

Initial Clinical Science Research & Development Data Monitoring Committee Report

Study Title:

Date Report Completed:

Principal Investigator and Site:

Site Investigator Name(s):

Last Name, First Name	VAMC #	VAMC Location

**** For each provide the Merit Review Application Page Number or Describe below:***

DATA MONITORING
Rationale for sample size; including justification for including or excluding certain populations from the study
The method of randomization (describing any stratification and blocking techniques) as well as who will be responsible for the randomization process, blinding and un-blinding
Specific description of what data will be collected, and the manner and frequency of data gathering; include how it will be verified for accuracy and completeness
Based on the power analysis, describe the target recruitment goal; including how many individuals will need to be consented and screened for target recruitment to occur

Describe the recruitment plan, feasibility of adequate recruitment, anticipated obstacles and how to minimize their impact

Methods for handling missing data points and subject dropouts/withdrawals.

Describe how study retention will be addressed

Definitions of the analytical sets (i.e. intent-to-treat, pre-protocol, and any other analytical subsets)

Summary of the all the statistical analyses for the primary, and important secondary hypotheses/research questions

Definitions of covariates to be included in adjustment models

Plans for and specific purpose of any interim looks at the data (with regard to stopping rules for superiority, futility, or sample size re-estimation)

SAFETY MONITORING

Describe any plans for subjects who withdraw or are withdrawn from a study prior to completion; including what treatment, if any, will these subjects receive and from whom

Explain what constitutes an unacceptable degree of change in a participant's condition, such that they are withdrawn from the study, who will be notified and what type of follow-up will be provided

Plans for subject follow-up during and after study procedures, until completion of study

Explain how medical and/or psychological stability of potential participants will be established, which staff is responsible, and how it will be monitored

Describe the monitoring plan for study-specific adverse events or serious adverse events and how their risk can be minimized

Provide a list of study-specific adverse and serious adverse events to be monitored and a plan for prospectively tracking them

Identify which events will be reported to the FDA, local IRB, or other oversight bodies