October 25, 2005

CURRICULUM VITAE

John M. Lachin, III, Sc.D.
The Biostatistics Center, 6110 Executive Boulevard, Rockville, Maryland, 20852.

EDUCATION

Sc.D., Biostatistics, University of Pittsburgh, 9/69-4/72.

B.S., Psychology, Tulane University, 6/65.

EMPLOYMENT

Present	Professor of Biostatistics and Epidemiology, and of Statistics Department of Epidemiology and Biostatistics, The School of Public Health and Health Services. Department of Statistics, Columbian School of Arts and Sciences. Former (now Co)-Director, The Biostatistics Center The George Washington University
1973-	Professor of Biostatistics and Epidemiology, and of Statistics, with tenure (2002), Professor of Statistics (1984, tenure 1987), Research Professor (1982), Associate Research Professor (1977), Assistant Research Professor (1973). Co-Director of the Biostatistics Center (2001), Director (1988), Co-Director (1985), Assistant Director (1980).
1972-1973	Mental Hygiene Epidemiologist and Director, Division of Program Information and Evaluation, Virginia State Department of Mental Health and Mental Retardation, Richmond; and Adjunct Assistant Professor, Department of Biometry, Medical College of Virginia, Health Sciences Division, Virginia Commonwealth University.
1969-1972	Statistician and Systems Analyst for the Research Center in Child Psychiatry, University of Pittsburgh School of Medicine, Pittsburgh Child Guidance Center.
1967-1969	Acting Chief, Statistics and Research Section, Division of Administrative Services, Louisiana State Department of Hospitals, Baton Rouge.

CURRENT RESPONSIBILITIES

Professor of Biostatistics and Epidemiology, and of Statistics. Each semester teaches one of the following courses in the Department of Epidemiology and Biostatistics, or the Department of Statistics: Courses taught include Introduction to Biostatistics (Statistics 127); Data Analysis (Statistics 210); Design of Medical Studies (Statistics 224); Biostatistical Methods (formerly Statistics 225, now PH 266); Advanced Biostatistical Methods (Statistics 226); or Survival Analysis (Statistics 227).

Former, now Co-, Director of the Biostatistics Center, a research facility of the Department of Statistics of the George Washington University with 100 employees and total funding of $25 million annually.

Principal Investigator and Director of the Coordinating Center for the Type 1 Diabetes TrialNet, a clinical research consortium to conduct multiple studies into the epidemiology, genetics, autoimmunity, prevention and treatment of type 1 diabetes mellitus, funded by the National Institute of Diabetes, Digestive and Kidney Diseases.

Principal Investigator and Director of the Coordinating Center for the study of the Epidemiology of Diabetes Intervention and Complications (EDIC), a long-term epidemiologic study of subjects with Type 1 diabetes funded by the National Institute of Diabetes, Digestive and Kidney Diseases.

Co-Principal Investigator of the Coordinating Center for the Diabetes Prevention Program Outcome Study (DPPOS), a long-term multi-center observational follow-up of subjects with impaired glucose tolerance and newly diagnosed Type 2 diabetes trial funded by the National Institute of Diabetes, Digestive and Kidney Diseases.

FORMER SIGNIFICANT RESPONSIBILITIES

Director, The Biostatistics Center, 1988-2000.

Program Director for Biostatistics and Chair of the Executive Committee for the graduate degree program in Biostatistics and Epidemiology, jointly by the Department of Epidemiology and Biostatistics and the Department of Statistics, 1995 - 2004.

Principal Investigator and Director of the Coordinating Center for large scale medical studies funded by the National Institutes of Health and industry, and PI for methodological research funded by the NIH. For complete list, see “Sponsored Research” below.

DOCTORAL STUDENTS

Milton Fan, Ph.D. Statistics, 1986, *Estimation of Parameters for the Logistic Regression Model with Partial Incomplete Observations.* (Currently with The Food and Drug Administration).

Yuko Palesch, Ph.D. Statistics, 1990, *R-Sample(R>2) Multivariate Rank Tests and Related Estimators of Population Differences.* (Currently with the Department of Biostatistics and Epidemiology, Medical University of South Carolina).

Naji Younes, Ph.D. Statistics, 1994, *A Family of Event-Time Models with Smooth Baseline Hazards*. (Currently with The Biostatistics Center, The George Washington University).

