The Patient Benefit of Arm-Acquiring in Platform Clinical Trials

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Abstract

We consider platform clinical trials, which are trials where new experimental treatment arms may be added during the trial. There is limited research on what decision rules should be used when choosing whether or not to add in a new arm. We investigate the effect of adding in a new experimental arm during the course of the trial in terms of patient benefit and develop optimal rules for when to add it in. We assume that arms have dichotomous (success/failure) responses and we use the traditional Bayesian Beta-Bernoulli decision-theoretic model for the design of response-adaptive clinical trials. The new arm, added with an uninformative prior, is to be tested against the control arm, which collects responses both before and after the new arm is added. We present exact results for the following issues: (i) whether it is worth adding the new arm, given the remaining length of the trial and the responses accumulated so far on the control arm, (ii) whether the new arm will be allocated to the first patient after being added to the trial, (iii-a) if not, then how many consecutive failures are needed on the control arm in order for the new arm to be allocated, (iii-b) if yes, then what happens if the first response on the new arm is a failure. Surprisingly, the structure of the answers to the above questions depends primarily on the frequency of successes (i.e. the posterior mean) and is almost independent of the total number of responses (i.e. the posterior variance) accumulated so far on the control arm.