

Data and Safety Monitoring

Depending on your responses, additional questions may appear.

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Attachments

Data & Safety Monitoring

* Has a Data and Safety Monitoring Plan (DSMP) document or Charter been issued by the Lead Site or Sponsor?

For example, industry sponsored clinical trials often issue documentation on data and safety monitoring plans.

Yes

DSMP Documentation

Please upload any officially issued DSMP or DSMB/C Charter documentation.

ATTACH

For any subsequent text field questions about DSMP related information, you can answer them directly or state what pages/sections to reference in the uploaded documents.

No

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* **Study Monitor**

Indicate the entity that will monitor the study data for safety. Check all that apply:

- Investigator
- Monitor independent of the study team (e.g., sponsor's medical monitor)
- Data Safety Monitoring Board or Committee (DSMB/C)

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* **Monitor or DSMB/C Information**

Who will have access to study records or specimens? Provide the following information for the monitor(s) or DSMB/C members:

- Name
- Credentials
- Role in Study Monitoring
- Expertise
- Title/Organization

If this information is not known, please provide a description of the expertise of the anticipated monitor(s) or board/committee members.

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* **Objectivity of Monitoring Entity**

Explain how the objectivity of the monitoring entity and the monitoring process will be ensured. (E.g., if the monitor is the investigator, the investigator should verify absence of conflict of interest, or when the monitor is from the sponsor, he/she is neither directly nor indirectly involved in the conduct or analyses.)

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* **Roles & Responsibilities Gathering and Monitoring Data**

Describe the roles in gathering and monitoring data for the investigators/research team, research coordinators, sponsor, monitoring entity, statistical consultant, etc. Be sure to address who has the following responsibilities:

- Recording data
- Verifying data accuracy, including the method and frequency (e.g., double data entry, outside audit, visual verification)
- Verifying procedures are conducted per the approved protocol
- Conducting periodic assessments
- Evaluating events/incidents to determine if any represent unanticipated problems involving risks to subjects or others and the appropriate action as a result of those events

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*** Monitored Information and Reporting**

Describe the following:

- The data and/or events that will be monitored, assessed, and reported to/by the monitoring entity.
- The mechanism(s) through which reports will be submitted to the monitoring entity.
- The frequency of any reports that will be submitted to the monitoring entity.
- The timeframe for reporting certain events, including unanticipated problems involving risks to subjects or others, to the monitoring entity and the IRB.

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*** Frequency of Monitoring and Reporting**

Indicate the frequency with which the monitoring entity will review and assess the data and/or events.

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*** Evaluation Methods**

Describe the procedures and methods the monitoring entity will use to evaluate the data and/or events, such as statistical analysis. For studies monitored by a DSMB/C, also describe the meeting structure, format, and quorum requirements.

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*** Criteria and Response to Findings**

Describe the criteria and plan for taking action in response to monitoring entity findings (e.g., reporting, stopping rules, protocol changes, or modifying subsequent monitoring activities).

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*** Communicating Findings**

Describe both the frequency and method in which monitoring entity findings and recommendations will be communicated to the investigator, sponsor, and other entities (e.g., FDA, other sites, etc.).

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*** Confidentiality of Data**

Describe how the confidentiality of the data provided to the monitoring entity will be maintained.

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