Oliver Bautista, Ph.D. Statistics, 1996, (Co-Advisor with K.K. Gordon Lan), *Analysis of Overdispersed Poisson Count Data.* (Currently with The Biostatistics Center, The George Washington University).

Mingxiu Hu, Ph.D. Statistics, 1997, *Robust Estimating Functions with Nuisance Parameters.* (Currently with Pfizer Corporation).

Theodore Diaz, Ph.D. Statistics, 1999, (Co-Advisor; Advisor: Robert Smythe). *Simultaneous Testing and Estimation of Trend in Proportion Using Historical Controls.*

Yvonne Sparling, Biostatistics, 2002, *Parametric Survival Models for Interval-Censored Data with Time-Dependent Covariates.*

Pablo Bonangelino, Biostatistics, 2003, (Co-Advisor with Thomas Louis). *Maximum Efficiency Robust Tests for the Focused Clustering of Disease.*

SPONSORED RESEARCH (Present and Past, as Principal Investigator (P.I. or Co-P.I.)

Type 1 Diabetes TrialNet: 09/29/2001 - 08/31/2008, Coordinating Center, P.I., NIDDK Cooperative Agreement 1 U01 DK61055-01.

Statistical Methods for Cancer Clinical Trials: 9/97-8/2000, P.I., NCI Grant 2R01-CA-55098-04A2.

Epidemiology of Diabetes Intervention and Complications: 3/96 - 2/2006, P.I., Coordinating Center, NIDDK Contract N01-DK-6-2204, $22,238,005.

Diabetes Prevention Program - 7/94-6/2001, Co- P.I. (Dr. Raymond Bain, P.I.), Coordinating Center, NIDDK Cooperative Agreement No. 5-U01-DK48489.

Diabetes Control and Complications Trial: 2/82-2/98, P.I., Coordinating Center, NIDDK Contract N01-AM-2-2206B.

Statistical Methods for Chronic Disease Clinical Trials: 7/88-6/91, P.I., NIDDK Grant R01-DK35952.

Study of Angiotensin Converting Enzyme Inhibition in Diabetic Nephropathy: 12/86 - 9/92, (P.I. 1986-10/88; Co-P.I. 10/88 - 9/92) Biostatistical Coordinating Center, co-funded by Grant from E.R. Squibb and Sons, and NIDDK Grant R01-DK-39826.

Collaborative Study of the Treatment of Lactic Acidosis with Dichloroacetate: 4/86-3/92, Co-P.I. (Dr. Elizabeth Wright, P.I.), Data Coordinating Center, subcontract to NIDDK Grant R01-DK-35448 (Dr. Peter Stacpoole, P.I., University of Florida).

Lupus Nephritis Collaborative Study: 4/81-6/88, P.I., Biostatistical Coordinating Center, NIDDK Grant R01-AM27769-02.

Bile Acid Metabolism and Liver Injury In Gallstone Patients: 4/83-9/85, P.I., Biostatistical Support Unit, Consortium Agreement under NIADDK Grant R01-AM31461 (Dr. Alan F. Hofmann, University of California at San Diego, Principal Investigator).

New Drug Application for Ursodeoxycholic Acid: 2/84-2/86, P.I., Biostatistical Unit, contract from Interstate Drug Exchange in collaboration with Garvey Associates, Inc.

National Cooperative Gallstone Study: 9/73-1/84, (P.I. effective 9/80) Biostatistical Support Unit, subcontract to NIADDK Contract N01-AM-0-2205. (Dr. Leslie J. Schoenfield, P.I., Cedars Sinai Medical Center).

Others: Principal Investigator, contracts from other pharmaceutical companies for analyses of phase II and phase III clinical trials. Co-investigator for other NIH grants and contracts.

MEMBERSHIPS

American Statistical Association
Biometric Society
Institute of Mathematical Statistics
Royal Statistical Society
International Statistical Institute
International Chinese Statistical Association
Society for Clinical Trials
Society for Epidemiologic Research
International Society for Clinical Biostatistics
American Diabetes Association
    Professional Section
    Council on Epidemiology and Statistics
European Association for the Study of Diabetes
International Diabetes Epidemiology Group
Drug Information Association

