Clinical Scenario Evaluation

# General information

## Project information

This report was generated by Gautier Paux using the Mediana package version 1.0.6. For more information about the Mediana package, see http://gpaux.github.io/Mediana.

Project title: Case study 3

Description: Simulation report for case study 3 of the Subgroup Analysis in Clinical Trials

## Simulation parameters

Random seed: 42938001

Number of simulations: 1e+05

Number of cores: 4

Start time: 2018-01-31 13:38:34

End time: 2018-01-31 13:48:02

Duration: 9.47 mins

# Data model

## Sample size

Number of samples: 4

Number of sample size sets: 1

1. Sample size

| **Sample size set** | **Sample** | **Size** |
| --- | --- | --- |
| Sample size 1 | Placebo Bio-Neg | 61 |
| Placebo Bio-Pos | 74 |
| Treatment Bio-Neg | 61 |
| Treatment Bio-Pos | 74 |

## Outcome distribution

Number of outcome parameter sets: 1

Outcome distribution: Exponential

1. Outcome parameter

| **Outcome parameter set** | **Sample** | **Parameter** |
| --- | --- | --- |
| Outcome 1 | {Placebo Bio-Neg} | rate = 0.092 |
| {Placebo Bio-Pos} | rate = 0.092 |
| {Treatment Bio-Neg} | rate = 0.082 |
| {Treatment Bio-Pos} | rate = 0.055 |

# Analysis model

## Tests

Number of tests/null hypotheses: 2

1. Tests

| **Test ID** | **Test type** | **Test parameters** | **Samples** |
| --- | --- | --- | --- |
| OP test | Log-rank test |  | {Placebo Bio-Neg, Placebo Bio-Pos}, {Treatment Bio-Neg, Treatment Bio-Pos} |
| Bio-Pos test | Log-rank test |  | {Placebo Bio-Pos}, {Treatment Bio-Pos} |

## Statistics

Number of descriptive statistics: 2

1. Statistics

| **Statistic ID** | **Statistic type** | **Statistic parameters** | **Samples** |
| --- | --- | --- | --- |
| Effect Size in Bio-Neg | Effect size (event) |  | {Placebo Bio-Neg}, {Treatment Bio-Neg} |
| Ratio Effect Size Bio-Pos vs Bio-Neg | Ratio of effect size (event) |  | {Placebo Bio-Pos}, {Treatment Bio-Pos}, {Placebo Bio-Neg}, {Treatment Bio-Neg} |

## Multiplicity adjustment

Procedure: Hochberg procedure

Tests: {OP test, Bio-Pos test}

Parameters: Weight={0.8,0.2}

# Evaluation model

## Criteria

Number of criteria: 6

1. Criteria

| **Criterion ID** | **Criterion parameters** | **Tests** | **Statistics** | **Label** |
| --- | --- | --- | --- | --- |
| Marginal power | alpha = 0.025 | OP test Bio-Pos test |  | OP test Bio-Pos test |
| Disjunctive power | alpha = 0.025 | OP test Bio-Pos test |  | Disjunctive power |
| Weighted power | alpha = 0.025 v1 = 0.3226 v2 = 0.1774 v3 = 0.5 influence\_threshold = 0.15 interaction\_threshold = 1.5 | OP test Bio-Pos test | Effect Size in Bio-Neg Ratio Effect Size Bio-Pos vs Bio-Neg | Weighted power (with conditions) |
| Probability of a broad claim | alpha = 0.025 influence\_threshold = 0.15 interaction\_threshold = 1.5 | OP test Bio-Pos test | Effect Size in Bio-Neg Ratio Effect Size Bio-Pos vs Bio-Neg | Probability of a broad claim |
| Probability of a restricted claim | alpha = 0.025 influence\_threshold = 0.15 interaction\_threshold = 1.5 | OP test Bio-Pos test | Effect Size in Bio-Neg Ratio Effect Size Bio-Pos vs Bio-Neg | Probability of a restricted claim |
| Probability of an enhanced claim | alpha = 0.025 influence\_threshold = 0.15 interaction\_threshold = 1.5 | OP test Bio-Pos test | Effect Size in Bio-Neg Ratio Effect Size Bio-Pos vs Bio-Neg | Probability of an enhanced claim |

# Simulation results

## Outcome Parameter 1

1. Results summary

| **Multiplicity Adjustment** | **Sample Size** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- | --- |
| Hochberg | Sample size 1 | Marginal power | OP test | 0.7975 |
| Marginal power | Bio-Pos test | 0.8010 |
| Disjunctive power | Disjunctive power | 0.8348 |
| Weighted power | Weighted power (with conditions) | 0.2561 |
| Probability of a broad claim | Probability of a broad claim | 0.1406 |
| Probability of a restricted claim | Probability of a restricted claim | 0.4226 |
| Probability of an enhanced claim | Probability of an enhanced claim | 0.2716 |