A Bayesian Decision-Theoretic Model of Sequential Experimentation with Delayed Response

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Stephen Chick[*], Martin Forster,[†] Paolo Pertile[‡]

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Abstract

We solve a Bayesian decision-theoretic model of a sequential experiment in which the real-valued primary end point is observed with delay. The solution yields a unified policy defining the optimal 'do not experiment'/'fixed sample size experiment'/'sequential experiment' regions as a function of the prior mean. The model can value the expected benefits accruing to study units, the fixed costs of switching from control to treatment, and it allows the patient horizon to fall as the number of units recruited rises. We apply the model to the field of medical statistics, using data from a published trial investigating the clinical- and cost-effectiveness of drug-eluting stents versus bare metal stents. We demonstrate the model's superiority over alternative trial designs when judged according to the maximisation of the net benefits of the trial, minus sampling costs, and we investigate how the size of the delay can determine the optimal choice of trial design. The optimal policy also performs well when judged according to the probability of making the correct selection of health technology and the relatively low probabilities of reversing a decision to stop accrual. The model's relevance for assisting in the design, commissioning and conduct of Phase III clinical trials and health technology assessments is considered.

Keywords: Bayesian inference; Clinical trials; Delayed observations; Sequential experimentation

[*]Department of Technology and Operations Management, INSEAD, Fontainebleau, France. stephen.chick@insead.edu

[†]Department of Economics and Related Studies, University of York, York, U.K. mf8@york.ac.uk

[‡]Department of Economics, University of Verona, 37129 Verona, Italy. paolo.pertile@univr.it