DATA AND SAFETY MONITORING PLAN
GUIDANCE DOCUMENT

What is a data and safety monitoring plan?

Some clinical trials (see the question: when) should have provision(s) for data and safety monitoring. The data and safety monitoring plan is a document describing these provisions.

Why do I need to incorporate a data and safety monitoring plan?

The purpose of data and safety monitoring of ongoing studies is to ensure the participant safety throughout the research process.

When do I need a data and safety monitoring plan?

Criteria for such requirement include, but are not limited to:

- Protocols that may result in serious adverse events;
- Protocols intended to provide definitive information about the effectiveness and/or safety of a medical intervention;
- Multiple clinical sites where there is a need for investigators to submit reports of adverse events to a central reporting entity, such as a coordinating center or statistical center, responsible for preparing timely summary reports of adverse events for distribution among the clinical sites, and to the IRBs;
- Controlled trials with mortality or major morbidity as a primary or secondary endpoint where increased morbidity or mortality may better be assessed through statistical comparisons of morbidity or mortality among treatment groups
- Protocols where it would be ethically important for the study to stop early if the primary question addressed has been definitively answered, even if secondary questions or complete safety information were not yet fully addressed.

What must be in a data and safety monitoring plan?

- The information evaluated,
- Harm and benefit to be monitored,
- Study endpoints,
- Timing of monitoring, and
- Decisions to be made by the monitoring process.

Who could monitor the data and safety and what does he/she need to do?

Monitoring might be conducted by the investigator, the sponsor (e.g., medical monitor, safety monitoring committee), or by an independent monitoring board. The monitoring person might compare the character, incidence and severity of actual harm to that expected, comparing the magnitude and probability of benefits to that expected, or to determine the causality of unexpected harm. Monitoring might occur at specific points in time, after a specific number of participants have been enrolled, or upon recognition of harm.

Why is the IRB concerned about data and safety monitoring plan?

The IRB must determine whether a data safety monitoring plan is required. When IRB members judge that a data safety and monitoring plan is appropriate, the IRB should evaluate the written plan before approving a study.