

References

A

- A'Hern, R. P. A.** 2001. "Sample size tables for exact single-stage phase II designs." *Statistics in Medicine*, Volume 20, pages 859-866.
- Abernethy, Robert B.** 1996. *The New Weibull Handbook, Second Edition*. Robert B. Abernethy, Florida.
- Agresti, A. and Min, Y.** 2005. "Simple improved confidence intervals for comparing matched proportions." *Statistics in Medicine*. Volume 24, pages 729-740. DOI: 10.1002/sim.1781.
- Ahn, C., Heo, M., Zhang, S.** 2015. *Sample Size Calculations for Clustered and Longitudinal Outcomes in Clinical Research*. CRC Press, New York.
- Al-Sunduqchi, Mahdi S.** 1990. *Determining the Appropriate Sample Size for Inferences Based on the Wilcoxon Statistics*. Ph.D. dissertation under the direction of William C. Guenther, Dept. of Statistics, University of Wyoming, Laramie, Wyoming.
- Altman, Douglas.** 1993. "Construction of Age-Related Reference Centiles Using Absolute Residuals," *Statistics in Medicine*, Volume 12, pages 917-924.
- Altman, D. and Chitty, L.S.** 1994. "Charts of Fetal Size: Methodology," *British Journal of Obstetrics and Gynaecology*, Volume 101, pages 29-34.
- Altman, D.G, Machin, D., Bryant, T.N., Gardner, M.J.** 2000. *Statistics with Confidence, 2nd Edition*. BMJ Publishing.
- Andersen, P., Borgan, O., Gill, R., Keiding, N.** 1993. *Statistical Models Based on Counting Processes*. Springer. New York.
- Anderson, T.W. and Darling, D.A.** 1954. "A test of goodness-of-fit." *J. Amer. Statist. Assoc*, Volume 49, pages 765-769.
- Armitage, P., and Colton, T.** 1998. *Encyclopedia of Biostatistics*. John Wiley, New York.
- Armitage, P., McPherson, C.K., and Rowe, B.C.** 1969. "Repeated significance tests on accumulating data." *Journal of the Royal Statistical Society, Series A*, 132, pages 235-244.
- Atkinson, A.C.** 1985. *Plots, Transformations, and Regression*. Oxford University Press, Oxford (also in New York).
- Atkinson, A.C., and Donev, A.N.** 1992. *Optimum Experimental Designs*. Oxford University Press, Oxford.

B

- Bain, L.J. and Engelhardt, M.** 1991. *Statistical Analysis of Reliability and Life-Testing Models*. Marcel Dekker. New York.
- Baio G., et al.** 2015. "Sample size calculation for a stepped wedge trial," *Trials*, 16: 354.
- Barnard, G.A.** 1947. "Significance tests for 2 x 2 tables." *Biometrika* 34:123-138.
- Baron, R.M. and Kenny, D.A.** 1986. "The moderator-mediator variable distinction in social psychological research." *Journal of Personality and Social Psychology*. Volume 5, Number 6, pages 1173-1182.
- Bartholomew, D.J.** 1963. "The Sampling Distribution of an Estimate Arising in Life Testing." *Technometrics*, Volume 5 No. 3, 361-374.
- Bartko, John J.** 1966. "The intraclass correlation coefficient as a measure of reliability." *Psychological Reports*, Vol 19, 3-11.

References

- Bartlett, M.S.** 1937. "Properties of sufficiency and statistical tests." *Proceedings of the Royal Statistical Society, Series A* 160, 268-282.
- Beal, S. L.** 1987. "Asymptotic Confidence Intervals for the Difference between Two Binomial Parameters for Use with Small Samples." *Biometrics*, Volume 43, Issue 4, 941-950.
- Bellera, C.A. and Hanley, J.A.** 2007. "A method is presented to plan the required sample size when estimating regression-based reference limits." *Journal of Clinical Epidemiology* 60:610-615.
- Benjamini, Y. and Hochberg, Y.** 1995. "Controlling the False Discovery Rate: A Practical and Powerful Approach to Multiple Testing," *Journal of the Royal Statistical Society, Series B (Methodological)*, Vol. 57, No. 1, 289-300.
- Benton, D. and Krishnamoorthy, K.** 2003. "Computing discrete mixtures of continuous distributions: noncentral chisquare, noncentral t and the distribution of the square of the sample multiple correlation coefficient." *Computational Statistics & Data Analysis*, Vol. 43, pages 249-267.
- Blackwelder, W.C.** 1993. "Sample size and power in prospective analysis of relative risk." *Statistics in Medicine*, Volume 12, 691-698.
- Blackwelder, W.C.** 1998. "Equivalence Trials." In *Encyclopedia of Biostatistics*, John Wiley and Sons. New York. Volume 2, 1367-1372.
- Bland, J. M. and Altman, D. G.** 1983. "Measurement in medicine: the analysis of method comparison studies." *Statistician*, Vol. 32, pages 307-317.
- Bland, J. M. and Altman, D. G.** 1986. "Statistical methods for assessing agreement between two methods of clinical measurement." *Lancet*, Vol. i, pages 307-310.
- Bland, J. M. and Altman, D. G.** 1999. "Measuring agreement in method comparison studies." *Statistical Methods in Medical Research*, Vol. 8, pages 135-160.
- Bonett, Douglas.** 2002. "Sample Size Requirements for Testing and Estimating Coefficient Alpha." *Journal of Educational and Behavioral Statistics*, Vol. 27, pages 335-340.
- Bonett, Douglas.** 2002. "Sample Size Requirements for Estimating Intraclass Correlation with Desired Precision." *Statistics in Medicine*, Vol. 21, pages 1331-1335.
- Bonett, D.G. and Price, R.M.** 2012. "Adjusted Wald Confidence Interval for a Difference of Binomial Proportions Based on Paired Data." *Journal of Educational and Behavioral Statistics*. Volume 17, number 4, pages 479-488. DOI:10.3102/1076998611411915.
- Bonett, D. G. and Wright, T. A.** 2000. "Sample Size Requirements for Estimating Pearson, Kendall and Spearman Correlations." *Psychometrika*, Vol. 65, No. 1 (March), pages 23-28.
- Borenstein, M., Hedges, L.V., Higgins, J.P.T., and Rothstein, H.R.** 2021. *Introduction to Meta-Analysis, Second Edition*. John Wiley and Sons.
- Borm, G.F., Fransen, J., and Lemmens, W.A.J.G.** 2007. "A simple sample size formula for analysis of covariance in randomized clinical trials." *Journal of Clinical Epidemiology*, Vol. 60, pages 1234-1238.
- Box, G.E.P.** 1954a. "Some theorems on quadratic forms applied in the study of analysis of variance problems; I: Effect of inequality of variance in the one-way classification." *Annals of Mathematical Statistics*, 25, pages 290-302.
- Box, G.E.P.** 1954b. "Some theorems on quadratic forms applied in the study of analysis of variance problems; II: Effects of inequality of variance and of correlation between errors in a two-way classification." *Annals of Mathematical Statistics*, 25, pages 484-498.
- Box, G.E.P., Hunter, S. and Hunter, J.S.** 1978. *Statistics for Experimenters*. John Wiley & Sons, New York.
- Breslow, N. E. and Day, N. E.** 1980. *Statistical Methods in Cancer Research: Volume 1. The Analysis of Case-Control Studies*. Lyon: International Agency for Research on Cancer.
- Brion, M.J.A., Shakhbazov, K., Visscher, P.M.** 2013. "Calculating statistical power in Mendelian randomization studies." *International Journal of Epidemiology*, 42, pages 1497-1501.

References

- Brown, H., and Prescott, R.** 2006. *Applied Mixed Models in Medicine*. 2nd ed. John Wiley & Sons Ltd. Chichester, West Sussex, England.
- Brown, M.B. and Forsythe, A.B.** 1974. "Robust Tests for Equality of Variances." *Journal of the American Statistical Association*, Vol. 69, pages 364-367.
- Browne, R.H.** 1995. "On the use of a pilot sample for sample size determination." *Statistics in Medicine*, 14, pages 1933-1940.
- Brush, Gary G.** 1988. *Volume 12: How to Choose the Proper Sample Size*, American Society for Quality Control, 310 West Wisconsin Ave, Milwaukee, Wisconsin, 53203.
- Burgess, Stephen.** 2014. "Sample size and power calculations in Mendelian randomization with a single instrumental variable and a binary outcome." *International Journal of Epidemiology*, 43, pages 922-929.
- Burgess, S. and Thompson, S.G.** 2015. *Mendelian Randomization Methods for Using Genetic Variants in Causal Estimation*. Chapman & Hall/CRC Press. New York.
- Bush, Stephen.** 2015. "Sample size determination for logistic regression: A simulation study." *Communications in Statistics – Simulation and Computation*, 44(2), pages 360-373.

C

- Callegaro, A., Curran, D., and Matthews, S.** 2020. "Burden-of-illness vaccine efficacy". *Pharmaceutical Statistics*. Volume 19, Issue 5, pages 636-645. <https://doi.org/10.1002/pst.2020>.
- Campbell, M.J. and Walters, S.J.** 2014. *How to Design, Analyse and Report Cluster Randomised Trials in Medicine and Health Related Research*. John Wiley & Sons. New York.
- Candlish, J., Teare, M.D., Dimairo, M., Flight, L., Mandefield, L., and Walters, S.J.** 2018. "Appropriate statistical methods for analysing partially nested randomised controlled trials with continuous outcomes: a simulation study". *BMC Medical Research Methodology*. Vol 18, pages 105.
- Casagrande, J. T., Pike, M.C., and Smith, P. G.** 1978. "The Power Function of the "Exact" Test for Comparing Two Binomial Distributions," *Applied Statistics*, Volume 27, No. 2, pages 176-180.
- Chakraborti, S., and Li, J.** 2007. "Confidence Interval Estimation of a Normal Percentile," *The American Statistician*, Volume 61, No. 4, pages 331-336.
- Chang, Mark.** 2008. *Classical and Adaptive Clinical Trial Designs*. John Wiley & Sons. Hoboken, New York.
- Chang, Mark.** 2008. *Adaptive Design Theory and Implementation Using SAS and R*. Chapman & Hall/CRC. Boca Raton, Florida.
- Chang, Mark.** 2014. *Adaptive Design Theory and Implementation Using SAS and R. Second Edition*. Chapman & Hall/CRC. Boca Raton, Florida.
- Chang, M.N., Guess, H.A., and Heyse, J.F.** 1994. "Reduction in Burden of Illness: A New Efficacy Measure for Prevention Trials". *Statistics in Medicine*. Vol 13, pages 1807-1814. <https://doi.org/10.1002/sim.4780131803>.
- Chang, Y.W., Tsong, Y., Dong, X., Zhao, Z.** 2014. "Sample size determination for a three-arm equivalence trial of normally distributed responses." *Journal of Biopharmaceutical Statistics*. Volume 24, pages 1190-1202.
- Chen, K.W.; Chow, S.C.; and Li, G.** 1997. "A Note on Sample Size Determination for Bioequivalence Studies with Higher-Order Crossover Designs." *Journal of Pharmacokinetics and Biopharmaceutics*, Volume 25, No. 6, pages 753-765.
- Chen, T. T.** 1997. "Optimal Three-Stage Designs for Phase II Cancer Clinical Trials." *Statistics in Medicine*, Volume 16, pages 2701-2711.
- Cheung, Ying Kuen.** 2013. "Sample size formulae for the Bayesian continual reassessment method." *Clinical Trials*, Volume 10, 852-861.

