

MODEL-BASED INFERENCE FOR SUBGROUP ANALYSIS

Dr. Juan Shen

Department of Statistics, Fudan University

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Abstract: In this talk, Subgroup analysis is an important problem in clinical trials. For example, when a new treatment is approved for use, there may be concerns that the efficacy is driven by extreme efficacy in a subgroup only. In recent years, researchers often attempt to identify a potential subgroup with an enhanced treatment effect. In this project, we assume that there exist two potential subgroups in which the subjects react differently to the treatment. We propose a logistic-normal mixture model where the group means as well as the mixing proportions may be covariate-dependent. Testing the existence of subgroups is critical in the mixture model, but requires nonstandard statistical tests. We derive a test based on a small number of EM iterations towards the likelihood, and propose the bootstrap approximation for the critical values of the test. When subgroups exist, the mixture model helps us identify the factors that are associated with the group membership. We apply the proposed method to the Aids Clinical Trials Group 320 study, and demonstrate that the patients with higher values of baseline CD4 or RNA tend to benefit significantly more by adding a protease inhibitor to two nucleoside analogues. We also extend our results to the logistic-normal mixture models with unequal variances across subgroups. $(y_n + 0.5\tau k_1)^2 + (t_n + 0.5\tau)$

Shanghai Center for Mathematical Sciences 22F East Guanghua Tower, Fudan University, No.220 Handan Road, Shanghai, China Tel: 55665643 Fax: 65642190 Postcode: 200433 Email: scms@fudan.edu.cn