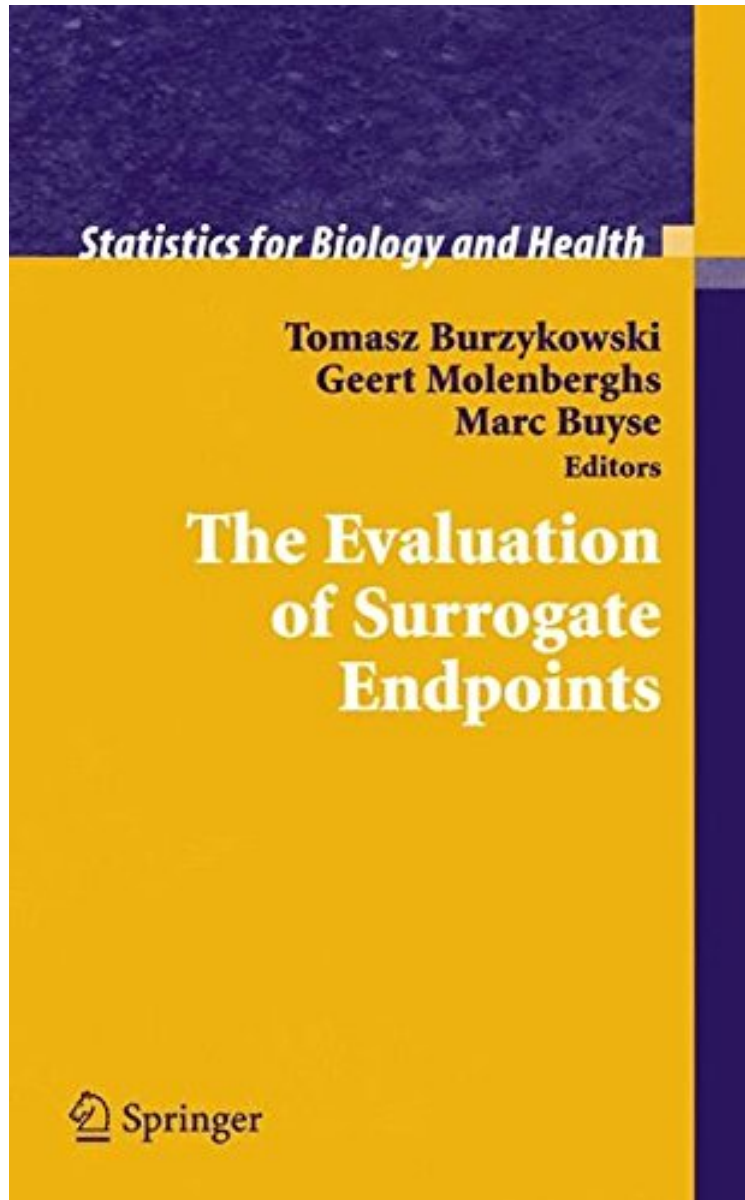


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# The Evaluation of Surrogate Endpoints (Statistics for Biology and Health)

*From Tomasz Burzykowski*  
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**From Tomasz Burzykowski : The Evaluation of Surrogate Endpoints (Statistics for Biology and Health)** before purchasing it in order to gage whether or not it would be worth my time, and all praised The Evaluation of Surrogate

## Endpoints (Statistics for Biology and Health):

Covers the latest research on a sensitive and controversial topic in a professional and well researched manner. Provides practical outlook as well as model guidelines and software tools that should be of interest to people who use the software tools described and those who do not. Related title by Co-author Geert Molenbergh has sold more than 3500 copies world wide. Provides dual viewpoints: from scientists in the industry as well as regulatory authorities.

