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## **BIVARIATE DESIGNS FOR EARLY PHASE CLINICAL TRIALS**

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Until recently, most of the research on dose-finding designs focussed on phase I trials, where the aim is to determine the highest dose of a new drug whose probability of toxicity is below a specified target level known as the dose limiting toxicity. This dose is called the maximum tolerated dose (MTD). Once this has been found, the safe doses are tested for effectiveness in a phase II trial, where the purpose is to find the lowest dose whose probability of efficacy is above a given threshold known as the minimum efficacious requirement. This dose is called the minimum effective dose (MED). So, upon completion of the phase I and II trials, a range of safe, effective doses lie between the MED and the MTD. In this talk, some of the bivariate methods which have been developed for combined phase I/II trials are reviewed and the main design issues discussed.

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