Classical and Adaptive Clinical Trial Designs Using ExpDesign Studio

Mark Chang

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ExpDesign Studio facilitates more efficient clinical trial design

This book introduces pharmaceutical statisticians, scientists, researchers, and others to ExpDesign Studio software for classical and adaptive designs of clinical trials. It includes the Professional Version 5.0 of ExpDesign Studio software that frees pharmaceutical professionals to focus on drug development and related challenges while the software handles the essential calculations and computations. After a hands-on introduction to the software and an overview of clinical trial designs encompassing numerous variations, *Classical and Adaptive Clinical Trial Designs Using ExpDesign Studio*:

- Covers both classical and adaptive clinical trial designs, monitoring, and analyses
- Explains various classical and adaptive designs including groupsequential, sample-size reestimation, dropping-loser, biomarker-adaptive, and response-adaptive randomization designs
- Includes instructions for over 100 design methods that have been implemented in ExpDesign Studio and step-by-step demos as well as real-world examples
- Emphasizes applications, yet covers key mathematical formulations
- Introduces readers to additional toolkits in ExpDesign Studio that help in designing, monitoring, and analyzing trials, such as the adaptive monitor, graphical calculator, the probability calculator, the confidence interval calculator, and more
- Presents comprehensive technique notes for sample-size calculation methods, grouped by the number of arms, the trial endpoint, and the analysis basis

Written with practitioners in mind, this is an ideal self-study guide for not only statisticians, but also scientists, researchers, and professionals in the pharmaceutical industry, contract research organizations (CROs), and regulatory bodies. It's also a go-to reference for biostatisticians, pharmacokinetic specialists, and principal investigators involved in clinical trials.

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The license for the ExpDesign Studio software on the CD included with this book is good for one-year after installation of the software. Prior to the expiration of this period, the software will generate a reminder about renewal for the license. The user should contact CTriSoft International (the owners of ExpDesign Studio) at www.CTriSoft.net or by email at license@ctrisoft.net, about renewal for the license.

This should have been made clear in the first printing of this book. We apologize for this error.

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