Please join the virtual Biometric Colloquium

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PLATFORM TRIALS: THE POTENTIALS AND THE CAVEATS OF ADDING ARMS

June 9th, 2021 at 9:15 am

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ABSTRACT:

Platform trial approach is becoming popular for the great potential to increase the efficiency of drug development process. This approach allows dropping and adding research arms throughout the course of an interventional study via protocol amendments. Methodological aspects of dropping arms have been well explored and discussed in the literature. The issues arising from adding new research comparisons remain less considered.

In this talk I will relate some aspects about adding arms and their impact on the inference. For example, one shall be mindful of the presence of a non-negligible time trend when using all control data in the analysis; the consequences of changing the treatment of the control arm, and of changing the patient inclusion and exclusion criteria during the lifetime of a platform trial. Consider comparisons where each intervention is compared with the treatment of the control group, I will focus on the topics of estimation and error rate control. I will discuss the statistical problems and present an overview on current methodology and some directions for future research.

This presentation is based on

Lee, K.M., Brown, L.C., Jaki, T. et al. Statistical consideration when adding new arms to ongoing clinical trials: the potentials and the caveats. Trials 22, 203 (2021). https://doi.org/10.1186/s13063-021-05150-7