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 1

Description: Clinical trial in patients with relapsing-remitting multiple sclerosis

## Simulation parameters

Random seed: 42938001

Number of simulations: 1000

Number of cores: 4

Start time: 2018-07-16 10:34:15

End time: 2018-07-16 10:34:36

Duration: 21.05 secs

# Data model

## Sample size

Number of samples: 2

Number of sample size sets: 6

1. Sample size

| **Sample size set** | **Sample** | **Size** |
| --- | --- | --- |
| N = 100 | Placebo | 100 |
| Treatment | 100 |
| N = 110 | Placebo | 110 |
| Treatment | 110 |
| N = 120 | Placebo | 120 |
| Treatment | 120 |
| N = 130 | Placebo | 130 |
| Treatment | 130 |
| N = 140 | Placebo | 140 |
| Treatment | 140 |
| N = 150 | Placebo | 150 |
| Treatment | 150 |

## Outcome distribution

Number of outcome parameter sets: 1

Outcome distribution: Negative binomial

1. Outcome parameter

| **Outcome parameter set** | **Sample** | **Parameter** |
| --- | --- | --- |
| Outcome 1 | {Placebo} | dispersion = 0.5, mean = 13 |
| {Treatment} | dispersion = 0.5, mean = 7.8 |

# Analysis model

## Tests

Number of tests/null hypotheses: 1

1. Tests

| **Test ID** | **Test type** | **Test parameters** | **Samples** |
| --- | --- | --- | --- |
| Treatment vs Placebo | Negative-binomial regression test |  | {Treatment}, {Placebo} |

# Evaluation model

## Criteria

Number of criteria: 1

1. Criteria

| **Criterion ID** | **Criterion parameters** | **Tests** | **Statistics** | **Label** |
| --- | --- | --- | --- | --- |
| Marginal power | alpha = 0.025 | Treatment vs Placebo |  | Treatment vs Placebo |

# Simulation results

## Outcome Parameter 1

1. Results summary

| **Sample Size** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- |
| N = 100 | Marginal power | Treatment vs Placebo | 0.7070 |
| N = 110 | Marginal power | Treatment vs Placebo | 0.7430 |
| N = 120 | Marginal power | Treatment vs Placebo | 0.7760 |
| N = 130 | Marginal power | Treatment vs Placebo | 0.8290 |
| N = 140 | Marginal power | Treatment vs Placebo | 0.8430 |
| N = 150 | Marginal power | Treatment vs Placebo | 0.8540 |