Medication Development for Protracted Abstinence in Alcoholism: Suvorexant Versus Placebo

NCT04229095

Statistical Analysis Plan-01/09/2022

Suvorexant Statistical Analysis Plan extracted from IND dated 01/09/2022

The difference between the 2 groups (suvorexant and placebo) in VAS strength of craving with alcohol cue compared to water cue at Visit 2 will be assessed as the primary endpoint with a linear mixed model. The model will include all relevant clinical parameters as potentially confounding. The Timeline Follow Back (TLFB) record of the daily number of standard drinks will be analyzed with latent growth modeling (slope and centered intercept) as a secondary endpoint. Subjects will be stratified by sex and Pittsburgh Sleep Quality Index (PSQI) total scores < 5 vs 5+. Safety will be primarily assessed by means of adverse events. Safety analysis will be based all randomized subjects and presented by treatment arm.