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 3

Description: Clinical trial in patients with asthma

## Simulation parameters

Random seed: 42938001

Number of simulations: 1000

Number of cores: 4

Start time: 2018-07-16 10:34:56

End time: 2018-07-16 10:35:02

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 = 330 | Placebo M- | 99 |
| Placebo M+ | 66 |
| Treatment M- | 99 |
| Treatment M+ | 66 |
| N = 340 | Placebo M- | 102 |
| Placebo M+ | 68 |
| Treatment M- | 102 |
| Treatment M+ | 68 |
| N = 350 | Placebo M- | 105 |
| Placebo M+ | 70 |
| Treatment M- | 105 |
| Treatment M+ | 70 |

## Outcome distribution

Number of outcome parameter sets: 1

Outcome distribution: Normal

1. Outcome parameter

| **Outcome parameter set** | **Sample** | **Parameter** |
| --- | --- | --- |
| Outcome 1 | {Placebo M-} | mean = 0.12, SD = 0.45 |
| {Placebo M+} | mean = 0.12, SD = 0.45 |
| {Treatment M-} | mean = 0.24, SD = 0.45 |
| {Treatment M+} | mean = 0.3, SD = 0.45 |

# Analysis model

## Tests

Number of tests/null hypotheses: 2

1. Tests

| **Test ID** | **Test type** | **Test parameters** | **Samples** |
| --- | --- | --- | --- |
| OP test | Student's t-test |  | {Placebo M-, Placebo M+}, {Treatment M-, Treatment M+} |
| M+ test | Student's t-test |  | {Placebo M+}, {Treatment M+} |

## Multiplicity adjustment

Procedure: Hochberg procedure

Tests: {OP test, M+ test}

Parameters: Weight={0.5,0.5}

# Evaluation model

## Criteria

Number of criteria: 3

1. Criteria

| **Criterion ID** | **Criterion parameters** | **Tests** | **Statistics** | **Label** |
| --- | --- | --- | --- | --- |
| Marginal power | alpha = 0.025 | OP testM+ test |  | OP testM+ test |
| Disjunctive power | alpha = 0.025 | OP testM+ test |  | Disjunctive power |
| Conjunctive power | alpha = 0.025 | OP testM+ test |  | Conjunctive power |

# Simulation results

## Outcome Parameter 1

1. Results summary

| **Multiplicity Adjustment** | **Sample Size** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- | --- |
| Hochberg adjustment | N = 330 | Marginal power | OP test | 0.7620 |
| Marginal power | M+ test | 0.6200 |
| Disjunctive power | Disjunctive power | 0.7900 |
| Conjunctive power | Conjunctive power | 0.5920 |
| N = 340 | Marginal power | OP test | 0.7750 |
| Marginal power | M+ test | 0.6370 |
| Disjunctive power | Disjunctive power | 0.8100 |
| Conjunctive power | Conjunctive power | 0.6020 |
| N = 350 | Marginal power | OP test | 0.8020 |
| Marginal power | M+ test | 0.6450 |
| Disjunctive power | Disjunctive power | 0.8250 |
| Conjunctive power | Conjunctive power | 0.6220 |