

# **Bayesian Model-Assisted Designs for the Easy Conduct and Efficient Design of Phase I/II Trials: Keep It Simple and Smart!**

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**Abstract:** Many novel adaptive designs have been published in the last two decades. Although these novel adaptive designs possess good statistical properties, most of them have not been widely implemented in real trials. Three major impediments are (1) complicated statistical modelling, (2) demanding computations, and (3) hard-to-be-used by clinical researchers. We introduce a new class of novel adaptive designs, known as model-assisted designs, to remove these hurdles and to facilitate the increasing use of novel designs to improve the efficiency and success of Phase I/II trials. Model-assisted designs combine the transparency and simplicity of the conventional algorithm-based designs with the superiority and rigorousness of model-based designs. They enjoy the superior performance comparable to more complicated, model-based designs, but can be implemented as simple as the conventional designs. A few model-assisted designs will be discussed including the Bayesian optimal interval (BOIN) design, the time-to-event BOIN (TITE-BOIN), the BOIN combination design, and the Bayesian Optimal Phase 2 (BOP2) design for simple complex endpoints, etc. Similar to all trial designs, the design parameters need to be carefully chosen and calibrated through simulation studies to ensure desirable operating characteristics. Freely available Shiny applications are provided at [www.trialdesign.org](http://www.trialdesign.org) to facilitate the adoption of model-assisted designs. Model-assisted designs establish a new KISS principle: Keep It Simple and Smart!