References

- Choi, S.C. and Stablein, D. M.** 1982. "Practical Tests for Comparing Two Proportions with Incomplete Data." *Applied Statistics*, Volume 31, No. 3, pages 256-262.
- Chow, S.C.** 2014. *Biosimilars – Design and Analysis of Follow-on Biologics*. Chapman & Hall/CRC Press. Boca Raton, Florida.
- Chow, S.C.** 2016. *Quantitative Methods for Traditional Chinese Medicine Development*. Chapman & Hall/CRC Press. New York.
- Chow, S.C.** 2019. *Analytical Similarity Assessment in Biosimilar Product Development*. Chapman & Hall/CRC Press. Boca Raton, Florida.
- Chow, S.C. and Chang, M.** 2007. *Adaptive Design Methods in Clinical Trials*. Chapman & Hall/CRC. Boca Raton, Florida.
- Chow, S.C. and Liu, J.P.** 1999. *Design and Analysis of Bioavailability and Bioequivalence Studies, 2nd Edition*. Marcel Dekker. New York.
- Chow, S.C. and Liu, J.P.** 2009. *Design and Analysis of Bioavailability and Bioequivalence Studies, 3rd Edition*. Chapman & Hall/CRC. Boca Raton, Florida.
- Chow, S.C., Shao, J., and Hu, O.Y.P.** 2002. "Assessing Sensitivity and Similarity in Bridging Studies." *Journal of Biopharmaceutical Statistics*, Vol 12(3), pages 385-400.
- Chow, S.C., Shao, J., and Wang, H.** 2003. *Sample Size Calculations in Clinical Research*. Marcel Dekker. New York.
- Chow, S.C., Shao, J., and Wang, H.** 2008. *Sample Size Calculations in Clinical Research, Second Edition*. Chapman & Hall/CRC. Boca Raton, Florida.
- Chow, S.C., Shao, J., Wang, H., and Likhnygina, Y.** 2018. *Sample Size Calculations in Clinical Research, Third Edition*. Chapman & Hall/CRC. Boca Raton, Florida.
- Chu, H., Nie, L., Cole, S.R.** 2006. "Sample size and statistical power assessing the effect of interventions in the context of mixture distributions with detection limits." *Statistics in Medicine*. Vol 25, pages 2647-2657.
- Ciarleglio, M.M., Arendt, C.D., Makuch, R.W., and Peduzzi, P.N.** 2015. "Selection of the treatment effect for sample size determination in a superiority clinical trial using a hybrid classical and Bayesian procedure". *Contemporary Clinical Trials*, Volume 41, pages 160-171. DOI: 10.1016/j.cct.2015.01.002.
- Ciarleglio, M.M., Arendt, C.D., and Peduzzi, P.N.** 2016. "Selection of the effect size for sample size determination for a continuous response in a superiority clinical trial using a hybrid classical and Bayesian procedure". *Clinical Trials*, Volume 13(3), pages 275-285. DOI: 10.1177.1740774516628825.
- Cochran, William G.** 1977. *Sampling Techniques. Third Edition*. John Wiley & Sons. New York.
- Cochran and Cox.** 1992. *Experimental Designs. Second Edition*. John Wiley & Sons. New York.
- Cohen, Jacob.** 1960. "A Coefficient of Agreement for Nominal Scales." *Educational and Psychological Measurement*. Vol 20, No. 1, pages 37-46.
- Cohen, Jacob.** 1988. *Statistical Power Analysis for the Behavioral Sciences*, Lawrence Erlbaum Associates, Hillsdale, New Jersey.
- Cohen, Jacob.** 1990. "Things I Have Learned So Far." *American Psychologist*, December, 1990, pages 1304-1312.
- Collett, D.** 1991. *Modelling Binary Data*. Chapman & Hall, New York, New York.
- Collett, D.** 1994. *Modelling Survival Data in Medical Research*. Chapman & Hall, New York, New York.
- Conlon, M. and Thomas, R.** 1993. "The Power Function for Fisher's Exact Test." *Applied Statistics*, Volume 42, No. 1, pages 258-260.
- Conover, W.J.** 1999. *Practical Nonparametric Statistics. 3rd Edition*. John Wiley & Sons, New York.
- Cook, R. D. and Weisburg, S.** 1999. *Applied Regression Including Computing and Graphics*. John Wiley and Sons, Inc.

References

- Cooper, J., Hedges, L.V., Valentine, J.C.** 2019. *The Handbook of Research Synthesis and Meta-Analysis*, Third Edition. Russell Sage Foundation.
- Cox, D. R.** 1972. "Regression Models and life tables." *Journal of the Royal Statistical Society, Series B*, Volume 34, pages 187-220. This article presents the proportional hazards regression model.

D

- D'Agostino, R.B., Belanger, A., D'Agostino, R.B. Jr.** 1990. "A Suggestion for Using Powerful and Informative Tests of Normality.", *The American Statistician*, November 1990, Volume 44 Number 4, pages 316-321.
- D'Agostino, R.B., Chase, W., Belanger, A.** 1988. "The Appropriateness of Some Common Procedures for Testing the Equality of Two Independent Binomial Populations.", *The American Statistician*, August 1988, Volume 42 Number 3, pages 198-202.
- Dallal, G.** 1986. "An Analytic Approximation to the Distribution of Lilliefors's Test Statistic for Normality," *The American Statistician*, Volume 40, Number 4, pages 294-296.
- Davis, Charles S.** 2002. *Statistical Methods for the Analysis of Repeated Measurements*. Springer-Verlag, New York.
- Davies, Owen L.** 1971. *The Design and Analysis of Industrial Experiments*. Hafner Publishing Company, New York.
- DeLong, E.R., DeLong, D.M., and Clarke-Pearson, D.L.** 1988. "Comparing the Areas Under Two or More Correlated Receiver Operating Characteristic Curves: A Nonparametric Approach." *Biometrics*, 44, pages 837-845.
- DeMets, D.L. and Lan, K.K.G.** 1984. "An overview of sequential methods and their applications in clinical trials." *Communications in Statistics, Theory and Methods*, 13, pages 2315-2338.
- DeMets, D.L. and Lan, K.K.G.** 1994. "Interim analysis: The alpha spending function approach." *Statistics in Medicine*, 13, pages 1341-1352.
- Demidenko, E.** 2004. *Mixed Models – Theory and Applications*. John Wiley & Sons. Hoboken, New Jersey.
- Desu, M. M. and Raghavarao, D.** 1990. *Sample Size Methodology*. Academic Press. New York. (Presents many useful results for determining sample sizes.)
- Devroye, Luc.** 1986. *Non-Uniform Random Variate Generation*. Springer-Verlag. New York. This book is currently available online at <http://jeff.cs.mcgill.ca/~luc/rnbookindex.html>.
- Dias, L.C., Morton, A., and Quigley, J.** 2018. *Elicitation, The Science and Art of Structuring Judgement*. Springer.
- Diggle, P.J., Liang, K.Y., and Zeger, S.L.** 1994. *Analysis of Longitudinal Data*. Oxford University Press. New York, New York.
- Diggle, P.J., Heagerty, P., Liang, K.Y., and Zeger, S.L.** 2013. *Analysis of Longitudinal Data, Second Edition*. Oxford University Press. New York, New York.
- Dixon, W. J. and Tukey, J. W.** 1968. "Approximate behavior of the distribution of Winsorized t," *Technometrics*, Volume 10, pages 83-98.
- Dmitrienko, A., Molenberghs, G., Churang-Stein, C., Offen, W.** 2005. *Analysis of Clinical Trials Using SAS: A Practical Guide*. SAS Institute Inc. Cary, NC.
- Dong, G., Hoaglin, D.C., et al.** 2020. "The Win Ratio: On Interpretation and Handling Ties." *Statistics in Biopharmaceutical Research*. 12(1):99-106.
- Dong, G., Qiu, J., Wang, D., and Vandemeulebroecke, M.** 2018. "The stratified win ratio." *Journal of Biopharmaceutical Statistics*. 28(4):778-796.
- Donnelly, Thomas G.** 1980. "ACM Algorithm 462: Bivariate Normal Distribution," *Collected Algorithms from ACM*, Volume II, New York, New York.

References

- Donner, Allan.** 1984. "Approaches to Sample Size Estimation in the Design of Clinical Trials--A Review," *Statistics in Medicine*, Volume 3, pages 199-214.
- Donner, A. and Eliasziw, M.** 1987. "Sample size requirements for reliability studies." *Statistics in Medicine*, Volume 6, pages 441-448.
- Donner, A. and Klar, N.** 1996. "Statistical Considerations in the Design and Analysis of Community Intervention Trials." *The Journal of Clinical Epidemiology*, Vol. 49, No. 4, 1996, pages 435-439.
- Donner, A. and Klar, N.** 2000. *Design and Analysis of Cluster Randomization Trials in Health Research*. Arnold. London.
- Donner, A. and Klar, N.** 2002. "Issues in the meta-analysis of cluster randomized trials." *Statistics in Medicine*, Vol. 21, pages 2971-2980.
- Donner, A., Piaggio, G., and Villar, J.** 2003. "Meta-Analysis of Cluster Randomization Trials." *Evaluation & The Health Professions*, Vol. 26, No. 3, pages 340-351.
- Draghici, S.** 2003. *Data Analysis Tools for DNA Microarrays*. Chapman & Hall/CRC. London.
- Dudoit, S., Shaffer, J.P., and Boldrick, J.C.** 2003. "Multiple Hypothesis Testing in Microarray Experiments," *Statistical Science*, Volume 18(1), pages 71-103.
- Dudoit, S., Yang, Y.H., Callow, M.J., and Speed, T.P.** 2002. "Statistical Methods for Identifying Differentially Expressed Genes in Replicated cDNA Experiments," *Statistica Sinica*, Volume 12, pages 111-139.
- Dunn, O. J.** 1961. "Multiple comparisons among means," *Journal of the American Statistical Association*, Volume 56, pages 52-64.
- Dunn, O. J.** 1964. "Multiple comparisons using rank sums," *Technometrics*, Volume 6, pages 241-252.
- Dunnett, C. W.** 1955. "A Multiple comparison procedure for Comparing Several Treatments with a Control," *Journal of the American Statistical Association*, Volume 50, pages 1096-1121.
- Dupont, William.** 1988. "Power Calculations for Matched Case-Control Studies," *Biometrics*, Volume 44, pages 1157-1168.
- Dupont, William and Plummer, Walton D.** 1990. "Power and Sample Size Calculations--A Review and Computer Program," *Controlled Clinical Trials*, Volume 11, pages 116-128.
- Dupont, W.D. and Plummer, W.D. Jr.** 1998. "Power and Sample Size Calculations for Studies Involving Linear Regression." *Controlled Clinical Trials*. Vol 19, pages 589-601.

E

- Ekbohm, Gunnar.** 1982. "On Testing the Equality of Proportions in the Paired Case with Incomplete Data." *Psychometrika*. Volume 47(4), pages 115-117.
- Edgington, E.** 1987. *Randomization Tests*. Marcel Dekker. New York. A comprehensive discussion of randomization tests with many examples.
- Edwards, L.K.** 1993. *Applied Analysis of Variance in the Behavior Sciences*. Marcel Dekker. New York.
- Efron, B.** 1971. "Forcing a Sequential Experiment to be Balanced." *Biometrika*. Volume 58, pages 403-417.
- Efron, B. and Tibshirani, R. J.** 1993. *An Introduction to the Bootstrap*. Chapman & Hall. New York.
- Elandt-Johnson, R.C. and Johnson, N.L.** 1980. *Survival Models and Data Analysis*. John Wiley. NY, NY.
- Eldridge, S. and Kerry, S.** 2012. *A Practical Guide to Cluster-Randomised Trials in Health Services Research*. John Wiley. NY, NY.
- Epstein, Benjamin.** 1960. "Statistical Life Test Acceptance Procedures." *Technometrics*. Volume 2.4, pages 435-446.

