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Nota di contenuto	Randomized Clinical Trials; Contents; Preface; 1 Introduction; 1.1 Introduction; 1.2 Some completed trials; 1.3 Choice of design; 1.4 Practical constraints; 1.5 Influencing clinical practice; 1.6 History; 1.7 How trials arise; 1.8 Ethical considerations; 1.9 Regulatory requirements; 1.10 Focus; 1.11 Further reading; 2 Design Features; 2.1 Introduction; 2.2 The research question; 2.3 Patient selection; 2.4 The consent process; 2.5 Choice of interventions; 2.6 Choice of design; 2.7 Assigning the interventions; 2.8 Making the assessments; 2.9 Analysis and reporting; 2.10 Technical details 2.11 Guidelines2.12 Further reading; 3 The Trial Protocol; 3.1 Introduction; 3.2 Protocol - abstract; 3.3 Protocol - background; 3.4 Protocol - research objectives; 3.5 Protocol - design; 3.6 Protocol - intervention details; 3.7 Protocol - eligibility; 3.8 Protocol - randomization; 3.9 Protocol - assessment and data collection; 3.10 Protocol - statistical considerations; 3.11 Protocol - ethical issues; 3.12 Protocol - organizational structure; 3.13 Protocol - publication policy; 3.14 Protocol - trial forms; 3.15 Protocol - appendices; 3.16 Regulatory requirements; 3.17 Guidelines

3.18 Protocols
4 Measurement and Data Capture; 4.1 Introduction; 4.2 Measures and endpoints; 4.3 Making the observations; 4.4 Baseline measures; 4.5 Types of measures; 4.6 Data recording; 4.7 Technical notes; 4.8 Guidelines; 5 Randomization; 5.1 Introduction; 5.2 Rationale; 5.3 Mechanics; 5.4 Application; 5.5 Carrying out randomization; 5.6 Documentation; 5.7 Unacceptable methods; 5.8 Software; 5.9 Guidelines; 6 Trial Initiation; 6.1 Introduction; 6.2 Trial organization; 6.3 Data collection and processing; 6.4 Data monitoring; 6.5 Ethical and regulatory requirements; 6.6 Launching the trial
6.7 Trial registries
6.8 Guidelines; 7 Trial Conduct; 7.1 Introduction; 7.2 Regular feedback; 7.3 Publicity; 7.4 Data monitoring committees; 7.5 Protocol modifications; 7.6 Preparing the publication(s); 7.7 The next trial?; 7.8 Protocols; 8 Basics of Analysis; 8.1 Introduction; 8.2 Confidence intervals; 8.3 Statistical tests; 8.4 Examples of analysis; 8.5 Other issues; 8.6 Practice; 8.7 Technical details; 9 Trial Size; 9.1 Introduction; 9.2 Significance level and power; 9.3 The fundamental equation; 9.4 Specific situations; 9.5 Practical considerations; 9.6 Further topics
9.7 Other methods and software
9.8 Guideline; 10 Reporting; 10.1 Introduction; 10.2 Publication guidelines; 10.3 Responsibilities; 10.4 Background; 10.5 Methods; 10.6 Findings; 10.7 When things go wrong; 10.8 Conclusions; 10.9 Guidelines; 11 Adaptations of the Basic Design; 11.1 Introduction; 11.2 Repeated measures; 11.3 Cluster-randomized trials; 11.4 Non-inferiority trials; 11.5 Guidelines; 12 Paired Designs; 12.1 Cross-over trials; 12.2 Split-mouth designs; 12.3 Paired organs; 13 More Than Two Interventions; 13.1 Introduction; 13.2 Unstructured comparisons
13.3 Comparisons with placebo (or standard)

Sommario/riassunto

Using examples and case studies from industry, academia and research literature, Randomized Clinical Trials provides a detailed overview of the key issues involved in designing, conducting, analysing and reporting randomized clinical trials. It examines the methodology for conducting Phase III clinical trials, developing the protocols, the practice for capturing, measuring, and analysing the resulting clinical data and their subsequent reporting. Randomized clinical trials are the principal method for determining the relative efficacy and safety of alternative treatments, interventio
