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

*Tomasz Burzykowski, Geert Molenberghs, Marc Buyse*

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Both 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. From the reviews: 'A strength of this book is its comprehensive and up-to-date presentation of issues pertinent to the evaluation of surrgoate 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

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