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://biopharmnet.com/mediana.

Project title: Case study 6

Description: Clinical trial in patients with schizophrenia - Several MTPs

## Simulation parameters

Random seed: 42938001

Number of simulations: 1000

Number of cores: 4

Start time: 2015-10-18 18:48:24

End time: 2015-10-18 18:48:51

Duration (mins): 0.45 mins

# Data model

## Sample size

Number of samples: 4

Number of sample size sets: 3

1. Sample size

| **Sample size set** | **Sample** | **Size** |
| --- | --- | --- |
| N = 220 | Placebo | 220 |
| Dose L | 220 |
| Dose M | 220 |
| Dose H | 220 |
| N = 240 | Placebo | 240 |
| Dose L | 240 |
| Dose M | 240 |
| Dose H | 240 |
| N = 260 | Placebo | 260 |
| Dose L | 260 |
| Dose M | 260 |
| Dose H | 260 |

## Outcome distribution

Number of outcome parameter sets: 2

Outcome distribution: Normal

1. Outcome parameter

| **Outcome parameter set** | **Sample** | **Parameter** |
| --- | --- | --- |
| Standard | Placebo | mean = 16, SD = 18 |
| Dose L | mean = 19.5, SD = 18 |
| Dose M | mean = 21, SD = 18 |
| Dose H | mean = 21, SD = 18 |
| Optimistic | Placebo | mean = 16, SD = 18 |
| Dose L | mean = 20, SD = 18 |
| Dose M | mean = 21, SD = 18 |
| Dose H | mean = 22, SD = 18 |

# Analysis model

## Tests

Number of tests/null hypotheses: 3

1. Tests

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

## Multiplicity adjustment

### No adjustment

Procedure: No adjustment

### Bonferroni adjustment

Procedure: Bonferroni procedure

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

Parameters: Weight={0.25,0.25,0.5}

### Holm adjustment

Procedure: Holm procedure

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

Parameters: Weight={0.25,0.25,0.5}

### Hochberg adjustment

Procedure: Hochberg procedure

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

Parameters: Weight={0.25,0.25,0.5}

# Outcome Parameter (Standard) and Multiplicity Adjustment (No adjustment)

1. Results summary

| **Sample Size** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- |
| N = 220 | Marginal power | Placebo vs Dose L | 0.5400 |
| Marginal power | Placebo vs Dose M | 0.8340 |
| Marginal power | Placebo vs Dose H | 0.8200 |
| Disjunctive power | Disjunctive power | 0.9310 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.7540 |
| N = 240 | Marginal power | Placebo vs Dose L | 0.5800 |
| Marginal power | Placebo vs Dose M | 0.8570 |
| Marginal power | Placebo vs Dose H | 0.8470 |
| Disjunctive power | Disjunctive power | 0.9540 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.7840 |
| N = 260 | Marginal power | Placebo vs Dose L | 0.6220 |
| Marginal power | Placebo vs Dose M | 0.8890 |
| Marginal power | Placebo vs Dose H | 0.8900 |
| Disjunctive power | Disjunctive power | 0.9700 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.8430 |

# Outcome Parameter (Standard) and Multiplicity Adjustment (Bonferroni adjustment)

1. Results summary

| **Sample Size** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- |
| N = 220 | Marginal power | Placebo vs Dose L | 0.3400 |
| Marginal power | Placebo vs Dose M | 0.6590 |
| Marginal power | Placebo vs Dose H | 0.7450 |
| Disjunctive power | Disjunctive power | 0.8550 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.5910 |
| N = 240 | Marginal power | Placebo vs Dose L | 0.3760 |
| Marginal power | Placebo vs Dose M | 0.7160 |
| Marginal power | Placebo vs Dose H | 0.7790 |
| Disjunctive power | Disjunctive power | 0.8830 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.6470 |
| N = 260 | Marginal power | Placebo vs Dose L | 0.4150 |
| Marginal power | Placebo vs Dose M | 0.7580 |
| Marginal power | Placebo vs Dose H | 0.8230 |
| Disjunctive power | Disjunctive power | 0.9130 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.7070 |

# Outcome Parameter (Standard) and Multiplicity Adjustment (Holm adjustment)

1. Results summary

| **Sample Size** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- |
| N = 220 | Marginal power | Placebo vs Dose L | 0.4900 |
| Marginal power | Placebo vs Dose M | 0.7450 |
| Marginal power | Placebo vs Dose H | 0.7710 |
| Disjunctive power | Disjunctive power | 0.8550 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.6750 |
| N = 240 | Marginal power | Placebo vs Dose L | 0.5330 |
| Marginal power | Placebo vs Dose M | 0.7790 |
| Marginal power | Placebo vs Dose H | 0.8020 |
| Disjunctive power | Disjunctive power | 0.8830 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.7190 |
| N = 260 | Marginal power | Placebo vs Dose L | 0.5840 |
| Marginal power | Placebo vs Dose M | 0.8170 |
| Marginal power | Placebo vs Dose H | 0.8500 |
| Disjunctive power | Disjunctive power | 0.9130 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.7760 |