F

- Fagerland, M.W., Lydersen, S., and Laake, P.** 2017. *Statistical Analysis of Contingency Tables*. Taylor & Francis/CRC. Boca Raton, Florida.
- Farrington, C. P. and Manning, G.** 1990. "Test Statistics and Sample Size Formulae for Comparative Binomial Trials with Null Hypothesis of Non-Zero Risk Difference or Non-Unity Relative Risk." *Statistics in Medicine*, Vol. 9, pages 1447-1454.
- Faulkenberry, G.D. and Weeks, D.L.** 1968. "Sample Size Determination for Tolerance Limits." *Technometrics*, Vol. 10, No. 2, pages 343-348.
- Fayers, P.M. and Machin, D.** 2016. *Quality of Life, Third Edition*. Wiley Blackwell. Hoboken, NJ.
- Feldt, L.S., Woodruff, D.J., and Salih, F.A.** 1987. "Statistical Inference for Coefficient Alpha." *Applied Psychological Measurement*, Vol. 11, pages 93-103.
- Feldt, L.S. and Ankenmann, R.D.** 1999. "Determining Sample Size for a Test of the Equality of Alpha Coefficients When the Number of Part-Tests is Small." *Psychological Methods*, Vol. 4(4), pages 366-377.
- Finkelstein D, Muzikansky A, Schoenfeld D.** 2003. "Comparing Survival of a Sample to that of a Standard Population," *Journal of the National Cancer Institute*, 95, pages 1434-1439.
- Fisher, R. A.** 1921. "On the probable error of a coefficient of correlation deduced from a small sample." *Metron*, i (4), 1-32.
- Fisher, R. A.** 1925. "Applications of "Student's" Distribution," *Metron*, 5, 90-104.
- Flack, V. F., Afifi, A. A., Lachenbruch, P. A., and Schouten, H. J. A.** 1988. "Sample Size Determinations for the Two Rater Kappa Statistic." *Psychometrika*, Volume 53, No. 3, pages 321-325.
- Fleiss, Joseph L.** 1981. *Statistical Methods for Rates and Proportions*. John Wiley & Sons. New York.
- Fleiss, Joseph L.** 1986. *The Design and Analysis of Clinical Experiments*. John Wiley & Sons. New York.
- Fleiss, J. L., Cohen, J., Everitt, B.S.** 1969. "Large Sample Standard Errors of Kappa and Weighted Kappa." *Psychological Bulletin*. Vol. 72, No.5, pages 323-327.
- Fleiss, J. L., Levin, B., Paik, M.C.** 2003. *Statistical Methods for Rates and Proportions. Third Edition*. John Wiley & Sons. New York.
- Fleming, T. R.** 1982. "One-sample multiple testing procedure for Phase II clinical trials." *Biometrics*, Volume 38, pages 143-151.
- Finney, D.J.** 1978. *Statistical Method in Biological Assay, 3rd Edition*. Macmillan. New York.
- Freedman, L.S.** 1982. "Tables of the Number of Patients Required in Clinical Trials using the Logrank Test." *Statistics in Medicine*, 1:121-129.
- Fritz, M.S. and MacKinnon, D.P.** 2007. "Required Sample Size to Detect the Mediated Effect." *Psychological Science*, Volume 18, Number 3, pages 233-239.
- Freeman, G., Cowling, B.J., Schooling, C.M.** 2013. "Power and sample size calculations for Mendelian randomization studies using one genetic instrument." *International Journal of Epidemiology*, 42, pages 1157-1163.

G

- Gao, F., Earnest, A., Matchar, D.B., Campbell, M.J., and Machin, D.** 2015. "Sample size calculations for the design of cluster randomized trials: A summary of methodology." *Contemporary Clinical Trials*, Volume 42, 41-50.

References

- Gans.** 1984. "The Search for Significance: Different Tests on the Same Data." *The Journal of Statistical Computation and Simulation*, 1984, pages 1-21.
- Gatsonis, C. and Sampson, A.R.** 1989. "Multiple Correlation: Exact Power and Sample Size Calculations." *Psychological Bulletin*, Vol. 106, No. 3, pages 516-524.
- Gart, John J. and Nam, Jun-mo.** 1988. "Approximate Interval Estimation of the Ratio in Binomial Parameters: A Review and Corrections for Skewness." *Biometrics*, Volume 44, Issue 2, 323-338.
- Gart, John J. and Nam, Jun-mo.** 1990. "Approximate Interval Estimation of the Difference in Binomial Parameters: Correction for Skewness and Extension to Multiple Tables." *Biometrics*, Volume 46, Issue 3, 637-643.
- Gehlback, Stephen.** 1988. *Interpreting the Medical Literature: Practical Epidemiology for Clinicians*. Second Edition. McGraw-Hill. New York. Telephone: (800)722-4726.
- Gentle, James E.** 1998. *Random Number Generation and Monte Carlo Methods*. Springer. New York.
- Gibbons, J.** 1976. *Nonparametric Methods for Quantitative Analysis*. Holt, Rinehart and Winston. New York.
- Gibbons, J.** 1985. *Nonparametric Methods for Quantitative Analysis (2nd Edition)*. American Sciences Press. New York.
- Gibbons, J., Chakraborti, S.** 2011. *Nonparametric Statistical Inference (5th Edition)*. CRC Press. New York.
- Gibbons, J.D., Olkin, I., and Sobel, M.** 1977. *Selecting and Ordering Populations, A New Statistical Methodology*. John Wiley & Sons. New York, New York.
- Goldstein, Richard.** 1989. "Power and Sample Size via MS/PC-DOS Computers," *The American Statistician*, Volume 43, Number 4, pages 253-260.
- Graybill, Franklin A.** 1961. *Introduction to Linear Statistical Models, Volume 1*. McGraw-Hill Series in Probability & Statistics.
- Greenwood, J. A. and Sandomire, M. M.** 1950. "Sample Size Required for Estimating the Standard Deviation as a Per Cent of its True Value", *Journal of the American Statistical Association*, Vol. 45, No. 250, pp. 257-260.
- Griffin, J.W.** 2021. "Calculating statistical power for meta-analysis using metapower", *The Quantitative Methods for Psychology*, Vol. 17, No. 1, pages 24-39.
- Griffiths, P. and Hill, I.D.** 1985. *Applied Statistics Algorithms*, The Royal Statistical Society, London, England. See page 243 for ACM algorithm 291.
- Gross and Clark** 1975. *Survival Distributions: Reliability Applications in Biomedical Sciences*. John Wiley, New York.
- Gu, K., Ng, H.K.T., Tang, M.L., and Schucany, W.** 2008. "Testing the Ratio of Two Poisson Rates," *Biometrical Journal*, Volume 50, Number 2, pages 283-298.
- Guo, J.H.** 2012. "Optimal sample size planning for the Wilcoxon-Mann-Whitney and van Elteren tests under cost constraints." *Journal of Applied Statistics*, 39(10), pages 2153-2164.
- Guenther, William C.** 1977. "Desk Calculation of Probabilities for the Distribution of the Sample Correlation Coefficient," *The American Statistician*, Volume 31, Number 1, pages 45-48.
- Guenther, William C.** 1977. *Sampling Inspection in Statistical Quality Control*. Griffin's Statistical Monographs, Number 37. London.

H

- Hahn, G. J. and Meeker, W.Q.** 1991. *Statistical Intervals*. John Wiley & Sons. New York.
- Hajian-Tilaki, K.** 2014. "Sample size estimation in diagnostic test studies of biomedical informatics." *Journal of Biomedical Informatics*, 48, 193-204.

References

- Hanley, J. A. and McNeil, B. J.** 1982. "The Meaning and Use of the Area under a Receiver Operating Characteristic (ROC) Curve." *Radiology*, 143, 29-36. April, 1982.
- Hanley, J. A. and McNeil, B. J.** 1983. "A Method of Comparing the Areas under Receiver Operating Characteristic Curves Derived from the Same Cases." *Radiology*, 148, 839-843. September, 1983.
- Harrer, M., Cuijpers, P., Furukawa, T.A., and Ebert, D.D.** 2022. *Doing Meta-Analysis with R: A Hands-On Guide*. CRC Press.
- Harris, E.K. and Boyd, J.C.** 1995. *Statistical Bases of Reference Values in Laboratory Medicine*. Marcel Dekker. New York.
- Harris, M., Horvitz, D. J., and Mood, A. M.** 1948. "On the Determination of Sample Sizes in Designing Experiments", *Journal of the American Statistical Association*, Volume 43, No. 243, pp. 391-402.
- Hauschke, D., Kieser, M., Diletti, E., Burke, M.** 1999. "Sample Size Determination for Proving Equivalence Based on the Ratio of Two Means for Normally Distributed Data." *Statistics in Medicine*, Volume 18, pages 93-105."
- Hauschke, D., Steinijans, V., Pigeot, I.** 2007. *Bioequivalence Studies in Drug Development*. John Wiley and Sons. New York."
- Hayes, R.J. and Bennett, S.** 1999. "Simple sample size calculation for cluster-randomized trials", *International Journal of Epidemiology*, Volume 28, pp. 319-326.
- Hayes, A.F.** 2018. *Introduction to Mediation, Moderation, and Conditional Process Analysis, Second Edition*. CRC The Guilford Press. New York.
- Hayes, R.J. and Moulton, L.H.** 2009. *Cluster Randomised Trials*. CRC Press. New York.
- Hedges, L.V. and Pigott, T.D.** 2001. "The Power of Statistical Tests in Meta-Analysis", *Psychological Methods*, Volume 6, No. 3, pages 203-217.
- Hedges, L.V., Pustejovsky, J.E., Shadish, W.R.** 2012. "A standardized mean difference effect size for single case designs." *Research Synthesis Methods*. DOI: 10.1002/jrsm.1052.
- Hedges, L.V., Pustejovsky, J.E., Shadish, W.R.** 2013. "A standardized mean difference effect size for multiple baseline designs across individuals." *Research Synthesis Methods*. DOI: 10.1002/jrsm.1086.
- Hedges, L.V., Shadish, W.R., Batley, P.N.** 2022. "Power analysis for single-case designs: Computations of (AB)k designs." *Behavior Research Methods*. DOI: 10.3758/s13428-022-01971-9.
- Hemming, K., and Girling, A.** 2014. "A menu-driven facility for power and detectable-difference calculations in stepped-wedge cluster-randomized trials," *The Stata Journal*, Volume 14, pages 363-380.
- Hemming, K., and Taljaard, M.** 2016. "Sample size calculations for stepped wedge and cluster randomised trials: a unified approach," *Journal of Clinical Epidemiology*, Volume 69, pages 137-146.
- Hemming, K., Lilford, R., and Girling A.J.** 2015. "Stepped-wedge cluster randomised controlled trials: a generic framework including parallel and multiple-level designs," *Statistics in Medicine*, Volume 34, pages 181-196.
- Hernandez-Bermejo, B. and Sorribas, A.** 2001. "Analytical Quantile Solution for the S-distribution, Random Number Generation and Statistical Data Modeling." *Biometrical Journal* 43, 1007-1025.
- Higgins, J.P.T. and Thomas, J.** 2019. *Cochrane Handbook for Systematic Reviews of Interventions, Second Edition*. Cochrane, Wiley, Blackwell.
- Hoaglin, Mosteller, and Tukey.** 1983. *Understanding Robust and Exploratory Data Analysis*. John Wiley & Sons. New York.
- Hoaglin, Mosteller, and Tukey.** 1985. *Exploring Data Tables, Trends, and Shapes*. John Wiley. New York.
- Hochberg, Y. and Tamhane, A. C.** 1987. *Multiple Comparison Procedures*. John Wiley & Sons. New York.
- Horn, P.S. and Pesce, A. J.** 2005. *Reference Intervals – A User's Guide*. AACCC Press. Washington D.C.
- Howe, W.G.** 1969. "Two-Sided Tolerance Limits for Normal Populations—Some Improvements." *Journal of the American Statistical Association*, 64, 610-620.

