

# **A Sequential Procedure for Recalculating Sample Sizes and Monitoring Comparative Diagnostic Trials**

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**Abstract:** Before a comparative diagnostic trial is carried out, the maximum sample sizes for the diseased group and the nondiseased group need to be obtained to achieve a nominal power to detect a meaningful difference in diagnostic accuracy. Sample size calculation depends on the variance of the statistic of interest, which is usually the difference between ROC summary measures of two diagnostic tests. To get an appropriate value for the variance, one often has to assume an arbitrary parametric model and the associated parameter values for the two groups of subjects under the two tests to be compared. It becomes more tedious to do so when the same subject undergoes two different tests, because certain correlation is then involved in modeling the test outcomes. The calculated variance based on incorrectly specified parametric models may be smaller than the true one, which will subsequently result in smaller maximum sample sizes, leaving the study to be underpowered. In this talk I will introduce a nonparametric adaptive method for comparative diagnostic trials to update the sample sizes using interim data while allowing early stopping during interim analyses. The method is able to maintain the nominal power and type I error of the trials, as demonstrated through simulation studies.

\*This is a joint work with Aiyi Liu at National Institute of Child Health and Human Development, Rockville, MD 20852, USA