Data & Safety Monitoring for Clinical Trials

The NIH requires data and safety monitoring for all types of clinical trials, including physiologic, toxicity, and dose-finding studies (Phase I); efficacy studies (Phase II); efficacy, effectiveness and comparative trials (Phase III).

Monitoring should be commensurate with risks. The method and degree of monitoring needed is related to the degree of risk involved. A monitoring committee is usually required to determine safe and effective conduct and to recommend conclusion of the trial when significant benefits or risks have developed or the trial is unlikely to be concluded successfully.

Data Safety Monitoring Plans

A Data and Safety Monitoring Plan (DSMP) is just one of the mechanisms used to ensure the safety of study subjects as well as maintain data validity, integrity, and scientific merit. DSMPs depend upon many variables, such as the degree of risk, disease being studied, subject population, and number of sites where the research is being conducted. Complex DSMPs frequently include a Data Safety Monitoring Board (DSMB).

NIH Data Safety Monitoring Plan Information and Templates

To assist investigators in complying with the NIH data safety monitoring policy, please visit guidance and sample DSMP templates on the NIH website.

DSMP Checklist

- Primary and secondary outcome measures
- Inclusion/exclusion criteria
- Sample size
- List of participating enrolling clinics or data collection centers
- Projected timetable
- Target population distribution (e.g., women, minorities, etc.)Data acquisition and transmission
- Data entry methods
- Data analysis plan
- Quality assurance plan
- Reporting mechanisms of AEs/SAEs to the IRB, FDA, and NIDA.
- Reporting mechanisms of IRB actions to sponsor or funder
- Report of changes or amendments to the protocol
- Trial stopping rules
- Conflict of interest
- Potential risks and benefits for participants
- Collection and reporting of AEs and SAEs
- Management of SAEs or other study risks

- Plans for Interim Analysis of efficacy data
- Responsibility for data and safety monitoring
- Frequency of DSM reviews
- Content of DSM report
- DSM Board Plan (if applicable)

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The Data Safety Monitoring Board (DSMB)

DSMBs are made up of multidisciplinary members who are knowledgeable in the conduct of research, and should include those with backgrounds in biostatistics, experimental design, bioethics, and experts in the medical field of concern. The DSMB advises investigators regarding the continuing safety of trial subjects and those yet to be recruited to the trial, as well as the continuing validity and scientific merit of the trial.

The DSMB performs the following general functions:

- Objectively appraise a study's progress
- Assess data quality via a formal and planned process
- Provide analytical expertise and rigor
- Determine the statistical significance of efficacy and/or risk?benefit ratio

DSMBs are responsible for reviewing data and endpoints on a timeline set forth by the DSMP in the protocol, and are typically required for the following types of studies:

- More than minimal risk
- Multiple study sites. It is more difficult to recognize a pattern of increased or unusual problems when investigators treat small fractions of the population separately
- Vulnerable population (pediatric, geriatric)
- Blinded studies
- New therapies or science
- Highly toxic therapies or dangerous procedures.
- High expected rates of morbidity or mortality in the study population.
- High chance of early termination of the study.

NCI guidelines are widely considered to be the most comprehensive and set forth requirements for DSMB composition and function; note that it is required that a majority of the members be drawn from outside the institution (or institute) conducting the study. DSMB membership is usually comprised of:

- Experts in the fields of medicine and science that are applicable to the study,
- Statistical experts,
- Lay representatives, and
- Other who can offer an unbiased assessment of the study progress

DSMB Collaboration with the IRB

The DSMB is not specifically required to communicate with the IRB, but the intent is clear that the important information get to the IRB.

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Related Guidance, Tools & Templates

- FDA Guidance for Clinical Trial Sponsors
- NIH Policy for Data and Safety Monitoring
- Further Guidance on a Data and Safety Monitoring for Phase I and Phase II Trials
- Webinar: Oversight of Clinical Investigations

UCLA Presentations:

- Data Monitoring: Assuring Safety & Study Integrity in Clinical Research
- Managing the Practice of Research

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