HONORS

American Association of Publishers award for "The Outstanding Professional And Scholarly Title Of 2002 In Mathematics And Statistics" for the book co-authored with W. Rosenberger entitled *Randomization in Clinical Trials: Theory and Practice*, John Wiley and Sons, 2002.
President, Society for Clinical Trials, 2002-3
Joseph Ciminera Lecture, Merck and Company, 2002
John C. Forbes Graduate Student Honors Colloquium. Medical College of Virginia, 1995
Co-recipient, the Charles H. Best Medal for Distinguished Service in the Cause of Diabetes. Awarded to the Diabetes Control and Complications Trial Study Group (J. Lachin, Director, Coordinating Center). American Diabetes Association, 1994.
Elected Member, International Statistical Institute, 1993
Distinguished Graduate Award, Graduate School of Public Health, University of Pittsburgh, 1992
Delta Omega National Honor Society, 1991
Elected Fellow, Royal Statistical Society, 1991
Elected Fellow, American Statistical Association, 1989

ADVISORY COMMITTEES

Data and Safety Monitoring Board (member). Apnea Positive Pressure Long-term Efficacy Study (APPLES). National Heart, Lung and Blood Institute, 2003 - .

Data and Safety Monitoring Board (Vice-chair). Look AHEAD: Action for Health in Diabetes. National Institute of Diabetes, Digestive and Kidney Diseases, 2001 - .

Steering Committee (member). A Diabetes Outcomes Progression Trial (ADOPT), Glaxo SmithKline, 2000 - .

Data and Safety Monitoring Committee (member). Aspirin and Folate Prevention of Large Bowel Polyps. National Cancer Institute, 1997 - 2004.

Data Safety and Quality Monitoring Group (member). Diabetes Prevention Trial - Type I. National Institute of Diabetes, Digestive and Kidney Diseases, 1994 - 2001.

Data and Safety Monitoring Committee (member), Studies of Vesnarinone in Congestive Heart Failure. Otsuka Pharmaceuticals Co., 1987 - 1994.

Treatment Effects Monitoring Advisory Committee (chairman), Glaucoma Laser Trial, National Eye Institute, Coordinating Center - Johns Hopkins University, 1983 - 1995.

Policy-Advisory Board (member), Hypertension Prevention Trial, National Heart, Lung and Blood Institute, Coordinating Center - Johns Hopkins University, 1982-1986.

Operations Committee (member), Veterans Administration Cooperative Study Protocol No. 213, "Treatment of Mild Hypertension in the Aged. Anti-Hypertensive Effectiveness and Patients' Toleration of Different Regimens," 1981-1986.

Patient Safety Monitoring Committee (member), National Cooperative Dialysis Study, National Institute of Arthritis, Diabetes, Digestive and Kidney Diseases, Coordinating Center - Harvard University School of Public Health, 1979-1981.

Gastrointestinal Drugs Advisory Committee (member), Food and Drug Administration, 1978-1982; consultant, 1983 - 1984.

Services Research and Epidemiologic Studies Review Committee (member), National Institute of Mental Health, 1977-1980.

Consultant to various review committees of the NIH and the FDA.

OTHER PROFESSIONAL ACTIVITIES (partial list, see "Presentations" below)

Perspectives on the Biostatistical Sciences: A Symposium in Memory of Samuel W. Greenhouse.
June 11, 2001, National Institutes of Health.
Chair, Organizing Committee; member, Program Committee

International Biometric Society (Eastern North American Region)

Liaison Officer to the American Statistical Association, 1989-91.

Society for Clinical Trials

President (2002-3)
Board of Directors, member, 1982 - 1986.
Finance Committee, chairman, 1981 - 1984.
Program Committee, member, 1978, 79, 80, 95.
Workshop Sessions, chairman, 1979, 80.

Organizer and lecturer, Pre-Conference Short Course, "Some Considerations in Clinical Trial Design and Analysis", 1987.
Organizer and speaker, Workshop on "The Role of Randomization in Clinical Trials", 1986.
Meeting host and chairman of session on "Organization and Management of Coordinating Centers," 1978.

Controlled Clinical Trials. Editorial Board, 1986-1989.

Symposia and Conferences (Partial List)

Metabolic Imprinting and the Long-term Complications of Diabetes Mellitus: Bench to Bedside and Back. April 10-11, 2004. National Institutes of Health.

Perspectives on the Biostatistical Sciences: A Symposium in Memory of Samuel W. Greenhouse. June 11, 2001, National Institutes of Health.

