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 5

Description: Clinical trial in patients with rheumatoid arthritis

## Simulation parameters

Random seed: 42938001

Number of simulations: 1000

Number of cores: 4

Start time: 2015-10-14 22:47:12

End time: 2015-10-14 22:48:07

Duration (mins): 0.91 mins

# Data model

## Sample size

Number of samples: 3

Number of sample size sets: 2

1. Sample size

| **Sample size set** | **Sample** | **Size** |
| --- | --- | --- |
| N = 100 | Placebo ACR20, Placebo HAQ-DI | 100 |
| DoseL ACR20, DoseL HAQ-DI | 100 |
| DoseH ACR20, DoseH HAQ-DI | 100 |
| N = 120 | Placebo ACR20, Placebo HAQ-DI | 120 |
| DoseL ACR20, DoseL HAQ-DI | 120 |
| DoseH ACR20, DoseH HAQ-DI | 120 |

## Outcome distribution

Number of outcome parameter sets: 3

Outcome distribution: Multivariate Mixed (Binomial, Normal)

1. Outcome parameter

| **Outcome parameter set** | **Sample** | **Parameter** |
| --- | --- | --- |
| Conservative | Placebo ACR20, Placebo HAQ-DI | prop = 0.3, mean = -0.1, SD = 0.5, corr = {1,0.5,0.5,1} |
| DoseL ACR20, DoseL HAQ-DI | prop = 0.4, mean = -0.2, SD = 0.5, corr = {1,0.5,0.5,1} |
| DoseH ACR20, DoseH HAQ-DI | prop = 0.5, mean = -0.3, SD = 0.5, corr = {1,0.5,0.5,1} |
| Standard | Placebo ACR20, Placebo HAQ-DI | prop = 0.3, mean = -0.1, SD = 0.5, corr = {1,0.5,0.5,1} |
| DoseL ACR20, DoseL HAQ-DI | prop = 0.45, mean = -0.25, SD = 0.5, corr = {1,0.5,0.5,1} |
| DoseH ACR20, DoseH HAQ-DI | prop = 0.55, mean = -0.35, SD = 0.5, corr = {1,0.5,0.5,1} |
| Optimistic | Placebo ACR20, Placebo HAQ-DI | prop = 0.3, mean = -0.1, SD = 0.5, corr = {1,0.5,0.5,1} |
| DoseL ACR20, DoseL HAQ-DI | prop = 0.5, mean = -0.3, SD = 0.5, corr = {1,0.5,0.5,1} |
| DoseH ACR20, DoseH HAQ-DI | prop = 0.6, mean = -0.4, SD = 0.5, 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 DoseL - ACR20 | Test for proportions |  | {Placebo ACR20}, {DoseL ACR20} |
| Placebo vs DoseH - ACR20 | Test for proportions |  | {Placebo ACR20}, {DoseH ACR20} |
| Placebo vs DoseL - HAQ-DI | Student's t-test |  | {DoseL HAQ-DI}, {Placebo HAQ-DI} |
| Placebo vs DoseH - HAQ-DI | Student's t-test |  | {DoseH HAQ-DI}, {Placebo HAQ-DI} |

## Multiplicity adjustment

Procedure: Multiple-sequence gatekeeping

Tests: {Placebo vs DoseH - ACR20, Placebo vs DoseL - ACR20, Placebo vs DoseH - HAQ-DI, Placebo vs DoseL - HAQ-DI}

1. Parameters:

| **Family** | **Hypotheses** | **Component procedure** | **Truncation parameter** |
| --- | --- | --- | --- |
| 1 | {Placebo vs DoseH - ACR20, Placebo vs DoseL - ACR20} | HolmAdj | 0.8 |
| 2 | {Placebo vs DoseH - HAQ-DI, Placebo vs DoseL - HAQ-DI} | HolmAdj | 1.0 |

# Outcome Parameter (Conservative)

1. Results summary

| **Multiplicity Adjustment** | **Sample Size** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- | --- |
| Multiple-sequence gatekeeping procedure | N = 100 | Marginal power | Placebo vs DoseL - ACR20 | 0.2950 |
| Marginal power | Placebo vs DoseH - ACR20 | 0.7420 |
| Marginal power | Placebo vs DoseL - HAQ-DI | 0.1320 |
| Marginal power | Placebo vs DoseH - HAQ-DI | 0.4740 |
| Disjunctive power - ACR20 | Disjunctive power - ACR20 | 0.7480 |
| Disjunctive power - HAQ-DI | Disjunctive power - HAQ-DI | 0.4770 |
| N = 120 | Marginal power | Placebo vs DoseL - ACR20 | 0.3420 |
| Marginal power | Placebo vs DoseH - ACR20 | 0.8210 |
| Marginal power | Placebo vs DoseL - HAQ-DI | 0.1730 |
| Marginal power | Placebo vs DoseH - HAQ-DI | 0.5870 |
| Disjunctive power - ACR20 | Disjunctive power - ACR20 | 0.8250 |
| Disjunctive power - HAQ-DI | Disjunctive power - HAQ-DI | 0.5880 |

# Outcome Parameter (Standard)

1. Results summary

| **Multiplicity Adjustment** | **Sample Size** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- | --- |
| Multiple-sequence gatekeeping procedure | N = 100 | Marginal power | Placebo vs DoseL - ACR20 | 0.5550 |
| Marginal power | Placebo vs DoseH - ACR20 | 0.9320 |
| Marginal power | Placebo vs DoseL - HAQ-DI | 0.3620 |
| Marginal power | Placebo vs DoseH - HAQ-DI | 0.7980 |
| Disjunctive power - ACR20 | Disjunctive power - ACR20 | 0.9390 |
| Disjunctive power - HAQ-DI | Disjunctive power - HAQ-DI | 0.8060 |
| N = 120 | Marginal power | Placebo vs DoseL - ACR20 | 0.6180 |
| Marginal power | Placebo vs DoseH - ACR20 | 0.9690 |
| Marginal power | Placebo vs DoseL - HAQ-DI | 0.4420 |
| Marginal power | Placebo vs DoseH - HAQ-DI | 0.8780 |
| Disjunctive power - ACR20 | Disjunctive power - ACR20 | 0.9700 |
| Disjunctive power - HAQ-DI | Disjunctive power - HAQ-DI | 0.8800 |

# Outcome Parameter (Optimistic)

1. Results summary

| **Multiplicity Adjustment** | **Sample Size** | **Criterion** | **Test/Statistic** | **Result** |
| --- | --- | --- | --- | --- |
| Multiple-sequence gatekeeping procedure | N = 100 | Marginal power | Placebo vs DoseL - ACR20 | 0.8380 |
| Marginal power | Placebo vs DoseH - ACR20 | 0.9860 |
| Marginal power | Placebo vs DoseL - HAQ-DI | 0.7030 |
| Marginal power | Placebo vs DoseH - HAQ-DI | 0.9550 |
| Disjunctive power - ACR20 | Disjunctive power - ACR20 | 0.9920 |
| Disjunctive power - HAQ-DI | Disjunctive power - HAQ-DI | 0.9590 |
| N = 120 | Marginal power | Placebo vs DoseL - ACR20 | 0.8850 |
| Marginal power | Placebo vs DoseH - ACR20 | 0.9940 |
| Marginal power | Placebo vs DoseL - HAQ-DI | 0.8060 |
| Marginal power | Placebo vs DoseH - HAQ-DI | 0.9810 |
| Disjunctive power - ACR20 | Disjunctive power - ACR20 | 0.9960 |
| Disjunctive power - HAQ-DI | Disjunctive power - HAQ-DI | 0.9820 |