

## Design and Conduct of Clinical Trials

### References and Readings

The references listed below represent a selection of references related to the areas of sampling, trial design, data analysis, and the University Group Diabetes Program (UGDP). The UGDP references were selected because they are often referred to during the course. A more comprehensive list of references for the whole field of clinical trials may be found in Appendix I of Meinert and Tonascia, 1986.

1. Amberson JB Jr, McMahon BT, Pinner M: A clinical trial of sanocrysin in pulmonary tuberculosis. Am Rev Tuberc 24:401 - 435, 1931. (Amberson et al, 1931)
2. Armitage P, McPherson CD, Rowe BC: Repeated significance tests on accumulating data. JRSS 132(series A):235 - 244, 1969. (Armitage et al, 1969)
3. Armitage PJ, Berry G: Statistical Methods in Medical Research. (2nd ed) Blackwell Scientific Publications, Oxford, 1987. (Armitage and Berry, 1987)
4. Bailey KR: Detecting fabrication of data in a multicenter collaborative animal study. Controlled Clin Trials 12:741 - 752, 1991. (Bailey KR, 1991)
5. Bailey NTJ: The Mathematical Approach to Biology and Medicine. John Wiley & Sons, New York, 1967. (Bailey, 1967)
6. Baldwin W: Impact of the NIH inclusion guidelines. Controlled Clin Trials 16:300, 1995. (Baldwin W, 1995)
7. Beecher HK: Ethics and clinical research. New Engl J Med 274:1354 - 1360, 1966. (Beecher, 1966)
8. Begg C, Cho M, Eastwood S, Horton R, Moher D, Olkin I, Pitkin R, Rennie D, Schulz KF, Simel D, Stroup DF: Improving the quality of reporting of randomized controlled trials: The CONSORT statement. JAMA 276:637 - 639, 1996. (Begg et al, 1996)
9. Berry DA: Interim analysis in clinical trials: Classical vs Bayesian approaches. Stat Med 4:521 - 526, 1985. (Berry, 1985)
10. Blackwelder WC: "Proving the null hypothesis" in clinical trials. Controlled Clin Trials 3:345 - 353, 1982. (Blackwelder WC, 1982)
11. Blackwelder WC, Chang MA: Sample size graphs for "proving the null hypothesis". Controlled Clin Trials 5:97 - 105, 1984. (Blackwelder and Chang, 1984)
12. Boissel JP, Gueyffier F, Haugh M: Response to "Inclusion of women and minorities in clinical trials and the NIH Revitalization Act of 1993 — The perspective of NIH clinical trialists". Controlled Clin Trials 16: 286-288, 1995
13. Borenstein M: The case for confidence intervals in controlled clinical trials. Controlled Clin Trials 15:411 - 428, 1994. (Borenstein M, 1994)
14. Bristol DR: Sample sizes for constructing confidence intervals and testing hypotheses. Stat Med 8:803 - 811, 1989. (Bristol DR, 1989)
15. Brittain E, Wittes J: The run-in period in clinical trials: The effect of misclassification on efficiency. Controlled Clin Trials 11:327 - 338, 1990. (Brittain and Wittes, 1990)

16. Buist AS, Greenlick MR: Response to "Inclusion of women and minorities in clinical trials and the NIH Revitalization Act of 1993 — The perspective of NIH clinical trialists". Controlled Clin Trials 16:296-298, 1995.
17. Buyse ME, Staquet MJ, Sylvester RJ: Cancer Clinical Trials: Methods and Practice. Oxford University Press, Oxford, 1984. (Buyse et al, 1984)
18. Canner PL: Monitoring clinical trials data for evidence of adverse or beneficial treatment effects. Essais Controles Multicentres: Principes et la Sante et de la Recherche Medicale (INSERM) 76:131 - 149, 1977a. (Canner, 1977a)
19. Canner PL: Monitoring treatment differences in long-term clinical trials. Biometrics 33:603 - 615, 1977b. (Canner, 1977b)
20. Canner PL, Huang YB, Meinert CL: On the detection of outlier clinics in medical and surgical trials: I. Practical considerations. Controlled Clin Trials 2:231 - 240, 1981. (Canner et al, 1981)
21. Casagrande JT, Pike MC, Smith PG: The power function of the "exact" test for comparing two binomial distributions. Appl Statist 27:176 - 180, 1978. (Casagrande et al, 1978)
22. Chalmers TC: A potpourri of RCT topics. Controlled Clin Trials 3:285 - 298, 1982. (Chalmers TC, 1982)
23. Chalmers TC: Randomization of the first patient. Med Clin North Am 59:1035 - 1038, 1975. (Chalmers, 1975)
24. Chalmers TC, Smith H Jr, Blackburn B, Silverman B, Schroeder B, Reitman D, Ambroz A: A method for assessing the quality of a randomized control trial. Controlled Clin Trials 2:31 - 49, 1981. (Chalmers et al, 1981)
25. Chassin MR, Hannan EL, DeBuono BA: Benefits and hazards of reporting medical outcomes publicly. N Engl J Med 334:394 - 398, 1996.
26. Classens MT, Bernot JL, Baron JA: Ethical issues in clinical trials, Br J Urology 76 (suppl 2): 29-36, 1995. (Chassin et al, 1996)
27. Chlebowski RT, Weiner JM, Ryden VMJ, Bateman JR: Factors influencing the interim interpretation of a breast cancer trial: Danger of achieving the "expected" result. Controlled Clin Trials 2:123 - 132, 1981. (Chlebowski et al, 1981)
28. Cochran WG: Some methods for strengthening the common  $X^2$  tests. Biometrics 10:417 - 451, 1954. (Cochran, 1954)
29. Cochran WG, Cox GM: Experimental Designs. (2nd ed). John Wiley & Sons Inc., New York, 1957. (Cochran and Cox, 1957)
30. Colton T, Freedman LS, Johnson AL, Machin D: Recent issues in clinical trials. Stat Med 8:401 - 516, 1989. (Colton et al, 1989)
31. Committee for the Assessment of Biometric Aspects of Controlled Trials of Hypoglycemic Agents: Report of the Committee for the Assessment of Biometric Aspects of Controlled Trials of Hypoglycemic Agents. JAMA 231:583 - 608, 1975. (Biometric Committee Report 1975)
32. Committee on Human Research: Policy and Procedures Manual for the Protection of Human Subjects. The Johns Hopkins School of Hygiene and Public Health, Baltimore, 1992. (CHR, 1992)
33. Committee on the Responsible Conduct of Research, Institute of Medicine, Division of Health Sciences Policy: The Responsible Conduct of Research in the Health Sciences. National Academy Press, Washington, DC, 1989. (Committee et al, 1989)

