**ANALYSIS POLICIES**

09 Feb 2015

The purpose of this document is to establish guidelines for data analysis for the ***EXAMPLE project***. The principal analyses of primary and secondary outcomes employ the "intent-to-treat" approach. The intent-to-treat analyses include all randomized patients with at least one post-baseline *ANALYTE* measurement and who have taken at least one dose of study medication. All patients are included in their randomly assigned treatment group; treatment group assignment is not altered based on the patient’s adherence to the assigned treatment regimen.

All statistical tests are two-sided with the overall significance level of the primary outcome α=0.05.

All ***EXAMPLE study*** manuscripts will have an analysis plan, data tables and figures, manuscript drafts, correspondence to/from journals.

| Topic | Policy |
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| Analysis Plan | * An analysis plan will be written for each paper proposal. Analysis will begin after the proposal has been approved by the Executive Committee. |
|  | * The Coordinating Center staff will revise the plan, adding a description of the statistical methods and the availability of the data items required. |
|  | * Deviations from the original approved analysis plan will be added to the plan to create a new version of the analysis plan document. |
|  | * Significant changes to the original plan may have to be approved by the executive committee. |
| Analysis methods | * Analysis will adhere to original design using methods appropriate for randomized clinical trials. |
|  | * All analyses comparing the ***EXAMPLE study*** treatment groups will be conducted under the principle of intention-to-treat, with all patients included in their originally assigned EXAMPLE study treatment group. |
|  | * Statistical methods that require deletion of subjects or visits are to be avoided as they break the randomization and introduce biases. |
|  | * Analyses will either 1) be conducted separately by treatment group or 2) incorporate treatment effects. |
|  | * Subgroups should be defined from baseline characteristics rather than outcomes.. |
| Data issues | * Extra data collection. Papers are viable when based on the data collected prospectively during the study. |
|  | * Papers should acknowledge deficiencies in the data collected rather than requiring additional retrospective data collection. |
| Conventions | * Significance. All results that are nominally significant at the 0.05 level will be indicated. Significance levels for tests including interactions will be stated in the analysis plan. |
|  | * Multiple testing. Hochberg’s (1988)improved Bonferroni procedure will be used to adjust for multiple comparisons where appropriate. The adjusted p-value will be reported and will be significant at the 0.05 level. |
| Reporting | * Tables. Groups will be presented in the following order: Placebo, Dose 1, Dose 2, and Dose 3. |
|  | * Categorization. Standard categorizations will be established. |