

References

1. Aickin, M. (1982). A program for balancing the allocation of subjects to treatment in a clinical trial. *Computers and Biomedical Research*, 15, 519-524.
2. Aickin, M. (1983). Some large trial properties of minimum likelihood allocation. *Journal of Statistical Planning and Inference*, 8, 11-20.
3. Aickin, M. (2001). Randomization, balance, and the validity and efficiency of design-adaptive allocation methods. *Journal of Statistical Planning and Inference*, 94, 97-119.
4. Aickin, M. (2002). Beyond randomization. *Journal of Alternative & Complementary Medicine*, 8(6), 765-772.
5. Aickin, M. (2009). A simulation study of the validity and efficiency of design-adaptive allocation to two groups in the regression situation. *The International Journal of Biostatistics*, 5 : Iss. 1, Article 19.
6. Atkinson, AC. (2002). The comparison of designs for sequential clinical trials with covariate information. *Journal of the Royal Statistical Society, A* 165(2), 349–373.
7. Atkinson, A. C. (1982). Optimum biased coin designs for sequential clinical trials with prognostic factors. *Biometrika*, 69, 61–67.
8. Begg, CB and Iglewicz B. (1980). A treatment allocation procedure for sequential clinical trials. *Biometrics*, 36, 81-90.
9. Berry, D. A. and Fristedt, B. (1985). *Bandit Problems: Sequential Allocation of Experiments*. Chapman and Hall, London.
10. Birkett, N. J. (1985). Adaptive allocation in randomized controlled trials. *Controlled Clinical Trials*, 6, 146–155.
11. Blackwell, D. and Hodges, J. L. Jr. (1957). Design for the control of selection bias. *Annal. of Mathematical Statistics*, 28, 449–460.
12. Branson, M. and Whitehead, W. (2002). Estimating a treatment effect in survival studies in which patients switch treatment. *Statistics in Medicine*, 21, 2449–2463.
13. Bretz, F. and Hothorn, L. A. (2002). Detecting dose-response using contrasts: Asymptotic power and sample size determination for binary data. *Statistics in Medicine*, 21, 3325–3335.

14. Brophy, J. M. and Joseph, L. (1995). Placing trials in context using Bayesian analysis. GUSTO revisited by reverend Bayes [see comments]. *Journal of American Medical Association*, 273, 871–875.
15. Brown Jr. BW. (1980). Statistical controversies in the design of clinical trials – some personal views. *Controlled Clinical Trials*, 1, 13–27.
16. Burman, C. F. and Sonesson, C. (2006). Are flexible designs sound? *Biometrics*, in press.
17. Chaloner, K. and Larntz, K. (1989). Optimal Bayesian design applied to logistic regression experiments. *Journal of Planning and Inference*, 21, 191–208.
18. Chang, M. (2005). A simple n-stage adaptive design, submitted.
19. Chang, M. (2005). Adaptive design based on sum of stagewise p-values, submitted.
20. Chang, M. (2005). Bayesian adaptive design with biomarkers. Presented at IBC's Second Annual Conference on Implementing Adaptive Designs for Drug Development, November 7–8, 2005, Nassau Inn, Princeton, New Jersey.
21. Chang, M. and Chow, S. C. (2005). A hybrid Bayesian adaptive design for dose response trials. *Journal of Biopharmaceutical Statistics*, 15, 667–691.
22. Chang, M. and Chow, S. C. (2006). Power and sample size for dose response studies. In *Dose Finding in Drug Development*, N. Ting (ed.). Springer, New York, New York.
23. Chang, M., Chow, S. C., and Pong, A. (2006). Adaptive design in clinical research - Issues, opportunities, and recommendations. *Journal of Biopharmaceutical Statistics*, 16, 299–309.
24. Chen, J. J., Tsong, Y., and Kang, S. (2000). Tests for equivalence or noninferiority between two proportions, *Drug Information Journal*, 34, 569–578.
25. Chow, S. C. and Shao, J. (2005). Inference for clinical trials with some protocol amendments. *Journal of Biopharmaceutical Statistics*, 15, 659–666.
26. Chow, S. C. and Shao, J. (2006). On margin and statistical test for noninferiority in active control trials. *Statistics in Medicine*, 25, 1101–1113.
27. Chow, S. C., Shao, J., and Hu, Y. P. (2002). Assessing sensitivity and similarity in bridging studies. *Journal of Biopharmaceutical Statistics*, 12, 385–400.

