Concordance between Laboratories Testing Clinical Samples In Clinical Trials during Vaccine Development

Eloi P. Kpamegan, Ph.D., MSF

Novavax, Inc., 9920 Belward Campus Drive, Rockville, MD 20850, USA

Abstract

Concordance study between two laboratories testing clinical samples is important to a clinical program to assess the comparability of test results, especially when the two laboratories performed the same test at different locations. Assays that measure immune response should not be compared using the simple linear regression model; instead literature publications recommend an "errors-in-variables" model that accounts for the variability in these assays. Concordance slope and intercept will be estimated using Tan and Iglewicz (1999) statistical linear relationship for various tests between laboratories.

Key words: Concordance slope, errors-in-variables, statistical linear relationship