



Sample Size Calculator

Determines the minimum number of subjects for adequate study power

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Study Group Design



vs.

Two independent
study groups



One study group
vs. population

Two study groups will each receive different treatments.

Primary Endpoint



Dichotomous
(yes/no)




Continuous
(means)


The primary endpoint is **binomial** - only two possible outcomes.
Eg, mortality (dead/not dead), pregnant (pregnant/not)

Statistical Parameters


Anticipated Incidence

Group 1 

73 %

Group 2 


63 %

Incidence 

Enrollment ratio 

1

Type I/II Error Rate

Alpha 

0.05

Power 

80%

Reset

Calculate

RESULTS

Dichotomous Endpoint, Two Independent Sample Study

Sample Size	
Group 1	340
Group 2	340
Total	680

Study Parameters	
Incidence, group 1	73%
Incidence, group 2	63%
Alpha	0.05
Beta	0.2

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About This Calculator

This calculator uses a number of different equations to determine the minimum number of subjects that need to be enrolled in a study in order to have sufficient statistical power to detect a treatment effect.¹

Before a study is conducted, investigators need to determine how many subjects should be included. By enrolling too few subjects, a study may not have enough statistical power to detect a difference (type II error). Enrolling too many patients can be unnecessarily costly or time-consuming.

Generally speaking, statistical power is determined by the following variables:

- ▶ **Baseline Incidence:** If an outcome occurs infrequently, many more patients are needed in order to detect a difference.
- ▶ **Population Variance:** The higher the variance (standard deviation), the more patients are needed to demonstrate a difference.
- ▶ **Treatment Effect Size:** If the difference between two treatments is small, more patients will be required to detect a difference.
- ▶ **Alpha:** The probability of a type-I error -- finding a difference when a difference does not exist. Most medical literature uses an alpha cut-off of 5% (0.05) -- indicating a 5% chance that a significant difference is actually due to chance and is not a true difference.
- ▶ **Beta:** The probability of a type-II error -- not detecting a difference when one actually exists. Beta is directly related to study power ($\text{Power} = 1 - \beta$). Most medical literature uses a beta cut-off of 20% (0.2) -- indicating a 20% chance that a significant difference is missed.

Post-Hoc Power Analysis

To calculate the post-hoc statistical power of an existing trial, please visit the [post-hoc power analysis calculator \(Power.aspx\)](#).

References and Additional Reading

1. Rosner B. *Fundamentals of Biostatistics*. 7th ed. Boston, MA: Brooks/Cole; 2011.

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- [Post-hoc Power Calculator \(Power.aspx\)](#)

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