American Diabetes Association Consensus Development Conference: C-Peptide as an Endpoint in Type 1 Diabetes Intervention Trials. Chicago, October 21-2, 2001.

Workshop on Future Directions in Prevention of Type 1 Diabetes, Miami, January 9-10, 2000. Invited Speaker.

American Diabetes Association Workgroup: Implications of the United Kingdom Prospective Diabetes Study, 1998.

NIH Workshop: Research Needs for the Design and Analysis of Surrogate Endpoints in Clinical Trials, Potomac, MD, 1998. Invited speaker.

American Diabetes Association Research Symposium on Prevention of Type I Diabetes in the General Population. Estes Park, Colorado, September 27-29, 1996. Invited speaker.

Harvard University Schering-Plough Workshop on Flexible Strategies for Clinical Trials. Boston, May 30-31, 1996. Invited speaker.

John C. Forbes Graduate Student Honors Colloquium. Medical College of Virginia, Virginia Commonwealth University, April 19-20, 1995. Distinguished guest lecturer.

International Clinical Epidemiology Networks (INCLEN) Ninth Annual Meeting, Rockefeller Foundation, Mombassa, Kenya, January 21-25, 1991. Invited speaker.

American Diabetes Association Conference on Peripheral Neuropathy in Diabetes. San Antonio, February 8-9, 1988. Invited speaker.

NIH Consensus Conference: Diet and Exercise in Noninsulin Dependent Diabetes Mellitus. December 8-10, 1986. Member, Consensus Panel.

NIH Centennial Initiative: Kidney Disease of Diabetes Mellitus. November 3-4, 1986. Member, Committee on Clinical Research.

Fifth Advanced Course in Gastroenterology, the Italian Society for Gastroenterology: Cirrhosis of the Liver, Methods and Fields of Research. San Miniato, Italy, October 28 - November 2, 1985. Invited speaker (see publication #40).

Biostatistics Symposium. Diabetes Research Center, University of Washington, Seattle, September 12, 1985. Invited speaker.

Symposium: Update on Treatment of Gallstones: Role of Ursodeoxycholic Acid. Scottsdale, Arizona, Nov. 29 - Dec. 2, 1984. Invited speaker.

Eighth International Bile Acids Meeting: Recent Advances in Bile Acids Research. Cortina D'Ampezzo, Italy, March 22-24, 1984.

Conference on Insulin Pump Therapy in Diabetes: Multi-Center Study of Effect on Microvascular Disease. The Kroc Foundation, Santa Ynez Valley, California, March 21-25, 1983. Invited speaker.

Conference on Changing Concepts in Bioavailability and Clinical Trials. University of Maryland School of Pharmacy, Baltimore, October 1982. Moderator, Session on Quality Assurance: Concepts and Procedures for Clinical Trials.

International Conference on Hepatotoxicity Due to Drugs and Chemicals. John E. Fogarty International Center for Advanced Study in the Health Sciences, NIH, Bethesda, Maryland, November 14-16, 1977. (See Publication #16.)

First Advanced Course in Gastroenterology, The Italian Society for Gastroenterology: The randomized Controlled Trial. Villa Monastero, Varenna, Italy, September 28 - October 2, 1975. (See book below.)

BOOKS

Rosenberger, W. and Lachin J.M. Randomization in Clinical Trials: Theory and Practice. John Wiley and Sons, 2002. (ISBN: 0-471-23626-8, 259 pages)

Lachin, J.M. Biostatistical Methods: The Assessment of Relative Risks. John Wiley and Sons, 2000. (ISBN: 0-471-36996-9; 541 pages)

Tygstrup N, Lachin JM, Juhl E. (editors). The Randomized Clinical Trial and Therapeutic Decisions. Marcel-Dekker, 1982. (ISBN: 0-8247-1856-9; 296 pages)

Lectures from the First Advanced Course in Gastroenterology. Dr. Lachin's chapters are entitled:

Statistical elements of the randomized clinical trial; pp. 77-102.
Statistical inference in clinical trials; pp 117-143.
Statistical analysis of the clinical trial; pp 155-194.
The execution of a protocol; pp. 219-234.

NAMED AUTHOR PUBLICATIONS (refereed designated by *)

*94. Lachin JM, Cleary PA, Crofford C, Genuth S, Nathan D, Clark C, Ferris F, Siebert C for the DCCT Research Group. Early termination of the Diabetes Control and Complications Trial. In *Data Monitoring in Clinical Trials: A Case Studies Approach*, DL DeMets, CD Furberg, LM Friedman (Eds). Springer, New York, New York..

