Informative study designs, where modelling and simulation based design features make a trial more informative than a comparable standard design

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Abstract

Drug development should extract maximum information from experimental protocols with minimized exposure of patients to invasive procedures and potentially harmful drug exposure and minimized investment of time and money. Aspects of study design are explored illustrating how information can be extracted more efficiently by investigating a range of exposures within individuals rather than relying on cross-sectional analyses, either by following individual patient responses as their drug concentrations decline or by within-individual dose escalation. The designs are evaluated considering the uncertainty in the parameters to assess robustness of these approaches.