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Autore	Macrì, Marcello
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Autore	Lui Kung-Jong
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Nota di contenuto	Binary Data Analysis of Randomized Clinical Trials with Noncompliance; Contents; Preface; About the Author; 1 Randomized clinical trials with noncompliance: issues, definitions and problems of commonly used analyses; 1.1 Randomized encouragement design (RED); 1.2 Randomized consent designs; 1.2.1 Single-consent randomized design (SCRD); 1.2.2 Double-consent randomized design (DCRD); 1.3 Treatment efficacy versus programmatic effectiveness; 1.4 Definitions of commonly used terms and assumptions; 1.5 Most commonly used analyses for a RCT with noncompliance; Exercises 2 Randomized clinical trials with noncompliance under parallel groups design 2.1 Testing superiority; 2.2 Testing noninferiority; 2.2.1 Using the difference in proportions; 2.2.2 Using the ratio of proportions; 2.2.3 Using the odds ratio of proportions; 2.3 Testing equivalence; 2.3.1 Using the difference in proportions; 2.3.2 Using the ratio of proportions; 2.3.3 Using the odds ratio of proportions; 2.4 Interval estimation; 2.4.1 Estimation of the proportion difference; 2.4.2 Estimation of the proportion ratio; 2.4.3 Estimation of the odds ratio; 2.5 Sample size determination

2.5.1 Sample size calculation for testing superiority 2.5.2 Sample size calculation for testing noninferiority; 2.5.3 Sample size calculation for testing equivalence; 2.6 Risk model-based approach; 2.6.1 Constant risk additive model; 2.6.2 Constant risk multiplicative model; 2.6.3 Generalized risk additive model; 2.6.4 Generalized risk multiplicative model; Exercises; Appendix; 3 Randomized clinical trials with noncompliance in stratified sampling; 3.1 Testing superiority; 3.2 Testing noninferiority; 3.2.1 Using the difference in proportions; 3.2.2 Using the ratio of proportions
3.2.3 Using the odds ratio of proportions 3.3 Testing equivalence; 3.3.1 Using the difference in proportions; 3.3.2 Using the ratio of proportions; 3.3.3 Using the odds ratio of proportions; 3.4 Interval estimation; 3.4.1 Estimation of the proportion difference; 3.4.2 Estimation of the proportion ratio; 3.4.3 Estimation of the odds ratio; 3.5 Test homogeneity of index in large strata; 3.5.1 Testing homogeneity of the proportion difference; 3.5.2 Testing homogeneity of the proportion ratio; 3.5.3 Test homogeneity of the odds ratio; Exercises; Appendix
4 Randomized clinical trials with noncompliance under cluster sampling 4.1 Testing superiority; 4.2 Testing noninferiority; 4.2.1 Using the difference in proportions; 4.2.2 Using the ratio of proportions; 4.2.3 Using the odds ratio of proportions; 4.3 Testing equivalence; 4.3.1 Using the difference in proportions; 4.3.2 Using the ratio of proportions; 4.3.3 Using the odds ratio of proportions; 4.4 Interval estimation; 4.4.1 Estimation of the proportion difference; 4.4.2 Estimation of the proportion ratio; 4.4.3 Estimation of the odds ratio; 4.5 Sample size determination
4.5.1 Sample size calculation for testing superiority

Sommario/riassunto

It is quite common in a randomized clinical trial (RCT) to encounter patients who do not comply with their assigned treatment. Since noncompliance often occurs non-randomly, the commonly-used approaches, including both the as-treated (AT) and as-protocol (AP) analysis, and the intent-to-treat (ITT) (or as-randomized) analysis, are all well known to possibly produce a biased inference of the treatment efficacy. This book provides a systematic and organized approach to analyzing data for RCTs with noncompliance under the most frequently-encountered situations. These include parallel sampling,