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Prior Effective Sample Size in Phase II Clinical Trials with Mixed Binary and Continuous Responses

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Abstract

The problem of finding Effective Sample Size (ESS) in Phase II clinical trials where toxicity and efficacy are the two components of the treatment response vector is considered. In particular, one of the components is assumed to be binary and the other is assumed to be continuous. The case of binary safety and continuous efficacy is studied for different prior distributions under different set up. Theoretical expressions are obtained in various situations. The methods are evaluated and compared by simulation studies. The proposed method is then illustrated by using some real life data on a phase II vaccine trial for Covid-19. This is a joint work with Dr. Jean-Francois Angers (University of Montreal) and Dr. Atanu Biswas (Indian Statistical Institute).

Keywords:
Binary Safety; Continuous Efficacy; Effective Sample Size; Mixed Responses; Multivariate T-prior; Phase II Clinical Trials.