References

- Hosmer, D. and Lemeshow, S.** 1989. *Applied Logistic Regression*. John Wiley & Sons. New York.
- Hosmer, D. and Lemeshow, S.** 1999. *Applied Survival Analysis*. John Wiley & Sons. New York.
- Hotelling, H.** 1933. "Analysis of a complex of statistical variables into principal components." *Journal of Educational Psychology* 24, 417-441, 498-520.
- Howe, W.G.** 1969. "Two-Sided Tolerance Limits for Normal Populations-Some Improvements." *Journal of the American Statistical Association*, Vol 64, No. 326, 610-620.
- Hsieh, F.Y.** 1989. "Sample Size Tables for Logistic Regression," *Statistics in Medicine*, Volume 8, pages 795-802.
- Hsieh, F.Y., Block, D.A., and Larsen, M.D.** 1998. "A Simple Method of Sample Size Calculation for Linear and Logistic Regression," *Statistics in Medicine*, Volume 17, pages 1623-1634.
- Hsieh, F.Y. and Lavori, P.W.** 2000. "Sample-Size Calculations for the Cox Proportional Hazards Regression Model with Nonbinary Covariates," *Controlled Clinical Trials*, Volume 21, pages 552-560.
- Hsu, Jason.** 1996. *Multiple Comparisons: Theory and Methods*. Chapman & Hall. London.
- Huffman, Michael.** 1984. "An Improved Approximate Two-Sample Poisson Test," *Applied Statistics*, Volume 33, Number 2, pages 224-226.
- Hussey, M.A., and Hughes, J.P.** 2007. "Design and analysis of stepped wedge cluster randomized trials," *Contemporary Clinical Trials*, Volume 28, pages 182-191.

J

- Jahn-Eimermacher, A., Ingel, K., and Schneider, A.** 2013. "Sample size in cluster-randomized trials with time to event as the primary endpoint." *Statistics in Medicine*, 32:739-751.
- Jan, S.L. and Shieh, G.** 2014. "Sample size determinations for Welch's test in one-way heteroscedastic ANOVA." *British Journal of Mathematical and Statistical Psychology*, 67:72-93.
- Jan, S.L. and Shieh, G.** 2016. "A systematic approach to designing statistically powerful heteroscedastic 2 x 2 factorial studies while minimizing financial costs." *BMC Medical Research Methodology*, 16:114.
<https://doi.org/10.1186/s12874-016-0214-3>
- Jan, S.L. and Shieh, G.** 2018. "The Bland-Altman range of agreement: Exact interval procedure and sample size determination." *Computers in Biology and Medicine*, 100:247-252.
<https://doi.org/10.1016/j.combiomed.2018.06.020>.
- Jan, S.L. and Shieh, G.** 2019. "On the Extended Welch Test for Assessing Equivalence of Standardized Means." *Statistics in Biopharmaceutical Research*, <https://doi.org/10.1080/19466315.2019.1654915>.
- Jennison, C., and Turnbull, B.W.** 2000. *Group Sequential Methods with Applications to Clinical Trials*. Chapman & Hall/CRC. New York.
- Johnson, N.L., Kotz, S., and Kemp, A.W.** 1992. *Univariate Discrete Distributions, Second Edition*. John Wiley & Sons. New York.
- Johnson, N.L., Kotz, S., and Balakrishnan, N.** 1994. *Continuous Univariate Distributions Volume 1, Second Edition*. John Wiley & Sons. New York.
- Johnson, N.L., Kotz, S., and Balakrishnan, N.** 1995. *Continuous Univariate Distributions Volume 2, Second Edition*. John Wiley & Sons. New York.
- Jones, B. and Kenward, M.** 2015. *Design and Analysis of Cross-Over Trials, 3rd Edition*. CRC Press, Boca Raton, Florida.
- Julious, Steven A.** 2004. "Tutorial in Biostatistics. Sample sizes for clinical trials with Normal data." *Statistics in Medicine*, 23:1921-1986.
- Julious, Steven A.** 2005. "Sample size of 12 per group rule of thumb for a pilot study." *Pharmaceutical Statistics*, 4, pages 187-291.

References

- Julious, S.A. and Owen, R.J.** 2006. "Sample size calculations for clinical studies allowing for uncertainty about the variance." *Pharmaceutical Statistics*, 5, pages 29-37.
- Julious, Steven A.** 2010. *Sample Sizes for Clinical Trials*. Chapman & Hall / CRC. Boca Raton, Florida.
- Julious, Steven A.** 2023. *Sample Sizes for Clinical Trials*. Second Edition. Chapman & Hall / CRC Press. Boca Raton, Florida.
- Julious, S.A. and Campbell, M.J.** 2012. "Tutorial in biostatistics: sample sizes for parallel group clinical trials with binary data." *Statistics in Medicine*, 31:2904-2936.
- Julious, Steven A.** 2012. Issues in Sample Size Calculations with Multiple Must-Win Comparisons. Power-point presentation accessed through Google Search. (See especially Slide 54).
- Julious, Steven A.** 2023. *Sample Sizes for Clinical Trials*. Second Edition. Chapman & Hall / CRC Press. Boca Raton, Florida.
- Julious, S.A. and McIntyre, N.E.** 2012. "Sample sizes for trials involving multiple correlated must-win comparisons." *Pharmaceutical Statistics*, Mar-Apr, 11(2):177-85.
- Jung, S.H. and Ahn, C.W.** 2003. "Sample size estimation for GEE method for comparing slopes in repeated measurements data." *Statistics in Medicine*, 22(8):1305-1315.
- Jung, S.H. and Ahn, C.W.** 2004. "K-Sample Test and Sample size Calculation for Comparing Slopes in Data with Repeated Measurements." *Biometrical Journal*, 46(5):554-564.
- Jung, S.H. and Ahn, C.W.** 2005. "Sample size for a two-group comparison of repeated binary measurements using GEE." *Statistics in Medicine*, 24(17):2583-2596.
- Jung, S.H., Kang, S. J., McCall, L. M., and Blumenstein, B.** 2005. "Sample Sizes Computation for Two-Sample Noninferiority Log-Rank Test", *J. of Biopharmaceutical Statistics*, Volume 15, pages 969-979.
- Jung, S.H., Lee, T., Kim, K.M., and George, S.L.** 2004. "Admissible two-stage designs for phase II cancer clinical trials." *Statistics in Medicine*, 23:561-569.
- Jung, Sin-Ho.** 2005. "Sample size for FDR-control in microarray data analysis" *Bioinformatics*, 21(14):3097-3104.
- Jung, Sin-Ho.** 2013. *Randomized Phase II Cancer Clinical Trials*. Chapman & Hall / CRC. Boca Raton, Florida.
- Juran, J.M.** 1979. *Quality Control Handbook*. McGraw-Hill. New York.

K

- Kalbfleisch, J.D. and Prentice, R.L.** 1980. *The Statistical Analysis of Failure Time Data*. John Wiley, New York.
- Karian, Z.A and Dudewicz, E.J.** 2000. *Fitting Statistical Distributions*. CRC Press, New York.
- Katz, D., Baptista, J., Azen, S. P., and Pike, M. C.** 1978. "Obtaining Confidence Intervals for the Risk Ratio in Cohort Studies," *Biometrics*, 34, pages 469-474.
- Kececioglu, Dimitri.** 1994. *Reliability & Life Testing Handbook, Volume 2*. Prentice Hall. Englewood Cliffs, New Jersey.
- Kendall, M. and Gibbons, J.D.** 1990. *Rank Correlation Methods, 5th Edition*. Oxford University Press. New York.
- Kendall, M. and Stuart, A.** 1987. *Kendall's Advanced Theory of Statistics. Volume 1: Distribution Theory*. Oxford University Press. New York.
- Kenett, R. S. and Zacks, S.** 2014. *Modern Industrial Statistics, 2nd Edition. Biometrics*. John Wiley, West Sussex, United Kingdom.
- Kenward, M. G. and Roger, J. H.** 1997. "Small Sample Inference for Fixed Effects from Restricted Maximum Likelihood," *Biometrics*, 53, pages 983-997.
- Keppel, Geoffrey.** 1991. *Design and Analysis: A Researcher's Handbook. Third Edition*. Prentice Hall. Englewood Cliffs, New Jersey.

References

- Kieser, M. and Hauschke, D.** 1999. "Approximate Sample Sizes for Testing Hypotheses about the Ratio and Difference of Two Means." *Journal of Biopharmaceutical Studies*, Volume 9, No. 4, pages 641-650.
- Kieser, M. and Wassmer, G.** 1996. "On the Use of the Upper Confidence Limit for the Variance from a Pilot Sample for Sample Size Determination," *Biometrical Journal*, 38, pages 941-949.
- Kirk, Roger E.** 1982. *Experimental Design: Procedures for the Behavioral Sciences*. Brooks/Cole. Pacific Grove, California.
- Kirk, Roger E.** 2013. *Experimental Design: Procedures for the Behavioral Sciences, 4th Edition*. Sage. Washington, D.C.
- Kieser, Meinhard.** 2020. *Methods and Applications of Sample Size Calculation and Recalculation in Clinical Trials*. Springer. Cham, Switzerland.
- Klein, J.P. and Moeschberger, M.L.** 1997. *Survival Analysis*. Springer-Verlag. New York.
- Kleinbaum, D.G. and Klein, M.** 2010. *Logistic Regression, A Self-Learning Text, 3rd Edition*. Springer. New York.
- Koch, G.G.; Atkinson, S.S.; Stokes, M.E.** 1986. *Encyclopedia of Statistical Sciences*. Volume 7. John Wiley. New York. Edited by Samuel Kotz and Norman Johnson.
- Koopman, P. A. R.** 1984. "Confidence Intervals for the Ratio of Two Binomial Proportions." *Biometrics*, Volume 40, Issue 2, 513-517.
- Kotz, S. and Johnson, N.** 1993. *Process Capability Indices*. Chapman & Hall.
- Kodell, R.L., Lensing, S.Y., Landes, R.D., Kumar, K.S, Hauer-Jensen, M.** 2010. Determination of sample sizes for demonstrating efficacy of radiation countermeasures, *Biometrics*, 66, 239-248.
- Kraemer, H.C.** 1980. "Robustness of the Distribution Theory of the Product Moment Correlation Coefficient," *Journal of Educational Statistics*, Volume 5, Number 2, pages 115-128.
- Kraemer, H. C. and Thiemann, S.** 1987. *How Many Subjects*, Sage Publications, 2111 West Hillcrest Drive, Newbury Park, CA. 91320. This is an excellent introduction to power analysis.
- Krishnamoorthy, K. and Mathew, T.** 2009. *Statistical Tolerance Regions*. John Wiley, New York.
- Krishnamoorthy, K. and Xia, Y.** 2008. "Sample Size Calculation for Estimating or Testing a Nonzero Squared Multiple Correlation Coefficient." *Multivariate Behavioral Research*, Vol. 43, pages 382-410.
- Kryzanowski, W.J. and Hand, D.J.** 2009. *ROC Curves for Continuous Data*. Chapman and Hall/CRC Press.
- Kupper, L.L. and Hafner, K.B.** 1989. "How appropriate are popular sample size formulas?" *The American Statistician*, 43(2), pages 101-105.

