

## **A novel group-sequential phase II design for clinical trials with binary endpoints based on Bayesian evidence values**

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In clinical research, the initial efficacy assessment of a new agent is typically considered in a phase IIA study which investigates the response rate of patients to the agent under consideration. Bayesian group-sequential designs for phase IIA studies are often based on the predictive probability approach, which calculates the probability of a positive conclusion based on interim data should the trial be conducted to the maximum planned sample size. Depending on the latter predictive probability, the trial can be stopped early for futility or efficacy. A novel group-sequential design based on Bayesian evidence values, the predictive evidence value (PEV) design, is proposed and analyzed. Importantly, it is shown that the predictive probability approach is a special case of the latter. Theoretical results show under which conditions the type I error rate can be improved by shifting to the PEV design. The PEV design offers another layer of flexibility for type I and II error control in Bayesian group-sequential clinical trial designs and a simulation study illustrates the results for binary endpoints.

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