

Assurance methods for designing a survival trial with delayed treatment effects

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An assurance (probability of success) calculation is a Bayesian alternative to a power calculation. They are becoming more regularly used in industry, especially in the design of Phase III confirmatory trials. Immunology (IO) is a rapidly evolving area in the development of anticancer drugs. A common phenomenon that arises from IO trials is one of delayed treatment effects, that is, a delay in the separation of the Kaplan-Meier survival curves. To calculate assurance for a trial in which a delayed treatment effect is likely to be present, uncertainty about key parameters needs to be considered. If uncertainty is not considered, then the number of patients recruited may not be enough to ensure we have adequate statistical power to detect a clinically relevant treatment effect. We present an elicitation technique for when a delayed treatment effect is likely to be present and show how to compute assurance using these elicited prior distributions. We provide an example to illustrate how this could be used in practice.