

Decision-making frameworks using multiple correlated endpoints

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Nowadays, quantitative decision making is an essential component of early clinical development. Rather than focusing on statistical significance only, some methods have been proposed in the literature that led to three-outcome decision-making frameworks by including a consider zone. NOGO/Consider/GO decision zones are determined based on pre-specified target value (TV) and minimum value (MV). In this context, historical data can be incorporated as an informative prior using Bayesian analysis.

We extended the classical decision-making framework to cases with multiple correlated endpoints that can be of various types (e.g. co-primary, hierarchical, ...). We considered bivariate normal and bivariate binomial endpoints, for one arm or two arms trials, both in Bayesian and Frequentist analyses. The aim is to consider exact approaches rather than simulations that are time-consuming to have efficient tools that user-friendly and convenient for practical use. Operating characteristics with different correlations and under different scenarios including MV and TV are presented.