*93. Lachin JM. Maximum Information Designs. *Clinical Trials*, 2, 453-464, 2005.

*92. Lachin JM. A review of methods for futility stopping based on conditional power. *Statistics in Medicine*, 24, 2747-2764, 2005.

91. Greenhouse JB and Lachin JM. Greenhouse, Samuel W. In *Encyclopedia of Biostatistics*, Second Edition. P. Armitage and T. Colton (Eds.), 2251-3. John Wiley & Sons, Ltd. Chichester, 2005

*90. Lachin JM. The role of measurement reliability in clinical trials. *Clinical Trials*, 1, 553 – 566, 2004.

*89. Dickersin K, Davis BR, Dixon DO, George SL, Hawkins BS, Lachin JM, Peduzzi P, Pocock S. The Society for Clinical Trials supports United States legislation mandating trials registration. *Clinical Trials*, 1, 417-420, 2004.

*88. Lachin JM. Conflicts of interest in data monitoring of industry versus publicly financed clinical trials. *Statistics in Medicine*, 23, 1519-1521, 2004.

*87. Palmer JP, Fleming GA, Greenbaum CJ, Herold KC, Jansa LD, Kolb H, Lachin JM, Polonsky KS, Pozzilli P, Skyler JS, Steffes MW. C-peptide is the appropriate outcome measure for type 1 diabetes clinical trials to preserve beta-cell function: report of an ADA workshop, 21-22 October 2001. *Diabetes*, 53, 250-64, 2004. Erratum: *Diabetes*, 53, 1934, 2004.

* 86. Lachin JM, Greenhouse SW, Bautista OM. Group sequential large sample T^2-like χ^2 tests for multivariate observations. *Statistics in Medicine*, 22, 3357-3368, 2003.

* 85. Lan KKG, Lachin JM, and Bautista OM. Over-ruling a group sequential boundary - a stopping rule versus a guideline. *Statistics in Medicine*, 22, 3347-3355, 2003.

* 84. Lachin, JM. A tribute to Samuel W. Greenhouse. *Statistics in Medicine*, 22, 3267-3276, 2003.

* 83. Hu MX and Lachin, JM. Corrections for Bias in Maximum Likelihood Parameter Estimates Due to Nuisance Parameters. *Communications in Statistics*, 32, 619-639, 2003.

* 82. Viberti G, Kahn SE, Greene DA, Herman WH, Zinman B, Holman RR, Haffner SM, Levy D, Lachin JM, Berry RA, Heise MA, Jones NP, Freed MI. A diabetes outcome progression trial (ADOPT): an international multicenter study of the comparative efficacy of rosiglitazone, glyburide, and metformin in recently diagnosed type 2 diabetes. *Diabetes Care*, 25, 1737-43, 2002.

* 81. Hu M and Lachin JM. Application of robust estimating equations to the analysis of quantitative longitudinal data, *Statistics in Medicine*, 20, 3411-3428, 2001.

80. Lachin JM and Greenhouse, J. Sam Greenhouse: 1918-2000. AmStat News, September, 4-5, 2001.

* 79. Bautista OM, Bain RP and Lachin JM. A flexible stochastic curtailing procedure for the log-rank test. *Controlled Clinical Trials*, 21, 428-439, 2000.

* 78. Lachin JM. Statistical Considerations in the Intent-to-treat Principle. *Controlled Clinical Trials*, 21, 167-189, 2000.

77. Hu, MX and Lachin, JM. Likelihood-based Approaches for Handling Nuisance Parameters. ASA *Proceedings of the Section on Bayesian Statistical Science*, 1999, 108-113.

* 76. Lachin JM. Worst-rank score analysis with informatively missing observations in clinical trials. *Controlled Clinical Trials*, 20, 408-422, 1999.

* 75. Monnier VM, Bautista O, Kenny D, Sell DR, Fogarty J, Dahms W, Cleary P, Lachin J, Genuth S and the DCCT Skin Collagen Ancillary Study Group. Skin collagen glycation, glycoxidation, and crosslinking are lower in subjects with long-term intensive versus conventional therapy of type I diabetes. *Diabetes*, 48, 870-880, 1999.

