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Title: Statistical Interactions in a Clinical Trial

Abstract: New statisticians entering industry tend to “test statistical interactions” whenever there is a need. However, in many real-world applications, especially in clinical development of new drugs, most of interactions need to be estimated, instead of to be tested. In this manuscript, the distinction between hypothesis testing and estimation will be articulated, and the use of statistical interactions in clinical development programs will be discussed. According to ICH E-9, the treatment by subgroup interaction should not be included in the pre-specified primary statistical analysis model. The reasons behind this ICH E-9 recommendation are also clarified in this manuscript.