STUDENT SEMINAR

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Title

A Robust Approach to Sample Size Calculation in Cancer **Immunotherapy Trials** with Delayed Treatment Effect

Speaker

Ting Ye

(3rd Year Ph.D. student in Statistics, UW-Madison)

Time & Place

Friday, May 4, 4pm, Social work 110

Snacks @ 3:45pm, Social work 110





Abstract

Immunotherapies are taking the center stage for cancer drug development and research. Many of these therapies, for example, immune checkpoint inhibitors, are known to have possible lag periods to achieve their full effects. Therefore the proportional hazard assumption is violated when comparing survival curves in randomized clinical trials evaluating such therapies. Limited work exists in determining sample size to account for the lag period which is usually unknown. Assuming that the lag period is within some reasonable range, this paper presents an approach to calculate sample size based on a maximin efficiency robust test. Both theoretical derivations and simulation results show the proposed approach can guarantee the desired power in worst case scenarios and often much more efficient than existing approaches. Application to a real trial design is also illustrated.