34. Committee on Science, Engineering, and Public Policy, Institute of Medicine: On Being A Scientist: Responsible Conduct in Research. National Academy Press, Washington, DC, 1995. (Committee et al, 1995)
35. Cornfield J: Principles of research. Am J Mental Defic 64:240 - 252, 1959. (Cornfield, 1959)
36. Cornfield J: A Bayesian test of some classical hypotheses -- with applications to sequential clinical trials. JASA 61:577 - 594, 1966a. (Cornfield, 1966a)
37. Cornfield J: Sequential trials, sequential analysis and the likelihood principle. Am Statistician 20:18 - 23, 1966b. (Cornfield, 1966b)
38. Cornfield J: The Bayesian outlook and its application (including discussion by S Geisser, HO Hartley, O Kempthorne, H Rubin). Biometrics 25:617 - 657, 1969. (Cornfield, 1969)
39. Cornfield J: The University Group Diabetes Program: A further statistical analysis of the mortality findings. JAMA 217:1676 - 1687, 1971. (Cornfield, 1971)
40. Cornfield J: Recent methodological contributions to clinical trials. Am J Epidemiol 104:408 - 421, 1976. (Cornfield J, 1976)
41. Coronary Drug Project Research Group: The Coronary Drug Project: Initial findings leading to modifications of its research protocol. JAMA 214:1303 - 1313, 1970. (CDP Research Group, 1970)
42. Coronary Drug Project Research Group: The Coronary Drug Project: Findings leading to further modifications of its protocol with respect to dextrothyroxine. JAMA 220:996 - 1008, 1972. (CDP Research Group, 1972)
43. Coronary Drug Project Research Group: The Coronary Drug Project: Design, methods, and baseline results. Circulation 47 (suppl 1):I-1 - I-50, 1973a. (CDP Research Group, 1973a)
44. Coronary Drug Project Research Group: The Coronary Drug Project: Findings leading to discontinuation of the 2.5-mg/day estrogen group. JAMA 226:652 - 657, 1973b. (CDP Research Group, 1973b)
45. Coronary Drug Project Research Group: Factors influencing long-term prognosis after recovery from myocardial infarction — Three-year findings of the Coronary Drug Project. J Chron Dis 27:267 - 285, 1974. (CDP Research Group, 1974)
46. Coronary Drug Project Research Group: The Coronary Drug Project: Clofibrate and niacin in coronary heart disease. JAMA 231:360 - 381, 1975. (CDP Research Group, 1975)
47. Coronary Drug Project Research Group: Influence of adherence to treatment and response of cholesterol on mortality in the Coronary Drug Project. N Engl J Med 303:1038 - 1041, 1980. (CDP Research Group, 1980)
48. Coronary Drug Project Research Group: Practical aspects of decision making in clinical trials: The Coronary Drug Project as a case study. Controlled Clin Trials 1:363 - 376, 1981. (CDP Research Group, 1981)
49. Coronary Drug Project Research Group: The Coronary Drug Project: Methods and Lessons of a Multicenter Clinical Trial. Controlled Clin Trials 4:273 - 522, 1983. (CDP Research Group, 1983)
50. Cutler SJ, Greenhouse SW, Cornfield J, Schneiderman MA: The role of hypothesis testing in clinical trials (with discussion by Zelen M, Shaw LW, Beebe GW). J Chronic Dis 19:857 - 882, 1966. (Cutler et al, 1966)

