

1. Record Nr.	UNINA9910132240603321
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Titolo	Clinical trials with missing data : a guide for practitioners // Michael O'Kelly, Bohdana Ratitch
Pubbl/distr/stampa	Chichester, West Sussex : , : John Wiley & Sons Inc., , 2014
ISBN	1-118-76253-3 1-118-76251-7 1-118-76250-9
Descrizione fisica	1 online resource (473 p.)
Collana	Statistics in practice
Altri autori (Persone)	RatitchBohdana
Disciplina	610.72/4
Soggetti	Clinical trials Clinical trials - Statistical methods
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Note generali	Description based upon print version of record.
Nota di bibliografia	Includes bibliographical references and index.
Nota di contenuto	Clinical Trials with Missing Data; Contents; Preface; References; Acknowledgments; Notation; Table of SAS code fragments; Contributors; 1 Whats the problem with missing data?; 1.1 What do we mean by missing data?; 1.1.1 Monotone and non-monotone missing data; 1.1.2 Modeling missingness, modeling the missing value and ignorability; 1.1.3 Types of missingness (MCAR, MAR and MNAR); 1.1.4 Missing data and study objectives; 1.2 An illustration; 1.3 Why cant I use only the available primary endpoint data?; 1.4 Whats the problem with using last observation carried forward? 1.5 Can we just assume that data are missing at random?1.6 What can be done if data may be missing not at random?; 1.7 Stress-testing study results for robustness to missing data; 1.8 How the pattern of dropouts can bias the outcome; 1.9 How do we formulate a strategy for missing data?; 1.10 Description of example datasets; 1.10.1 Example dataset in Parkinsons disease treatment; 1.10.2 Example dataset in insomnia treatment; 1.10.3 Example dataset in mania treatment; Appendix 1.A: Formal definitions of MCAR, MAR and MNAR; References; 2 The prevention of missing data; 2.1 Introduction 2.2 The impact of "too much" missing data 2.2.1 Example from human immunodeficiency virus; 2.2.2 Example from acute coronary syndrome; 2.2.3 Example from studies in pain; 2.3 The role of the statistician in

the prevention of missing data; 2.3.1 Illustrative example from HIV; 2.4 Methods for increasing subject retention; 2.5 Improving understanding of reasons for subject withdrawal; Acknowledgments; Appendix 2.A: Example protocol text for missing data prevention; Section X Subject retention; References; 3 Regulatory guidance - a quicktour
3.1 International conference on harmonization guideline: Statistical principles for clinical trials: E93.2 The US and EU regulatory documents; 3.3 Key points in the regulatory documents on missing data; 3.4 Regulatory guidance on particular statistical approaches; 3.4.1 Available cases; 3.4.2 Single imputation methods; 3.4.3 Methods that generally assume MAR; 3.4.4 Methods that are used assuming MNAR; 3.5 Guidance about how to plan for missing data in a study; 3.6 Differences in emphasis between the NRC report and EU guidance documents; 3.6.1 The term "conservative"
3.6.2 Last observation carried forward 3.6.3 Post hoc analyses; 3.6.4 Non-monotone or intermittently missing data; 3.6.5 Assumptions should be readily interpretable; 3.6.6 Study report; 3.6.7 Training; 3.7 Other technical points from the NRC report; 3.7.1 Time-to-event analyses; 3.7.2 Tipping point sensitivity analyses; 3.8 Other US/EU/international guidance documents that refer to missing data; 3.8.1 Committee for medicinal products for human use guideline on anti-cancer products, recommendations on survival analysis
3.8.2 US guidance on considerations when research supported by office of human research protections is discontinued

Sommario/riassunto

"This book provides practical guidance for statisticians, clinicians, and researchers involved in clinical trials in the biopharmaceutical industry, medical and public health organisations. Academics and students needing an introduction to handling missing data will also find this book invaluable. The authors describe how missing data can affect the outcome and credibility of a clinical trial, show by examples how a clinical team can work to prevent missing data, and present the reader with approaches to address missing data effectively. The book is illustrated throughout with realistic case studies and worked examples, and presents clear and concise guidelines to enable good planning for missing data. The authors show how to handle missing data in a way that is transparent and easy to understand for clinicians, regulators and patients. New developments are presented to improve the choice and implementation of primary and sensitivity analyses for missing data. Many SAS code examples are included - the reader is given a toolbox for implementing analyses under a variety of assumptions"--Provided by publisher.
