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 2

Description: Simulation report for case study 2 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 12:46:05

End time: 2018-01-31 13:04:06

Duration: 18.02 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 - E1, Placebo - E2 | 100 |
| Dose L - E1, Dose L - E2 | 200 |
| Dose H - E1, Dose H - E2 | 200 |

## Outcome distribution

Number of outcome parameter sets: 4

Outcome distribution: Multivariate Normal

1. Outcome parameter

| **Outcome parameter set** | **Sample** | **Parameter** |
| --- | --- | --- |
| Scenario 1 | {Placebo - E1}, {Placebo - E2} | {mean = -12, SD = 20}, {mean = -0.8, SD = 1}, corr = {1,0.5,0.5,1} |
| {Dose L - E1}, {Dose L - E2} | {mean = -18, SD = 20}, {mean = -1.1, SD = 1}, corr = {1,0.5,0.5,1} |
| {Dose H - E1}, {Dose H - E2} | {mean = -20, SD = 20}, {mean = -1.1, SD = 1}, corr = {1,0.5,0.5,1} |
| Scenario 2 | {Placebo - E1}, {Placebo - E2} | {mean = -12, SD = 20}, {mean = -0.8, SD = 1}, corr = {1,0.5,0.5,1} |
| {Dose L - E1}, {Dose L - E2} | {mean = -18, SD = 20}, {mean = -1.1, SD = 1}, corr = {1,0.5,0.5,1} |
| {Dose H - E1}, {Dose H - E2} | {mean = -18, SD = 20}, {mean = -1.1, SD = 1}, corr = {1,0.5,0.5,1} |
| Scenario 3 | {Placebo - E1}, {Placebo - E2} | {mean = -12, SD = 20}, {mean = -0.8, SD = 1}, corr = {1,0.5,0.5,1} |
| {Dose L - E1}, {Dose L - E2} | {mean = -18, SD = 20}, {mean = -1.2, SD = 1}, corr = {1,0.5,0.5,1} |
| {Dose H - E1}, {Dose H - E2} | {mean = -20, SD = 20}, {mean = -1.2, SD = 1}, corr = {1,0.5,0.5,1} |
| Scenario 4 | {Placebo - E1}, {Placebo - E2} | {mean = -12, SD = 20}, {mean = -1.2, SD = 1}, corr = {1,0.5,0.5,1} |
| {Dose L - E1}, {Dose L - E2} | {mean = -18, SD = 20}, {mean = -1.2, SD = 1}, corr = {1,0.5,0.5,1} |
| {Dose H - E1}, {Dose H - E2} | {mean = -18, SD = 20}, {mean = -1.2, SD = 1}, corr = {1,0.5,0.5,1} |

# Analysis model

## Tests

Number of tests/null hypotheses: 4

1. Tests

| **Test ID** | **Test type** | **Test parameters** | **Samples** |
| --- | --- | --- | --- |
| Placebo vs Dose H - E1 | Student's t-test |  | {Dose H - E1}, {Placebo - E1} |
| Placebo vs Dose L - E1 | Student's t-test |  | {Dose L - E1}, {Placebo - E1} |
| Placebo vs Dose H - E2 | Student's t-test |  | {Dose H - E2}, {Placebo - E2} |
| Placebo vs Dose L - E2 | Student's t-test |  | {Dose L - E2}, {Placebo - E2} |

## Multiplicity adjustment

### Procedure B1

Procedure: Chain procedure

Tests: {Placebo vs Dose H - E1, Placebo vs Dose L - E1, Placebo vs Dose H - E2, Placebo vs Dose L - E2}

Parameters:

Weight={1,0,0,0}

Transition matrix={0,0.8,0.2,0,0,0,0,1,0,0,0,0,0,0,0,0}

### Procedure B2

Procedure: Chain procedure

Tests: {Placebo vs Dose H - E1, Placebo vs Dose L - E1, Placebo vs Dose H - E2, Placebo vs Dose L - E2}

Parameters:

