

1. Record Nr.	UNINA9910817442103321
Autore	Meinert Curtis L
Titolo	Clinical trials handbook : design and conduct // Curtis L. Meinert
Pubbl/distr/stampa	Somerset, N.J., : Wiley, 2012
ISBN	9781118422793 1118422791 9781118422878 1118422872 9781118422823 1118422821
Edizione	[1st ed.]
Descrizione fisica	1 online resource (599 p.)
Classificazione	REF028000
Disciplina	615.1072/4
Soggetti	Drugs - Testing Clinical trials
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 index.
Nota di contenuto	Machine generated contents note: Preface xiOn planning xiiiExplanatory notes, focus, and conventions xvi. General 31. Terminology 42. Definitions 63. Measurement units 84. Trial type 95. Design and flow schematics 126. Design and operating principles 137. Counting and analysis rules 148. Multi-study umbrella name 169. Study name 18II. Design specifications 2110. Objective 2211. Specific aims 2412. Experimental variable 2513. Treatment unit 2614. Primary outcome 2815. Outcome measures 3116. Design synopsis 33III. Funding 3717. Type of funding initiative 3818. Funding: Specifications 4019. Funding: Terminology 4220. Funding: Type 5021. Funding: Initiative 5122. Funding: Period 5323. Funding: Budget 5424. Funding: Mode 56IV. Treatment groups/treatment administration 5925. Study groups 6026. Comparison group 6227. Study treatments 6428. Test treatments 6629. Control/comparison treatment 6830. Placebo treatment 7531. Sham treatment 8032. Treatment modality 8233. Treatment schedule 8334. Treatment compliance measures 8535. Protocol overrides 8836. Protocol bailouts 90V. Masking 9337. Mask/masking: Definitions 9438. Masking principles 9739. Masking,

censoring, and shielding specifications 9940. Drug masking procedure 10141. Drug packaging and labeling 10342. Drug supply 10643. Masking safeguards 10844. Unmasking treatment assignment 10945. Results blackouts 110VI. Bias and variance control 11346. Bias control procedures 11447. Stratification 11748. Variance control procedures 12049. Separations 122VII. Treatment assignment/randomization 12350. Assignment methods: Fixed vs adaptive 12451. Treatment assignment: Random vs nonrandom 12652. Randomization: Complete vs restricted 12953. Randomization unit 13254. Randomization: Procedures 134VIII. IRBs and consents 13555. IRBs 13656. IRBs: Models and procedures 13857. Consent 14358. Consent: Checklist 15059. Consent: Disclaimers and notifications 15360. Consent: Principles and purpose 15561. Consent: Process 15762. Consent: Types 16063. Consent: Questions and answers 162IX. Enrollment and followup 16764. Notation 16865. Timing conventions 17166. Required approvals, permissions, accesses, and supplies 17367. Start-up design 17568. Start-up checklist 17969. Recruitment design 18070. Enrollment goals 18271. Enrollment quotas 18472. Followup: Terminology 18973. Followup: Method 19374. Followup: Length 19575. Closeout design 19676. Missed visit 19977. Dropout 20078. Loss to followup 20479. Study timetable 20780. Critical event path analysis 20981. Eligibility criteria 21282. Exclusions from enrollment 21583. Eligibility and exclusions by reason 219X. Sample size 22184. Sample size: Design 22285. Sample size: Specifications 22686. Sample size: Calculation 22987. Fixed versus sequential sample size designs 23188. Fixed versus adaptive designs 23389. Designed subgroup comparisons 235XI. Data collection and processing 23990. Contact schedule 24091. Examinations/visits 24192. Examination/clinic visit schedule 24593. Data collection 24994. Data collection: Schedules and procedures 25295. Data flow 25596. Data processing procedures 25797. Laboratory tests 26098. Readings 26299. Tissue repositories 266100. Form design: Principles and procedures 268101. Time window specifications 272102. Data entry design 274103. Data sharing: Internal 280104. Data sharing: External 283XII. Study centers 287105. Center types 288106. Centers 291107. Center requirements 293XIII. Investigators/study staff 297108. Investigator requirements 298109. Clinic staffing requirements 300110. Research group/Investigators 302XIV. Committees 305111. Key committees 306112. Standing and working committees 307113. Committee rules and procedures 308114. Study officers 312115. Study chair/vice-chair 313116. Executive committee 317117. Executive committee members 319118. Steering committee 320119. Steering committee members 322120. Steering committee: Questions, answers, and observations 324121. Steering committee representation models 327XV. Treatment effects monitoring 331122. Treatment effects monitoring 332123. Treatment effects monitoring: Purpose 334124. Treatment effects monitoring: Approach 336125. Treatment effects monitoring: Masking 338126. Stopping rules and guidelines 340127. Treatment effects monitoring: Questions and answers 342128. Treatment effects monitoring committee 345129. Treatment effects monitoring committee: Questions and answers 347XVI. Quality control and assurance 351130. Quality control and assurance procedures 352131. Performance monitoring 356132. Training procedures 358133. Assurances and certifications 359134. Site visiting procedures 361135. Audit procedures 364XVII. Data analysis 367136. Analysis datasets 368137. Analysis questions regarding study results publications 370138. Frequentist vs Bayesian analysis 372139. Final analysis 374140. Subgroup analysis 376XVIII. Publication/presentation 379141. Publication 380142. Publication

policy 382143. Authorship 384144. Credits 389145. Presentation policy 393XIX. Policies 395146. Policies 396147. Publicity policy 397148. Policy on access to study documents 398149. Policy on access to study data and results 400150. Policy on advertising for patients 403151. Policy on incentive payments 404152. Policy on payment of patient related travel expenses 406153. Ancillary study policy 407154. Policy on patient care related payments 409155. Policy on conflicts of interest 410156. Substudy policy 413XX. Adverse events 415157. Adverse events 416158. Adverse event reporting procedures 420XXI. Miscellaneous 423159. Key study documents 424160. Design synopsis 425161. Slide sets 426162. Study CV 427163. Study website 428164. Study history log 429165. Landmark events and dates 431166. Registration 433Appendices 435Appendix 1. Design summaries 437Appendix 2. Sample design slide sets 457Appendix 3. Template worksheets and slides 489References 505Index 516.

Sommario/riassunto

"Written by an eminent epidemiologist and clinician, this comprehensive book outlines and categorizes the required methodological steps employed in the clinical trial evaluation process. The author appropriately mixes the scientific, logistical, ethical, psychological, behavioral, and administrative issues inherent in the field, while also emphasizing conduct, performance, and protocol. With questions posed to pique reader interest; concepts readily available through an organizational hierarchy; and PowerPoint slide suggestions showcased throughout, this is a must-have book for all practicing clinicians and teachers of clinical trials courses"--