28. Chow, S. C., Shao, J., and Wang, H. (2003). *Sample Size Calculation in Clinical Research*. Marcel Dekker, New York, New York.
29. Chow, S.C., Chang, M., and Pong, A. (2005). Statistical consideration of adaptive methods in clinical development. *Journal of Biopharmaceutical Statistics*, 15, 575–591.
30. Chow, Shein-Chung and Chang, Mark (2007). *Adaptive design methods in clinical trials*. Taylor & Francis Group, Boca Raton.
31. Chuang-Stein, C. and Agresti, A. (1997). A review of tests for detecting a monotone dose-response relationship with ordinal response data. *Statistics in Medicine*, 16, 2599–2618.
32. Chuang-Stein, C., Anderson, K., Gallo, P., and Collins, S. (2006). *Sample size re-estimation*, submitted.
33. Coad, D. S. and Rosenberger, W. F. (1999). A comparison of the randomized play-the-winner and the triangular test for clinical trials with binary responses. *Statistics in Medicine*, 18, 761–769.
34. Crowley, J. (2001). *Handbook of Statistics in Clinical Oncology*. Marcel Dekker, New York, New York.
35. Ebbutt A, Kay R, McNamara J, Engler J. (1997). The analysis of trials using a minimisation algorithm. *PSI Annual Conference Report*, 12-14.
36. Efron B. (1971). Forcing sequential experiments to be balanced. *Biometrika*, 58, 403-417.
37. Endo A, Nagatani F, Hamada C, Yoshimura I. (2006) Minimization method for balancing continuous prognostic variables between treatment and control groups using Kullback-Leibler divergence. *Contemporary Clinical Trials*, 27, 420-431.
38. Faries, D. (1994). Practical modification of the continual reassessment method for phase I cancer clinical trials. *Journal of Biopharmaceutical Statistics*, 4, 147–164.
39. FDA (2010). *Guidance for industry. Adaptive design clinical trials for drugs and biologics (draft guidance)*. The United States Food and Drug Administration, Rockville.
40. Forsythe AB, Stitt FW. (1977). Randomization or minimization in the treatment assignment of patient trials: validity and power of tests. *Technical Report No. 28*, Health Sciences Computing Facility, University of California, Los Angeles.
41. Friedman, B. (1949). A simple urn model. *Comm. Pure Appl. Math.*, 2, 59–70.

42. Gallo, P., Chuang-Stein, C., Dragalin, V., Gaydos, B., Krams, M., and Pinheiro, J. (2006). Adaptive design in clinical drug development - An executive summary of the PhRMA Working Group (with discussions). *Journal of Biopharmaceutical Statistics*, 16, 275–283.
43. Gasprini, M. and Eisele, J. (2000). A curve-free method for phase I clinical trials. *Biometrics*, 56, 609–615.
44. Gelman, A., Carlin, J. B., and Rubin, D. B. (2003). *Bayesian Data Analysis*, 2nd ed. Chapman and Hall/CRC, New York, New York.
45. Gillis, P. R. and Ratkowsky, D. A. (1978). The behaviour of estimators of the parameters of various yield-density relationships. *Biometrics*, 34, 191–198.
46. Goodman, S. N. (1999). Towards evidence-based medical statistics I: The p-value fallacy. *Annals of Internal Medicine*, 130, 995–1004.
47. Goodman, S. N. (2005). Introduction to Bayesian methods I: Measuring the strength of evidence. *Clinical Trials*, 2, 282–290.
48. Goodman, S. N., Lahurak, M. L., and Piantadosi, S. (1995). Some practical improvements in the continual reassessment method for phase I studies. *Statistics in Medicine*, 5, 1149–1161.
49. Gould, A. L. (1992). Interim analyses for monitoring clinical trials that do not materially affect the type I error rate. *Statistics in Medicine*, 11, 55–66.
50. Gould, A. L. (1995). Planning and revising the sample size for a trial. *Statistics in Medicine*, 14, 1039–1051.
51. Gould, A. L. (2001). Sample size re-estimation: Recent developments and practical considerations. *Statistics in Medicine*, 20, 2625–2643.
52. Green H, McEntegart DJ, Byrom B, Ghani S, Shepherd S. (2001). Minimization in crossover trials with non-prognostic strata: theory and practical application. *Journal of Clinical Pharmacy and Therapeutics*, 26, 121-128.
53. Hardwick, J. P. and Stout, Q. F. (2002). Optimal few-stage designs. *Journal of Statistical Planning and Inference*, 104, 121–145.
54. Hommel, G. (2001). Adaptive modifications of hypotheses after an interim analysis. *Biometrical Journal*, 43, 581–589.
55. Jennison, C. and Turnbull, B. W. (2000). *Group Sequential Method with Applications to Clinical Trials*. Chapman and Hall/CRC Press, New York, New York.
56. Jennison, C. and Turnbull, B. W. (2005). Meta-analysis and adaptive group sequential design in the clinical development process. *Journal of Biopharmaceutical Statistics*, 15, 537–558.

