

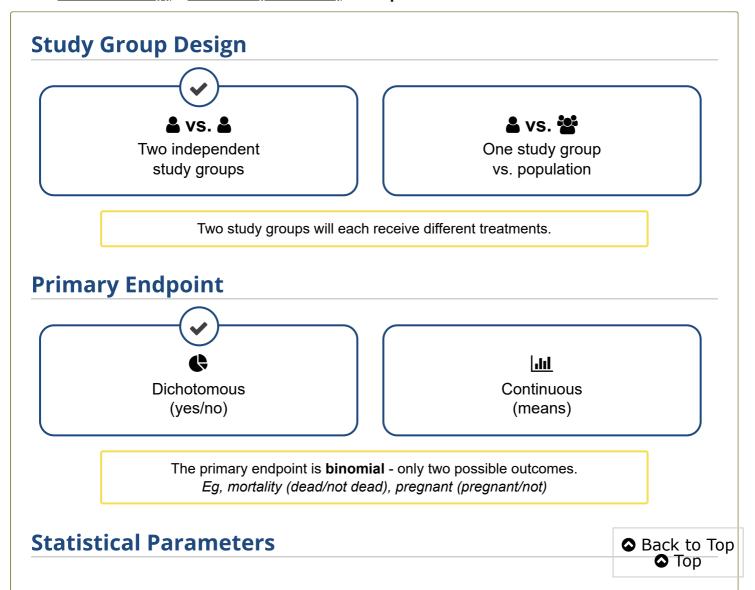
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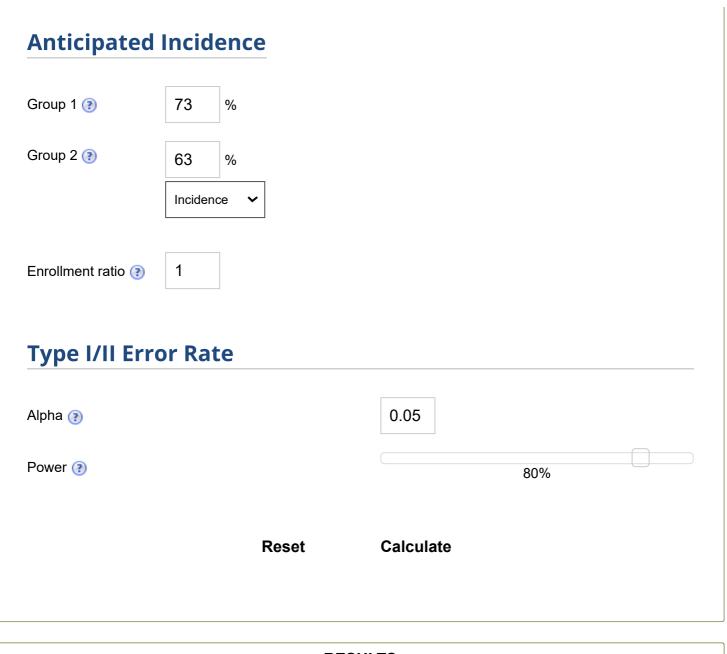
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Sample Size Calculator

Determines the minimum number of subjects for adequate study power

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RESULTS

Dichotomous Endpoint, Two Independent Sample Study

Sample Size		
Group 1	340	
Group 2	340	
Total	680	

Study Parameters	3			
Incidence, group 1	73%			
Incidence, group 2	63%			
Alpha	0.05	◇ E	ack to T	-ор
Beta	0.2		• Гор	

Power	0.8	
	ulations	

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 (Power = 1 β). 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 <u>post-hoc power</u> <u>analysis calculator (Power.aspx)</u>.

References and Additional Reading

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



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