51. Data Management for Multicenter Studies: Methods and Guidelines: [Monograph of that Title]. Controlled Clin Trials 16(suppl):1S - 179S, 1995. (Data Mgmt Multi Studies, 1995)
52. Day SF, Graham DF: Sample size and power for comparing two or more treatment groups in clinical trials. BMJ 299:663 - 665, 1989. (Day and Graham, 1989)
53. Day SJ, Graham DF: Sample size estimation for comparing two or more treatment groups in clinical trials. Stat Med 10:33 - 43, 1991. (Day and Graham, 1991)
54. DeLacey G, Record C, Wade J: How accurate are quotations and references in medical journals. BMN 291:884 - 886, 1985. (DeLacey et al, 1985)
55. DeMets DL: Practical aspects in data monitoring: a brief review. Stat Med 6:753 - 760, 1987. (DeMets DL, 1987)
56. DeMets DL, Meinert CL: Data integrity. Controlled Clin Trials 12:727 - 730, 1991. (DeMets and Meinert, 1991)
57. Dickersin K: The existence of publication bias and risk factors for its occurrence. JAMA 263:1385 - 1389, 1990. (Dickersin K, 1990)
58. Dickersin K, Min Yuan-I, Meinert, CL: Factors influencing publication of research results. Follow-up of applications submitted to two institutional review boards. JAMA 267:374 - 378, 1992. (Dickersin et al, 1992)
59. Dixon WJ, Massey FJ: Introduction to Statistical Analysis. 3rd ed). McGraw-Hill Book Co., New York, 1969. (Dixon and Massey, 1969)
60. Donner A: Approaches to sample size estimation in the designing of clinical trials — A review. Stat Med 3:199 - 214, 1984. (Donner A, 1984)
61. Dunnett CW: A multiple comparison procedure for comparing several treatments with a control. JASA 50:1096 - 1121, 1955. (Dunnett, 1955)
62. Dupont WD, Plummer WD: Power and sample size calculations. A review and computer program. Controlled Clin Trials 11:116 - 128, 1990. (Dupont and Plummer, 1990)
63. Ederer F, Podgor MJ, and the Diabetic Retinopathy Study Group: Assessing possible late treatment effects in stopping a clinical trial early: A case study: Diabetic Retinopathy Study Report No. 9. Controlled Clin Trials 5:373 - 381, 1984. (Ederer et al, 1984)
64. Ellenberg SS: Randomization designs in comparative clinical trials. N Engl J Med 310:1404 - 1408, 1984. (Ellenberg SS, 1984)
65. Feigl P: A graphical aid for determining sample size when comparing two independent proportions. Biometrics 34:111 - 122, 1978. (Feigl P, 1978)
66. Feinstein A: The role of observational studies in the evaluation of therapy. Stat Med 3:341 - 345, 1984. (Feinstein, 1984)
67. Feinstein AR: Clinical biostatistics: VII. An analytic appraisal of the University Group Diabetes Program (UGDP) study. Clin Pharmacol Ther 12:167 - 191, 1971. (Feinstein, 1971)
68. Feller W: An Introduction to Probability Theory and Its Applications: Vol 1. (3rd ed). John Wiley & Sons, New York, 1968. (Feller, 1968)
69. Fisher B, Bauer M, Margolese R, et al: Five-year results of a randomized clinical trial comparing total mastectomy and segmental mastectomy with or without radiation in the treatment of breast cancer. N Engl J Med 312:665 - 673, 1985. (Fisher et al, 1985)

70. Fisher B, Costantino J, Redmond C, et al: A randomized clinical trial evaluating tamoxifen in the treatment of patients with node-negative breast cancer who have estrogen-receptor-positive tumors. N Engl J Med 320:479 - 484, 1989. (Fisher et al, 1989)
71. Fisher B, Costantino J, Redmond C, et al: Lumpectomy compared with lumpectomy and radiation therapy for the treatment of intraductal breast cancer. N Engl J Med 328:1581 - 1586, 1993. (Fisher et al, 1993)
72. Fisher B, Redmond CK: Fraud in breast-cancer trials. N Engl J Med 330:1458 - 1460, 1994. (Fisher and Redmond, 1994)
73. Fisher B, Redmond C, Dimitrov NV, et al: A randomized clinical trial evaluating sequential methotrexate and fluorouracil in the treatment of patients with node-negative breast cancer who have estrogen-receptor-negative tumors. N Engl J Med 320:473 - 478, 1989. (Fisher et al, 1989)
74. Fisher B, Redmond C, Poisson R, et al: Eight-year results of a randomized clinical trial comparing total mastectomy and lumpectomy with or without irradiation in the treatment of breast cancer. N Engl J Med 320:822 - 828, 1989. (Fisher et al, 1989)
75. Fisher RA, MacKenzie WA: Studies in crop variation: II. The manurial response of different potato varieties. J Agric Sci 13:311 - 320, 1923. (Fisher and MacKenzie, 1923)
76. Fleiss JL: Statistical Methods for Rates and Proportions. Wiley-Interscience Publications, New York, 1972. 972)
77. Fleiss JL: The Design and Analysis of Clinical Experiments. John Wiley & Sons, New York, 1986. (Fleiss, 1986)
78. Fleming TR, DeMets DL: Monitoring of clinical trials: Issues and recommendations. Controlled Clin Trials 14:183 - 197, 1993. (Fleming and DeMets, 1993)
79. Food and Drug Administration, Department of Health and Human Services: Code of Federal Regulations Title 45 Public Welfare: Part 46-Protection of Human Subjects. DHHS, Bethesda, Jan 26, 1981. (Food and Drug Administration)
80. Food and Drug Administration, Department of Health and Human Services: Federal Register Vol. 46: Protection of Human Subjects Informed Consent. 8942-8980 DHHS, Bethesda, Jan 27, 1981. (FDA, 1981)
81. Food and Drug Administration, Office of Science and Technology Policy: Federal Register Vol. 53: Federal Policy for the Protection of Human Subjects. 45660 DHHS, Bethesda, Nov 10, 1988. (FDA, 1988)
82. Food and Drug Administration: Oral hypoglycemic drugs: Availability of agency analysis and reopening of comment period on proposed labeling requirements. Federal Register 43:52732 - 52734, Nov 14, 1978. (FDA, 1978)
83. Food and Drug Administration: Report of an FDA Task Force. Fialuridine: Hepatic and Pancreatic Toxicity. Rockville, MD, 12 November 1993. (FDA, 12 November 1993)
84. Freedman B: Equipoise and the ethics of clinical research. N Engl J Med 317:141 - 145, 1987. (Freedman, 1987)
85. Freedman B: AIDS and the ethics of clinical trials: Learning the right lessons. Controlled Clin Trials 13:1 - 5, 1992. (Freedman, 1992)
86. Freedman LS, Simon R, Foulkes MA, Friedman L, Geller NL, Gordon DJ, Mowery R: Inclusion of women and minorities in clinical trials and the NIH

