When does my clinical trial need a Data Monitoring Committee (DMC)?

DMC is **REQUIRED** if:

- Your study is subject to the 21 Code of Federal Regulations in emergency settings in which the informed consent requirement is excepted, OR
- Your study is sponsored by a government agency (such as the NIH or the VA) that requires the use of DMCs in applicable clinical trials

DMC is **RECOMMENDED** in any of these circumstances:

SIGNIFICANT SCOPE

- If it is a large, multi-center study of long duration
- If the study has an adaptive design with a planned interim analysis
- If the study addresses a topic of widespread public concern and potentially significant clinical impact

SCIENTIFIC VALIDITY ASSURANCE

- If it is a double-blind study of sufficient duration that external factors may call for modification during the trial (because the DMC can intervene without adding bias)

SAFETY CONCERNS

- If there is a known possibility of serious toxicity with the study treatment
- If the treatment procedure presents inherent invasiveness or risk
- If it is probable that an interim analysis might ethically require termination of the study before its planned completion

POPULATION RISKS

- If the study is being performed in a potentially fragile or vulnerable population (e.g. children, pregnant women, the elderly, psychiatric patients), or a population at elevated risk of death or other serious outcomes (even when the study objective addresses a lesser endpoint)

DMC is probably not **NECESSARY** if:

- Your study is at the early stage of product development
- Your study addresses lesser outcomes such as relief of symptoms
- Your study is of short duration (making it impractical to convene a DMC in a timely fashion to review the data) and has no major safety concerns
- Your study involves known risks that are minimal
- Your study is at the early stage of product development
- Your study involves behavioral or administrative issues

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