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| Nota di contenuto | Preface -- General Introduction -- Significant and Insignificant Adverse Effect -- Incidence Ratios and Reporting Ratios of Adverse Effects -- Safety Analysis and the Alternative Hypothesis -- Forest Plots of Adverse Effects -- Graphics of Adverse Effects -- Repeated Measures Methods for Testing Adverse Effects -- Benefit Risk Ratios -- Equivalence, Non-inferiority and Superiority Testing of Adverse Effects -- Part II The Analysis of Dependent Adverse Effects -- Independent and Dependent Adverse Effects. Categorical Predictors Assessed as Dependent Adverse Effects. Adverse Effect of the Dependent Type in Crossover Trial -- Confoundings and Interactions Assessed as Dependent Adverse Effects -- Subgroup Characteristics Assessed as Dependent Adverse Effects -- Random Effects Assessed as Dependent Adverse Effects -- Outliers Assessed as Dependent Adverse Effects -- Index. . |
| Sommario/riassunto | The authors, as professors in statistics at various universities in Europe, are worried about the poor quality of safety data analysis of clinical trials, despite its importance in drug development and pharmacovigilance. Clinical trials, not adequately addressing safety, are unethical. An effective approach for the purpose is to present summaries of prevalences. In order to estimate the probability, that the |

differences between treatment and control group did not occur merely by chance, a statistical test can be performed. This pretty crude method has recently be supplemented with better sensitive methodologies, based on machine learning clusters and networks, and multivariate analyses. Another important novelty with safety data analysis is the new insights into hypothesis testing, favoring the alternative hypotheses instead of the null hypotheses. Finally the issue of dependency is addressed. Adverse effects may be either dependent or independent of the main outcome. Dependent adverse effect are dependent not only on the treatment modalities, but also on the outcome of the trials. Random heterogeneities, outliers, confounders, interaction factors are common in clinical trials, and all of them can be considered kinds of adverse effects of the dependent type. Random regressions and analyses of variance, high dimensional clusterings, partial correlations, structural equations models, and other Bayesian methods are helpful for their analysis. The current edition was particularly written for medical and health professionals and students. It provides examples of modern analytic methods so far largely unused. All of the 16 chapters have two core characteristics, first they are for current usage, second they try and tell what readers need to know in order to understand the methods. Step by step analyses are given and self-assessment examples are supplied. Each chapter can be studied as a stand-alone.