Bayesian Design in Clinical Trials

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Message from the Guest Editors

The Bayesian methodology is well-suited to address the issues arising in the planning, the analysis, and the conduct of clinical trials. Due of their flexibility, Bayesian design methods based on the accrued data of on-going trials have been recommended by both the US Food and Drug Administration (FDA) and the European Medicines Agency for dose–response trials in early clinical development. More generally, since the inherent adaptive nature of Phase I and Phase II designs, the Bayesian approach tends to be more efficient.

Another distinctive feature of the Bayesian approach is that it naturally allows for dealing with external information, such as historical data, findings from previous studies, and expert opinions through prior elicitation. In fact, it provides a framework for embedding and handling the variability of such auxiliary information within the planning and analysis of the study. A growing body of literature examines the use of historical data to augment newly collected data, especially in clinical trials where patients are difficult to recruit. Many works describe the importance of using the available data in clinical trials and how this can be done properly.

Special Issue

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Message from the Editor-in-Chief

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