

Bayesian Monitoring of A Longitudinal Clinical Trial Using R2WinBUGS

Yue Wang^{1,*}, Narinder Nangia¹

1. Clinical Statistics, Abbott Laboratories, Abbott Park, IL, USA
* Contact author: yue.wang@abbott.com

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Learning stage study (a proof of concept or a dose-ranging study) is crucial in the drug development process as decisions to continue or halt development of the drug candidate meeting desired target product profile must be made with incomplete information. It is important to characterize the dose-response curve and estimate probability of success at an interim stage in a clinical trial to facilitate decision-making about further development of the experimental drug. When interim analyses are conducted, some subjects will have complete data, but others will have incomplete or partial information. We handle the partial data using a longitudinal model and Bayesian imputation. An algorithm that characterizes relationship between the early responses of subjects and their final responses in a longitudinal hierarchical model is developed to account for the uncertainty associated with having missing observations in estimating the dose-response curve. This algorithm facilitates remote execution of WinBUGS from within R using **R2WinBUGS**. Implementation of the Bayesian approach for monitoring a longitudinal clinical trial will be presented using a normal dynamic linear model for the dose-response curve.