Clinical scenario evaluation

# General information

## Project information

This report was generated by [Mediana's User] using the Mediana package. For more information about the Mediana package, see http://biopharmnet.com/mediana.

Project title: Case study 2

Description: Clinical trial in patients with schizophrenia

## Simulation parameters

Random seed: 42938001

Number of simulations: 1000

Number of cores: 4

Start time: 2015-10-04 18:17:01

End time: 2015-10-04 18:17:14

Duration (mins): 0.22 mins

# Data model

## Sample size

Number of samples: 4

Number of sample size sets: 3

1. Sample size

| **Sample size set** | **Sample** | **Size** |
| --- | --- | --- |
| N = 220 | Placebo | 220 |
| Dose L | 220 |
| Dose M | 220 |
| Dose H | 220 |
| N = 240 | Placebo | 240 |
| Dose L | 240 |
| Dose M | 240 |
| Dose H | 240 |
| N = 260 | Placebo | 260 |
| Dose L | 260 |
| Dose M | 260 |
| Dose H | 260 |

## Outcome distribution

Number of outcome parameter sets: 1

Outcome distribution: Normal

1. Outcome parameter

| **Outcome parameter set** | **Sample** | **Parameter** |
| --- | --- | --- |
| Outcome 1 | Placebo | mean = 16, SD = 18 |
| Dose L | mean = 19.5, SD = 18 |
| Dose M | mean = 21, SD = 18 |
| Dose H | mean = 21, SD = 18 |

# Analysis model

## Tests

Number of tests/null hypotheses: 3

1. Tests

| **Test ID** | **Test type** | **Test parameters** | **Samples** |
| --- | --- | --- | --- |
| Pl vs Dose L | Student's t-test |  | {Placebo}, {Dose L} |
| Pl vs Dose M | Student's t-test |  | {Placebo}, {Dose M} |
| Pl vs Dose H | Student's t-test |  | {Placebo}, {Dose H} |

## Multiplicity adjustment

Procedure: Hochberg procedure

Tests: {Pl vs Dose L, Pl vs Dose M, Pl vs Dose H}

Parameters: Weight={0.33,0.33,0.33}

# Outcome Parameter 1

1. Results summary

| **Sample Size** | **Multiplicity Adjustment** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- | --- |
| N = 220 | Multiplicity adjustment scenario 1 | Marginal power | Pl vs Dose L | 0.5060 |
| Marginal power | Pl vs Dose M | 0.7590 |
| Marginal power | Pl vs Dose H | 0.7510 |
| Disjunctive power | Disjunctive power | 0.8430 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.6780 |
| N = 240 | Marginal power | Pl vs Dose L | 0.5450 |
| Marginal power | Pl vs Dose M | 0.7930 |
| Marginal power | Pl vs Dose H | 0.7880 |
| Disjunctive power | Disjunctive power | 0.8730 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.7210 |
| N = 260 | Marginal power | Pl vs Dose L | 0.5880 |
| Marginal power | Pl vs Dose M | 0.8330 |
| Marginal power | Pl vs Dose H | 0.8430 |
| Disjunctive power | Disjunctive power | 0.9150 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.7760 |