

1. Record Nr.	UNINA9910143422903321
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Titolo	A manager's guide to the design and conduct of clinical trials [[electronic resource] /] / Phillip I. Good
Pubbl/distr/stampa	Hoboken, NJ, : Wiley-Liss, c2006
ISBN	1-280-44821-0 9786610448210 0-470-32719-7 0-471-93091-1 0-471-93087-3
Edizione	[2nd ed.]
Descrizione fisica	1 online resource (274 p.)
Disciplina	610.72/4 610.724
Soggetti	Clinical trials Clinical medicine - Research Electronic books.
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 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 Physicians F. 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
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Noncompliance Adverse 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