L

- Lachenbruch, Peter A.** 2001. "Power and sample size requirements for two-part models", *Statistics in Medicine*, Volume 20, pages 1235-1238.
- Lachin, John M.** 2000. *Biostatistical Methods*. John Wiley & Sons. New York.
- Lachin, John M.** 2011. *Biostatistical Methods: The Assessment of Relative Risks, Second Edition*. John Wiley & Sons. New York.
- Lachin, John M.** 2008. "Sample size evaluation for a multiply matched case-control study using the score test from a conditional logistic (discrete Cox PH) regression model." *Statistics in Medicine*, Vol 27, pages 2509-2523.
- Lachin, John M. and Foulkes, Mary A.** 1986. "Evaluation of Sample Size and Power for Analyses of Survival with Allowance for Nonuniform Patient Entry, Losses to Follow-up, Noncompliance, and Stratification," *Biometrics*, Volume 42, September, pages 507-516.
- Lakatos, Edward.** 1988. "Sample Sizes Based on the Log-Rank Statistic in Complex Clinical Trials", *Biometrics*, Volume 44, March, pages 229-241.

References

- Lakatos, Edward.** 2002. "Designing Complex Group Sequential Survival Trials", *Statistics in Medicine*, Volume 21, pages 1969-1989.
- Lan, K.K.G. and DeMets, D.L.** 1983. "Discrete sequential boundaries for clinical trials." *Biometrika*, 70, pages 659-663.
- Lan, K.K.G. and Zucker, D.M.** 1993. "Sequential monitoring of clinical trials: the role of information and Brownian motion." *Statistics in Medicine*, 12, pages 753-765.
- Lance, G.N. and Williams, W.T.** 1967. "A general theory of classificatory sorting strategies. I. Hierarchical systems." *Comput. J.* 9, pages 373-380.
- Lance, G.N. and Williams, W.T.** 1967. "Mixed-data classificatory programs I. Agglomerative systems." *Aust. Comput. J.* 1, pages 15-20.
- Landis, J.R. and Koch, G.G.** 1977. "The measurement of observer agreement for categorical data." *Biometrics*, 33, pages 159-174.
- Lawless, Jerald F.** 1982. *Statistical Models and Methods for Lifetime Data*. John Wiley, New York.
- Lawless, Jerald F.** 2003. *Statistical Models and Methods for Lifetime Data, 2nd Edition*. John Wiley, New York.
- Lawson, John.** 1987. *Basic Industrial Experimental Design Strategies*. Center for Statistical Research at Brigham Young University. Provo, Utah. 84602.
- Lee, E.T.** 1980. *Statistical Methods for Survival Data Analysis*. Lifetime Learning Publications. Belmont, California.
- Lee, E.T.** 1992. *Statistical Methods for Survival Data Analysis*. Second Edition. John Wiley & Sons. New York.
- Lee, M.-L. T.** 2004. *Analysis of Microarray Gene Expression Data*. Kluwer Academic Publishers. Norwell, Massachusetts.
- Lee, S.J., and Zelen, M.** 2000. "Clinical Trials and Sample Size Considerations: Another Perspective" *Statistical Science*, Volume 15(2), pages 95-110.
- Lehmann, E.L.** 1975. *Nonparametrics - Statistical Methods Based on Ranks*. Holden-Day, Inc. Oakland, California.
- Lenth, Russell V.** 1987. "Algorithm AS 226: Computing Noncentral Beta Probabilities," *Applied Statistics*, Volume 36, pages 241-244.
- Lenth, Russell V.** 1989. "Algorithm AS 243: Cumulative Distribution Function of the Non-central t Distribution," *Applied Statistics*, Volume 38, pages 185-189.
- Lev, Joseph.** 1949. "The Point Biserial Coefficient of Correlation," *Annals of Mathematical Statistics*, Volume 20, No. 1 (March, 1949), pages 125-126.
- Levene, Howard.** 1960. "Contributions to Probability and Statistics: Essays in Honor of Harold Hotelling." Editors: Ingram Olkin, Harold Hotelling, et alia. Stanford University Press. Pages 278-292.
- Levy, P.S. and Lemeshow, S.** 2008. *Sampling of Populations*. Fourth Edition. John Wiley & Sons. New York.
- Lewis, J.A.** 1999. "Statistical principles for clinical trials (ICH E9) an introductory note on an international guideline." *Statistics in Medicine*, 18, pages 1903-1942.
- Li, J. and Fine, J.** 2004. "On sample size for sensitivity and specificity in prospective diagnostic accuracy studies" *Statistics in Medicine*, 23, pages 2537-2550.
- Liang, K. and Zeger, S.** 1986. "Longitudinal data analysis using generalized linear models." *Biometrika*, 73(1), pages 13-22.
- Lin, Lawrence I-Kuei.** 1989. "A concordance correlation coefficient to evaluate reproducibility." *Biometrics*, 45, pages 255-268.
- Lin, Lawrence I-Kuei.** 1992. "Assay validation using the Concordance Correlation Coefficient." *Biometrics*, 48, pages 599-604.
- Lin, Lawrence I-Kuei.** 2000. "A Note on the concordance correlation coefficient." *Biometrics*, 56, pages 324-325.
- Lin, L., Hedayat, A.S., and Wu, W.** 2012. *Statistical Tools for Measuring Agreement*. Springer, New York.

References

- Lin, L., Hedayat, A., Sinha, B., Yang, M.** 2002. "Statistical Methods in Assessing Agreement." *Journal of the American Statistical Association*, 97(457), pages 257-270.
- Linnert, Kristian.** 1990. "Estimation of the linear relationship between the measurements of two methods with proportional errors." *Statistics in Medicine*, 9, pages 1463-1473.
- Linnert, Kristian.** 1999. "Necessary Sample Size for Method Comparison Studies Based on Regression Analysis." *Clinical Chemistry*, 45:6, pages 882-894.
- Lipsey, Mark W.** 1990. *Design Sensitivity Statistical Power for Experimental Research*, Sage Publications, 2111 West Hillcrest Drive, Newbury Park, CA. 91320.
- Littell, R. C. et al.** 2006. *SAS for Mixed Models – Second Edition*. SAS Institute Inc., Cary, North Carolina.
- Liu, H. and Wu, T.** 2005. "Sample Size Calculation and Power Analysis of Time-Averaged Difference," *Journal of Modern Applied Statistical Methods*, Vol. 4, No. 2, pages 434-445.
- Liu, J., Hsueh, H., Hsieh, E., and Chen, J.J.** 2002. "Tests for equivalence or non-inferiority for paired binary data," *Statistics in Medicine*, Volume 21, pages 231-245.
- Liu, J.P, Hsueh, H., Chen, J.J.** 2002. "Sample Size Requirements for Evaluation of Bridging Evidence." *Biometrical Journal*, Volume 44 (8), pages 969-981.
- Locke, C.S.** 1984. "An exact confidence interval for untransformed data for the ratio of two formulation means," *J. Pharmacokinetic. Biopharm.*, Volume 12, pages 649-655.
- Lohr, Sharon L.** 2019. *Sampling. Design and Analysis. 2nd Edition*. CRC Press. Boca Raton, FL.
- Lou, Y., Cao, J., and Ahn, C.** 2017. "Sample size estimation for comparing rates of change in K-group repeated count outcomes," *Communications in Statistics—Theory and Methods.*, Volume 46(22), pages 11204-11213.
- Looney, S.W.** 1996. "Sample size determination for correlation coefficient inference: Practical problems and practical solutions," *American Statistical Association 1996 Proceedings of the Section on Statistical Education*. Pages 240-245.
- Lu, M.J., Zhong, W.H., Liu, Y.X., Miao, H.Z., Li, Y.C., Ji, M.H.** 2016. "Sample Size for Assessing Agreement between Two Methods of Measurement by Bland-Altman Method," *The International Journal of Biostatistics*, Article 20150039 (published online).
- Lu, Y. and Bean, J.A.** 1995. "On the sample size for one-sided equivalence of sensitivities based upon McNemar's test," *Statistics in Medicine*, Volume 14, pages 1831-1839.
- Luh, W.M. and Guo, J.H.** 2016. "Allocating sample sizes to reduce budget for fixed-effect 2 x 2 heterogeneous analysis of variance," *Journal of Experimental Education*, 84:197-211.
- Lui, Kung-Jong.** 2013. "Sample size determination for testing equality in Poisson frequency data under an AB/BA crossover trial." *Pharmaceutical Statistics*. Volume 12, pages 74-81.
- Lui, Kung-Jong.** 2016. *Crossover Designs: Testing, Estimation, and Sample Size*. John Wiley & Sons Ltd. Chichester, West Sussex, England.
- Lui, Xiaofeng Steven.** 2014. *Statistical Power Analysis for the Social and Behavioral Sciences*. Routledge, Taylor and Francis, New York, NY.

M

- Machin, D., Campbell, M., Fayers, P., and Pinol, A.** 1997. *Sample Size Tables for Clinical Studies, 2nd Edition*. Blackwell Science. Malden, Mass.
- Machin, D., Campbell, M., Tan, S.B., and Tan, S.H.** 2009. *Sample Size Tables for Clinical Studies, 3rd Edition*. Wiley-Blackwell. Chichester, United Kingdom.
- Machin, D., Campbell, M., Tan, S.B., and Tan, S.H.** 2018. *Sample Sizes for Clinical, Laboratory and Epidemiology Studies, 4th Edition*. Wiley-Blackwell. Chichester, United Kingdom.

References

- Mai, Y. and Zhang, A.** 2017. Statistical power analysis for comparing means with binary or count data based on analogous ANOVA. In L. A. van der Ark, M. Wiberg, S. A. Culpepper, J. A. Douglas, & W.-C. Wang (Eds.), *Quantitative Psychology - The 81st Annual Meeting of the Psychometric Society, Asheville, North Carolina*, 2016: Springer.
- Martinez and Iglewicz.** 1981. "A test for departure from normality based on a biweight estimator of scale." *Biometrika*, 68, 331-333.
- Marubini, E. and Valsecchi, M.G.** 1996. *Analysing Survival Data from Clinical Trials and Observational Studies*. John Wiley: New York, New York.
- Mathews, Paul.** 2010. *Sample Size Calculations – Practical Methods for Engineers and Scientists*. Mathews Malnar and Bailey, Inc. Fairport Harbor, OH. www.mmbstatistical.com.
- Matsumoto, M. and Nishimura, T.** 1998. "Mersenne twister: A 623-dimensionally equidistributed uniform pseudorandom number generator" *ACM Trans. On Modeling and Computer Simulations*.
- Maxwell, S.E. and Delaney, H.D.** 1990. *Designing Experiments and Analyzing Data*. Wadsworth Publishing: Belmont, California.
- Maxwell, S.E. and Delaney, H.D.** 2003. *Designing Experiments and Analyzing Data, 2nd Edition*. Psychology Press. New York.
- McClish, D.K.** 1989. "Analyzing a Portion of the ROC Curve." *Medical Decision Making*, 9: 190-195.
- McNemar, Q.** 1947. "Note on the sampling error of the difference between two correlated proportions or percentages." *Psychometrika*, 12, 153-157.
- Meeker, W.Q. and Escobar, L.A.** 1998. *Statistical Methods for Reliability Data*. John Wiley: New York, New York.
- Metz, C.E.** 1978. "Basic principles of ROC analysis." *Seminars in Nuclear Medicine*, Volume 8, No. 4, pages 283-298.
- Miettinen, O.S. and Nurminen, M.** 1985. "Comparative analysis of two rates." *Statistics in Medicine* 4: 213-226.
- Moerbeek, M. and Wong, W.K.** 2008. "Sample size formulae for trials comparing group and individual treatments in a multilevel model." *Statistics in Medicine* 27: 2850-2864.
- Montgomery, Douglas.** 1984. *Design and Analysis of Experiments*. John Wiley & Sons, New York.
- Montgomery, Douglas.** 1991. *Introduction to Statistical Quality Control*. John Wiley & Sons, New York.
- Montgomery, Douglas.** 2013. *Introduction to Statistical Quality Control, 7th Edition*. John Wiley & Sons, New York.
- Moore, D. S. and McCabe, G. P.** 1999. *Introduction to the Practice of Statistics*. W. H. Freeman and Company. New York.
- Moura, Eduardo C.** 1991. *How To Determine Sample Size And Estimate Failure Rate in Life Testing*. ASQC Quality Press. Milwaukee, Wisconsin.
- Mukerjee, H., Robertson, T., and Wright, F.T.** 1987. "Comparison of Several Treatments With a Control Using Multiple Contrasts." *Journal of the American Statistical Association*, Volume 82, No. 399, pages 902-910.
- Muller, K. E., and Barton, C. N.** 1989. "Approximate Power for Repeated-Measures ANOVA Lacking Sphericity." *Journal of the American Statistical Association*, Volume 84, No. 406, pages 549-555.
- Muller, K. E., Edwards, L.J., Simpson, S.L., and Taylor, D.J.** 2007. "Statistical tests with accurate size and power for balanced linear mixed models." *Statistics in Medicine*, Volume 26, pages 3639-3660.
- Muller, K. E., LaVange, L.E., Ramey, S.L., and Ramey, C.T.** 1992. "Power Calculations for General Linear Multivariate Models Including Repeated Measures Applications." *Journal of the American Statistical Association*, Volume 87, No. 420, pages 1209-1226.
- Muller, K. E. and Stewart, P.W.** 2006. *Linear Model Theory: Univariate, Multivariate, and Mixed Models*. John Wiley & Sons Inc. Hoboken, New Jersey.

