# Traditional design with multiple outcomes

## Description

The simulation report presents key operating characteristics of a multiplicity adjustment for multiple treatment-control comparisons in a trial with a normally distributed endpoint.

## Table 1. Number of enrolled patients

| **Trial arm** | **Sample size** |
| --- | --- |
| Control | 100 |
| Treatment 1 | 100 |
| Treatment 2 | 100 |
| Treatment 3 | 100 |

## Table 2. Treatment effect assumptions

| **Trial arm** | **Parameter** | **Value** |
| --- | --- | --- |
| Control | Mean | 0.1 |
|  | SD | 1.5 |
| Treatment 1 | Mean | -0.4 |
|  | SD | 1.5 |
| Treatment 2 | Mean | -0.45 |
|  | SD | 1.5 |
| Treatment 3 | Mean | -0.5 |
|  | SD | 1.5 |

A lower value of the endpoint indicates a beneficial effect.

## Table 3. Hypothesis definitions

| **Hypothesis** | **Definition** |
| --- | --- |
| Hypothesis 1 | Null hypothesis of no difference between Treatment 1 and control |
| Hypothesis 2 | Null hypothesis of no difference between Treatment 2 and control |
| Hypothesis 3 | Null hypothesis of no difference between Treatment 3 and control |

## Table 4. Multiple testing procedure

| **Parameter** | **Value** |
| --- | --- |
| Multiple testing procedure | Hochberg |

## Table 5. Multiple testing procedure: Initial hypothesis weights

| **Hyp 1** | **Hyp 2** | **Hyp 3** |
| --- | --- | --- |
| 0.3333 | 0.3333 | 0.3333 |

## Table 6. Other design parameters

| **Parameter** | **Value** |
| --- | --- |
| Dropout rate at the end of the treatment period (%) | 30 |

## Table 7. Simulation parameters

| **Parameter** | **Value** |
| --- | --- |
| One-sided Type I error rate | 0.025 |
| Number of simulations | 10000 |

## Table 8. Simulation results: Hypothesis-specific power

| **Hypothesis** | **Power (%)** | **Adjusted power (%)** |
| --- | --- | --- |
| Hypothesis 1 | 66 | 60.9 |
| Hypothesis 2 | 73.3 | 67 |
| Hypothesis 3 | 80.2 | 73 |

Power: Probability of rejecting each hypothesis of no effect without a multiplicity adjustment. Adjusted power: Probability of rejecting each hypothesis of no effect using a multiplicity adjustment based on the specified multiple testing procedure.

## Table 9. Simulation results: Overall power

| **Overall power** | **Power (%)** |
| --- | --- |
| Disjunctive power | 83 |
| Conjunctive power | 50.1 |

Disjunctive power: Probability of rejecting at least one hypothesis of no effect using a multiplicity adjustment based on the specified multiple testing procedure. Conjunctive power: Probability of rejecting all hypotheses of no effect using a multiplicity adjustment based on the specified multiple testing procedure.