ADVARRA

When do I Need a DMC?

To better understand when you may need a data monitoring committee (DMC), it's helpful to know a DMC's role in research.

- A DMC, also referred to as data safety monitoring board (DSMB), is an independent group of experts who conduct a periodic review of accumulated worldwide clinical data during a clinical trial.
- The primary purpose of a DMC is to report early evidence of benefit or harm in a study, accounting for the safety of participants and integrity and validity of the data.

When would you have a DMC?

- For some trials—particularly blinded and placebo-controlled trials—the sponsor likely doesn't know if the drug works as predicted until the trial's end. The only group that will look at masked or unblinded study data is a DMC.

> A DMC will keep an eye on the trial while it's going on. They can detect if a drug isn't working and can notify the sponsor if the trial needs to stop early or be adjusted.

Why are DMCs needed?

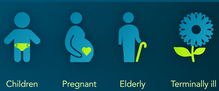
Independent DMC review and oversight is essential for mitigating risks to study participants and ensuring certain types of trials have adequate data safety monitoring plans.

There are two guidelines requiring sponsors to have adequate data safety monitoring plans in their clinical protocols:

1. US Food and Drug Administration (FDA) guidance
2. Good clinical practice (GCP) E6 R2

US FDA and European Union (EU) European Medicines Agency (EMA) indicate an independent DMC is an **effective** and **appropriate** way to provide an adequate safety monitoring plan for clinical trials where:

- The trial is blinded or has endpoints, and the independent group evaluates data to determine if the study meets pre-determined endpoints, futility, or other stopping rules, thus terminating early.
- There are other reasons for a safety concern, such as a particularly invasive procedure.
- Prior information suggests serious toxicity possibility. Periodic analysis of adverse event (AE) data is needed to determine if toxicity endpoints are met.
- The study is performed in a potentially fragile population. This includes, but is not limited to:



- The study's targeted population is at elevated risk of death or other serious adverse events (SAEs), even if the study addresses a lesser endpoint.
- The trial is large, of long duration, or multicenter, where a single group evaluates and analyzes the consolidated study safety data.

If any of these attributes apply to your study, establishing an independent DMC or DSMB should be considered. Your institutional review board (IRB), ethics committee (EC), or regulators may require it as well.

Want to learn more about DMCs? Watch our webinar:

Do You Have Appropriate Oversight? Understanding the Role of DSMBs