References

Myers, R.H. 1990. *Classical and Modern Regression with Applications*. PWS-Kent Publishing Company. Boston, Massachusetts.

N

- Naik, D.N. and Rao, S.S.** 2001. "Analysis of multivariate repeated measures data with a Kronecker product structured covariance matrix." *Journal of Applied Statistics*, Volume 28(1), 91-105.
- Nam, Jun-mo.** 1987. "A Simple Approximation for Calculating Sample Sizes for Detecting Linear Trend in Proportions," *Biometrics*, Volume 43, 701-705.
- Nam, Jun-mo.** 1992. "Sample Size Determination for Case-Control Studies and the Comparison of Stratified and Unstratified Analyses," *Biometrics*, Volume 48, 389-395.
- Nam, Jun-mo.** 1997. "Establishing equivalence of two treatments and sample size requirements in matched-pairs design," *Biometrics*, Volume 53, 1422-1430.
- Nam, J-m. and Blackwelder, W.C.** 2002. "Analysis of the ratio of marginal probabilities in a matched-pair setting," *Statistics in Medicine*, Volume 21, 689-699.
- Nauta, Jozef.** 2020. *Statistics in Clinical and Observational Vaccine Studies*, 2nd Edition. Springer. Cham, Switzerland.
- Nelson, Wayne.** 1982. *Applied Life Data Analysis*. John Wiley & Sons. New York, New York.
- Neter, J., Kutner, M., Nachtsheim, C., and Wasserman, W.** 1996. *Applied Linear Statistical Models*. Richard D. Irwin, Inc. Chicago, Illinois.
- Neter, J., Wasserman, W., and Kutner, M.** 1983. *Applied Linear Regression Models*. Richard D. Irwin, Inc. Chicago, Illinois.
- Newcombe, Robert G.** 1998a. "Two-Sided Confidence Intervals for the Single Proportion: Comparison of Seven Methods." *Statistics in Medicine*, Volume 17, 857-872.
- Newcombe, Robert G.** 1998b. "Interval Estimation for the Difference Between Independent Proportions: Comparison of Eleven Methods." *Statistics in Medicine*, Volume 17, 873-890.
- Newcombe, Robert G.** 1998c. "Improved Confidence Intervals for the Difference Between Binomial Proportions Based on Paired Data." *Statistics in Medicine*, Volume 17, 2635-2650.
- Ng, H.K.T, Gu, K., Tang, M.L.** 2007. "A comparative study of tests for the difference of two Poisson means." *Computational Statistics & Data Analysis*, Volume 51, 3085-3099.
- Noether, G.E.** 1987. "Sample size determination for some common nonparametric tests." *Journal of the American Statistical Association*, Volume 82(1), 645-647.
- Novikov, I., Fund, N., and Freedman, L.S.** 2010. "A modified approach to estimating sample size for simple logistic regression with one continuous covariate," *Statistics in Medicine*, Volume 29(1), 97-107.
-

O

- O'Brien, P.C. and Fleming, T.R.** 1979. "A multiple testing procedure for clinical trials." *Biometrics*, 35, pages 549-556.
- O'Brien, R.G. and Kaiser, M.K.** 1985. "MANOVA Method for Analyzing Repeated Measures Designs: An Extensive Primer." *Psychological Bulletin*, 97, 316-333.
- O'Hagan, A., Stevens, J.W., and Campbell, M.J.** 2005. "Assurance in clinical trial design". *Pharmaceutical Statistics*, 4, pages 187-201.

References

- O'Hagan, A., Buck, C.E., Daneshkhah, A., Eiser, J.R., Garthwaite, P.H., Jenkinson, D.J., Oakley, J.E., and Rakow, T.** 2006. *Uncertain Judgements – Eliciting Experts' Probabilities*. John Wiley and Sons.
- Obuchowski, N.A.** 1998. "Sample Size Calculations in Studies of Test Accuracy." *Statistical Methods in Medical Research*, 7, pages 371-392.
- Obuchowski, N.A. and McClish, D.** 1997. "Sample Size Determination for Diagnostic Accuracy Studies Involving Binormal ROC Curve Indices." *Statistics in Medicine*, 16, pages 1529-1542.
- Obuchowski, N.A. and Zhou, X.H.** 2002. "Prospective studies of diagnostic test accuracy when disease prevalence is low." *Biostatistics*, 3, pages 477-492.
- Odeh, R.E., Chou, Y.M., and Owen, D.B.** 1987. "The Precision for Coverages and Sample Size Requirements for Normal Tolerance Intervals." *Communications in Statistics – Simulation and Computation*, 16(4), pages 969-985.
- Odeh, R.E. and Fox, M.** 1991. *Sample Size Choice*. Marcel Dekker, Inc. New York, NY.
- Odeh, R.E. and Owen, D.B.** 1980. *Tables for Normal Tolerance Limits, Sampling Plans, and Screening*. Marcel Dekker, Inc. New York, NY.
- O'Hagan, A, Stevens, J.W., and Campbell, M.J.** 2005. "Assurance in clinical trial design." *Pharmaceutical Statistics*, Volume 4, pages 187-201.
- O'Neill, Robert T.** 1988. "On Sample Sizes to Estimate the Protective Efficacy of a Vaccine." *Statistics in Medicine* 7: 1279-1288.
- O'Neill and Wetherill.** 1971 "The Present State of Multiple Comparison Methods," *The Journal of the Royal Statistical Society*, Series B, vol.33, 218-250).
- O'Quigley, J, Pepe, M, Fisher, L.** 1990. "Continual reassessment method: A practical design for phase I clinical studies in cancer." *Biometrics*, Volume 46, 33-48.
- Overall, J.E. and Doyle, S.R.** 1994. "Estimating Sample Sizes for Repeated Measurement Designs." *Controlled Clinical Trials*, Volume 15, pages 100-123.
- Ostle, B. and Malone, L. C.** 1988. *Statistics in Research. Fourth Edition*. Iowa State Press. Ames, Iowa. A comprehension book on statistical methods.
- Owen, Donald B.** 1956. "Tables for Computing Bivariate Normal Probabilities," *Annals of Mathematical Statistics*, Volume 27, pages 1075-1090.
- Owen, Donald B.** 1965. "A Special Case of a Bivariate Non-Central t-Distribution," *Biometrika*, Volume 52, pages 437-446.

P

- Parmar, M.K.B. and Machin, D.** 1995. *Survival Analysis*. John Wiley and Sons. New York.
- Pan, Z. and Kupper, L.** 1999. "Sample Size Determination for Multiple Comparison Studies Treating Confidence Interval Width as Random." *Statistics in Medicine* 18, 1475-1488.
- Patterson, S.D. and Jones, B.** 2017. *Bioequivalence and Statistics in Clinical Pharmacology*. Second Edition. Chapman & Hall/CRC Press. New York.
- Pearson, E.S. and Hartley, H.O.** 1976. *Biometrika Tables For Statistics, Volume 1*. Biometrika Trust. London.
- Phadnis, Milind A.** 2019. 'Sample size calculation for small sample single-arm trials for time-to-event data', *Contemporary Clinical Trials Communications*, Volume 15, 100360. <https://doi.org/10.1016/j.conctc.2019.100360>.
- Phadnis, M. A., Sharma, P., Thewarapperuma, N., Chalise, P.** 2020. 'Assessing accuracy of Weibull shape parameter estimate from historical studies for subsequent sample size calculation in clinical trials with time-to-

References

- event outcome', Contemporary Clinical Trials Communications, Volume 17, 100548.
<https://doi.org/10.1016/j.conctc.2020.100548>.
- Phillips, Kem F.** 1990. "Power of the Two One-Sided Tests Procedure in Bioequivalence," *Journal of Pharmacokinetics and Biopharmaceutics*, Volume 18, No. 2, pages 137-144.
- Piantadosi, S.** 2005. *Clinical Trials – A Methodological Perspective*. John Wiley & Sons. New Jersey.
- Piantadosi, S, Fisher, JD, Grossman, S.** 1998. "Practical implementation of a modified continual reassessment method for dose-finding trials." *Cancer Chemotherapy Pharmacology*, Volume 41, 429-436.
- Pintilie, M.** 2002. "Dealing with Competing Risks: Testing Covariates and Calculating Sample Size," *Statistics in Medicine*, Volume 21, pages 3317-3324.
- Pintilie, M.** 2006. *Competing Risks: A Practical Perspective*. John Wiley & Sons, Chichester, United Kingdom.
- Pocock, S.J.** 1977. "Group sequential methods in the design and analysis of clinical trials." *Biometrika*, 64, pages 191-199.
- Pocock, S.J.** 1983. *Clinical Trials – A Practical Approach*. John Wiley & Sons. New York.
- Pocock, S.J., Ariti, C.A., Collier, T.J., Wang, D.** 2012. 'The win ratio: a new approach to the analysis of composite endpoints in clinical trials based on clinical priorities.' *European Heart Journal*. 33. 176-182.
- Price, K., Storn R., and Lampinen, J.** 2005. *Differential Evolution – A Practical Approach to Global Optimization*. Springer. Berlin, Germany.
- Prihoda, Tom.** 1983. "Convenient Power Analysis For Complex Analysis of Variance Models." *Poster Session of the American Statistical Association Joint Statistical Meetings*, August 15-18, 1983, Toronto, Canada.
- Proschan, M.A., Lan, K.K.G., and Wittes, J.T.** 2006. *Statistical Monitoring of Clinical Trials*. Springer. New York, New York.
-

Q

- Quan, H and Shih, W.J.** 1996. "Assessing reproducibility by the within-subject coefficient of variation with random effects models." *Biometrics*, vol. 52, no. 4, pages 1195-1203.
-

R

- Raaijmakers, Jeroen G. W.** 1987. "Statistical Analysis of the Michaelis-Menten Equation." *Biometrics*, vol. 43, no. 4, pages 793-803.
- Raghavarao, D. and Padgett, L.** 2014. *Repeated Measurements and Cross-Over Designs*. John Wiley & Sons. New York.
- Ramsey, Philip H.** 1978 "Power Differences Between Pairwise Multiple Comparisons," *JASA*, vol. 73, no. 363, pages 479-485.
- Rao, C.R. , Mitra, S.K., & Matthai, A.** 1966. *Formulae and Tables for Statistical Work*. Statistical Publishing Society, Indian Statistical Institute, Calcutta, India.
- Reboussin, D.M., DeMets, D.L., Kim, K, and Lan, K.K.G.** 1992. "Programs for computing group sequential boundaries using the Lan-DeMets Method." Technical Report 60, Department of Biostatistics, University of Wisconsin-Madison.
- Rencher, Alvin C.** 1998. *Multivariate Statistical Inference and Applications*. John Wiley. New York, New York.
- Robins, Greenland, and Breslow.** 1986. "A General Estimator for the Variance of the Mantel-Haenszel Odds Ratio," *American Journal of Epidemiology*, vol.42, pages 719-723.

