Clinical Scenario Evaluation

# General information

## Project information

This report was generated by [Mediana's User] using the Mediana package version 1.0.4. 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: 2017-02-05 20:00:33

End time: 2017-02-05 20:01:50

Duration: 1.28 mins

# Data model

## Design

Number of design parameter sets: 1

1. Design

|  | **Enrollment** | | |  |  | **Dropout** | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Design parameter set** | **Enrollment period** | **Enrollment distribution** | **Enrollment distribution parameter** | **Follow-up period** | **Study duration** | **Dropout distribution** | **Dropout distribution parameter** |
| Design 1 | 9 | Uniform |  |  | 21 | Exponential | rate = 0.0115 |

## 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 | 390 |
| Event 2 | 420 |

## 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: 4

1. Statistics

| **Statistic ID** | **Statistic type** | **Statistic parameters** | **Samples** |
| --- | --- | --- | --- |
| Events Placebo | Number of Events |  | {Placebo} |
| Events Treatment | Number of Events |  | {Treatment} |
| Patients Placebo | Number of Patients |  | {Placebo} |
| Patients Treatment | Number of Patients |  | {Treatment} |

# Evaluation model

## Criteria

Number of criteria: 3

1. Criteria

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

# Simulation results

## Outcome Parameter 1

1. Results summary

| **Event Set** | **Design Parameter** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- | --- |
| Event 1 | Design 1 | Marginal power | Placebo vs treatment | 0.9680 |
| Mean Events | Mean Events Placebo | 145.2540 |
| Mean Events | Mean Events Treatment | 245.3880 |
| Mean Patients | Mean Patients Placebo | 208.2710 |
| Mean Patients | Mean Patients Treatment | 416.5420 |
| Event 2 | Marginal power | Placebo vs treatment | 0.9770 |
| Mean Events | Mean Events Placebo | 156.3650 |
| Mean Events | Mean Events Treatment | 264.2240 |
| Mean Patients | Mean Patients Placebo | 224.2720 |
| Mean Patients | Mean Patients Treatment | 448.5440 |