

Data Analysis Plan for IRB #6856: Vilazodone in Separation Anxiety Disorder

Aggregate statistics for demographic and clinical characteristics of the two groups were calculated and compared using chi-square tests and t-tests, as appropriate. All quantitative post-randomization outcomes were graphed and their distribution assessed for outlier values.

To compare outcomes in the two groups, mixed effect logistic regression was used for the categorical outcomes and mixed effect regression models for quantitative outcomes, with subject-specific random effects and a first order auto-correlation structure for observations within the same individual. Time was included in the model as an additive factor (due to relatively low sample size, we did not test for differential time effect through interaction with group).