Mathematics, Statistics, and Computer Science   **@ UIC**

Statistics and Data Science Seminar

Design and Analysis of Clinical Studies using Restricted Mean Survival Time

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Abstract: For a study with an event time as the endpoint, its survival function contains all the information regarding the temporal, stochastic profile of this outcome variable. The survival probability at a specific time point, say t, however, does not transparently capture the temporal profile of this endpoint up to t. An alternative is to use the restricted mean survival time (RMST) at time t to summarize the profile. The RMST is the mean survival time of all subjects in the study population followed up to t, and is simply the area under the survival curve up to t. The advantages of using such a quantification over the survival rate have been discussed in the setting of a fixed-time analysis. In this research, we generalize this approach by considering a curve based on the RMST over time as an alternative summary to the survival function. Inference, for instance, based on simultaneous confidence bands for a single RMST curve and also the difference between two RMST curves are proposed. The latter is informative for evaluating two groups under an equivalence or noninferiority setting, and quantifies the difference of two groups in a time scale. In addition, we extend RMET to the setting of multiple endpoints, which includes classical competing risks and semi-competing risks. The methods are illustrated with the data from two clinical trials.

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