Clinical Scenario Evaluation

# General information

## Project information

This report was generated by [Mediana's User] using the Mediana package version 1.0.7. For more information about the Mediana package, see http://gpaux.github.io/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: 2018-07-16 10:34:42

End time: 2018-07-16 10:34:48

Duration: 5.83 secs

# 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** |
| --- | --- | --- | --- |
| Placebo vs Dose L | Student's t-test |  | {Placebo}, {Dose L} |
| Placebo vs Dose M | Student's t-test |  | {Placebo}, {Dose M} |
| Placebo vs Dose H | Student's t-test |  | {Placebo}, {Dose H} |

## Multiplicity adjustment

Procedure: Hochberg procedure

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

Parameters: Weight={0.33,0.33,0.33}

# Evaluation model

## Criteria

Number of criteria: 3

1. Criteria

| **Criterion ID** | **Criterion parameters** | **Tests** | **Statistics** | **Label** |
| --- | --- | --- | --- | --- |
| Marginal power | alpha = 0.025 | Placebo vs Dose LPlacebo vs Dose MPlacebo vs Dose H |  | Placebo vs Dose LPlacebo vs Dose MPlacebo vs Dose H |
| Disjunctive power | alpha = 0.025 | Placebo vs Dose LPlacebo vs Dose MPlacebo vs Dose H |  | Disjunctive power |
| Dose H and at least one dose | alpha = 0.025 | Placebo vs Dose LPlacebo vs Dose MPlacebo vs Dose H |  | Dose H and at least one of the two other doses are significant |

# Simulation results

## Outcome Parameter 1

1. Results summary

| **Sample Size** | **Multiplicity Adjustment** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- | --- |
| N = 220 | Multiplicity adjustment scenario 1 | Marginal power | Placebo vs Dose L | 0.5060 |
| Marginal power | Placebo vs Dose M | 0.7590 |
| Marginal power | Placebo 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 | Placebo vs Dose L | 0.5450 |
| Marginal power | Placebo vs Dose M | 0.7930 |
| Marginal power | Placebo 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 | Placebo vs Dose L | 0.5880 |
| Marginal power | Placebo vs Dose M | 0.8330 |
| Marginal power | Placebo 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 |