Exploratory Subgroup Analysis in Clinical Research

Readership: graduate students, clinicians and statistics researchers.

This is a useful book, which covers different methods to perform subgroup analysis. It is very well written and easily understood by a broad audience without prior knowledge of subgroup analysis. This book focuses on classical regression models like (generalized) linear models and the proportional hazards model for survival data and emphasizes applications with relatively few biomarkers or covariates. Clinicians and statisticians from the area of clinical development and regulation would benefit most, although the topic of subgroup analysis has a much wider scope.

The book is very well structured. First, it describes the history of subgroup analyses and introduces historical subgroup analyses which are each remarkable for a special reason. Next, it defines subgroups and presents examples of the good, the bad and the ugly subgroup analyses from the past, followed by different methods to analyze data from subgroups, including hierarchical models, methods to obtain estimates of expected individual treatment effects and prediction models (Chapter 4-8). Each method is illustrated with case studies. This book also carefully addresses selection bias by the bootstrap method and the risk of selecting too many false positive results in subgroup analyses.

Overall, it is an exciting book and it would provide an excellent basis for subgroup analyses.

Lili Zhao: *zhaolili@umich.edu*

Department of Biostatistics

1415 Washington Heights, University of Michigan, Ann Arbor, MI 48109 USA