Weight={1,0,0,0}

Transition matrix={0,1,0,0,0,0,0,1,0,1,0,0,0,0,1,0}

# Evaluation model

## Criteria

Number of criteria: 5

1. Criteria

| **Criterion ID** | **Criterion parameters** | **Tests** | **Statistics** | **Label** |
| --- | --- | --- | --- | --- |
| Marginal power | alpha = 0.025 | Placebo vs Dose H - E1 Placebo vs Dose L - E1 Placebo vs Dose H - E2 Placebo vs Dose L - E2 |  | Placebo vs Dose H - E1 Placebo vs Dose L - E1 Placebo vs Dose H - E2 Placebo vs Dose L - E2 |
| Disjunctive power | alpha = 0.025 | Placebo vs Dose H - E1 Placebo vs Dose L - E1 Placebo vs Dose H - E2 Placebo vs Dose L - E2 |  | Disjunctive power |
| Subset Disjunctive power | alpha = 0.025 | Placebo vs Dose H - E1 Placebo vs Dose L - E1 Placebo vs Dose H - E2 Placebo vs Dose L - E2 |  | Subset Disjunctive power |
| Weighted power | alpha = 0.025 weight = c(0.4, 0.4, 0.1, 0.1) | Placebo vs Dose H - E1 Placebo vs Dose L - E1 Placebo vs Dose H - E2 Placebo vs Dose L - E2 |  | Weighted power (v1 = 0.4, v2 = 0.4, v3 = 0.1, v4 = 0.1) |
| Partition-based weighted power | alpha = 0.025 weight = c(0.2, 0.35, 0.45) | Placebo vs Dose H - E1 Placebo vs Dose L - E1 Placebo vs Dose H - E2 Placebo vs Dose L - E2 |  | Partition-based weighted power (v1 = 0.20, v2 = 0.35, v3 = 0.45) |

# Simulation results

## Outcome Parameter (Scenario 1)

1. Results summary

| **Multiplicity Adjustment** | **Sample Size** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- | --- |
| Procedure B1 | Sample size 1 | Marginal power | Placebo vs Dose H - E1 | 0.9016 |
| Marginal power | Placebo vs Dose L - E1 | 0.6337 |
| Marginal power | Placebo vs Dose H - E2 | 0.4301 |
| Marginal power | Placebo vs Dose L - E2 | 0.4854 |
| Disjunctive power | Disjunctive power | 0.9016 |
| Subset Disjunctive power | Subset Disjunctive power | 0.6064 |
| Weighted power | Weighted power (v1 = 0.4, v2 = 0.4, v3 = 0.1, v4 = 0.1) | 0.7056 |
| Partition-based weighted power | Partition-based weighted power (v1 = 0.20, v2 = 0.35, v3 = 0.45) | 0.3063 |
| Procedure B2 | Marginal power | Placebo vs Dose H - E1 | 0.9016 |
| Marginal power | Placebo vs Dose L - E1 | 0.6657 |
| Marginal power | Placebo vs Dose H - E2 | 0.4466 |
| Marginal power | Placebo vs Dose L - E2 | 0.5247 |
| Disjunctive power | Disjunctive power | 0.9016 |
| Subset Disjunctive power | Subset Disjunctive power | 0.5247 |
| Weighted power | Weighted power (v1 = 0.4, v2 = 0.4, v3 = 0.1, v4 = 0.1) | 0.7241 |
| Partition-based weighted power | Partition-based weighted power (v1 = 0.20, v2 = 0.35, v3 = 0.45) | 0.3248 |

