Data Safety Monitoring Board (DSMB)

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A Data and Safety Monitoring Board (DSMB) is a group of individuals with pertinent expertise that reviews accumulating data from an ongoing clinical trial. 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

Required forms for submission to DSMB to be submitted to the Office of Regulatory Affairs.

1. CTSI Serious Adverse Event Reporting Form
2. Single Subject Exception Request Form

Learn more about Data & Safety Monitoring at UCLA

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Source URL:https://www.researchgo.ucla.edu/regulatory-dsmb

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