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: 2015-10-04 18:32:06

End time: 2015-10-04 18:32:31

Duration (mins): 0.43 mins

# Data model

## Sample size

Number of samples: 4

Number of sample size sets: 3

1. Sample size

| **Sample size set** | **Sample** | **Size** |
| --- | --- | --- |
| N = 250 | Placebo | 250 |
| Dose L | 250 |
| Dose M | 250 |
| Dose H | 250 |
| N = 275 | Placebo | 275 |
| Dose L | 275 |
| Dose M | 275 |
| Dose H | 275 |
| N = 300 | Placebo | 300 |
| Dose L | 300 |
| Dose M | 300 |
| Dose H | 300 |

## Outcome distribution

Number of outcome parameter sets: 2

Outcome distribution: Normal

1. Outcome parameter

| **Outcome parameter set** | **Sample** | **Parameter** |
| --- | --- | --- |
| Outcome 1 | Placebo | mean = 16, SD = 18 |
| Dose L | mean = 19.5, SD = 18 |
| Dose M | mean = 21, SD = 18 |
| Dose H | mean = 21, SD = 18 |
| Outcome 2 | Placebo | mean = 16, SD = 20 |
| Dose L | mean = 19.5, SD = 20 |
| Dose M | mean = 21, SD = 20 |
| Dose H | mean = 21, SD = 20 |

# Analysis model

## Tests

Number of tests/null hypotheses: 3

1. Tests

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

## Multiplicity adjustment

### No adjustment

Procedure: No adjustment

### Bonferroni adjustment

Procedure: Bonferroni procedure

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

Parameters: Weight={0.25,0.25,0.5}

### Holm adjustment

Procedure: Holm procedure

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

Parameters: Weight={0.25,0.25,0.5}

### Hochberg adjustment

Procedure: Hochberg procedure

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

Parameters: Weight={0.25,0.25,0.5}

# Outcome Parameter 1 and Multiplicity Adjustment (No adjustment)

1. Results summary

| **Sample Size** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- |
| N = 250 | Marginal power | Pl vs Dose L | 0.5990 |
| Marginal power | Pl vs Dose M | 0.8690 |
| Marginal power | Pl vs Dose H | 0.8890 |
| Disjunctive power | Disjunctive power | 0.9680 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.8250 |
| N = 275 | Marginal power | Pl vs Dose L | 0.6350 |
| Marginal power | Pl vs Dose M | 0.9090 |
| Marginal power | Pl vs Dose H | 0.9080 |
| Disjunctive power | Disjunctive power | 0.9800 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.8580 |
| N = 300 | Marginal power | Pl vs Dose L | 0.6780 |
| Marginal power | Pl vs Dose M | 0.9340 |
| Marginal power | Pl vs Dose H | 0.9290 |
| Disjunctive power | Disjunctive power | 0.9860 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.8960 |

# Outcome Parameter 2 and Multiplicity Adjustment (Bonferroni adjustment)

1. Results summary

| **Sample Size** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- |
| N = 250 | Marginal power | Pl vs Dose L | 0.3990 |
| Marginal power | Pl vs Dose M | 0.7170 |
| Marginal power | Pl vs Dose H | 0.8090 |
| 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 | 0.6600 |
| N = 275 | Marginal power | Pl vs Dose L | 0.4470 |
| Marginal power | Pl vs Dose M | 0.7730 |
| Marginal power | Pl vs Dose H | 0.8530 |
| Disjunctive power | Disjunctive power | 0.9420 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.7330 |
| N = 300 | Marginal power | Pl vs Dose L | 0.4840 |
| Marginal power | Pl vs Dose M | 0.8150 |
| Marginal power | Pl vs Dose H | 0.8870 |
| Disjunctive power | Disjunctive power | 0.9530 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.7780 |

# Outcome Parameter 1 and Multiplicity Adjustment (Holm adjustment)

1. Results summary

| **Sample Size** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- |
| N = 250 | Marginal power | Pl vs Dose L | 0.5590 |
| Marginal power | Pl vs Dose M | 0.7940 |
| Marginal power | Pl vs Dose H | 0.8360 |
| 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 | 0.7380 |
| N = 275 | Marginal power | Pl vs Dose L | 0.6110 |
| Marginal power | Pl vs Dose M | 0.8480 |
| Marginal power | Pl vs Dose H | 0.8810 |
| Disjunctive power | Disjunctive power | 0.9420 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.8020 |
| N = 300 | Marginal power | Pl vs Dose L | 0.6550 |
| Marginal power | Pl vs Dose M | 0.8810 |
| Marginal power | Pl vs Dose H | 0.9050 |
| Disjunctive power | Disjunctive power | 0.9530 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.8470 |

