AN ADAPTIVE APPROACH TO DESIGNING LONGITUDINAL CLINICAL TRIALS

W. Yuan[1], A. Liu[2], C. Wu[2] and K. F. Yu[2]

[1]*Food and Drug Administration, Rockville, U.S.A.*
[2]*National Institute of Child Health and Human Development, Rockville, U.S.A.*

Email: *vivian.yuan@fda.hhs.gov*

In designing longitudinal studies the level of significance of a test and its power to detect a meaningful clinical difference can be substantially adversely affected if nuisance parameters such as the measurement variation and the intra-subject correlation are incorrectly specified. In this paper, we propose adaptive procedures that allow sample size to be re-estimated using estimates of these nuisance parameters obtained in the mid-course of the study. Simulation results show these procedures to be effective in controlling error rates.