- Revitalization Act of 1993 - The perspective of NIH clinical trialists. Controlled Clin Trials 16:277 - 285, 1995.
87. Freedman LS: Tables of the number of patients required in clinical trials using the logrank test. Stat Med 1:121 - 130, 1982. (Freedman LS, 1982)
  88. Freedman LS, Simon R, Foulkes MA, Friedman L, Geller NL, Gordon DJ, Mowery R: Inclusion of women and minorities in clinical trials and the NIH Revitalization Act of 1993 -- The perspective of NIH clinical trials. Controlled Clin Trials 16:277 - 285, 1995. (Freedman et al, 1995)
  89. Fried C: Medical Experimentation: Personal Integrity and Social Policy. Amsterdam North Holland Publishing, New York, 1974. (Fried, 1974)
  90. Friedman LM, Furberg CD, DeMets DL: Fundamentals of Clinical Trials. (2nd ed). PSG Publishing Co., Inc., Littleton, MA, 1985. (Friedman et al, 1985)
  91. Gail M: Power computations for designing comparative Poisson trials. Biometrics 30:231 - 237, 1974. (Gail, 1974)
  92. Gail M: Monitoring and stopping clinical trials. In: Statistics in Medical Research. (ed by: Mike V, Stanley K). John Wiley & Sons, New York, 1982. (Gail, 1982)
  93. Gail M, Gart JJ: The determination of sample sizes for use with the exact conditional test in 2 x 2 comparative trials. Biometrics 29:441 - 448, 1973. (Gail and Gart, 1973)
  94. Gehan EA: The evaluation of therapies: Historical control studies. Stat Med 3:315 - 324, 1984. (Gehan, 1984)
  95. Gehan EA, Lemak NA: Statistics in Medical Research. Developments in Clinical Trials. Plenum Medical Book Company, New York, 1994. (Gehan and Lemak, 1994)
  96. Gehlbach SH: Interpreting the Medical Literature. McGraw-Hill, Inc., New York, 1993. (Gehlbach SH, 1993)
  97. Glaucoma Laser Trial Research Group: The Glaucoma Laser Trial: 1. Acute effects of argon laser trabeculoplasty on intraocular pressure. Arch Ophthalmol 107:1135 - 1142, 1989. (GLT Research Group, 1989)
  98. Glaucoma Laser Trial Research Group: The Glaucoma Laser Trial (GLT): 3. Design and methods. Controlled Clin Trials 12:504 - 524, 1991. (GLT Research Group, 1991)
  99. Gore SM: Inclusion of women and minorities in clinical trials. Controlled Clin Trials 16:290-292, 1995.
  100. Green SB, Byar DP: Using observational data from registries to compare treatments: The fallacy of omnimetrics. Stat Med 3:361 - 370, 1984. (Green and Byar, 1984)
  101. Grizzle JE: A note on stratifying versus complete random assignment in clinical trials. Controlled Clin Trials 3:365 - 368, 1982. (Grizzle, 1982)
  102. Haggard HW: The Lame, the Halt, and the Blind: The Vital Role of Medicine in the History of Civilization. Harper and Brothers, New York, 1932. (Haggard, 1932)
  103. Hawkins BS: Controlled clinical trials in the 1980s: A bibliography. Controlled Clin Trials 12:1 - 272, 1991. (Hawkins BS, 1991)
  104. Hulley SB, Cummings SR: Designing Clinical Research: An Epidemiologic Approach. Williams and Wilkins, Baltimore, 1988. (Hulley and Cummings, 1988)
  105. Hypertension Prevention Trial Research Group: The Hypertension Prevention Trial (HPT): Design, Methods, and Baseline Results (C Meinert, J Tonascia, S

