eProtocol Application "Risks" section: Data and Safety Monitoring Plan (DSMP)

A Data and Safety Monitoring Plan (DSMP) is required for studies that present Medium or High risk to participants. (See Overall Evaluation of Risk above). If Low Risk, a DSMP may not be necessary.

Multi-site Phase III clinical trials funded by NIH require the DSM Plan to have a Data Safety Monitoring Board or Committee (DSMC or DSMB). The FDA recommends that all multi-site clinical trials that involve interventions that have potential for greater than minimal risk to study participants also have a DSMB or DSMC. The role of the DSMC or DSMB is to ensure the safety of participants by analyzing pooled data from all sites, and to oversee the validity and integrity of the data. Depending on the degree of risk and the complexity of the protocol, monitoring may be performed by an independent committee, a board (DSMC/DSMB), a sponsor’s Data Safety Committee (DSC), a Medical Monitor, a sponsor’s safety officer, or by the Protocol Director (PD).

Provisions for monitoring should be tailored to the expected risks of the research; the type of subject population being studied; and the nature, size (in terms of projected subject enrollment and the number of institutions enrolling subjects), and complexity of the research protocol.

For example, for a multicenter clinical trial involving a high level of risk to subjects, frequent monitoring by a DSMB/DMC may be appropriate, whereas for research involving no more than minimal risk to subjects, it may be appropriate to not include any monitoring provisions.

Helpful Hints:
1) For sponsored trials, check the clinical/sponsor protocol for the information being asked for in this section. If the protocol does not contain a DSM Plan or Charter, ask the sponsor if additional information is available.
2) The IRB will ask to see the most current report from the monitoring board, committee, or safety officer. You must attach it at continuing review, or as soon after continuing review as it becomes available by submitting a modification.
3) For multi-site trials, federal guidance asks that the IRB review recommendations of the monitoring entity, not the raw data on which the recommendations are based.
4) This section is not asking about the sponsor’s on-site monitoring activity.

1. What type of data and/or events will be reviewed under the monitoring plan, e.g. adverse events, protocol deviations, aggregate data?

Additional types of events or data that the Data and Safety Monitor might review under the data and safety monitoring plan:

- Aggregate Data Analysis Reports
2. Identify who will be responsible for Data and Safety Monitoring, e.g. Stanford Cancer Institute DSMC, an independent monitoring committee, the sponsor, Stanford investigators independent of the study, the PD, or other person(s).

Note that the Stanford Cancer Institute DSMC does not monitor externally sponsored trials, except for the instances noted below.

The Stanford Cancer Institute DSMC:

- monitors investigator-initiated, institutionally-sponsored trials
- reviews safety reports (grade 3 and above) for all Cancer Institute trials, and
- reviews protocol deviations for all Cancer Institute trials

3. Provide the scope and composition of the monitoring board, committee, or safety monitor, e.g. information about each member’s relevant experience or area of expertise.

If the Monitor is the Stanford Cancer Center DSMC or the PD, enter "N/A".

Composition of the monitoring board can be identified by degrees (e.g., MD/PhD/NP), areas of expertise, specialty, university affiliation, or years of experience, if known. DSMB members need not be identified by name.

For example, a board or committee might be composed of a statistician, a physician specialist in the disease being studied, a bioethicist and an epidemiologist.

4. Reporting SAEs, SUSARs, or UPs: Confirm that you will report Serious Adverse Events (SAEs), Suspected Unexpected Serious Adverse Reactions (SUSARs), or Unanticipated Problems (UPs) to the person or committee monitoring the study in accordance with Sponsor requirements and FDA regulations.

For example, within 24 hours of learning of a death, or within 5 days of learning of an unanticipated problem (UP) involving risks to participants or others.

5. If applicable, how frequently will the Monitoring Committee meet? Will the Monitoring Committee provide written recommendations about continuing the study to the Sponsor and IRB?

1) The frequency of the meetings depends upon the specific trial, but a typical frequency is one to three times per year. Data and Safety Monitoring entities meet at planned intervals (e.g. quarterly, semi-annually, or after specified enrollment targets.) and provide a written summary or recommendations, such as:
• Continue study as designed;
• Terminate the study;
• Continue study with modifications; or
• Temporarily suspend enrollment and/or study intervention until some uncertainty is resolved.

2) Check your sponsor’s protocol for the DSM Plan or Charter or ask the sponsor.

3) Do not provide the IRB with detailed reports sent to the DSMC/B to review; the IRB reviews reports from the DSMC/B.

6. Specify triggers or stopping rules that will dictate when the study will end, or when some action is required.

If you specified this in Section 2g [Study Endpoints] earlier in this application enter "See 2g".

7. Indicate to whom the data and safety monitoring person, board, or committee will disseminate the outcome of the review(s), e.g., to the IRB, the study sponsor, the investigator, or other officials, as appropriate.

See Section VI of this guidance:  http://www.hhs.gov/ohrp/policy/advevntguid.html [1]

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