References

- Robins, Breslow, and Greenland.** 1986. "Estimators of the Mantel-Haenszel variance consisten in both sparse data and large-strata limiting models," *Biometrics*, vol. 42, pages 311-323.
- Rosenberger, W.F., and Lachin, J.M.** 2002. *Randomization in Clinical Trials – Theory and Practice*. John Wiley & Sons. New York.
- Rosner, Bernard.** 2011. *Fundamentals of Biostatistics*. Brooks/Cole. Boston, MA.
- Rothmann, M.D., Wiens, B.L., and Chan, I.S.F.** 2012. *Design and Analysis of Non-Inferiority Trials*. CRC Press. Boca Raton, Florida.
- Royston, P.** 1991. "Constructing time-specific reference ranges." *Statistics in Medicine*. Volume 10, pages 675-690.
- Royston, P. and Altman, D. G.** 1994. "Regression using Fractional Polynomials of Continuous Covariates: Parsimonious Parametric Modelling," *Appl. Statist.*, Volume 43, No. 3, pages 429-467.
- Royston, P. and Sauerbrei, W.** 2008. *Multivariable Model-building*. John Wiley & Sons. New York.
- Royston, P. and Wright, E. M.** 1998. "A method for estimating age-specific reference intervals ('normal ranges') based on fractional polynomials and exponential transformation," *J. R. Statist. Soc. A*, Volume 161, Part 1, pages 79-101.
- Ryan, Thomas P.** 1989. *Statistical Methods for Quality Improvement*. Wiley. New York.
- Ryan, Thomas P.** 2013. *Sample Size Determination and Power*. John Wiley & Sons. Hoboken, New Jersey.

S

- Sachs, Lothar.** 1984. *Applied Statistics: A Handbook of Techniques*. Springer-Verlag. New York, New York.
- Sahai, Hardeo & Khurshid, Anwer.** 1995. *Statistics in Epidemiology*. CRC Press. Boca Raton, Florida.
- Satterthwaite, F.E.** 1946. "An approximate distribution of estimate of variance components," *Biometric Bulletin*, 2:110-114.
- Saville, D.J.** 1990. "Multiple comparison procedures: The practical solution." *The American Statistician*, 44, 174-180.
- Schilling, Edward.** 1982. *Acceptance Sampling in Quality Control*. Marcel-Dekker. New York.
- Schilling, E. G. and Neubauer, D. V.** 2017. *Acceptance Sampling in Quality Control*, Third Edition. CRC Press. New York.
- Schlesselman, James J.** 1982. *Case-Control Studies*. Oxford University Press. New York.
- Schmid, C. H., Stijnen, T., and White, I.R.** 2021. *Handbook of Meta-Analysis*. CRC Press. New York.
- Schmidt R., Kwiczen R, Faldum A, Berthold F, Hero B, and Ligges S.** 2015. "Sample size calculation for the one-sample log-rank test," *Statistics in Medicine*, 34(6), pages 1031-1040.
- Schoenfeld, David A.** 1981. "The asymptotic properties of nonparametric tests for comparing survival distributions" *Biometrika*, Volume 68, pages 316-319.
- Schoenfeld, David A.** 1983. "Sample-Size Formula for the Proportional-Hazards Regression Model" *Biometrics*, Volume 39, pages 499-503.
- Schoenfeld, David A. and Richter, Jane R.** 1982. "Nomograms for Calculating the Number of Patients Needed for a Clinical Trial with Survival as an Endpoint," *Biometrics*, March 1982, Volume 38, pages 163-170.
- Schork, M. and Williams, G.** 1980. "Number of Observations Required for the Comparison of Two Correlated Proportions." *Communications in Statistics-Simula. Computa.*, B9(4), 349-357.
- Schultz, J.R., Nichol, F.R., Elfring, G.L., and Weed, S.D.** 1973. "Multiple-stage procedures for drug screening." *Biometrics*, 29, pages 293-300.

References

- Schuirman, Donald.** 1981. "On hypothesis testing to determine if the mean of a normal distribution is continued in a known interval," *Biometrics*, Volume 37, pages 617.
- Schuirman, Donald.** 1987. "A Comparison of the Two One-Sided Tests Procedure and the Power Approach for Assessing the Equivalence of Average Bioavailability," *Journal of Pharmacokinetics and Biopharmaceutics*, Volume 15, Number 6, pages 657-680.
- Senn, Stephen.** 1993. *Cross-over Trials in Clinical Research*. John Wiley & Sons. New York.
- Senn, Stephen.** 2002. *Cross-over Trials in Clinical Research*. Second Edition. John Wiley & Sons. New York.
- Shapiro, S.S. and Wilk, M.B.** 1965. "An analysis of Variance test for normality." *Biometrika*, Volume 52, pages 591-611.
- Shieh, Gwown.** 2016. "A comparative appraisal of two equivalence tests for multiple standardized effects," *Computer Methods and Programs in Biomedicine*. Vol 126, pages 110-117.
<https://dx.doi.org/10.1016/j.cmpb.2015.12.004>.
- Shieh, Gwown.** 2017. "Power and Sample Size Calculations for Contrast Analysis in ANCOVA." *Multivariate Behavioral Research*. Vol 52:1, 1-11, DOI: 10.1080/00273171.2016.1219841.
- Shieh, Gwown.** 2017. "Precise confidence intervals of regression-based reference limits: Method comparisons and sample size requirements." *Computers in Biology and Medicine*. Vol 91, pages 191-197.
<https://doi.org/10.1016/j.compbimed.2017.10.015>.
- Shieh, Gwown.** 2018. "The appropriateness of Bland-Altman's approximate confidence intervals for limits of agreement." *BMC Medical Research Methodology*. Link: <https://doi.org/10.1186/s12874-018-0505-y>.
- Shieh, Gwown.** 2018. "On Detecting a Minimal Important Difference among Standardized Means". *Current Psychology*. Vol 37, pages 640-647. Doi: 10.1007/s12144-016-9549-5.
- Shieh, Gwown.** 2019. "Assessing Agreement Between Two Methods of Quantitative Measurements: Exact Test Procedure and Sample Size Calculation." *Statistics in Biopharmaceutical Research*. Link: <https://doi.org/10.1080/19466315.2019.1677495>.
- Shieh, G. and Jan, S-L, G.** 2013. "Determining Sample Size With a Given Range of Mean Effects in One-Way Heteroscedastic Analysis of Variance." *The Journal of Experimental Education*, 81(3):281-294.
- Shieh, G. and Jan, S-L, G.** 2015. "Power and sample size calculations for testing linear combinations of group means under variance heterogeneity with applications to meta and moderation analysis." *Psicologica*, 36:367-390.
- Shieh, G. and Kung, C.F.** 2007. "Methodological and computational considerations for multiple correlation analysis," *Behavior Research Methods*, Vol. 39, No. 4, pages 731-734.
- Shrout, P.E. and Fleiss, J.L.** 1979. "Intraclass Correlations: Uses in Assessing Rater Reliability," *Psychological Bulletin*, Vol. 86, No. 2, pages 420-428.
- Shuster, Jonathan J.** 1990. *CRC Handbook of Sample Size Guidelines for Clinical Trials*. CRC Press, Boca Raton, Florida.
- Signorini, David.** 1991. "Sample size for Poisson regression," *Biometrika*, Volume 78, 2, pages 446-450.
- Sim, J. and Lewis, M.** 2012. "The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency." *Journal of Clinical Epidemiology*, 65, pages 301-308.
- Simon, Richard.** 1989. "Optimal Two-Stage Designs for Phase II Clinical Trials," *Controlled Clinical Trials*, Volume 10, pages 1-10.
- Simon, R., Wittes, R.E., and Ellenberg, S.S.** 1985. "Randomized Phase II Clinical Trials," *Cancer Treatment Reports*, Volume 69, No. 12, pages 1375-1381.
- Simpson, S.L., Edwards, L.J., Muller, K. E., Sen, P.K., and Styner, M.A.** 2010. "A linear exponent AR(1) family of correlation structures." *Statistics in Medicine*, Volume 29, No. 17, pages 1825-1838.
- Smith, P.G. and Morrow, R.H.** 1996. *Field Trials of Health Intervention in Developing Countries: A Toolbox*. Macmillan Education. Oxford, England.

References

- Smith, R.L.** 1984. "Sequential Treatment Allocation using Biased Coin Designs." *Journal of the Royal Statistical Society B*. Volume 46, pages 519-543.
- Sobel, M.E.** 1982. "Asymptotic confidence intervals for indirect effects in structural equation models." *Sociological Methodology*. Volume 13, pages 290-312.
- Statxact 5.** 2001. *Statistical Software for exact nonparametric inference, user manual*. Cytel Software Corporation. Cambridge, Massachusetts.
- Stekel, D.** 2003. *Microarray Bioinformatics*. Cambridge University Press. Cambridge, United Kingdom.
- Strom, B.L., Kimmel, S.E., Hennessy, S.** 2013. *Textbook of Pharmacoepidemiology, 2nd Edition*. Wiley-Blackwell. Chichester, United Kingdom.
- Stucke, K. and Kieser, M.** 2013. "Sample size calculations for noninferiority trials with Poisson distributed count data." *Biometrical Journal*. Volume 55, pages 203-216.
- Sun X, Peng P, and Tu D.** 2011. "Phase II cancer clinical trials with a one-sample log-rank test and its corrections based on the Edgeworth expansion," *Contemporary Clinical Trials*, 32, pages 108-113.
- Swets, John A.** 1996. *Signal Detection Theory and ROC Analysis in Psychology and Diagnostics - Collected Papers*. Lawrence Erlbaum Associates. Mahway, New Jersey.

T

- Tang, Yongqiang.** 2009. "Comments on 'Sample size evaluation for multiply matched case-control study using the score test from a conditional logistic (discrete Cox PH) regression model.'" *Statistics in Medicine* 28, 175-177.
- Tango, Toshiro.** 1998. "Equivalence Test and Confidence Interval for the Difference in Proportions for the Paired-Sample Design." *Statistics in Medicine*, Volume 17, 891-908.
- Tate, R. F.** 1954. "Correlation Between a Discrete and a Continuous Variable. Point-Biserial Correlation." *Annals of Mathematical Statistics*. Vol 25, No. 3 (Sep, 1954), 603-607.
- Tate, R. F.** 1955. "Applications of Correlation Models for Biserial Data." *Journal of the American Statistical Association*. Vol 50, No. 272 (Dec, 1955), 1078-1095.
- Tate, R. F.** 1955. "The Theory of Correlation Between Two Continuous Variables when One is Dichotomized." *Biometrika*. Vol 42, No. 1/2 (Jun, 1955), 205-216.
- Thabane, L., Ma, J., Chu, R., Cheng, J., Ismaila, A., Rios, L.P., Robson, R., Thabane, M., Giangregorio, L., and Goldsmith, C.H.** 2010. "A tutorial on pilot studies: the what, why and how." *BMC Medical Research Methodology*, 10:1.
- Therneau, T.M. and Grambsch, P.M.** 2000. *Modeling Survival Data*. Springer: New York, New York.
- Thode, Henry C.** 2002. *Testing for Normality*. Marcel Dekker, Inc. New York.
- Thompson, P. C.** 1995. "A Hybrid Paired and Unpaired Analysis for the Comparison of Proportions." *Statistics in Medicine*, Vol. 14, pages 1463-1470.
- Thompson, Simon G.** 1998. *Encyclopedia of Biostatistics, Volume 4*. John Wiley & Sons. New York. Article on Meta-Analysis on pages 2570-2579.
- Tubert-Bitter, P., Manfredi, R., Lellouch, J., Begaud, B.** 2000. "Sample size calculations for risk equivalence testing in pharmacoepidemiology." *Journal of Clinical Epidemiology* 53, 1268-1274.
- Tukey, J.W. and McLaughlin, D.H.** 1963. "Less Vulnerable confidence and significance procedures for location based on a single sample: Trimming/Winsorization." *Sankhya, Series A* 25, 331-352.

