Contents

ACKNOWLEDGEMENTS .................................................................................................................. ix
PREFACE ................................................................................................................................ xi
PRESENTING AUTHORS ........................................................................................................... xiii

INTRODUCTION
David R. Cox ................................................................................................................................ 1

CHAPTER 1: MEASUREMENT, SCALE DEVELOPMENT, AND STUDY DESIGN ....................... 7
Regulatory Aspects of Quality of Life
Clare Gnecco, Peter A. Lachenbruch .......................................................................................... 9

Biases in the Retrospective Calculation of Reliability and Responsiveness
from Longitudinal Studies
Geoff Norman, Paul Stratford, Glenn Regehr ........................................................................ 21

Application of the Multiattribute Utility Theory to the Development of a
Preference based Health-Related Quality of Life Instrument
Catherine Le Galès .................................................................................................................... 33

Strategy and Methodology for Choice of Items in Psychometric
Measurement: Designing a Quality of Life Instrument for Hip and
Knee Osteoarthritis
Francis Guillemin, Joel Coste, Nathalie Retel-Rude, Elisabeth Spitz,
Michèle Baumann, Cyrille Tarquinio, Catherine Luttenbacher,
Jacques Pouchot ....................................................................................................................... 51

Conception, Development and Validation of Instruments for Quality of Life
Assessment: An Overview
Arin Judith Chwalow, Adekunle B. Adesina ........................................................................ 63

Methodological Issues in the Analysis of Quality of Life Data in Clinical
Trials: Illustrations from the National Surgical Adjuvant Breast and
Bowel Project (NSABP) Breast Cancer Prevention Trial
Stephanie Land, Samuel Wieand, Richard Day, Tom Ten Have,
Joseph P. Costantino, Wei Lang, Patricia A. Ganz .................................................................. 71

Disease-Specific Versus Generic Measurement of Health-Related Quality of
Life in Cross-Sectional and Longitudinal Studies: an Inpatient
Investigation of the SF-36 and Four Disease-Specific Instruments
Serge Briançon, Bernadette Gergonne, Francis Guillemin, Fabienne
Empereur, Sylvie Klein ............................................................................................................. 87
CHAPTER 2: ANALYSIS AND INTERPRETATION OF MULTIPLE ENDPOINTS .................. 101

Analyzing Longitudinal Health-Related Quality of Life Data: Missing Data and Imputation Methods
Dennis A. Revicki ........................................... 103

Comparison of Treatments with Multiple Outcomes
Pascale Tubert-Bitter, Daniel A. Block, Tze L. Lai ................................. 113

The Use of Soft Endpoints in Clinical Trials: The Search for Clinical Significance
Janet Wittes .................................................. 129

CHAPTER 3: ITEM RESPONSE THEORY AND RASCH MODELS ............................ 141

Parametric and Nonparametric Item Response Theory Models in Health Related Quality of Life Measurement
Ivo W. Molenaar ............................................. 143

Questionnaire Reliability Under the Rasch Model
Agnes Hamon, Mounir Mesbah .................................................. 155

Item Response Theory (IRT): Applications in Quality of Life Measurement, Analysis and Interpretation
David Cella, Chih-Hung Chang, Allen W. Heinemann .......................... 169

Graphical Rasch Models
Svend Kreiner and Karl Bang Christensen ........................................ 187

CHAPTER 4: JOINT ANALYSIS OF QUALITY OF LIFE AND SURVIVAL ................. 205

Semi-Markov Models for Quality of Life Data with Censoring
Natacha Hette, Catherine Huber-Carol ............................................. 207

A Model Relating Quality of Life to Latent Health Status and Survival
Mei-Ling Ting Lee, G. Alex Whitmore ........................................... 219

Applying Survival Data Methodology to Analyze Longitudinal Quality of Life Data
Lucile Awad, Emmanuel Zuber, Mounir Mesbah ................................ 231

Latent Class Models to Describe Changes Over Time: A Case Study
Hans C. van Houwelingen ..................................................... 245
CHAPTER 5: QUALITY-ADJUSTED SURVIVAL ANALYSIS AND RELATED METHODS

Prevalence Analysis of Recurrent and Transient Health States in Quality of Life Studies
Andrew Kramar, Remi Lancar ................................. 263

Measures of Quality Adjusted Life and Quality of Life Deficiency:
Statistical Perspectives
Prenab K. Sen .................................................. 275

Quality-Adjusted Survival Analysis in Cancer Clinical Trials
Bernard F. Cole, Kerry L. Kilbridge .......................... 287

CHAPTER 6: METHODS FOR INFORMATIVELY MISSING LONGITUDINAL QUALITY-OF-LIFE DATA

Handling of Missing Data
Michel Chavance .............................................. 303

Guidelines For Administration of Self-Reported Health-Related Quality of Questionnaires: How to Minimize Avoidable Missing Data?
Dominique Dubois ........................................... 307

Joint Analysis of Survival and Nonignorable Missing Longitudinal Quality-of-Life Data
Jean-François Dupuy ......................................... 309

Multiple Imputation for Non-Random Missing Data in Longitudinal Studies of Health-Related Quality of Life
Diane L. Fairclough ........................................... 323

Strategies to Fit Pattern-Mixture Models
Geert Molenberghs, Herbert Thijs, Geert Verbeke, Bart Michiels, Michael G. Kenward ................. 339

Analysis of Longitudinal Quality of Life Data with Informative Dropout
Margaret C. Wu, Craig B. Borkowf, Paul S. Albert ................. 353