NIH Policy requires that all grantees have in place procedures for data monitoring of clinical trials, to ensure the safety of participants and the validity of data \(^{(1)}\).

The 1999 NIH policy requires that a *Data Monitoring Committee (DMC)* be established for all phase III randomized clinical trials funded by NCI. \(^{(3)}\)

This policy states that the DMC is responsible for reviewing:

- interim analyses of outcome data and cumulative toxicity data summaries to determine whether the trial should continue as originally designed, should be changed, or should be terminated based on these data,
- reports of related studies to determine whether the monitored study needs to be changed or terminated, and
- major proposed modifications to the study prior to their implementation (e.g., termination, dropping an arm based on toxicity results or other reported trial outcomes, increasing target sample size).

DMC findings should be communicated to the study leadership, and the NCI Division Director.

The April 2001 NCI guideline \(^{(4)}\) clarifies the policy somewhat, stating that "there is no longer a blanket requirement for DSMB *(DMC)* in the cases of low-risk behavioral and nutritional trials... All such trials should include a data...monitoring plan, but this may or may nor include a DSMB *(DMC)*".

This document goes on to define the Essential Elements of a Data Monitoring Plan:

1. Monitoring the progress of trials and safety of participants
2. Plans for assuring compliance with requirements regarding the reporting of adverse events.
3. Plans for assuring that any action resulting in temporary or permanent suspension of an NCI-funded clinical trial is reported to the NCI grant program director.
4. Plans for ensuring data accuracy and protocol compliance

NIH-funded phase I and II clinical trials must also have a Data Monitoring Plan, which does not necessarily include a Data Monitoring Committee, but which is appropriate for the "potential risks, complexity and nature of the trial" \(^{(2)}\).

\(^{(1)}\) NIH Policy for Data and Safety Monitoring, (June 1998)

\(^{(2)}\) Further Guidance on Data and Safety Monitoring for Phase I and Phase II Trials, (June 2000)

\(^{(3)}\) Policy for the National Cancer Institute for Data and Safety Monitoring of Clinical Trials.

\(^{(4)}\) Essential Elements of a Data and Safety Monitoring Plan for Clinical Trials Funded by the National Cancer Institute.

*NIH, NCI use the term Data Safety Monitoring Board (DSMB) when referring to a Data Monitoring Committee (DMC)