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Take-Home Challenge for Align Technology: Task 2

Description: We recently improved our product design to reduce the aligner breakage rate and want to measure the impact of the improvement.

Question to answer: How many samples do we need to show a 15% point reduction in breakage rate (before – after =15%) after the product improvement? We can assume 95% confidence level and 90% power.

Answer:

This is an example of a one-sample dichotomous outcome. References can be found here and a useful calculator here, where the general formula for sample size N in this case is:

$$N = \frac{p_0 q_0 \left\{ z_{1-\alpha/2} + z_{1-\beta} \sqrt{\frac{p_1 q_1}{p_0 q_0}} \right\}^2}{(p_0 - p_1)^2}$$

where:

- p_0, p_1 = breakage rate of study group and population, respectively
- $p_0 - p_1 = 0.15$ represents the reduction in breakage rate
- $q_i = (1 - p_i)$
- $\alpha = 0.05$
- $\beta = 0.1$
- $z_{1-\alpha/2} = 1.96$
- $z_{1-\beta} = 1.28$

Thus, the most complete answer we can give without actually knowing the original population breakage rate is:

$$N = \frac{p_0 q_0 \left\{ 1.96 + 1.282 \sqrt{\frac{p_1 q_1}{p_0 q_0}} \right\}^2}{(0.15)^2}$$

That said, we can make it a little easier for our programmers with a little algebraic manipulation. Let's rewrite the entire formula so that p_0 is the only unknown variable, to be filled in by a later team:

$$N = \frac{p_0 (1 - p_0) \left\{ 1.96 + 1.282 \sqrt{\frac{(p_0 - 0.15)(1.15 - p_0)}{p_0 (1 - p_0)}} \right\}^2}{(0.15)^2}$$

Thank you for reading!