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 1

Description: Simulation report for case study 1 of the Clinical Trials with Multiple Objectives chapter

## Simulation parameters

Random seed: 42938001

Number of simulations: 1e+05

Number of cores: 4

Start time: 2018-01-31 12:39:00

End time: 2018-01-31 12:45:53

Duration: 6.87 mins

# Data model

## Sample size

Number of samples: 3

Number of sample size sets: 1

1. Sample size

| **Sample size set** | **Sample** | **Size** |
| --- | --- | --- |
| Sample size 1 | Placebo | 100 |
| Dose L | 100 |
| Dose H | 100 |

## Outcome distribution

Number of outcome parameter sets: 3

Outcome distribution: Binomial

1. Outcome parameter

| **Outcome parameter set** | **Sample** | **Parameter** |
| --- | --- | --- |
| Scenario 1 | {Placebo} | prop = 0.3 |
| {Dose L} | prop = 0.5 |
| {Dose H} | prop = 0.5 |
| Scenario 2 | {Placebo} | prop = 0.3 |
| {Dose L} | prop = 0.4 |
| {Dose H} | prop = 0.5 |
| Scenario 3 | {Placebo} | prop = 0.3 |
| {Dose L} | prop = 0.5 |
| {Dose H} | prop = 0.45 |

# Analysis model

## Tests

Number of tests/null hypotheses: 2

1. Tests

| **Test ID** | **Test type** | **Test parameters** | **Samples** |
| --- | --- | --- | --- |
| Placebo vs Dose H | Test for proportions |  | {Placebo}, {Dose H} |
| Placebo vs Dose L | Test for proportions |  | {Placebo}, {Dose L} |

## Multiplicity adjustment

### No adjustment

Procedure: No adjustment

### Procedure F

Procedure: Fixed-sequence procedure

Tests: {Placebo vs Dose H, Placebo vs Dose L}

### Procedure H

Procedure: Hochberg procedure

Tests: {Placebo vs Dose H, Placebo vs Dose L}

Parameters: Weight={0.5,0.5}

# Evaluation model

## Criteria

Number of criteria: 4

1. Criteria

| **Criterion ID** | **Criterion parameters** | **Tests** | **Statistics** | **Label** |
| --- | --- | --- | --- | --- |
| Marginal power | alpha = 0.025 | Placebo vs Dose HPlacebo vs Dose L |  | Placebo vs Dose HPlacebo vs Dose L |
| Disjunctive power | alpha = 0.025 | Placebo vs Dose HPlacebo vs Dose L |  | Disjunctive power |
| Weighted power | alpha = 0.025weight = c(0.4, 0.6) | Placebo vs Dose HPlacebo vs Dose L |  | Weighted power (v1 = 0.4, v2 = 0.6) |
| Partition-based weighted power | alpha = 0.025weight = c(0.15, 0.25, 0.6) | Placebo vs Dose HPlacebo vs Dose L |  | Partition-based weighted power (v1 = 0.15, v2 = 0.25, v12 = 0.6) |

# Simulation results

## Outcome Parameter (Scenario 1)

1. Results summary

| **Multiplicity Adjustment** | **Sample Size** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- | --- |
| No adjustment | Sample size 1 | Marginal power | Placebo vs Dose H | 0.8322 |
| Marginal power | Placebo vs Dose L | 0.8313 |
| Disjunctive power | Disjunctive power | 0.9346 |
| Weighted power | Weighted power (v1 = 0.4, v2 = 0.6) | 0.8317 |
| Partition-based weighted power | Partition-based weighted power (v1 = 0.15, v2 = 0.25, v12 = 0.6) | 0.4784 |
| Procedure F | Marginal power | Placebo vs Dose H | 0.8322 |
| Marginal power | Placebo vs Dose L | 0.7289 |
| Disjunctive power | Disjunctive power | 0.8322 |
| Weighted power | Weighted power (v1 = 0.4, v2 = 0.6) | 0.7702 |
| Partition-based weighted power | Partition-based weighted power (v1 = 0.15, v2 = 0.25, v12 = 0.6) | 0.4528 |
| Procedure H | Marginal power | Placebo vs Dose H | 0.8107 |
| Marginal power | Placebo vs Dose L | 0.8095 |
| Disjunctive power | Disjunctive power | 0.8913 |
| Weighted power | Weighted power (v1 = 0.4, v2 = 0.6) | 0.8100 |
| Partition-based weighted power | Partition-based weighted power (v1 = 0.15, v2 = 0.25, v12 = 0.6) | 0.4698 |

## Outcome Parameter (Scenario 2)

1. Results summary

| **Multiplicity Adjustment** | **Sample Size** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- | --- |
| No adjustment | Sample size 1 | Marginal power | Placebo vs Dose H | 0.8295 |
| Marginal power | Placebo vs Dose L | 0.3149 |
| Disjunctive power | Disjunctive power | 0.8450 |
| Weighted power | Weighted power (v1 = 0.4, v2 = 0.6) | 0.5207 |
| Partition-based weighted power | Partition-based weighted power (v1 = 0.15, v2 = 0.25, v12 = 0.6) | 0.2630 |
| Procedure F | Marginal power | Placebo vs Dose H | 0.8295 |
| Marginal power | Placebo vs Dose L | 0.2994 |
| Disjunctive power | Disjunctive power | 0.8295 |
| Weighted power | Weighted power (v1 = 0.4, v2 = 0.6) | 0.5114 |
| Partition-based weighted power | Partition-based weighted power (v1 = 0.15, v2 = 0.25, v12 = 0.6) | 0.2592 |
| Procedure H | Marginal power | Placebo vs Dose H | 0.7592 |
| Marginal power | Placebo vs Dose L | 0.3077 |
| Disjunctive power | Disjunctive power | 0.7675 |
| Weighted power | Weighted power (v1 = 0.4, v2 = 0.6) | 0.4883 |
| Partition-based weighted power | Partition-based weighted power (v1 = 0.15, v2 = 0.25, v12 = 0.6) | 0.2507 |

## Outcome Parameter (Scenario 3)

1. Results summary

| **Multiplicity Adjustment** | **Sample Size** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- | --- |
| No adjustment | Sample size 1 | Marginal power | Placebo vs Dose H | 0.5962 |
| Marginal power | Placebo vs Dose L | 0.8312 |
| Disjunctive power | Disjunctive power | 0.8818 |
| Weighted power | Weighted power (v1 = 0.4, v2 = 0.6) | 0.7372 |
| Partition-based weighted power | Partition-based weighted power (v1 = 0.15, v2 = 0.25, v12 = 0.6) | 0.4063 |
| Procedure F | Marginal power | Placebo vs Dose H | 0.5962 |
| Marginal power | Placebo vs Dose L | 0.5456 |
| Disjunctive power | Disjunctive power | 0.5962 |
| Weighted power | Weighted power (v1 = 0.4, v2 = 0.6) | 0.5658 |
| Partition-based weighted power | Partition-based weighted power (v1 = 0.15, v2 = 0.25, v12 = 0.6) | 0.3350 |
| Procedure H | Marginal power | Placebo vs Dose H | 0.5794 |
| Marginal power | Placebo vs Dose L | 0.7848 |
| Disjunctive power | Disjunctive power | 0.8186 |
| Weighted power | Weighted power (v1 = 0.4, v2 = 0.6) | 0.7026 |
| Partition-based weighted power | Partition-based weighted power (v1 = 0.15, v2 = 0.25, v12 = 0.6) | 0.3922 |