Randomized controlled trials (RCT's) are an indispensable source of information about efficacy of treatments in almost any disease area. With the availability of multiple treatment options, comparative effectiveness research (CER) is gaining importance for better and informed health care decisions. However design and analysis of effectiveness trial is much more complex than the efficacy trial. The effect of including an active comparator arm/s in a RCT is immense. This gives rise to superiority and non-inferiority trials. The non-inferiority (NI) RCT design plays a fundamental role in CER, which will be also focus of Dr. Ghosh’s presentation. In the past decade many statistical methods have been developed, though largely in the Frequentist setup. However, availability of historical placebo-controlled trial is useful and if integrated in the current NI trial design, can provide better precision for CER. This may reduce sample size burden and improves statistical power significantly in current trial. Bayesian paradigm provides a natural path to integrate historical as well as current trial data via sequential learning in the NI setup. Dr. Ghosh will discuss both fraction margin and fixed margin based Bayesian approach for three-arm trial. He will also discuss some interesting open problems related to CER using NI trial in the RCT framework.

For additional information or questions, please contact Deborah Curtis at curtisd@wustl.edu.