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Autore	Guyénot, E.
Titolo	Enciclopedie scientifique / E. Guyénot
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Nota di bibliografia	Includes bibliographical references and indexes.
Nota di contenuto	A MANAGER'S GUIDE TO THE DESIGN AND CONDUCT OF CLINICAL TRIALS; Contents; 1 Cut Costs and Increase Profits; No Excuse for the Wastage; Front-Loaded Solution; Downsizing; Think Transnational; A Final Word; 2 Guidelines; Start with Your Reports; The Wrong Way; Keep It in the Computer; Don't Push the River; KISS; Plug the Holes as They Arise; Pay for Results, Not Intentions; Plan, Do, Then Check; PART I PLAN; 3 Prescription for Success; Plan; A. Predesign Phase; B. Design the Trials; Do; C. Obtain Regulatory Agency Approval for the Trials; D. Form the Implementation Team E. Line Up Your Panel of PhysiciansF. Develop the Data Entry Software; G. Test the Software; H. Train; I. Recruit Patients; J. Set Up External Review Committees; K. Conduct the Trials; L. Develop Suite of Programs for Use in Data Analysis; M. Analyze and Interpret the Data; Check; N. Complete the Submission; 4 Staffing for Success; The People You Need; Design Team; Obtain Regulatory Approval for the Trials; Track Progress; Implementation Team; Develop Data Entry Software; Test the Software; Line Up Your Panel of Physicians; External Laboratories; Site Coordinators; External Review Committees Recruit and Enroll PatientsTransnational Trials; Conduct the Trials; Programs for Data Analysis; Analyze and Interpret the Data; The People You Don't Need; For Further Information; 5 Design Decisions; Should the Study Be Performed?; Should the Trials Be Transnational?; Study Objectives; End Points; Secondary End Points; Should We Proceed with a Full-Scale Trial?; Tertiary End Points; Baseline Data; Who Will Collect the Data?; Quality Control; Study Population; Timing; Closure; Planned Closure; Unplanned Closure; Be Defensive. Review, Rewrite, Review Again; Checklist for Design Budgets and ExpendituresFor Further Information; 6 Trial Design; Baseline Measurements; Controlled Randomized Clinical Trials; Randomized Trials; Blocked Randomization; Stratified Randomization; Single- vs. Double-Blind Studies; Allocation Concealment; Exceptions to the Rule; Sample Size; Which Formula?; Precision of Estimates; Bounding Type I and Type II Errors; Equivalence; Software; Subsamples; Loss Adjustment; Number of Treatment Sites; Alternate Designs; Taking Cost into Consideration; For Further Information; 7 Exception Handling; Patient Related; Missed Doses; Missed Appointments NoncomplianceAdverse Reactions; Reporting Adverse Events; When Do You Crack the Code?; Investigator Related; Lagging Recruitment; Protocol Deviations; Site-Specific Problems; Closure; Intent to Treat; Is Your Planning Complete?; PART II DO; 8 Documentation; Guidelines; Common Technical Document; Reporting Adverse Events; Initial Submission to the Regulatory Agency; Sponsor Data; Justifying the Study; Objectives; Patient Selection; Treatment Plan; Outcome Measures and Evaluation; Procedures; Clinical Follow-Up; Adverse Events; Data Management, Monitoring, Quality Control; Statistical Analysis Investigator Responsibilities
Sommario/riassunto	This newly updated edition of the benchmark guide to computer-assisted clinical trials provides a comprehensive primer for prospective managers. It covers every critical issue of the design and conduct of clinical trials, including study design, organization, regulatory agency liaison, data collection and analysis, as well as recruitment, software, monitoring, and reporting.Keeping the same user-friendly format as

the original, this Second Edition features new examples and the latest developments in regulatory guidelines, such as e-submission procedures and computerized direct data acq