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Editorial

The papers in this Special Issue represent some recent developments in the interface between statistics and clinical trials. Some of these papers were presented at statistics conferences and subsequently invited by the Guest Editors to submit to the journal for review.

The first four papers were presented at the Third International Workshop on Sequential Methodologies at Stanford University in 2011. Zhao, Cook, Jackson and Nelson discuss the performance of group sequential methods for observational post-licensure safety surveillance of vaccines and other medical products. Li, Chan and Anderson introduce an adaptive design for vaccine efficacy testing when the incidence rate is unknown at the design stage. Sverdlov, Ryeznik and Wong address the issue of allocating subjects adaptively to multiple treatment arms using optimal design theory. He, Lai and Liao describe a new approach to futility stopping in clinical trial designs and the statistical theory underlying this approach.

The paper by Jin and Stockbridge was presented at the First Pacific Coast Statisticians and Pharmacometricians Innovation Conference in 2010. It addresses the problem of predicting acute hypotensive episodes from ambulatory blood pressure telemetry. The paper by Lai, Liao and Zhu was developed from a talk on clinical development plans in drug development given by Zhu to statisticians in the pharmaceutical industry and in academia at a Workshop on Statistical Methods held at Fudan University in 2010. The paper by Chen and Jin on a new conditional test for non-inferiority in a match-pairs design, and that by Yang and Ye on a dose-finding design of a Phase I cancer trial with polychotomous toxicity outcomes, were presented at the Second Joint Biostatistics Symposium in Beijing, 2012.

Efficient design of Phase II cancer trials is discussed by Ivanova, Monaco and Stinchcombe who extend Simon's two-stage design to polychotomous responses. Hu, Lu and Tai address the issue of the type I error probability of a chi-square test when the response probability changes during a clinical trial. Tseng, Elashoff, Ning Li and Gang Li discuss robust inference from longitudinal data when there are non-ignorable and non-monotonic missing data.

We are grateful to all authors for their contributions and to the referees for their helpful and timely reviews.

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Ying Lu (Guest Editor)
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