U

Upton, G.J.G. 1982. "A Comparison of Alternative Tests for the 2 x 2 Comparative Trial.", *Journal of the Royal Statistical Society, Series A*, Volume 145, pages 86-105.

V

Valentine, J.C., Pigott, T.D., and Rothstein, H.R. 2010. "How Many Studies Do You Need? A Primer on Statistical Power for Meta-Analysis", *Journal of Education and Behavioral Statistics*, Volume 35, No. 2, pages 215-247.

Viechtbauer, W., Smits, L., Kotz, D., Bude, L., Spigt, M., Serroyen, J., Crutzen, R. 2015. "A simple formula for the calculation of sample size in pilot studies." *Journal of Clinical Epidemiology*. Vol 68, pages 1375-1379.

Vierron, E. and Giraudeau, B. 2007. "Sample size calculation for multicenter randomized trial: Taking the center effect into account." *Contemporary Clinical Trials*, Vol 28, pages 451-458.

Vierron, E. and Giraudeau, B. 2009. "Design effect in multicenter studies: gain or loss of power?" *BMC Medical Research Methodology*, 9:39. This article is available from www.biomedcentral.com/1471-2288/9/39

Vittinghoff, E., Neilands, T.B. 2015. "Sample size for Joint Testing of Indirect Effects." *Prevention Science*, Volume 16, Issue 8, pages 1128-1135.

Vittinghoff, E., Sen, S., and McCulloch, C.E. 2009. "Sample size calculations for evaluating mediation." *Statistics in Medicine*, Volume 28, pages 541-557.

Vonesh, E.F. and Schork, M.A. 1986. "Sample Sizes in the Multivariate Analysis of Repeated Measurements." *Biometrics*, Volume 42, pages 601-610.

W

Walter, S.D., Eliasziw, M., and Donner, A. 1998. "Sample Size and Optimal Designs For Reliability Studies." *Statistics in Medicine*, 17, 101-110.

Wang, H., Chow, S.C., and Li, G. 2002. "On Sample Size Calculation based on Odds Ratio in Clinical Trials." *Journal of Biopharmaceutical Statistics*. Volume 12, No. 4, pages 471-483.

Wang, J., Zhang, S., and Ahn, C. 2017. "Power analysis for stratified cluster randomisation trials with cluster size being the stratifying factor." *Statistical Theory and Related Fields*, Volume 1, No. 1, pages 121-127.

Wang, J., Zhang, S., and Ahn, C. 2018. "Sample Size Calculation for Comparing Time-Averaged Responses in K-group Repeated Binary Outcomes." (To appear in) *Communications for Statistical Applications and Methods*.

Wang, J., Zhang, S., and Ahn, C. 2018. "Sample size calculation for count outcomes in cluster randomization trials with varying cluster sizes." *Communications in Statistics--Theory and Methods*. Published Online in December 2018. DOI: 10.1080/03610926.2018.1532004.

Wei, L.J., and Lachin, J.M. 1988. "Properties of the Urn Randomization in Clinical Trials." *Controlled Clinical Trials*. Volume 9, pages 345-364.

Welch, B.L. 1938. "The significance of the difference between two means when the population variances are unequal." *Biometrika*, 29, 350-362.

Welch, B.L. 1947. "The Generalization of "Student's" Problem When Several Different Population Variances Are Involved," *Biometrika*, 34, 28-35.

Welch, B.L. 1949. "Further Mote on Mrs. Aspin's Tables and on Certain Approximations to the Tabled Function." *Biometrika*, 36, 293-296.

References

- Welch, B.L.** 1951. "On the Comparison of Several Mean Values: An Alternative Approach," *Biometrika*, 38, 330-336.
- Wellek, Stefan.** 2010. *Testing Statistical Hypotheses of Equivalence and Noninferiority*. Chapman & Hall/CRC, Boca Raton, Florida.
- Westlake, W.J.** 1981. "Bioequivalence testing—a need to rethink," *Biometrics*, Volume 37, pages 591-593.
- Whitehead, A.L., Julious, S.A., Cooper, C.L., and Campbell, M.J.** 2016. "Estimating the sample size for a pilot randomized trial to minimize the overall trial sample size for the external pilot and main trial for a continuous outcome variable," *Statistical Methods in Medical Research*, 25(3), pages 1057-1073.
- Whitehead, John.** 1993. "Sample Size Calculations for Ordered Categorical Data," *Statistics in Medicine*, Volume 12, pages 2257-2271.
- Whittemore, Alice.** 1981. "Sample Size for Logistic Regression with Small Response Probability," *Journal of the American Statistical Association*, Volume 76, pages 27-32.
- Williams, D.A.** 1971. "A Test for Differences between Treatment Means When Several Dose Levels are Compared with a Zero Dose Control," *Biometrics*, Volume 27, No. 1 (March), pages 103-117.
- Williams, D.A.** 1972. "The Comparison of Several Dose Levels with a Zero Dose Control," *Biometrics*, Volume 28, No. 2 (June), pages 519-531.
- Wilson, E.B.** 1927. "Probable Inference, the Law of Succession, and Statistical Inference," *Journal of the American Statistical Association*, Volume 22, pages 209-212. This article discusses the 'score' method that has become popular when dealing with proportions.
- Winer, B.J.** 1991. *Statistical Principles in Experimental Design (Third Edition)*. McGraw-Hill. New York, NY. A very complete analysis of variance book.
- Wolfinger, R., Tobias, R. and Sall, J.** 1994. "Computing Gaussian likelihoods and their derivatives for general linear mixed models," *SIAM Journal of Scientific Computing*, 15, no.6, pages 1294-1310.
- Woolson, R.F., Bean, J.A., and Rojas, P.B.** 1986. "Sample Size for Case-Control Studies Using Cochran's Statistic," *Biometrics*, Volume 42, pages 927-932.
- Wu, Jianrong.** 2014. "A New One-Sample Log-Rank Test," *Journal of Biometrical Biostatistics*, 5; 210.
- Wu, Jianrong.** 2015. "Sample size calculation for the one-sample log-rank test," *Pharmaceutical Statistics*, Volume 14, pages 26-33.
- Wu, Jianrong.** 2015. "Single-arm phase II trial design under parametric cure models," *Pharmaceutical Statistics*, wileyonlinelibrary.com, DOI: 10.1002/pst.1678.

X

- Xie, T. and Waksman, J.** 2003. "Design and sample size estimation in clinical trials with clustered survival times as the primary endpoint." *Statistics in Medicine*, 22:2835-2846.
- Xu, X., Zhu, H., and Ahn, C.** 2019. "Sample size considerations for stratified cluster randomization design with binary outcomes and varying cluster size." to appear in *Statistics in Medicine* in 2019.

Y

- Yamane, Taro.** 1967. *Elementary Sampling Theory*. Prentice-Hall. Englewood Cliffs, New Jersey.
- Yateman, Nigel A. and Skene, Allan M.** 1992. "Sample Sizes for Proportional Hazards Survival Studies with Arbitrary Patient Entry and Loss to Follow-Up Distributions." *Statistics in Medicine*, 11:1103-1113.

References

- Young, D.S., Gordon, C.M, Zhu, S., and Olin, B.D.** 2016. "Sample size determination strategies for normal tolerance intervals using historical data." *Quality Engineering*, Volume 28(3), pages 337-351.
- Yu, R.X. and Ganju, J.** 2022. "Sample size formula for a win ratio endpoint." *Statistics in Medicine*. 41(6):950-963. doi:10.1002/sim.9297.
- Yuen, K.K. and Dixon, W. J.** 1973. "The approximate behavior and performance of the two-sample trimmed t," *Biometrika*, Volume 60, pages 369-374.
- Yuen, K.K.** 1974. "The two-sample trimmed t for unequal population variances," *Biometrika*, Volume 61, pages 165-170.

Z

- Zar, Jerrold H.** 1984. *Biostatistical Analysis (Second Edition)*. Prentice-Hall. Englewood Cliffs, New Jersey.
- Zar, Jerrold H.** 2010. *Biostatistical Analysis (Fifth Edition)*. Prentice-Hall. Englewood Cliffs, New Jersey.
- Zhang, S. and Ahn, C.** 2013. "Sample Size Calculations for Comparing Time-Averaged Responses in K-Group Repeated-Measurement Studies." *Computational Statistics & Data Analysis*, Vol. 58(1), pages 283-291.
- Zhang, S., Cao, J., and Ahn, C.** 2014. "A GEE approach to determine sample size for pre- and post-intervention experiments with dropout." *Computational Statistics and Data Analysis*, Vol. 69, pages 114-121.
- Zhang, S., Cao, J., and Ahn, C.** 2017. "Inference and sample size calculation for clinical trials with incomplete observations of paired binary outcomes." *Statistics in Medicine*, Vol. 36, pages 581-591.
- Zhang, Z. and Yuan, K.H.** 2018. *Practical Statistical Power Analysis: Using WebPower and R*. ISDSA Press. Granger, IN.
- Zhao, Yan D.** 2006. "Sample size estimation for the van Elteren test--a stratified Wilcoxon-Mann-Whitney test." *Statistics in Medicine*, 25, pages 2675-2687.
- Zhao, Y.D., Qu, Y. Rahardja, D.** 2006. "Power Approximation for the van Elteren test based on location-scale family of distributions." *Journal of Biopharmaceutical Statistics*, 16, pages 803-815.
- Zhao, Y.D., Rahardja, D., and Qu, Y.** 2008. "Sample Size Calculation for the Wilcoxon-Mann-Whitney Test Adjusting for Ties." *Statistics in Medicine*, 27:462-468.
- Zhou, X., Obuchowski, N., McClish, D.** 2002. *Statistical Methods in Diagnostic Medicine*. John Wiley & Sons, Inc. New York, New York. This is a great book on the designing and analyzing diagnostic tests. It is especially useful for its presentation of ROC curves.
- Zhu, H.** 2017. "Sample Size Calculation for Comparing Two Poisson or Negative Binomial Rates in Non-Inferiority or Equivalence Trials." *Statistics in Biopharmaceutical Research*, 9(1), 107-115, doi:10.1080/19466315.2016.1225594.
- Zhu, H. and Lakkis, H.** 2014. *Sample Size Calculation for Comparing Two Negative Binomial Rates*. *Statistics in Medicine*, Volume 33, pages 376-387.
- Zhu, H., Zhang, S., and Ahn, C.** 2017. "Sample size considerations for split-mouth design." *Statistical Methods in Medical Research*, Vol. 26(6), pages 2543-2551.
- Zou, G. Y.** 2012. *Sample size formulas for estimating intraclass correlation coefficients with precision and assurance*. *Statistics in Medicine*, Volume 31, pages 3972-3981.