# Traditional design with multiple outcomes

## Description

The simulation report presents key operating characteristics of a multiplicity adjustment or a global testing procedure for multiple endpoints in a trial with a normally distributed endpoint.

## Table 1. Number of enrolled patients

| **Trial arm** | **Sample size** |
| --- | --- |
| Control | 180 |
| Treatment | 180 |

## Table 2. Treatment effect assumptions

| **Endpoint** | **Trial arm** | **Parameter** | **Value** |
| --- | --- | --- | --- |
| Endpoint 1 | Control | Mean | 35 |
|  |  | SD | 100 |
|  | Treatment | Mean | 60 |
|  |  | SD | 100 |
| Endpoint 2 | Control | Mean | 110 |
|  |  | SD | 270 |
|  | Treatment | Mean | 200 |
|  |  | SD | 270 |

A higher value of the endpoint indicates a beneficial effect.

## Table 3. Hypothesis definitions

| **Hypothesis** | **Definition** |
| --- | --- |
| Hypothesis 1 | Null hypothesis of no difference between the treatment and control with respect to Endpoint 1 |
| Hypothesis 2 | Null hypothesis of no difference between the treatment and control with respect to Endpoint 2 |

## Table 4. Endpoint correlation matrix

| **Endpoint** | **Endpoint 1** | **Endpoint 2** |
| --- | --- | --- |
| Endpoint 1 | 1 | 0.35 |
| Endpoint 2 | 0.35 | 1 |

## Table 5. Global testing procedure

| **Parameter** | **Value** |
| --- | --- |
| Global testing procedure | O'Brien |

## Table 6. Other design parameters

| **Parameter** | **Value** |
| --- | --- |
| Dropout rate (%) | 5 |

## 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 (%)** |
| --- | --- |
| Hypothesis 1 | 65.3 |
| Hypothesis 2 | 89.3 |

Power: Probability of rejecting each hypothesis of no effect without a multiplicity adjustment.

## Table 9. Simulation results: Overall power

| **Overall power** | **Power (%)** |
| --- | --- |
| Global power | 92.1 |

Global power: Probability of rejecting at least one hypothesis of no effect using the specified global testing approach.