57. Jennison, C. and Turnbull, B. W. (2006). Adaptive and non-adaptive group sequential tests. *Biometrika*, 93, in press.
58. Jennison, C. and Turnbull, B. W. (2006). Efficient group sequential designs when there are several effect sizes under consideration. *Statistics in Medicine*, 25, in press.
59. Jennison, C. and Turnbull, B.W. (1990). Statistical approaches to interim monitoring of medical trials: A review and commentary. *Statistics in Medicine*, 5, 299–317.
60. Jennison, C. Turnbull, B. W. (2003). Mid-course sample size modification in clinical trials based on the observed treatment effect. *Statistics in Medicine*, 22, 971–993.
61. Johnson, N. L., Kotz, S., and Balakrishnan, N. (1994). *Continuous Univariate Distributions, Vol. 1*. John Wiley and Sons, New York, New York.
62. Kalbeisch, J. D. and Prentice, R. T. (1980). *The Statistical Analysis of Failure Time Data*. Wiley, New York, New York.
63. Kelly, P. J., Sooriyarachchi, M. R., Stallard, N., and Todd, S. (2005). A practical comparison of group-sequential and adaptive designs. *Journal of Biopharmaceutical Statistics*, 15, 719–738.
64. Kelly, P. J., Stallard, N., and Todd, S. (2005). An adaptive group sequential design for phase II/III clinical trials that select a single treatment from several. *Journal of Biopharmaceutical Statistics*, 15, 641–658.
65. Kieser, M. and Friede, T. (2000). Re-calculating the sample size in internal pilot study designs with control of the type I error rate. *Statistics in Medicine*, 19, 901–911.
66. Kieser, M. and Friede, T. (2003). Simple procedures for blinded sample size adjustment that do not affect the type I error rate. *Statistics in Medicine*, 22, 3571–3581.
67. Kieser, M., Bauer, P., and Lehmacher, W. (1999). Inference on multiple endpoints in clinical trials with adaptive interim analyses. *Biometrical Journal*, 41, 261–277.
68. Klotz JH. (1978). Maximum entropy constrained balance randomization for clinical trials. *Biometrics*, 34, 283-287.
69. Liu, Q., Proschan, M. A., and Pledger, G. W. (2002). A unified theory of twostage adaptive designs. *Journal of American Statistical Association*, 97, 1034–1041.

70. Lokhnygina, Y. (2004). Topics in design and analysis of clinical trials. Ph.D. Thesis, Department of Statistics, North Carolina State University. Raleigh, North Carolina.
71. Louis, T. A. (2005). Introduction to Bayesian methods II: Fundamental concepts. *Clinical Trials*, 2, 291–294.
72. Müller, H. H. and Schäfer, H. (2001). Adaptive group sequential designs for clinical trials: Combining the advantages of adaptive and classical group sequential approaches. *Biometrics*, 57, 886–891.
73. Maca, J., Bhattacharya, S., Dragalin, V., Gallo, P., and Krams, M. (2006). Adaptive seamless phase II/III designs - Background, operational aspects, and examples, submitted.
74. Machin, David and Fayers, Peter (2010). *Randomized Clinical Trials, Design, Practice and Reporting*. John Wiley and Sons, New York, New York.
75. Marubini, E. and Valsecchi, M. G. (1995). *Analysis Survival Data from Clinical Trials and Observational Studies*. John Wiley and Sons, New York, New York.
76. Maxwell, C., Domenet, J. G., and Joyce, C. R. R. (1971). Instant experience in clinical trials: A novel aid to teaching by simulation. *J. Clin. Pharmacol.*, 11, 323–331.
77. Mehta, C. R. and Patel, N. R. (2005). Adaptive, group sequential and decision theoretic approaches to sample size determination, submitted.
78. Mehta, C. R. and Tsiatis, A. A. (2001). Flexible sample size considerations using information-based interim monitor. *Drug Information Journal*, 35, 1095–1112.
79. Melfi, V. and Page, C. (1998). Variability in adaptive designs for estimation of success probabilities. In *New Developments and Applications in Experimental Design*, IMS Lecture Notes Monograph Series, 34, 106–114.
80. Mendelhall, W. and Hader, R. J. (1985). Estimation of parameters of mixed exponentially distributed failure time distributions from censored life test data. *Biometrika*, 45, 504–520.
81. Montori, V. M., Devereaux, P. J., Adhikari, N. K. J., Burns, K. E. A. et al. (2005). Randomized trials stopped early for benefit - A systematic review. *Journal of American Medical Association*, 294, 2203–2209.
82. Neuhauser, M. and Hothorn, L. (1999). An exact Cochran-Armitage test for trend when dose-response shapes are a priori unknown. *Computational Statistics & Data Analysis*, 30, 403–412.

