

Statistics and Data Science Seminar

Paths to precision medicine: Exploratory Subgroup Analysis in Clinical Trials

Xin Huang (AbbVie, Inc)

Abstract: Mechanistic relationships between the clinical outcome (efficacy or safety endpoints) versus putative biomarkers, clinical baseline and related predictors are usually unknown, and must be deduced empirically from experimental data. Such relationships enable the implementation of a personalized medicine strategy in clinical trials to help stratify patients in terms of disease progression, clinical response, treatment differentiation, etc. These relationships are often requires complex modelling to develop the prognostic and predictive signatures. For the purpose of easier interpretation and implementation in the clinical practice, defining a multivariate biomarker signature in terms of thresholds on the biomarker combinations is preferable. In this presentation, we propose some methods for developing such signatures in the context of continuous, binary and time-to-event endpoints. Results from simulations and case-study illustration will also be provided.

Wednesday, April 15 at 4:00 PM in SEO 636