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A mixture model using likelihood-based and Bayesian approaches for identifying responders and non-responders in longitudinal clinical trials

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A longitudinal mixture model for classifying patients into responders and non-responders is established using both likelihood-based and Bayesian approaches. The model takes into consideration responders in the control group. Therefore, it is especially useful in situations where the placebo response is strong. Under our model, a treatment shows evidence of being effective if it increases the proportion of responders or increases the response rate among responders in the treated group compared to the control group. Therefore, the model has flexibility to accommodate different situations. The proposed method is illustrated using simulation and a depression clinical trial dataset for the likelihood-based approach, and the same depression clinical trial dataset for the Bayesian approach. The likelihood-based and Bayesian approaches generated consistent results for the depression trial data. In both the placebo group and the treated group, patients are classified into two components with distinct response rate. The proportion of responders as shown to be significantly higher in the treated group compared to the control group suggesting the treatment paroxetine is effective.

Biography

Entsuah Anthony Richard is a fellow of the American Statistical Association and presently an Executive Director of Late Development Statistics at Merck Research Labs and Head of Research Group 4 (Neuroscience, Respiratory and Immunology areas). Previously, he was an Assistant Vice President of Biostatistics at Wyeth Research Labs (Pfizer). Prior to joining the industry in 1988), he was an Assistant Professor of Biometry at University of Illinois in Chicago. He has published extensively both in statistical and clinical journals and has given many presentations over the years. He has led approval of various compounds as the statistical lead and has been an invited seminar presenter at the US FDA.

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Notes:

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