Cut Costs and Increase Profits
No Excuse for the Wastage
Front-Loaded Solution
Downsizing
Think Transnational
A Final Word
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
Plan
Prescription for Success
Plan
Predesign Phase
Design the Trials Do
Obtain Regulatory Agency Approval for the Trials
Form the Implementation Team
Line Up Your Panel of Physicians
Develop the Data Entry Software
Test the Software
Train
Recruit Patients
Set Up External Review Committee
Conduct the Trials
Develop Suite of Programs for Use in Data Analysis
Analyze and Interpret the Data Check
Complete the Submission
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 Patients
Transnational Trials
Conduct the Trials
Programs for Data Analysis
Analyze and Interpret the Data
For Further Information
The People You Don’t Need

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 Expenditures
For Further Information
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
Exception Handling
Patient Related
Missed Doses
Missed Appointments
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?
DO
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