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Medication Development in Alcoholism: CORT118335 versus Placebo

Statistical Plan extracted from IND-09/28/2020

Statistical Data Analysis Plan extracted from IND dated 09/28/2020

The difference between the 2 groups in total VAS score from the cue reactivity testing at visit 3 will be assessed with a linear mixed model. The model will include all relevant clinical parameters e.g., miricorilant plasma concentration. Naturalistic secondary outcome measures i.e., number of standard drinks per day collected with the Timeline Followback (TLFB) will be analyzed for group differences with the same strategy as the primary endpoint. Safety will be primarily assessed by means of adverse events (AEs). Additional clinical evaluations for safety assessments will include routine monitoring of blood chemistry, hematology, urinalysis, vital signs, and ECG. Safety analysis will be based on all patients included in the study population and presented by treatment arm.