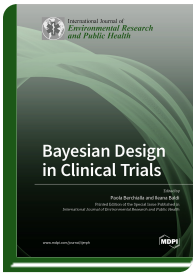
International Journal of
Environmental Research and Public Health

Indexed in: PubMed
CITESCORE 7.3

Special Issue Reprint

Bayesian Design in Clinical Trials



www.mdpi.com/books/reprint/5059

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ISBN 978-3-0365-3333-9 (Hardback)
ISBN 978-3-0365-3334-6 (PDF)

In the last decade, the number of clinical trials using Bayesian methods has grown dramatically. Nowadays, regulatory authorities appear to be more receptive to Bayesian methods than ever. The Bayesian methodology is well suited to address the issues arising in the planning, analysis, and conduct of clinical trials. Due to their flexibility, Bayesian design methods based on the accrued data of ongoing trials have been recommended by both the US Food and Drug Administration and the European Medicines Agency for dose-response trials in early clinical development. A distinctive feature of the Bayesian approach is its ability to deal 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 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, which is the case for rare diseases, for example. Many works explore how this can be done properly, since using historical data has been recognized as less controversial than eliciting prior information from experts' opinions.

In this book, applications of Bayesian design in the planning and analysis of clinical trials are introduced, along with methodological contributions to specific topics of Bayesian statistics. Finally, two reviews regarding the state-of-the-art of the Bayesian approach in clinical field trials are presented.

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