



JOHNS HOPKINS
BLOOMBERG
SCHOOL of PUBLIC HEALTH

Department of Biostatistics

BIostatISTICS SEMINAR,

Aligning Estimands and Their Estimators

– A Case Study

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Abstract:

Draft ICH E9(R1) Addendum on “Estimand and Sensitivity Analysis in Clinical Trials” provides different strategies for addressing intercurrent events in defining the estimand and describing the treatment effect that is targeted. Clinical trials are often faced with more than one intercurrent event and the set of intercurrent events for consideration will depend on the specific therapeutic setting and trial objectives. This presentation will consider a case study of a trial investigating treatment effect of a new drug in subjects who are asymptomatic at risk for developing Alzheimer’s dementia to illustrate the definition of different estimands which correspond to different scientific questions of interest. The potential intercurrent events will be identified and the case study will highlight how the selection of various strategies for intercurrent events translates into different estimators. A simulation investigation will also be presented, illustrating how the selection of the estimators for an estimand could have a strong impact on the estimates of the treatment effect.

Johns Hopkins Bloomberg School of Public Health, Department of Biostatistics
Monday, April 15, 12:15:1-15, Room W2008 (Refreshments 12:00pm)

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