- Tonascia, editors). Controlled Clin Trials 10 (suppl):1S - 117S, 1989. (HPT Research Group, 1989)
106. Hypertension Prevention Trial Research Group: The Hypertension Prevention Trial: Three-year effects of dietary changes on blood pressure. Arch Intern Med 150:153 - 162, 1990. (HPT Research Group, 1990)
  107. Iber FL, Riley WA, Murray PJ: Conducting Clinical Trials. Plenum Medical Book Company, New York, 1987.
  108. Institute of Medicine Committee to Review the Fialuridine (FIAU/FIAC) Clinical Trials: Review of the Fialuridine (FIAU) Clinical Trials. Division of Health Sciences Policy, IOM. National Academy Press, Washington, DC, 1995. (IOM, 1995)
  109. International Committee of Medical Journal Editors: Uniform requirements for manuscripts submitted to biomedical journals. NEJM 336:309 - 315, 1997. (Intl Comm Med J Eds, 1997)
  110. Johnson N, Lilford RJ, Brazier W: At what level of collective equipoise does a clinical trial become ethical. J Med Ethics 17:30 - 34, 1991. (Johnson et al, 1991)
  111. Joint Committee on Clinical Investigation: Human Subjects Research: Guidelines of the Joint Committee on Clinical Investigation. The Johns Hopkins Schools of Medicine and Nursing, Hospital, and The Kennedy Institute, Baltimore, 1991. (JCCI, 1991)
  112. Kalbfleisch JD, Prentice RL: The Statistical Analysis of Future Time Data. John Wiley & Sons, New York, 1980. and Prentice, 1980)
  113. Kalish LA, Begg CB: Treatment allocation method in clinical trials: A review. Stat Med 4:129 - 144, 1985. (Kalish and Begg, 1985)
  114. Kaplan EL, Meier P: Nonparametric estimation for incomplete observations. JASA 53:457 - 481, 1958. (Kaplan and Meier, 1958)
  115. Katz J, Capron AM, Glass ES: Experimentation with Human Beings. Russell Sage Foundation, New York, 1972. (Katz et al, 1972)
  116. Kilo C, Miller JP, Williamson JR: The Achilles heel of the University Group Diabetes Program. JAMA 243:450 - 457, 1980. (Kilo et al, 1980)
  117. Kohn A: False Prophets: Fraud and Error in Science and Medicine (Rev Ed). Basil Blackwell, Inc., Cambridge, MA, 1988. (Kohn A, 1988)
  118. Kolata GB: Controversy over study of diabetes drugs continues for nearly a decade. Science 203:986 - 990, 1979. (Kolata, 1979)
  119. Lachin JM: Introduction to sample size determination and power analysis for clinical trials. Controlled Clin Trials 2:93 - 114, 1981. (Lachin JM, 1981)
  120. Lachin JM: Sample size determination for r x c comparative trials. Biometrics 33:315 - 324, 1977. (Lachin JM, 1977)
  121. Lachin JM, Foulkes MA: Evaluation of sample size and power for analyses of survival with allowance for non uniform patient entry, losses to follow-up, non-compliance and stratification. Biometrics 42:507 - 519, 1986. (Lachin and Foulkes, 1986)
  122. Lakatos E: Sample sizes based on the log-rank statistic in complex clinical trials. Biometrics 44:229 - 242, 1988. (Lakatos E, 1988)
  123. Lakatos E: Sample size in clinical trials with time dependent rates of losses and non compliance. Controlled Clin Trials 7:189 - 199, 1986. (Lakatos E, 1986)

124. Lee KL, McNeer JF, Starmer CF, Harris PJ, Rosati RA: Clinical judgment and statistics: Lessons from a simulated randomized trial in coronary artery disease. Circulation 61:508 - 515, 1980. (Lee et al, 1980)
125. Leventhal BG, Wittes RE: Research Methods in Clinical Oncology. Raven Press, New York, 1988.
126. Levine, RJ: The Need to Revise the Declaration of Helsinki. NEJM 341:531-534, 1999(Leventhal and Wittes, 1988)
127. Levine RJ: Ethics and Regulation of Clinical Research. (2nd ed). Urban and Schwarzenberg, Baltimore-Munich, 1986. (Levine, 1986)
128. Lilford RJ, Jackson J: Equipoise and the ethics of randomization. J R Soc Med 88:552 - 559, 1995. (Lilford and Jackson, 1995)
129. Machin D, Campbell MJ: Statistical Tables for the Design of Clinical Trials. Blackwell Scientific Publications, Oxford, 1987. (Machin and Campbell, 1987)
130. Macular Photocoagulation Study Group: Changing the protocol: A case report from the Macular Photocoagulation Study. Controlled Clin Trials 5:203 - 216, 1984. (Macular Photocoagulation Study Group, 1984)
131. Marks HM: The Progress of Experiment: Science and Therapeutic Reform in the United States, 1990-1990. Cambridge University Press, New York, 1997. (Marks HM, 1997)
132. McMaster University Health Sciences Center: How to read clinical journals: I. Why to read them and how to start reading them critically. Can Med Assoc J 124:555 - 558, 1981a. (McMaster 1, 1981a)
133. McMaster University Health Sciences Center: How to read clinical journals: V. To distinguish useful from useless or even harmful therapy. Can Med Assoc J 124:1156 - 1162, 1981b. (McMaster 2, 1981b)
134. Medical Research Council: Clinical trials of new remedies (annotations). Lancet 2:304, 1931. (Medical Research Council, 1931)
135. Meier P: Stratification in the design of a clinical trial. Controlled Clin Trials 1:355 - 361, 1981. (Meier, 1981)
136. Meinert CL: Redesign of trials under different enrolment mixes. Stat Med 18:241 - 251, 1999. (Meinert, 1999)
137. Meinert CL: Beyond CONSORT: Need for improved reporting standards for clinical trials. JAMA 279:1487 - 1489, 1998. (Meinert, 1998)
138. Meinert CL: Clinical trials and treatment effects monitoring. Controlled Clin Trials 19:515 - 522, 1998. (Me
139. Meinert CL: Masked monitoring in trials: Blind stupidity?. NEJM 338:1381 - 1382, 1998. (Meinert, 1998b)
140. Meinert CL: Clinical trials overview. In: Encyclopedia of Biostatistics. (ed by: Armitage P, Colton T) pp 699-713, John Wiley & Sons, New York, 1998. (Meinert, 1998c)
141. Meinert CL: Letter to Richard J. Whitley regarding presentation and publication. Personal Communication. December 4, 1995. (Whitley, 1995)  
[Presentation/Publication]
142. Meinert CL: The valid analysis requirement for clinical trials. Scientific Am 2:4 - p, 1995. (Meinert, 1995) (clinical trials, 1995)
143. Meinert CL: The inclusion of women in clinical trials. Science 269:795 - 796, 1995. (Science, 1995)



