GUEST EDITOR'S NOTE

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THIS EDITION OF the *Drug Information Journal* contains papers relevant to statistical issues in a regulatory environment. Regulatory reform and international harmonization of regulatory requirements are becoming major trends in pharmaceutical research and development (R&D). The genesis of this special issue of the journal was based, in part, on the recent adoption of International Conference on Harmonization (ICH) guidelines and increasing globalization of the drug development process. How biostatistical theory and practice are affected by, and impact upon, interpretation of the ICH guidelines represents an important component of the drug approval process. Thus, the purpose of this issue is to provide an overview of current statistical thinking and methodologies in this changing environment. While such a far-reaching objective cannot be achieved fully, a broad array of papers has been collected which provides a valuable resource for statisticians, clinicians, and regulatory affairs personnel.

To this end, we assembled a set of papers that describe key features of the design, conduct, and analysis of medical studies. Accordingly, this issue is organized into three

areas: design, conduct, and analysis. A highlight of the design section is a discussion of statistical issues in applying ICH guidelines in clinical trials. Also included are a discussion of a behavioral Bayes method for determining the size of a clinical trial, and the conceptualization of therapeutic equivalence. The conduct section includes an evaluation of statistical validation of surrogate endpoints, a discussion of statistical issues involved in medical device postmarketing surveillance, and a review of pooling in integrated safety databases. A diverse group of methodologic issues are raised and discussed in the analysis section, including statistical and regulatory issues relating to adjustment of treatment effect for covariates in clinical trials. Equivalence testing, and sequential and multiple testing in dose-response studies also are discussed, along with an overview of handling missing data in clinical trials.

Indeed, no collection of papers can fully address the myriad of statistical issues involved in the drug development process. Our sincerest hope is that readers will find this issue to be timely and useful in their activities.

Finally, as guest editor, I wish to extend my thanks to Norman Silliker in his capacity as my editorial assistant, to the members of the DIA editorial board and staff, and especially to all the authors. You have all contributed greatly in making this issue of the *Drug Information Journal* a success.

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