ASA-BI Statistics Webinar Series

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April 24th, Tuesday
9-10 am EST

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Title

A practical design for a dual-agent dose-escalation trial that incorporates pharmacokinetic data

Abstract

Model-based dose-escalation trial designs assume a model for the dose-toxicity relationship. It is common for model-based dose recommendations to be based only on observation of dose-limiting toxicities. Other data, such as pharmacokinetic (PK) data, is often used subjectively by clinical teams to aid decision making. Utilising PK data in model-based dose-recommendations could therefore reduce the subjectivity of its use in decision making, as well as increasing the efficiency and precision of escalation.

In the dual-agent setting, toxicity and PK data from the corresponding single-agent trials are available. This historical data can be used to advise the dual-agent trial design. We propose combining outputs of independent models for the dose-toxicity and dose-PK relationships using escalation rules. The design is shown to be efficient and practical using a simulation study.

Professional Biography

Dr. Cotterill is a senior statistician at the Cancer Research UK Clinical Trials Unit at the University of Birmingham. She works as part of the Trials Acceleration Programme (TAP) which provides efficient design and set-up of early phase clinical trials in blood cancer. Her research has focused on Bayesian designs for early phase clinical trials. She also has industry experience from two companies, in the early phase clinical biostatistics group at Novartis oncology, and as part of the pharmacometrics and pre-clinical biostatistics group at Baxalta (now part of Shire).

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