144. Meinert CL: Comments on NIH Clinical trials valid analysis requirement. Controlled Clin Trials 16:304 - 306, 1995. (NIH, 1995)
145. Meinert CL: Letter to Claude Len fant. Personal Communication. June 27, City, 1995. (Meinert CL, June 1995)
146. Meinert CL: Letter to Co-chairs of the National Academy of Sciences Institute of Medicine Committee on the Legal and Ethical Issues Relating to the Inclusion of Women in Clinical Trials. Personal Communication. April 9, 1993. [Representation/Quotas] (Meinert CL, 1993)
147. Meinert CL: Letter to SOCA Leadership: Proposed Publicity Release Schedule. Personal Communication. October 6, 1991. (SOCA, 1991) [Presentation/Publication]
148. Meinert CL, Tonascia S: Clinical Trials: Design, Conduct, and Analysis. Oxford University Press, New York, 1986. (Meinert and Tonascia, 1986)
149. Meinert CL: Clinical Trials Dictionary: Terminology and Usage Recommendations. Johns Hopkins Center for Clinical Trials, Baltimore, 1996. (Meinert CL, 1996)
150. Meinert CL, Tonascia S, Higgins KH: Content of reports on clinical trials: A critical review. Controlled Clin Trials 5:328 - 347, 1984. (Meinert et al, 1984)
151. Miller RG Jr: Developments in multiple comparisons: 1966-1976. JASA 72:779 - 788, 1977. (Miller, 1977)
152. Moher D: CONSORT: An evolving tool to help improve the quality of reports of randomized controlled trials. JAMA 279:1489 - 1491, 1998. (Meinert, 1998c)
153. Moses LE, Oakford RY: Tables of Random Permutations. Stanford University Press, Stanford CA, 1963. (Moses and Oakford, 1963)
154. Mosteller F, Gilbert JP, McPeck B: Reporting standards and research strategies for controlled trials: Agenda for the editor. Controlled Clin Trials 1:37 - 58, 1980. (Mosteller et al, 1980)
155. Multiple Risk Factor Intervention Trial Research Group: Multiple Risk Factor Intervention Trial: Quality Control of Technical Procedures and Data Acquisition (Morgan J, Kjelsberg MO, eds). Controlled Clin Trials 7(suppl):1s - 202s, 1986. (MRFIT Research Group, 1986)
156. National Heart Lung and Blood Institute: Proceedings of the Workshop on the Development of Markers for Use as Adherence Measures in Clinical Studies, May 24-25, 1982 (TP Blaszkowski, W Insull Jr, eds). Controlled Clin Trials 5(suppl):451 - 587, 1984. (NHLBI Adherence Workshop, 1984)
157. National Heart Lung and Blood Institute: Proceedings of the Workshop on the Recruitment Experience in NHLBI-Sponsored Clinical Trials, April 14-15, 1986 (DB Hunninghake, TP Blaszkowski, eds). Controlled Clin Trials 8(suppl):1s - 150s, 1987. (NHLBI Recruitment Workshop, 1987)
158. National Institutes of Health: Draft Report of the Advisory Committee to the Director, Subcommittee on Review of FIAU Studies. Bethesda, MD, 29 April 1994. (NIH, 29 April 1994)
159. Neaton JD, Bartsch GE, Broste SK, Cohen JD, Simon NM for the MRFIT Research Group: A case of data alteration in the Multiple Risk Factor Intervention Trial (MRFIT). Controlled Clin Trials 12:731 - 740, 1991. (Neaton et al, 1991)
160. O'Brien PC: The appropriateness of analysis of variance and multiple-comparison procedures. Biometrics 39:787 - 788, 1983. (O'Brien, 1983)
161. O'Brien PC, Fleming TR: A multiple testing procedure for clinical trials. Biometrics 35:549 - 556, 1979. (O'Brien and Fleming, 1979)