From the reviews: "A strength of this book is its comprehensive and up-to-date presentation of issues pertinent to the evaluation of surrogate endpoints...This book makes an important contribution to the clinical trials literature..." *Journal of Biopharmaceutical Statistics*, 2006 "Many of the chapters deal with real-life data examples and studies involving surrogate outcomes, many written by authors who were directly involved in these studies...The editors have written nice background sections...until a more concise manuscript on this topic is written, this book will remain the most important resource for biostatisticians and researchers in this area." Debajyoti Sinha for the *Journal of the American Statistical Association*, December 2006 "This book is a reflection of the ongoing debate on the definition and use of surrogate markers...I see the book as an invitation to join the debate. There is much work to be done and reading the book might inspire many to participate. It will be useful for researchers in this and related fields, such as joint modeling of longitudinal and survival data and multivariate meta-analysis. The book is well organized, is a pleasure to read, and is very well documented with up-to-date references." Hans C. Van Houwelingen for *Biometrics*, September 2006 "This edited volume deals with a topic that has been the subject of much debate since publication of Prentices 1989 attempt to formalize the definition of a surrogate marker or endpoint. This work focuses on evaluation of a surrogate endpoint. an attempt has been made to maintain common notations whenever possible. The editors have succeeded in producing a very useful book." (V. T. Farewell, *Short Book s*, Vol. 25 (2), 2005) "I enjoyed reading the book and I certainly learned a lot about these fascinating areas. The book is suitable as a textbook for a postgraduate course in statistics but is also an invaluable reference for the applied statisticians working in industry, academia, or regulatory authority." (*ISCB News Book s*, 2008)From the Back CoverBoth humanitarian and commercial considerations have spurred intensive search for methods to reduce the time and cost required to develop new therapies. The identification and use of surrogate endpoints, i.e., measures that can replace or supplement other endpoints in evaluations of experimental treatments or other interventions, is a general strategy that has stimulated both enthusiasm and skepticism. Surrogate endpoints are useful when they can be measured earlier, more conveniently, or more frequently than the "true" endpoints of primary interest. Regulatory agencies around the globe, particularly in the United States, Europe, and Japan, are introducing provisions and policies relating to the use of surrogate endpoints in registration studies. But how can one establish the adequacy of a surrogate? What kind of evidence is needed, and what statistical methods portray that evidence most appropriately? This book offers a balanced account on this controversial topic. The text presents major developments of the last couple of decades, together with a unified, meta-analytic framework within which surrogates can be evaluated from several angles. Methodological development is coupled with perspectives on various therapeutic areas. Academic views are juxtaposed with standpoints of scientists working in the biopharmaceutical industry as well as of colleagues from the regulatory authorities. Tomasz Burzykowski is Assistant Professor of Biostatistics at the Limburgs Universitair Centrum in Belgium. Dr. Burzykowski has published methodological work on the analysis of survey data, meta-analyses of clinical trials, and validation of surrogate endpoints. He is a co-author of numerous papers applying statistical methods to clinical data in different disease areas (cancer, cardiovascular diseases, dermatology, orthodontics). Geert Molenberghs is Professor of Biostatistics at the Limburgs Universitair Centrum in Belgium. Dr. Molenberghs published methodological work on surrogate markers in clinical trials, categorical data, longitudinal data analysis, and on the analysis of non-response in clinical and epidemiological studies. He serves as Joint Editor for *Applied Statistics* (2001-2004) and is President of the International Biometric Society (2004-2005). He was elected Fellow of the American Statistical Association and received the Guy Medal in Bronze from the Royal Statistical Society. Marc Buyse founded the International Drug Development Institute in 1991. He is Past President of the International Society for Clinical Biostatistics, Past President of the Quetelet Society, and Past Board Member of the Society for Clinical Trials. He is currently the Executive Director of IDDI (International Drug Development Institute) and Associate Professor of biostatistics at the Limburgs Universitair Centrum, Center for Statistics, Diepenbeek, Belgium. He has published extensively in the fields of biostatistics and oncology. His research interests include meta-analysis, surrogate endpoints, statistical detection of fraud, and the design and statistical analysis of clinical trials.