

Non-Inferiority: Binary Outcome

Objective: Determine whether one group is inferior to another, within a certain margin

A researcher wants to see if a new topical antifungal is non-inferior to the current standard-of-care. The researcher plans a double-blind study with participants being equally randomized into one of two arms. One gets the current standard-of-care while the other receives the newly developed topical antifungal. The outcome of interest is the response rate to the drug. The current standard-of-care has an 82% response rate, and the researcher is expecting a similar response rate for the new drug. The literature has shown that other similar drugs would be deemed non-inferior to the standard-of-care if the new drug has a response rate no more than ten percentage points less than the rate in the standard arm. The researcher needs to determine what sample size they will need for their experiment to have 80% power and a significance level of 5%.

Required Information	Inputs
What is the desired power for the test?	80%
At what significance level do you want to test your hypothesis?	5%
Success probability of the control group?	82%
Success probability of the intervention group?	82%
What is the non-inferiority margin?	10%
Is your hypothesis one-sided or two-sided?	One-sided
What will the ratio of samples be in the intervention group to the control group?	1:1

Binomial Noninferiority

This program calculates the required sample size for a two-arm non-inferiority design with a binomial outcome.
For further details, view the [Help Document](#).

User Input	Program Output						
<p>Select the Desired Input Parameters</p> <p> <input checked="" type="radio"/> Noninferiority Margin <input type="radio"/> Success Probability in Experimental Arm (Under H0) </p>							
<p>Select the Hypothesis Test Parameters</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tbody> <tr> <td style="background-color: #ffff00;">Alpha Level (one-sided) 0.05</td> <td style="background-color: #ffff00;">Power Level 0.80</td> <td style="background-color: #ffff00;">Proportion of Patients in Experimental Arm 0.5</td> </tr> <tr> <td style="background-color: #ffff00;">Noninferiority Margin (Standard Arm - Experimental Arm (Under H0)) 0.10</td> <td style="background-color: #ffff00;">Success Probability in Standard Arm 0.82</td> <td style="background-color: #ffff00;">Success Probability in Experimental Arm (Under Ha) 0.82</td> </tr> </tbody> </table>		Alpha Level (one-sided) 0.05	Power Level 0.80	Proportion of Patients in Experimental Arm 0.5	Noninferiority Margin (Standard Arm - Experimental Arm (Under H0)) 0.10	Success Probability in Standard Arm 0.82	Success Probability in Experimental Arm (Under Ha) 0.82
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<p>Calculate Sample Size</p> <p style="text-align: center;"> Non-inferiority margin Probability of successful response in control group from literature Expected Probability of successful response in intervention group </p>							
<p>Sample Size 365</p> <p style="text-align: right;">TABLES</p>							

A total sample size of at least 365 is necessary, meaning 183 participants in each group for a total of 366.

Example using the Southwest Oncology Group's Statistical Tools (<https://stattools.crab.org/>)