# Cluster-randomized design

## Description

The simulation report presents key operating characteristics of a cluster-randomized design for a Phase III clinical trial.

## Table 1. Number of completers

| **Trial arm** | **Sample size** |
| --- | --- |
| Control | 960 |
| Treatment | 960 |

Completers are defined as patients who complete the trial and are included in the final analysis.

## Table 2. Primary efficacy endpoint

| **Parameter** | **Value** |
| --- | --- |
| Endpoint type | Binary |
| Direction of favorable outcome | A lower value of the endpoint indicates a more favorable outcome |

## Table 3. Cluster scheme parameters

| **Trial arm** | **Number of clusters** | **Cluster sizes** |
| --- | --- | --- |
| Control | 12 | 80, 80, 80, 80, 80, 80, 80, 80, 80, 80, 80, 80 |
| Treatment | 12 | 80, 80, 80, 80, 80, 80, 80, 80, 80, 80, 80, 80 |

A design with pre-defined cluster sizes is assumed.

## Table 4. Treatment effect assumptions

| **Trial arm** | **Parameter** | **Value** |
| --- | --- | --- |
| Control | Rate (%) | 60 |
| Treatment | Rate (%) | 40 |

## Table 5. Variability parameters

| **Trial arm** | **Parameter** | **Value** |
| --- | --- | --- |
| Control | Intra-cluster correlation coefficient | 0.1 |
| Treatment | Intra-cluster correlation coefficient | 0.1 |

## Table 6. Analysis and simulation parameters

| **Parameter** | **Value** |
| --- | --- |
| Data analysis method | Generalized estimating equations (GEE) |
| One-sided Type I error rate | 0.025 |
| Number of simulations | 1000 |

## Table 7. Simulation results: Descriptive statistics

| **Parameter** | **Trial arm** | **Statistic** | **Value** |
| --- | --- | --- | --- |
| Rate (%) | Control | Mean | 60 |
|  |  | 25%P, 75%P | 56.8, 63.2 |
|  |  | 2.5%P, 97.5%P | 50.6, 69.5 |
|  | Treatment | Mean | 40.1 |
|  |  | 25%P, 75%P | 36.8, 43.4 |
|  |  | 2.5%P, 97.5%P | 31.3, 49.4 |

Descriptive statistics computed from each simulation run: 2.5%P (2.5th percentile), 25%P (25th percentile), 75%P (75th percentile) and 97.5%P (97.5th percentile).

## Table 8. Simulation results: Power calculations

| **Analysis method** | **Power (%)** |
| --- | --- |
| Standard analysis | 84.6 |
| Bias-corrected analysis (Kauermann-Carroll correction) | 82.3 |
| Bias-corrected analysis (Mancl-DeRouen correction) | 79.7 |