The Data Safety Monitoring Board (DSMB)

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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 CTSI DSMB offers oversight for those investigator initiated trials that do not have an external DSMB oversight mechanism. 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 CTSI 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: "The study leadership will provide information on cumulative toxicities and relevant recommendations to the local principal investigators, to be shared with their IRBs."

Please contact the Office of Regulatory Affairs for more information.

Last updated: 26 Aug 2022

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