BIOS 7400 Clinical Trials Assignment 2

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# Assignment I

Write out the following formula for a control group labeled as Y. Discuss how randomization in treatment allocation can help cancel out the bias of the effect of regression to the mean.

# Assignment II

Use the data (data\_surrogate.txt) to perform surrogate validation analysis.

* Use outcome1 as surrogate outcome and outcome2 as the true clinical outcome
* Provide the calculation of PE, RE and .
* Based on the calculation results, can you support outcome1 as a good surrogate for outcome2?

In order to check Prentice's criteria, the linear models was conducted as below.

where Z: treatment group. Assume "-1": Case group and "1": Control group. We also assume j indexes subjects and and are normal with mean 0.

We have 0 missing value in our dataset.

## Caculate PE, RE,and

Assume the assumptions are accetptable. The caculation of PE, RE, and as below.

P1\_1<-lm(formula = Outcome2~Treatment+Outcome1,data = DT2)  
P1\_2<-lm(formula = Outcome2~Treatment,data = DT2)

PE= = = 0.5631

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# Assignment III

Use the DBP dataset.

* Please use t test and Wilcoxon rank‐sum test to test the difference of the treatment on blood pressure change (the difference between the blood pressure measured on time 4, DBP4, and measured on time 1, DBP1).
* Present the results and write the report on your findings.

# Assignment IV

Use the CRASH trial (Corticosteroid Randomization After Significant Head Injury) data to compare the odds for “death” over “survival” between corticosteroid and placebo treatments.

* Use the prop.test in R to perform the statistical analysis
* The comparison should be made for “best prognosis”, “intermediate prognosis” and “worst prognosis” groups as well as all the subjects pooled together.
* Calculate the risk difference, risk ratio and odds ratio for the comparisons
* Present the results and write a report on your findings.