National Institute of Cardiovascular Diseases, Karachi, Pakistan

RESEARCH DEPARTMENT

A Data and Safety Monitoring Board (DSMB)

A Data and Safety Monitoring Board (DSMB) is an independent group of experts responsible for monitoring the safety, progress, and efficacy of a clinical trial or research study. Its primary purpose is to ensure participant safety and maintain the integrity of the data. Below are key policies typically associated with a DSMB:

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1. Purpose and Scope

- The DSMB oversees the ethical and scientific integrity of a study.
- It evaluates data related to participant safety, study conduct, and interim results (if applicable).
- These policies apply to studies involving significant risk or where early stopping for safety, efficacy, or futility is a consideration.

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2. Composition of the DSMB

- **Membership:** Composed of independent experts in relevant fields, including clinical research, biostatistics, and the study's therapeutic area.
- **Independence:** Members must not have conflicts of interest with the sponsor, investigators, or study.
- **Roles:** Typically includes a chairperson, statistician, and subject matter experts, with at least one member focusing on participant safety.

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3. Responsibilities of the DSMB

- **Study Review:** Assess study protocols, design, endpoints, and safety monitoring plans.
- **Adverse Event Monitoring:** Evaluate reports of adverse events and unanticipated problems.
- **Interim Data Analysis:** Analyze interim data to determine if modifications or termination of the study are necessary.
- **Recommendations:** Guide the sponsor on study continuation, modification, or termination.
- **Data and Material Transfers**: ensures the secure, ethical, and efficient sharing of study-related materials and data while maintaining confidentiality and regulatory compliance. If transferring materials and data sharing, ensure compliance with Material Transfer Agreements (MTA)and Data Transfer Agreements (DTA)

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4. Meetings

- **Frequency:** Hold regularly scheduled meetings, with the flexibility to convene emergency meetings for urgent issues.
- **Documentation:** Minutes of all meetings must be recorded and archived.
- **Quorum:** A minimum number of members must be present for decisions to be valid.

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5. Data Monitoring

- **Blinded vs. Unblinded Data:** Policies must specify whether the DSMB will review blinded or unblinded data.
- **Confidentiality:** All data and discussions are confidential and shared only with authorized parties.
- **Stopping Rules:** Clear criteria must be established for pausing or stopping the study based on safety or efficacy concerns.

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6. Conflict of Interest

- Members must disclose any potential conflicts of interest before joining the board.
- Policies must prohibit the participation of individuals with direct financial or professional ties to the sponsor or study team.

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7. Reporting

- The DSMB provides periodic reports to the sponsor, which may include:
    - Safety concerns.
    - Interim results and trends.
    - Recommendations for study adjustments or continuation.
- Final reports are included in regulatory submissions as needed.

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8. Authority

- The DSMB has the authority to recommend changes to the protocol, halt enrollment, or terminate the study.
- While the sponsor retains ultimate decision-making power, they are expected to respect DSMB recommendations.

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9. Training and Compliance

- All DSMB members must receive training on study protocols, DSMB policies, and regulatory requirements.
- Compliance with applicable regulatory guidelines (e.g., FDA, EMA, ICH-GCP) is mandatory.

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10. Documentation and Records

- All DSMB decisions, recommendations, and supporting data must be thoroughly documented and retained for regulatory and ethical review.