83. O'Quigley, J., Pepe, M., and Fisher, L. (1990). Continual reassessment method: A practical design for phase I clinical trial in cancer. *Biometrics*, 46, 33–48.
84. Offen, W. and others (2006). Multiple co-primary endpoints: Medical and statistical solutions. *Drug Information Journal*, in press.
85. Offen, W. W. (2003). Data Monitoring Committees (DMC). In *Encyclopedia of Biopharmaceutical Statistics*, Chow, S. C. (ed.) Marcel Dekker, New York, New York.
86. Ohashi Y. (1990). Randomization in cancer clinical trials: permutation test and development of a computer program. *Environmental Health Perspectives*, 87, 13-17.
87. Pocock SJ. (1979). Allocation of patients to treatment in clinical trials. *Biometrics*, 35, 183-197.
88. Pocock, S. J. and Simon, R. (1975). Sequential treatment assignment with balancing for prognostic factors in the controlled clinical trials. *Biometrics*, 31, 103–115.
89. Proschan, M. A. (2005). Two-stage sample size re-estimation based on a nuisance parameter: A review. *Journal of Biopharmaceutical Statistics*, 15, 539–574.
90. Rosenberger WF. (1996). New directions in adaptive designs. *Statistical Science*, 11, 137–149.
91. Rovers MM, Straatman H, Zielhuis GA. (2000). Comparison of balanced and random allocations in clinical trials: a simulation study. *European Journal of Epidemiology*, 16, 1123-1129.
92. Scott NW, McPherson GC, Ramsay CR, Campbell MK. (2002). The method of minimization for allocation to clinical trials: a review. *Controlled Clinical Trials*, 23(6), 662-674.
93. Senn S. (1997). *Statistical Issues in Drug Development*. Chichester UK: Wiley, 77-81.
94. Shih, W. J. (2001). Sample size re-estimation - A journey for a decade. *Statistics in Medicine*, 20, 515–518.
95. Simon R. (1979). Restricted randomization designs in clinical trials. *Biometrics*, 35, 503-512.
96. Sommer, A. and Zeger, S. L. (1991). On estimating efficacy from clinical trials. *Statistics in Medicine*, 10, 45–52.
97. Taves DR. (1974). Minimization: a new method of assigning patients to treatment and control groups. *Clinical Pharmacology and Therapeutics*, 15(5), 443-453.

98. Tu D, Shalay K, Pater J. (2000). Adjustment of treatment effect for covariates in clinical trials: statistical and regulatory issues. *Drug Information Journal*, 34, 511-523.
99. Wang, S. K. and Tsiatis, A. A. (1987). Approximately optimal one-parameter boundaries for a sequential trials. *Biometrics*, 43, 193–200.
100. Wei, L. J. and Durham, S. (1978). The randomized play-the-winner rule in medical trials. *Journal of American Statistical Association*, 73, 840–843.
101. Williams, G., Pazdur, R., and Temple, R. (2004). Assessing tumor-related signs and symptoms to support cancer drug approval. *Journal of Biopharmaceutical Statistics*, 14, 5–21.
102. Zelen, M. (1974). The randomization and stratification of patients to clinical trials. *Journal of Chronic Diseases*, 28, 365–375.