non-commercial trials, the TMG performs the role of a Trial Steering Committee (TSC); however, as a trial increases in size and complexity, more formal structures, such as a TSC, become appropriate. Where a DSMB or TSC is not convened, the objectivity of the TMG may be enhanced by inclusion of one or more independent members.

#### **c) Trial Steering Committee (TSC)**

Most commonly used in commercial trials and large international non-commercial trials, a TSC is appointed by the sponsor to provide expert oversight for the trial. The TSC may include investigators, other experts not otherwise involved in the trial and, usually, representatives of the sponsor [4]. Although blinded, the TSC acts as a body that takes responsibility for the scientific integrity of the protocol and the assessment of study quality and conduct [6]. The TSC will also oversee the timely analysis, writing up and publication of the main trial results. Safety issues raised by DSMBs and other safety monitoring groups (such as a sponsor's internal pharmacovigilance department) would be reported to the TSC. As the executive decision-making group, the TSC provides additional independent oversight for trials.

#### **d) Medical Monitor**

An independent medical monitor may perform a variety of roles related to safety oversight, such as the ongoing monitoring of reports of serious adverse events (SAEs) submitted by investigational sites to identify safety concerns and make recommendations for continuing or stopping a trial.

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<sup>9</sup> For example, in a Phase I trial, external members may not be needed if the decision to stop or review the trial can be made objectively using a pre-specified decision-making algorithm. However, if a trial's data monitoring plan lacks objective criteria for continuing or stopping the trial, inclusion of an independent expert member (or members) may provide a greater level of objectivity in any decision-making process.

### e) Clinical Event Committee (CEC)

A CEC is a panel of independent experts that conducts a central review of trial endpoints in a blinded and unbiased manner, ascertaining whether they meet protocol definitions. Although such endpoint adjudication committees are not strictly trial oversight committees, they contribute to the quality of the clinical trial by providing a central review of trial endpoints. They are particularly useful when endpoints are complex to assess, include subjective components, or the study cannot be blinded.

**Note:** Sponsors are encouraged [9-10] to adopt a systematic, risk-based approach to monitor the ongoing safety of their trials and a variety of practices may be employed. In some trials, more than one type of committee performing a range of complementary roles may be utilised to provide an appropriate level of oversight. In others, much simpler structures and practices may be adequate to provide oversight.

## 11. What is the role of the Human Research Ethics Committee (HREC)?

For ongoing trials, the HREC is responsible for considering information arising from the trial that may bear on the continued ethical acceptability of the trial at the study site(s) it oversees. Although HRECs conduct periodic reviews of ongoing trials, they do not review interim results. Instead, they rely on information provided by the sponsor. As such, the HREC should ensure that the sponsor has appropriate arrangements in place to monitor the safety of participants during the trial by reviewing the sponsor's plans for safety monitoring described in the protocol or ethics application. Information could include details of what interim results will be monitored and when analyses will be completed, who will review interim results, and what guidelines will be followed for modification or termination of a study. As part of their review, the HREC should be given information to assess how trial risks will be mitigated and managed. For randomised controlled trials, the protocol or ethics application should enable the HREC to determine the following:

- if a DSMB is to be convened, what its main role and function will be
- if a DSMB is not to be convened, whether this is justified given the nature of the trial
- that appropriate (risk-based) processes for monitoring trial safety and data integrity are planned.

As the trial progresses, the HREC should be provided with information in annual reports<sup>10</sup> that enable an assessment of whether ongoing safety monitoring is being conducted appropriately, that the trial's safety monitoring plans are being followed and, where necessary, that the plans are being adapted to take into account new findings.

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<sup>10</sup> In the case of early phase trials, more frequent reports may be required by the HREC.

