Basel Biometric Section of the Austro-Swiss Region of the International Biometric Society

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BBS Seminar
Basel, 29 Nov 2011, 16:00 – 17:30

Seminar Room 3, Swiss TPH
Socinstrasse 55a, Basel

PROGRAM

16:00 **Welcome**

16:00 – 16:45 Dr Boris Choy (Business School, The University of Sydney)

Nonignorable dropout models for longitudinal binary data with random effects: An application of Monte Carlo approximation through the Gibbs output

Abstract

The analysis of longitudinal data with nonignorable dropout remains an active area in biostatistics research. Nonignorable dropout (ND) refers to the type of dropout when the probability of dropout depends on the missing observations at or after the time of dropout. Failure to account for such dependence may result in biased inference. Motivated by a methadone clinic data of longitudinal binary observations with dropouts, we propose a conditional first order autoregressive (AR1) logit model for the outcome measurements. The model is further extended to incorporate random effects in order to account for the population heterogeneity and intra-cluster correlation. The purposed models account for the dropout mechanism by a separate logit model in some covariates and missing outcomes for the binary dropout indicators. For model implementation, we proposed a likelihood approach through Monte Carlo approximation to the Gibbs output that evaluates the complicated likelihood function for the random effect ND model without tear. Finally simulation studies are performed to evaluate the biases on the parameter estimates of the outcome model for different dropout mechanisms.

16:45 – 17:30 Dr Mouna Akacha (Novartis, Basel)

Implementing Current Regulatory Guidance on the Treatment of Missing Data: An Industry Perspective

Abstract

Incomplete data due to missed visits, dropouts or non-return of questionnaires are very common in the clinical trial setting. In this context, missingness usually occurs for reasons outside the control of the investigators and may be related to the primary outcome of interest, hence complicating the data analysis. Two guidance documents on the treatment of missing data were published in the last two years: The 'Guideline on Missing Data in Confirmatory Clinical Trials' by the CHMP and the guidance document by the National Academy of Science titled 'The Prevention and Treatment of Missing Data in Clinical Trials' which was commissioned by the FDA. In this talk, we will briefly review the missing data challenge and present the key messages of the guidance documents. An industry perspective on implementing the current regulatory guidelines will be provided. In addition, we will discuss recent health authority interactions with regard to the missing data challenge and present a case study for which we received somewhat inconsistent health authority comments.