162. Packard FR: Life and Times of Ambroise Pare, 1510-1590. Paul B. Hoeber, New York, 1921.
163. Passaman E, Of mice but not men: Problems of the randomized clinical trial. NEJM 324:1585-1591, 1991(1991)
164. Patulin Clinical Trials Committee (of the Medical Research Council): Clinical trial of Patulin in the common cold. Lancet 2:373 - 375, 1944. (Patulin CT Committee, 1944)
165. Persantine-Aspirin Reinfarction Study Research Group: Persantine-Aspirin Reinfarction Study: Design, methods, and baseline results. Circulation 62 (suppl):II-1 - II-42, 1980. (PARIS Research Group, 1980)
166. Peto R, Pike MC, Armitage P, Breslow NE, Cox DR, Howard SV, Mantel N, McPherson K, Peto J, Smith PG: Design and analysis of randomized clinical trials requiring prolonged observation of each patient: I: Introduction and design. Br J Cancer 34:585 - 612, 1976. (Peto et al, 1976)
167. Peto R, Pike MC, Armitage P, Breslow NE, Cox DR, Howard SV, Mantel N, McPherson K, Peto J, Smith PG: Design and analysis of randomized clinical trials requiring prolonged observation of each patient: II. Analysis and examples. Br J Cancer 35:1 - 39, 1977. (Peto et al, 1977)
168. Piantadosi S: Commentary regarding "Inclusion of women and minorities in clinical trials and the NIH Revitalization Act of 1993 — the perspective of NIH clinical trialists". Controlled Clin Trials 16:307 - 309, 1995. (Piantadosi S, 1995)
169. Piantadosi S: Clinical Trials: A Methodologic Perspective. John Wiley & Sons, New York, 1997. (Piantadosi S, 1997)
170. Pocock SJ: Clinical Trials: A Practical Approach. John Wiley & Sons, Chichester, 1983. (Pocock, 1983)
171. Pocock SJ: Statistical aspects of clinical trial design. The Statistician 31:1 - 18, 1982.
172. Pocock SJ: Statistical and ethical issues in monitoring clinical trials. Stat Med 12: 1459-1469, 1993.
173. Raghavan D: Clinical surrogates and equipoise: An analogy to lawyers who represent themselves? (Editorial). Eur J Cancer 27:1072 - 1074, 1991. (Raghavan, 1991)
174. Rand Corporation (The): A Million Random Digits with 100,000 Normal Deviates. The Free Press, Glencoe, Ill, 1955. (Rand Corporation, 1955)
175. Rondel RK, Varley SA, Webb CF (eds): Clinical Data Management. John Wiley & Sons, New York, 1993. (Rondel et al, 1993)
176. Royall RM: Ethics and statistics in randomized clinical trials. Stat Sci 6:52 - 88, 1991. (Royall RM, 1991)
177. Rubenstein LV, Gail MH, Santner TJ: Planning the duration of a comparative clinical trial with loss to follow-up and a period of continued observation. J Chronic Dis 34:469 - 479, 1981. (Rubenstein et al, 1981)
178. Sackett DL, Gent M: Controversy in counting and attributing events in clinical trials. N Engl J Med 301:1410 - 1412, 1979. (Sackett and Gent, 1979)
179. Sahai H, Khurshid A: Formulae and tables for the determination of sample sizes and power in clinical trials for testing differences in proportions for the two-sample design: A review. Stat Med 15:1 - 21, 1996. (Sahai Khurshid, 1996)
180. Schlant RC, Forman S, Stamler J, Canner PL for the Coronary Drug Project Research Group: The natural history of coronary heart disease: Prognostic factors

- after recovery from myocardial infarction in 2,789 men: The 5-year findings of the Coronary Drug Project. Circulation 66:401 - 414, 1982. (Schlant et al, 1982)
181. Schlesselman JJ: Sample size requirements in cohort and case-control studies of disease. Am J Epidemiol 99:382 - 384, 1974. (Schlesselman, 1974)
  182. Schlesselman JJ: Case-Control Studies. Oxford University Press, New York, 1982. (Schlesselman, 1982)
  183. Schoenfeld DA: Sample size formula for the proportional hazards regression model. Biometrics 39:499 - 503, 1983. (Schoenfeld DA, 1983)
  184. Schor S: The University Group Diabetes Program: A statistician looks at the mortality results. JAMA 217:1671 - 1675, 1971. (Schor, 1971)
  185. Schwartz D, Flamant R, Lellouch J: Clinical Trials. Academic Press, New York, 1980. (Schwartz et al, 1980)
  186. Schwarz RP: Maintaining integrity and credibility in industry-sponsored clinical research. Controlled Clin Trials 12:753 - 760, 1991. (Schwarz RP, 1991)
  187. Seltzer RS: A summary of criticisms of the findings of the University Group Diabetes Program (UGDP). Diabetes 21:976 - 979, 1972. (Seltzer, 1972)
  188. Senn S: A personal view of some controversies in allocating treatment to patients in clinical trials. Stat Med 14:2661 - 2674, 1995. (Senn S, 1995)
  189. Shapiro SH, Louis TA (eds): Clinical Trials: Issues and Approaches. Marcel Dekker, New York, 1983.
  190. Shimm DS, Spece RG: Ethical issues and clinical trials. Drugs 46: 579-584, 1993.
  191. Shuster E, Fifty Years Later: The Significance of Nuremberg Code. NEJM 337(20):1436-1440, 1997.
  192. Sieghart P, Dawson J: Computer-aided medical ethics. J Med Ethics 13:185 - 188, 1987. (Sieghart and Dawson, 1987)
  193. Sigma Xi: Honor in Science. The Scientific Research Society, New Haven, 1986. (Sigma Xi, 1986)
  194. Silverman WA: Human Experimentation: A Guided Step into the Unknown. Oxford University Press, New York, 1985. (Silverman, 1985)
  195. Simel DL, Feussner JR: Suspended Judgment. Clinical trials of informed consent. Controlled Clin Trials 13:321 - 324, 1992. (Simel and Feussner, 1992)
  196. Simon R: A decade of progress in statistical methodology for clinical trials. Stat Med 10:1789 - 1817, 1991. (Simon R, 1991)
  197. Singer, SW, Meinert CL: Format-independent data collection forms. Controlled Clin Trials 16:363 - 376, 1995. (Singer, et al, 1995)
  198. Smith PG, Morrow RH: Methods for Field Trials of Interventions Against Tropical Diseases: A "Toolbox". Oxford University Press, Oxford, 1991. (Smith and Morrow, 1991)
  199. Snedecor GW, Cochran WG: Statistical Methods. (7th ed). Iowa State University Press, Ames, Iowa, 1980. (Snedecor and Cochran, 1980)
  200. Souhami RL, Whitehead J (eds): Workshop on early stopping rules in cancer clinical trials (Robinson College, Cambridge, UK, April 13-15, 1993). Stat Med 13:1293 - 1499, 1994. (Souhami and Whitehead, 1994)
  201. Standards of Reporting Trials Group: A proposal for structured reporting of randomized controlled trials. JAMA 272:1926 - 1931, 1994. (Standards of Reporting Trials, 1994)
  202. Studies of Ocular Complications of AIDS Research Group in collaboration with the AIDS Clinical Trials Group: Studies of Ocular Complications of AIDS

