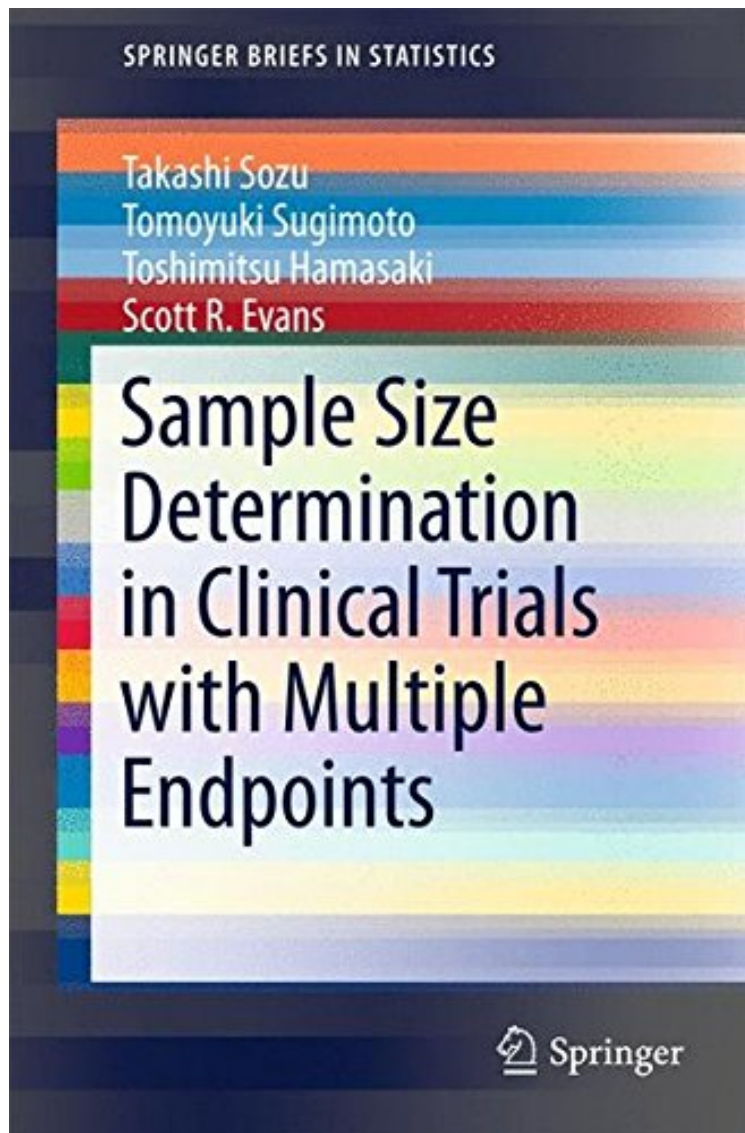


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Takashi Sozu, Tomoyuki Sugimoto, Toshimitsu Hamasaki, Scott R. Evans
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Takashi Sozu, Tomoyuki Sugimoto, Toshimitsu Hamasaki, Scott R. Evans : Sample Size Determination in Clinical Trials with Multiple Endpoints (SpringerBriefs in Statistics) before purchasing it in order to gage whether or not it would be worth my time, and all praised Sample Size Determination in Clinical Trials with Multiple

Endpoints (SpringerBriefs in Statistics):

This book integrates recent methodological developments for calculating the sample size and power in trials with more than one endpoint considered as multiple primary or co-primary, offering an important reference work for statisticians working in this area. The determination of sample size and the evaluation of power are fundamental and critical elements in the design of clinical trials. If the sample size is too small, important effects may go unnoticed; if the sample size is too large, it represents a waste of resources and unethically puts more participants at risk than necessary. Recently many clinical trials have been designed with more than one endpoint considered as multiple primary or co-primary, creating a need for new approaches to the design and analysis of these clinical trials. The book focuses on the evaluation of power and sample size determination when comparing the effects of two interventions in superiority clinical trials with multiple endpoints. Methods for sample size calculation in clinical trials where the alternative hypothesis is that there are effects on ALL endpoints are discussed in detail. The book also briefly examines trials designed with an alternative hypothesis of an effect on AT LEAST ONE endpoint with a prespecified non-ordering of endpoints.

Sample Size Determination in Clinical Trials with Multiple Endpoints is a new release that will likely be embraced by any statistician involved in the planning of trials with more than one primary outcome. The book comprises much of the authors original work from recent years. Sample Size Determination in Clinical Trials with Multiple Endpoints is a useful complement to the widespread sample size books, especially for statisticians interested in designs with coprimary endpoints. (Philip Pallmann, *Biometrical Journal*, Vol. 59 (1), 2017) From the Back Cover This book integrates recent methodological developments for calculating the sample size and power in trials with more than one endpoint considered as multiple primary or co-primary, offering an important reference work for statisticians working in this area. The determination of sample size and the evaluation of power are fundamental and critical elements in the design of clinical trials. If the sample size is too small, important effects may go unnoticed; if the sample size is too large, it represents a waste of resources and unethically puts more participants at risk than necessary. Recently many clinical trials have been designed with more than one endpoint considered as multiple primary or co-primary, creating a need for new approaches to the design and analysis of these clinical trials. The book focuses on the evaluation of power and sample size determination when comparing the effects of two interventions in superiority clinical trials with multiple endpoints. Methods for sample size calculation in clinical trials where the alternative hypothesis is that there are effects on ALL endpoints are discussed in detail. The book also briefly examines trials designed with an alternative hypothesis of an effect on AT LEAST ONE endpoint with a prespecified non-ordering of endpoints.

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Takashi Sozu Dr. Sozu is Associate Professor of Biostatistics at Kyoto University School of Public Health. He is an Associate Editor of *Japanese Journal of Biometrics*. He is the member of the International Biometric Society and the elected member of the International Statistical Institute. He was awarded the Young Biostatistician Award from Biometric Society of Japan, Best Paper Award from Japanese Society for Alternatives to Animal Experiments, Prize for Outstanding Achievement in Education and Research at Osaka University, and Best Teacher Award at Kyoto University School of Public Health. His current research interest is design and analysis of clinical trials with multiple primary endpoints.
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Toshimitsu Hamasaki Dr. Hamasaki is the Chief of Biostatistics and Data Management Office at National Cerebral and Cardiovascular Center and is a Professor of Innovative Clinical Trials and Data Science at Osaka University Graduate School of Medicine (Cooperative Graduate School Program). Dr. Hamasaki was the member of ICH E5 informal discussion group to develop the Q A document. He was the Editor-in-Chief of the *Journal of the Japanese Society of Computational Statistics*, and currently, he serves as an Associate Editor for *Japanese Journal of Applied Statistics* and *Journal of Japanese Society of Computational Statistics and Statistics in Biopharmaceutical Research*, and series editor for *Japan Statistical Society Research Series in Statistics*. He is an elected member of International Statistical Institute. Dr. Hamasaki has received the Distinguished Article Award from the Japanese Society of Computational Statistics and Hida-Mizuno Prize from the Behaviormetric Society of Japan.
Scott R Evans Dr. Evans is a Senior Research Scientist at Harvard University where he teaches clinical trials and is the Director of the Statistical and Data Management Center for the Antibacterial Resistance Leadership Group. He is a Fellow of the American Statistical Association (ASA) and has received the Robert Zackin Distinguished Collaborative Statistician Award for significant statistical contributions to HIV research and a Recognition Award for contributions of statistical expertise to the Harvard School of Public Health (HSPH) IRB. Dr. Evans is a member of an FDA Advisory Committee and has served and chaired numerous Data Monitoring Committees and Scientific Advisory

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