**\_\_\_\_ Final Analysis Report**

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1. **Descriptive Statistics of Per Protocol Sample**

## Protocol Defined Inclusion and Exclusion Criteria

**Per Protocol Definition:**

**ITT Definition:**

**Inclusion Criteria:**

**Exclusion Criteria**:

* 1. Descriptive Study and Sample Characteristics of Per Protocol (PP) Sample

***Table 1.***

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Group A** | **Group B** | **p-value** |
| **(N=)** | **(N=)** |  |
|  | *Mean (SD /*(%) | *Mean (SD)/*(%) |  |
| Age |  |  |  |
| Gender |  |  |  |
| Male |  |  |  |
| Site (%) |  |  |  |
| Race (%) |  |  |  |
| Ethnicity |  |  |  |
| VABS Group (%) |  |  |  |

* 1. Reported Adverse Events

**Adverse Events Reported in the A Group**

**Adverse Events Reported in the B Group**

1. **Baseline Descriptive Statistics and Group Differences**
   1. Baseline Descriptive Statistics for all Per Protocol Subjects

***Table 4.***

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Group A**  **(N=)** | **Group B**  **(N=)** | **p-values** |
|  | *Mean (SD)*  *[min-max]* | *Mean (SD)*  *[min-max]* |  |

1. **Final Per Protocol Analysis** 
   1. PP ***End of Study Statistics*** for all Subjects

***Table 5.***

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Group A**  **(N=)** | **Group B**  **(N=)** | **p-values** |
|  | *Mean (SD)*  *[min-max]* | *Mean (SD)*  *[min-max]* |  |

* 1. PP Primary Outcome Measure Analysis

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Group A**  **(N=)** | | **Group A Change Score** | **Group B**  **(N=)** | | **Group B Change Score** | **Interaction F-Statistics** |
|  | *Pre-Mean (SD)* | *Post-Mean (SD)* |  | *Pre-Mean (SD)* | *Post-Mean (SD)* |  |  |

*\*Indicates a significant Group×Time (pre-post) interaction test statistic at p<.05 for*

*^Indicates a trend-level Group×Time (pre-post) interaction test statistic at p<.10 for*

† *Indicates a significant estimated marginal means for post-hoc pairwise comparison test of within-group change at p<.05*

* 1. PP Secondary Outcome Measure Analysis

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Group A**  **(N=)** | | **Group A Change Score** | **Group B**  **(N=)** | | **Group B Change Score** | **Interaction F-Statistics** |
|  | *Pre-Mean (SD)* | *Post-Mean (SD)* |  | *Pre-Mean (SD)* | *Post-Mean (SD)* |  |  |

*\*Indicates a significant Group×Time (pre-post) interaction test statistic at p<.05 for*

*^Indicates a trend-level Group×Time (pre-post) interaction test statistic at p<.10 for*

† *Indicates a significant estimated marginal means for post-hoc pairwise comparison test of within-group change at p<.05*

***Figure 1a. Error Bars Reflecting Change in Primary and Secondary Endpoints Across Study***

***Figure 1b. Error Bars Reflecting Change in Secondary Endpoints Across Study***

1. **Written Report**