- foscarnet-ganciclovir cytomegalovirus retinitis trial: 1. Rationale, design, and methods. Controlled Clin Trials 13:22 - 39, 1992a. (SOCA Research Group, 1992a)
203. Studies of Ocular Complications of AIDS Research Group in collaboration with the AIDS Clinical Trials Group: Mortality in patients with the acquired immunodeficiency syndrome treated with either foscarnet or ganciclovir for cytomegalovirus retinitis. N Engl J Med 326:213 - 220, 1992b. (SOCA Research Group, 1992b)
204. Sutton HG: Cases of rheumatic fever. Guy's Hosp Rep 11:392 - 428, 1865. (Sutton, 1865)
205. Taylor KM, Margolese RG, Soskolne CL: Physicians' reasons for not entering eligible patients in a randomized clinical trial of surgery for breast cancer. N Engl J Med 310:1363 - 1367, 1984. (Taylor et al, 1984)
206. Tukey JW: Some thoughts on clinical trials, especially problems of multiplicity. Science 198:679 - 684, 1977. (Tukey, 1977)
207. Tuskegee Syphilis Study Ad Hoc Advisory Panel: Tuskegee Syphilis Study Ad Hoc Advisory Panel: Final Report. United States Public Health Service, Washington, 1973. (Tuskegee Study Panel, 1973)
208. United States Supreme Court: Forsham, et al, versus Harris, Secretary of Health, Education and Welfare, et al. Certiorari to the United States Court of Appeals for the District of Columbia Circuit. No. 78-1118, argued Oct. 31, 1979, decided March 3, 1980. (US Supreme Court, 1980)
209. University Group Diabetes Program Research Group: A study of the effects of hypoglycemic agents on vascular complications in patients with adult-onset diabetes: I. Design, methods and baseline characteristics. Diabetes 19(suppl 2):747 - 783, 1970a. (UGDP Research Group, 1970a)
210. University Group Diabetes Program Research Group: A study of the effects of hypoglycemic agents on vascular complications in patients with adult-onset diabetes: II. Mortality results. Diabetes 19(suppl 2):785 - 830, 1970b. (UGDP Research Group, 1970b)
211. University Group Diabetes Program Research Group: A study of the effects of hypoglycemic agents on vascular complications in patients with adult-onset diabetes: III. Clinical implications of UGDP results. JAMA 218:1400 - 1410, 1971a. (UGDP Research Group, 1971a)
212. University Group Diabetes Program Research Group: A study of the effects of hypoglycemic agents on vascular complications in patients with adult-onset diabetes: IV. A preliminary report on phenformin results. JAMA 217:777 - 784, 1971b. (UGDP Research Group, 1971b)
213. University Group Diabetes Program Research Group: The UGDP controversy: Clinical trials versus clinical impressions. Diabetes 21:1035 - 1040, 1972. (UGDP Research Group, 1972)
214. University Group Diabetes Program Research Group: A study of the effects of hypoglycemic agents on vascular complications in patients with adult-onset diabetes: V. Evaluation of phenformin therapy. Diabetes 24(suppl 1):65 - 184, 1975. (UGDP Research Group, 1975)
215. University Group Diabetes Program Research Group: A study of the effects of hypoglycemic agents on vascular complications in patients with adult-onset diabetes: VI. Supplementary report on nonfatal events in patients treated with tolbutamide. Diabetes 25:1129 - 1153, 1976. (UGDP Research Group, 1976)

216. University Group Diabetes Program Research Group: A study of the effects of hypoglycemic agents on vascular complications in patients with adult-onset diabetes: VII. Mortality and selected nonfatal events with insulin treatment. JAMA 240:37 - 42, 1978. (UGDP Research Group, 1978)
217. University Group Diabetes Program Research Group: A study of the effects of hypoglycemic agents on vascular complications in patients with adult-onset diabetes: VIII. Evaluation of insulin therapy: Final report. Diabetes 31(suppl 5):1 - 78, 1982. (UGDP Research Group, 1982)
218. Working Group (ad hoc) for Critical Appraisal of the Medical Literature: A proposal for more informative abstracts of clinical articles. Ann Intern Med 106:598 - 604, 1987. (Work Group for Med Lit, 1987)
219. Wright P, Haybittle J: Design of forms for clinical trials (1). BMJ 2:529 - 530, 1979.
220. Wright P, Haybittle J: Design of forms for clinical trials (2). BMJ 2:590 - 592, 1979.
221. Wright P, Haybittle J: Design of forms for clinical trials (3). BMJ 2:650 - 651, 1979.
222. Yusuf S, Held P, Teo KK, Toretzky ER: Selection of patients for randomized controlled trials: Implications of wide or narrow eligibility criteria. Stat Med 9:73 - 86, 1990. (Yusuf et al, 1990)
223. Yusuf S, Wittes J, Probstfield J, Tyroler HA: Analysis and interpretation of treatment effects in subgroups of patients in randomized clinical trials. JAMA 266:93 - 98, 1991. (Yusuf et al, 1991)
224. Zelen M: A new design for randomized clinical trials. N Engl J Med 300:13 - 49, 1979.