

Traveling Course

Council of Chapters



Course Title:

Survival Analysis Methods Correcting for Treatment Switching Effects in RCTs: Theory and SAS/R Code

Instructors:

Dr. Jing Xu, Senior Director, Takeda
Dr. Bingxia Wang, Senior Director, Takeda
Dr. Qingxia (Cindy) Chen, Professor,
Department of Biostatistics, Vanderbilt University

Course Length:

Full day and open to both in-person and virtual

Abstract:

In many late phase oncology randomized controlled trials (RCTs), control arm patients are permitted to take active treatment (1-way crossover), or patients in both control and active arms are permitted to take alternative treatments (2-way treatment switching) after disease progression due to ethical considerations. In both situations, the effect of active intervention on overall survival (OS) is no longer directly observable. The intent-to-treat (ITT) analysis of the observed data will reflect the trial outcome per the treatment policy strategy but may not be able to make causal inference for the active intervention effect on OS. The latter is important for the payer agency's evaluation and is helpful for regulatory decisions on drug applications.

During the last decade, several complex statistical methods have been adapted and applied to RCTs to recover the causal OS effect of randomized active intervention under settings that allow for treatment switching. These methods include but are not limited to MSM, TSE, IPCW, RPSFTM, IPE, Three-State Model. This course will review theory, regulatory guidance and demonstrate SAS code for these methods. It will discuss the pros and cons and practical issues when each method is applied under the RCT setting. Case studies will be presented to illustrate the application of each method.

For pre-readings, slide decks for the course will be distributed to registered attendees through emails 3 days before the course date by the course organizer. SAS/R code will be available upon request after the course through email to a course instructor.