Clinical Scenario Evaluation

# General information

## Project information

This report was generated by [Mediana's User] using the Mediana package version 1.0.8. For more information about the Mediana package, see http://gpaux.github.io/Mediana.

Project title: Case study 1

Description: Clinical trial in patients with metastatic colorectal cancer

## Simulation parameters

Random seed: 42938001

Number of simulations: 1000

Number of cores: 4

Start time: 2020-04-18 14:39:53

End time: 2020-04-18 14:40:05

Duration: 12.00 secs

# Data model

## Number of events

Number of samples: 2

Randomization ratio: (1:2)

Number of event sets: 2

1. Event

| **Event set** | **Total number of events** |
| --- | --- |
| Event 1 | 210 |
| Event 2 | 300 |

## Outcome distribution

Number of outcome parameter sets: 1

Outcome distribution: Exponential

1. Outcome parameter

| **Outcome parameter set** | **Sample** | **Parameter** |
| --- | --- | --- |
| Outcome 1 | {Placebo} | rate = 0.116 |
| {Treatment} | rate = 0.077 |

# Analysis model

## Tests

Number of tests/null hypotheses: 1

1. Tests

| **Test ID** | **Test type** | **Test parameters** | **Samples** |
| --- | --- | --- | --- |
| Placebo vs treatment | Log-rank test |  | {Placebo}, {Treatment} |

## Statistics

Number of descriptive statistics: 1

1. Statistics

| **Statistic ID** | **Statistic type** | **Statistic parameters** | **Samples** |
| --- | --- | --- | --- |
| Hazard Ratio | Hazard Ratio | method = Cox | {Placebo}, {Treatment} |

# Evaluation model

## Criteria

Number of criteria: 2

1. Criteria

| **Criterion ID** | **Criterion parameters** | **Tests** | **Statistics** | **Label** |
| --- | --- | --- | --- | --- |
| Marginal power | alpha = 0.025 | Placebo vs treatment |  | Placebo vs treatment |
| Hazard Ratio |  |  | Hazard Ratio | Average Hazard Ratio |

# Simulation results

## Outcome Parameter 1

1. Results summary

| **Event Set** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- |
| Event 1 | Marginal power | Placebo vs treatment | 0.7700 |
| Hazard Ratio | Average Hazard Ratio | 0.6727 |
| Event 2 | Marginal power | Placebo vs treatment | 0.8940 |
| Hazard Ratio | Average Hazard Ratio | 0.6726 |