

DATA AND SAFETY MONITORING REVIEW REQUIREMENTS FOR YALE INVESTIGATOR-INITIATED STUDIES/ STUDIES WITHOUT EXTERNAL MONITORING

Per the DSMC Charter, Trials being monitored by the YCC DSMC will remain under the YCC DSMC purview until a DSMC review has occurred that includes the research activity of the last subject who completed the intervention, or until the DSMC feels there are no patient safety concerns that require further monitoring. The DSMC will determine the length of continued DSMC review on a study-by-study basis. Typically for studies without external monitoring, such as investigator-initiated trials, the protocol specific Data and Safety Monitoring Plan includes DSMC review every six months

Submission Requirements

- Study Narrative

Study Narrative Criteria (to be written, signed, and dated by PI)

- Objectives of the study
- Design & treatment administration
- Safety data
 - PI should comment on adverse events observed to date *i.e. noting expectedness and unexpectedness of observed toxicities*
- Dose Limiting Toxicities (DLTs) for Phase 1 studies
 - Describe in detail protocol specific DLTs and if any DLTs have been observed to date
 - *Definition: Describes side effects of a drug or other treatment that are serious enough to prevent an increase in dose or level of that treatment*
- Efficacy results
 - *Summarize subject response data as determined by protocol i.e. RECIST*
- Study specific stopping rules:
Per DSMC Charter: For investigator-initiated trials led by Yale that have a two stage design with stopping rules, the Principal Investigator will submit a summary of progress to date outlining responses or other criteria used in the protocol to determine moving to the second stage of the trial. **Prior to beginning accrual to the second stage, the DSMC will review the summary and data and approve continuing as planned.**
 - The PI should discuss the current accrual and subject response and/or toxicities as applicable to the stopping rules that are planned for the study

Definition: in randomized controlled trials and other systematic experiments on human subjects, rules laid down in advance that specify conditions under which the experiment will be terminated, unequivocal demonstration that one regimen in a randomized controlled trial is clearly superior to the other, or that one is clearly harmful.

- Conclusion and plans
- eCRF completeness
 - No more than 10% of the eCRF data should be outstanding at any given time while the trial is active.
 - Calculation= $(To\ Do\ Forms + Started\ Forms) \div (Total\ \#\ of\ Forms - Planned\ \#\ of\ Forms)$
- Verification of accuracy and completeness of OnCore- *OnCore DSMC Console Export Report should be used to verify that all information in OnCore is up-to-date for committee review*