Public Abstract

First Name:Min
Middle Name:
Last Name:Yi
Adviser's First Name:Nancy
Adviser's Last Name:Flournoy
Co-Adviser's First Name:
Co-Adviser's Last Name:
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The beta distribution is a simple and flexible model in which responses are naturally
confined to the finite interval, (0, 1). The parameters of the distribution can be related to covariates such as dose and gender through a regression model. The Ballooned Beta- logistic model, with expected responses equal to the Four Parameter Logistic model, is introduced. It expands the response boundaries of the beta regression model from (0, 1) to (L, U ), where L and U are unknown parameters. Un- der the Ballooned Beta-logistic model, expected responses follow a logistic function, but it differs from the classical Four Parameter Logistic model, which has normal additive normal errors, with positive probability of response from negative infinity to positive infinity. In contrast, the Ballooned Beta-logistic model naturally has skewed responses with smaller response variances at more extreme covariate values and symmetric responses with relative large variance at central values of the covariate. These features are common in bioassay data at different concentrations. The asymptotic normality of maximum likelihood estimators is obtained even though the support of this non-regular regression model depends on unknown parameters.
We find maximum likelihood estimates of boundaries converge faster to L and U than do extreme values at the minimum and maximum concentrations. We also find that maximum likelihood estimators perform better than least squares estimators when the covariate range is not sufficiently wide. Given multiple enzyme-linked immunosorbent assay (ELISA) data from different plates, the motivating question in a validation study was whether all plates had equivalent performance. A step-wise procedure is applied to measure equivalence of boundaries, slope and EC50 values.
First, we establish suitability criteria for estimates of L and U under the Ballooned Beta- logistic model, after which plates with boundary estimates outside these limit would be considered as ”reference failures”. Second, we use a bivariate normal approximation to evaluate the equivalence of Hill slopes and the dose giving, half maximal responses, the EC50 values, among plates considering L and U to be nuisance parameters, after
accepting the boundary equivalences. A series of confidence ellipsoids, an indicator of laboratories inhomogeneity, are drawn to detect plates with outlying slopes and EC50s.
The maximum likelihood estimates of parameters are obtained using a combination of a grid search with the Netwon-Raphson method. Moreover, different non-linear models compared in terms of their EC10, EC50, and EC90 values and the bootstrap method is
applied to draw 95% bootstrap predictive intervals for responses over all concentrations.