# Outcome Parameter (Standard) and Multiplicity Adjustment (Hochberg adjustment)

1. Results summary

| **Sample Size** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- |
| N = 220 | Marginal power | Placebo vs Dose L | 0.5010 |
| Marginal power | Placebo vs Dose M | 0.7550 |
| Marginal power | Placebo vs Dose H | 0.7830 |
| Disjunctive power | Disjunctive power | 0.8620 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.6900 |
| N = 240 | Marginal power | Placebo vs Dose L | 0.5510 |
| Marginal power | Placebo vs Dose M | 0.7880 |
| Marginal power | Placebo vs Dose H | 0.8170 |
| Disjunctive power | Disjunctive power | 0.8910 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.7370 |
| N = 260 | Marginal power | Placebo vs Dose L | 0.5950 |
| Marginal power | Placebo vs Dose M | 0.8240 |
| Marginal power | Placebo vs Dose H | 0.8600 |
| Disjunctive power | Disjunctive power | 0.9170 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.7890 |

# Outcome Parameter (Optimistic) and Multiplicity Adjustment (No adjustment)

1. Results summary

| **Sample Size** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- |
| N = 220 | Marginal power | Placebo vs Dose L | 0.6370 |
| Marginal power | Placebo vs Dose M | 0.8320 |
| Marginal power | Placebo vs Dose H | 0.9400 |
| Disjunctive power | Disjunctive power | 0.9760 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.8500 |
| N = 240 | Marginal power | Placebo vs Dose L | 0.6650 |
| Marginal power | Placebo vs Dose M | 0.8640 |
| Marginal power | Placebo vs Dose H | 0.9580 |
| Disjunctive power | Disjunctive power | 0.9870 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.8770 |
| N = 260 | Marginal power | Placebo vs Dose L | 0.7010 |
| Marginal power | Placebo vs Dose M | 0.8900 |
| Marginal power | Placebo vs Dose H | 0.9730 |
| Disjunctive power | Disjunctive power | 0.9890 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.9200 |

# Outcome Parameter (Optimistic) and Multiplicity Adjustment (Bonferroni adjustment)

1. Results summary

| **Sample Size** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- |
| N = 220 | Marginal power | Placebo vs Dose L | 0.4160 |
| Marginal power | Placebo vs Dose M | 0.6320 |
| Marginal power | Placebo vs Dose H | 0.8960 |
| Disjunctive power | Disjunctive power | 0.9310 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.6780 |
| N = 240 | Marginal power | Placebo vs Dose L | 0.4640 |
| Marginal power | Placebo vs Dose M | 0.6820 |
| Marginal power | Placebo vs Dose H | 0.9280 |
| Disjunctive power | Disjunctive power | 0.9590 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.7240 |
| N = 260 | Marginal power | Placebo vs Dose L | 0.5010 |
| Marginal power | Placebo vs Dose M | 0.7530 |
| Marginal power | Placebo vs Dose H | 0.9510 |
| Disjunctive power | Disjunctive power | 0.9740 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.7830 |

# Outcome Parameter (Optimistic) and Multiplicity Adjustment (Holm adjustment)

1. Results summary

| **Sample Size** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- |
| N = 220 | Marginal power | Placebo vs Dose L | 0.5990 |
| Marginal power | Placebo vs Dose M | 0.7590 |
| Marginal power | Placebo vs Dose H | 0.9060 |
| Disjunctive power | Disjunctive power | 0.9310 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.7680 |
| N = 240 | Marginal power | Placebo vs Dose L | 0.6390 |
| Marginal power | Placebo vs Dose M | 0.8020 |
| Marginal power | Placebo vs Dose H | 0.9350 |
| Disjunctive power | Disjunctive power | 0.9590 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.8110 |
| N = 260 | Marginal power | Placebo vs Dose L | 0.6800 |
| Marginal power | Placebo vs Dose M | 0.8480 |
| Marginal power | Placebo vs Dose H | 0.9580 |
| Disjunctive power | Disjunctive power | 0.9740 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.8670 |

# Outcome Parameter (Optimistic) and Multiplicity Adjustment (Hochberg adjustment)

1. Results summary

| **Sample Size** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- |
| N = 220 | Marginal power | Placebo vs Dose L | 0.6100 |
| Marginal power | Placebo vs Dose M | 0.7730 |
| Marginal power | Placebo vs Dose H | 0.9150 |
| Disjunctive power | Disjunctive power | 0.9350 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.7840 |
| N = 240 | Marginal power | Placebo vs Dose L | 0.6500 |
| Marginal power | Placebo vs Dose M | 0.8140 |
| Marginal power | Placebo vs Dose H | 0.9390 |
| Disjunctive power | Disjunctive power | 0.9610 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.8240 |
| N = 260 | Marginal power | Placebo vs Dose L | 0.6890 |
| Marginal power | Placebo vs Dose M | 0.8560 |
| Marginal power | Placebo vs Dose H | 0.9590 |
| Disjunctive power | Disjunctive power | 0.9750 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.8760 |