## Outcome Parameter (Scenario 2)

1. Results summary

| **Multiplicity Adjustment** | **Sample Size** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- | --- |
| Procedure B1 | Sample size 1 | Marginal power | Placebo vs Dose H - E1 | 0.6838 |
| Marginal power | Placebo vs Dose L - E1 | 0.5420 |
| Marginal power | Placebo vs Dose H - E2 | 0.3730 |
| Marginal power | Placebo vs Dose L - E2 | 0.4209 |
| Disjunctive power | Disjunctive power | 0.6838 |
| Subset Disjunctive power | Subset Disjunctive power | 0.5100 |
| Weighted power | Weighted power (v1 = 0.4, v2 = 0.4, v3 = 0.1, v4 = 0.1) | 0.5697 |
| Partition-based weighted power | Partition-based weighted power (v1 = 0.20, v2 = 0.35, v3 = 0.45) | 0.2464 |
| Procedure B2 | Marginal power | Placebo vs Dose H - E1 | 0.6838 |
| Marginal power | Placebo vs Dose L - E1 | 0.5628 |
| Marginal power | Placebo vs Dose H - E2 | 0.3953 |
| Marginal power | Placebo vs Dose L - E2 | 0.4500 |
| Disjunctive power | Disjunctive power | 0.6838 |
| Subset Disjunctive power | Subset Disjunctive power | 0.4500 |
| Weighted power | Weighted power (v1 = 0.4, v2 = 0.4, v3 = 0.1, v4 = 0.1) | 0.5832 |
| Partition-based weighted power | Partition-based weighted power (v1 = 0.20, v2 = 0.35, v3 = 0.45) | 0.2607 |

## Outcome Parameter (Scenario 3)

1. Results summary

| **Multiplicity Adjustment** | **Sample Size** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- | --- |
| Procedure B1 | Sample size 1 | Marginal power | Placebo vs Dose H - E1 | 0.9016 |
| Marginal power | Placebo vs Dose L - E1 | 0.6337 |
| Marginal power | Placebo vs Dose H - E2 | 0.7091 |
| Marginal power | Placebo vs Dose L - E2 | 0.6000 |
| Disjunctive power | Disjunctive power | 0.9016 |
| Subset Disjunctive power | Subset Disjunctive power | 0.7986 |
| Weighted power | Weighted power (v1 = 0.4, v2 = 0.4, v3 = 0.1, v4 = 0.1) | 0.7450 |
| Partition-based weighted power | Partition-based weighted power (v1 = 0.20, v2 = 0.35, v3 = 0.45) | 0.3264 |
| Procedure B2 | Marginal power | Placebo vs Dose H - E1 | 0.9016 |
| Marginal power | Placebo vs Dose L - E1 | 0.6658 |
| Marginal power | Placebo vs Dose H - E2 | 0.6079 |
| Marginal power | Placebo vs Dose L - E2 | 0.6353 |
| Disjunctive power | Disjunctive power | 0.9016 |
| Subset Disjunctive power | Subset Disjunctive power | 0.6353 |
| Weighted power | Weighted power (v1 = 0.4, v2 = 0.4, v3 = 0.1, v4 = 0.1) | 0.7513 |
| Partition-based weighted power | Partition-based weighted power (v1 = 0.20, v2 = 0.35, v3 = 0.45) | 0.3410 |

## Outcome Parameter (Scenario 4)

1. Results summary

| **Multiplicity Adjustment** | **Sample Size** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- | --- |
| Procedure B1 | Sample size 1 | Marginal power | Placebo vs Dose H - E1 | 0.6833 |
| Marginal power | Placebo vs Dose L - E1 | 0.5442 |
| Marginal power | Placebo vs Dose H - E2 | 0.0053 |
| Marginal power | Placebo vs Dose L - E2 | 0.0176 |
| Disjunctive power | Disjunctive power | 0.6833 |
| Subset Disjunctive power | Subset Disjunctive power | 0.0207 |
| Weighted power | Weighted power (v1 = 0.4, v2 = 0.4, v3 = 0.1, v4 = 0.1) | 0.4933 |
| Partition-based weighted power | Partition-based weighted power (v1 = 0.20, v2 = 0.35, v3 = 0.45) | 0.2185 |
| Procedure B2 | Marginal power | Placebo vs Dose H - E1 | 0.6833 |
| Marginal power | Placebo vs Dose L - E1 | 0.5650 |
| Marginal power | Placebo vs Dose H - E2 | 0.0071 |
| Marginal power | Placebo vs Dose L - E2 | 0.0224 |
| Disjunctive power | Disjunctive power | 0.6833 |
| Subset Disjunctive power | Subset Disjunctive power | 0.0224 |
| Weighted power | Weighted power (v1 = 0.4, v2 = 0.4, v3 = 0.1, v4 = 0.1) | 0.5023 |
| Partition-based weighted power | Partition-based weighted power (v1 = 0.20, v2 = 0.35, v3 = 0.45) | 0.2221 |