**Superiority Trials**

compare two treatment groups on a continuous outcome

formally test H0: HA:

design the study to show H0: HA:

by convention, test H0 against a two-sided HA

**Sample Size Calculations of Continuous Outcomes**

outcome standard error, same for each group

expected mean difference

critical value corresponding to significance level , usually 1.96

standard normal value not exceeded with probability , usually 0.84

At least subjects per group, or subjects total are needed to have an 80% chance to detect a significant mean difference of or more. There’s still a 20% chance there is an unsuccessful trial even if all the assumptions are correct.

if is underestimated, the study is underpowered, but might still find significant results

if isn’t as large as assumed, study might be underpowered

if is overestimated, the trial might be unfeasible

if is underestimated, the trial won’t be able to demonstrate difference between groups

better to overestimate and terminate the trial earlier than to underestimate

sample size accounting for loss to follow-up =

**Sample Size Calculations of Binary Outcomes**

critical value corresponding to significance level , usually 1.96

standard normal value not exceeded with probability , usually 0.84

At least subjects per group, or subjects total are needed to have an 80% chance to detect a significant mean difference of or more. There’s still a 20% chance there is an unsuccessful trial even if all the assumptions are correct.

sample size accounting for loss to follow-up =