Clinical Scenario Evaluation

# General information

## Project information

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

Project title: Case study 4

Description: Clinical trial in patients with metastatic colorectal cancer

## Simulation parameters

Random seed: 42938001

Number of simulations: 1000

Number of cores: 4

Start time: 2016-11-13 23:35:27

End time: 2016-11-13 23:35:35

Duration: 7.84 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** |
| --- | --- |
| Total number of events = 270 | 270 |
| Total number of events = 300 | 300 |

## Outcome distribution

Number of outcome parameter sets: 1

Outcome distribution: Multivariate Exponential for PFS and OS

1. Outcome parameter

| **Outcome parameter set** | **Sample** | **Parameter** |
| --- | --- | --- |
| Outcome 1 | Placebo PFS, Placebo OS | rate = 0.116, rate = 0.046, corr = {1,0.3,0.3,1} |
| Treatment PFS, Treatment OS | rate = 0.077, rate = 0.036, corr = {1,0.3,0.3,1} |

# Analysis model

## Tests

Number of tests/null hypotheses: 2

1. Tests

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

## Multiplicity adjustment

Procedure: Fixed-sequence procedure

Tests: {PFS test, OS test}

# Evaluation model

## Criteria

Number of criteria: 1

1. Criteria

| **Criterion ID** | **Criterion parameters** | **Tests** | **Statistics** | **Label** |
| --- | --- | --- | --- | --- |
| Marginal power | alpha = 0.025 | PFS test OS test |  | PFS test OS test |

# Simulation results

## Outcome Parameter 1

1. Results summary

| **Multiplicity Adjustment** | **Event Set** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- | --- |
| Fixed-sequence procedure | Total number of events = 270 | Marginal power | PFS test | 0.7650 |
| Marginal power | OS test | 0.3990 |
| Total number of events = 300 | Marginal power | PFS test | 0.8180 |
| Marginal power | OS test | 0.4480 |