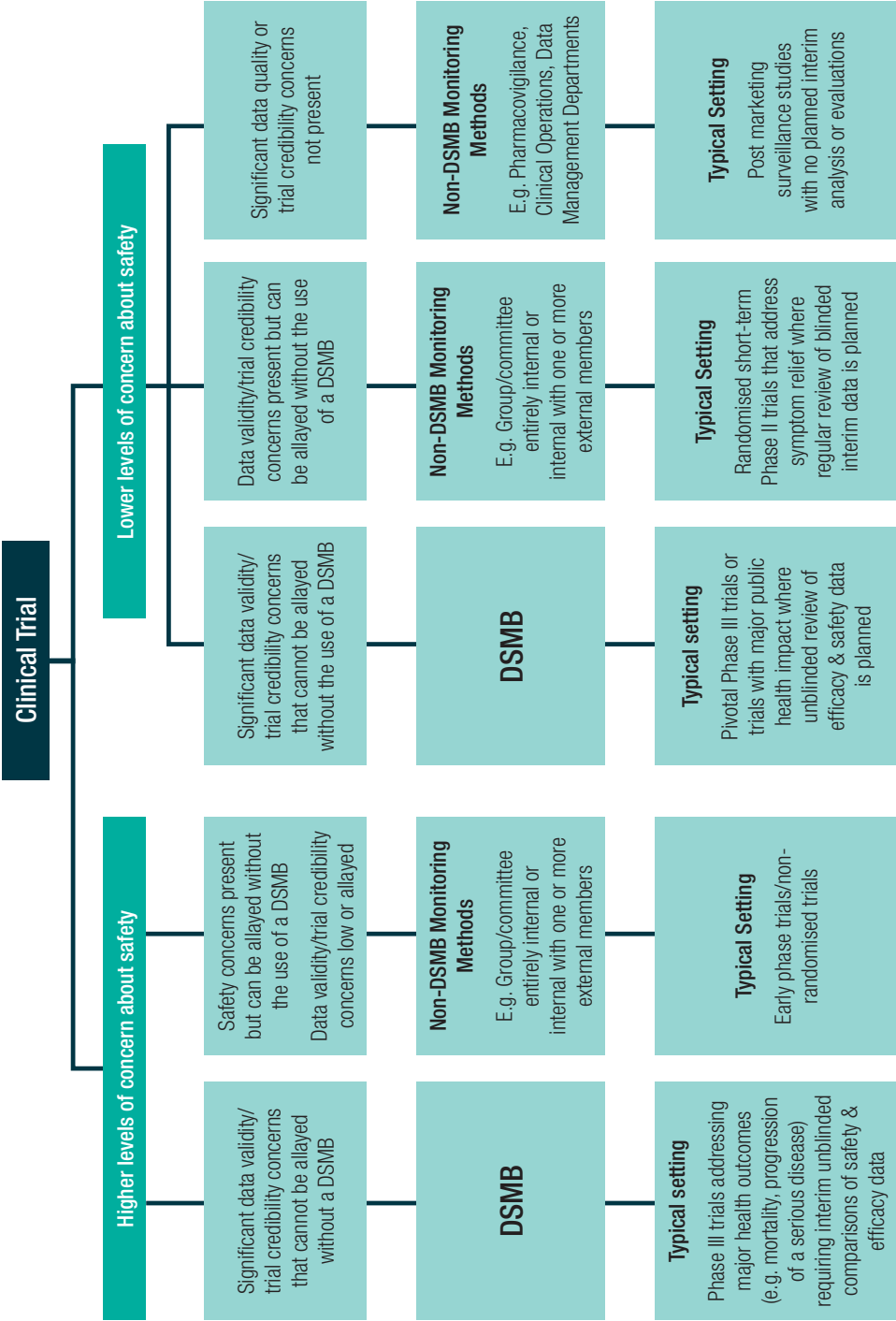
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# Appendix I: Example Decision Making Tree for Establishment of a DSMB<sup>11</sup>



Constructed from guidance provided in *Data Monitoring Committees in Clinical Trials: A Practical Perspective*. S Ellenberg, Thomas R Fleming, David L DeMets [2]

<sup>11</sup> HRECs should be aware that the absence of a DSMB should not be a barrier to conducting a trial if the sponsor is able to utilise other (non-DSMB) monitoring methods to adequately mitigate risk.

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## Working Party

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