# Outcome Parameter 2 and Multiplicity Adjustment (Hochberg adjustment)

1. Results summary

| **Sample Size** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- |
| N = 250 | Marginal power | Pl vs Dose L | 0.5700 |
| Marginal power | Pl vs Dose M | 0.8030 |
| Marginal power | Pl vs Dose H | 0.8460 |
| Disjunctive power | Disjunctive power | 0.9180 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.7520 |
| N = 275 | Marginal power | Pl vs Dose L | 0.6190 |
| Marginal power | Pl vs Dose M | 0.8550 |
| Marginal power | Pl vs Dose H | 0.8880 |
| Disjunctive power | Disjunctive power | 0.9460 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.8120 |
| N = 300 | Marginal power | Pl vs Dose L | 0.6620 |
| Marginal power | Pl vs Dose M | 0.8860 |
| Marginal power | Pl vs Dose H | 0.9090 |
| Disjunctive power | Disjunctive power | 0.9550 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.8540 |

# Outcome Parameter 1 and Multiplicity Adjustment (No adjustment)

1. Results summary

| **Sample Size** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- |
| N = 250 | Marginal power | Pl vs Dose L | 0.4980 |
| Marginal power | Pl vs Dose M | 0.7880 |
| Marginal power | Pl vs Dose H | 0.7940 |
| Disjunctive power | Disjunctive power | 0.9180 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.7140 |
| N = 275 | Marginal power | Pl vs Dose L | 0.5270 |
| Marginal power | Pl vs Dose M | 0.8250 |
| Marginal power | Pl vs Dose H | 0.8450 |
| 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 | 0.7810 |
| N = 300 | Marginal power | Pl vs Dose L | 0.5700 |
| Marginal power | Pl vs Dose M | 0.8610 |
| Marginal power | Pl vs Dose H | 0.8680 |
| Disjunctive power | Disjunctive power | 0.9530 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.8120 |

# Outcome Parameter 2 and Multiplicity Adjustment (Bonferroni adjustment)

1. Results summary

| **Sample Size** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- |
| N = 250 | Marginal power | Pl vs Dose L | 0.2790 |
| Marginal power | Pl vs Dose M | 0.6100 |
| Marginal power | Pl vs Dose H | 0.7140 |
| Disjunctive power | Disjunctive power | 0.8350 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.5370 |
| N = 275 | Marginal power | Pl vs Dose L | 0.3160 |
| Marginal power | Pl vs Dose M | 0.6600 |
| Marginal power | Pl vs Dose H | 0.7670 |
| Disjunctive power | Disjunctive power | 0.8710 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.6000 |
| N = 300 | Marginal power | Pl vs Dose L | 0.3590 |
| Marginal power | Pl vs Dose M | 0.6930 |
| Marginal power | Pl vs Dose H | 0.7990 |
| Disjunctive power | Disjunctive power | 0.8860 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.6540 |

# Outcome Parameter 1 and Multiplicity Adjustment (Holm adjustment)

1. Results summary

| **Sample Size** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- |
| N = 250 | Marginal power | Pl vs Dose L | 0.4310 |
| Marginal power | Pl vs Dose M | 0.6850 |
| Marginal power | Pl vs Dose H | 0.7340 |
| Disjunctive power | Disjunctive power | 0.8350 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.6150 |
| N = 275 | Marginal power | Pl vs Dose L | 0.4810 |
| Marginal power | Pl vs Dose M | 0.7420 |
| Marginal power | Pl vs Dose H | 0.7920 |
| Disjunctive power | Disjunctive power | 0.8710 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.6900 |
| N = 300 | Marginal power | Pl vs Dose L | 0.5180 |
| Marginal power | Pl vs Dose M | 0.7700 |
| Marginal power | Pl vs Dose H | 0.8150 |
| Disjunctive power | Disjunctive power | 0.8860 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.7230 |

# Outcome Parameter 2 and Multiplicity Adjustment (Hochberg adjustment)

1. Results summary

| **Sample Size** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- |
| N = 250 | Marginal power | Pl vs Dose L | 0.4500 |
| Marginal power | Pl vs Dose M | 0.6980 |
| Marginal power | Pl vs Dose H | 0.7450 |
| Disjunctive power | Disjunctive power | 0.8400 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.6350 |
| N = 275 | Marginal power | Pl vs Dose L | 0.4900 |
| Marginal power | Pl vs Dose M | 0.7510 |
| Marginal power | Pl vs Dose H | 0.8040 |
| Disjunctive power | Disjunctive power | 0.8770 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.7040 |
| N = 300 | Marginal power | Pl vs Dose L | 0.5350 |
| Marginal power | Pl vs Dose M | 0.7860 |
| Marginal power | Pl vs Dose H | 0.8220 |
| Disjunctive power | Disjunctive power | 0.8920 |
| Dose H and at least one dose | Dose H and at least one of the two other doses are significant | 0.7400 |