Yale SCHOOL OF PUBLIC HEALTH
Biostatistics

Presentation

Joint Modeling of Response and Time to Event in Phase II-III Cancer

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Abstract:

Whereas traditional phase II cancer trials are usually single-arm, with tumor response as endpoint, and phase III trials are randomized and incorporate interim analyses with progression-free survival or other failure time as endpoint, we propose a new approach that seamlessly expands a randomized phase II study of response rate into a randomized phase III study of time to failure. This approach is based on advances in group sequential designs and joint modeling of the response rate and time to event. The joint modeling is reflected in the primary and secondary objectives of the trial, and the sequential design allows the trial to adapt to increase in information on response and survival patterns during the course of the trial, and to stop early either for conclusive evidence on efficacy of the experimental treatment, or for the futility in continuing the trial to demonstrate it, based on the

data collected so far. This is joint work with Tze Leung Lai and Philip Lavori at Stanford University.

12:00 Noon Thursday, April 11th 2013
300 George St. - 157 IFE Auditorium
Lunch will be served