74. Lachin JM. Sample size determination. In *Encyclopedia of Biostatistics*, P. Armitage and T. Colton (Eds.), Wiley, New York, 3892-3903, 1998.

* 73. Younes N and Lachin JM. Link-based models for survival data with interval and continuous time censoring. *Biometrics*, 53, 1199-1211, 1997.

* 72. Lachin JM. Group sequential monitoring of distribution-free analyses of repeated measures. *Statistics in Medicine*, 16, 653-668, 1997.

* 71. Lachin JM. Distribution-Free marginal analysis of repeated measures. *Drug Information Journal*, 30, 1017-1028, 1996.

* 70. Nicolucci A, Carinci JG, Graepel TC, Hohman TC, Ferris F, and Lachin JM. The efficacy of Tolrestat in the treatment of diabetic peripheral neuropathy: a meta-analysis of individual patient data. *Diabetes Care*, 19, 1091-1096, 1996.

* 69. Lan KKG and Lachin JM. Martingales without tears. *Lifetime Data Analysis*, 1, 361-375, 1995.

* 68. Rosenberger WF, Lachin JM, and Bain RP. Nonparametric test of stochastic ordering for multiple longitudinal measures. *Journal of Biopharmaceutical Statistics*, 5, 235-243,1995.

* 67. Lan KKG, Rosenberger WF and Lachin JM. Sequential monitoring of survival data with the Wilcoxon statistic. *Biometrics*, 51,1175-1183,1995.

66. Lachin JM and Bautista OM. Stratified-adjusted versus unstratified assessment of sample size and power for analyses of proportions. *Recent Advances in Clinical Trial Design and Analysis*, P.F. Thall (Ed.), Kluwer, Boston, 203-223,1995.

65. Lachin JM. Discussion: Adaptive designs in clinical trials: the Lilly experience. *Biopharmaceutical Report*, 3: 6,1995.

* 64. Stacpoole PW, Wright EC, Baumgartner TG, Bersin RM, Buchalter S, Curry SH, Duncan C, Harman EM, Henderson GN, Jenkinson S, Lachin JM, Lorenz A, Schneider SH, Siegel JH, Summer WR, Thompson D, Wolfe CL, Zorovich B, and the DCA Lactic Acidosis Study Group. Natural history and course of acquired lactic acidosis in adults. *The American Journal of Medicine*, 97:47-54,1994.

* 63. Rosenberger WF and Lachin JM. The use of response-adaptive designs in clinical trials. *Controlled Clinical Trials*, 14, 471-484, 1993.

* 62. Lan KKG, Rosenberger WF, Lachin JM. Use of spending functions for occasional or continuous monitoring of data in clinical trials. *Statistics in Medicine*, 12, 2219-2231, 1993.

* 61. Palesch YY and Lachin JM. Asymptotically distribution-free multivariate rank tests for multiple samples with partially incomplete observations. *Statistica Sinica*, 4, 373-387, 1994.

* 60. Stacpoole, PW, Wright EC, Baumgartner TG, Bersin RM, Buchalter S, Curry SH, Duncan, CA, Harman EM, Henderson GN, Jenkinson S, Lachin JM, Lorenz A, Schneider SH, Siegel JH, Summer WR, Thompson D, Wolfe CL, Zorovich B, and the Dichloroacetate-Lactic Acidosis Study Group. A controlled clinical trial of dichloroacetate for treatment of lactic acidosis in adults. *The New England Journal of Medicine*, 327, 1564-1569, 1992.

* 59. Su JQ and Lachin JM. Group sequential distribution-free methods for the analysis of multivariate observations. *Biometrics*, 48, 1033-1042, 1992.

* 58. Lachin JM. Power and sample size evaluation for the McNemar test with application to matched case-control studies. *Statistics in Medicine*, 11, 1239-1251, 1992.

* 57. Lachin JM. Some large sample distribution-free estimators and tests for multivariate partially incomplete data from two populations. *Statistics in Medicine*, 11, 1151-1170, 1992.

* 56. Lewis EJ, Hunsicker LG, Lan S, Rohde RD, Lachin JM and the Lupus Nephritis Collaborative Study Group. A controlled trial of plasmapheresis therapy in severe lupus nephritis. *The New England Journal of Medicine*, 326, 1373-1379, 1992.

* 55. Lachin JM and Lan SL. Statistical considerations in the termination of a clinical trial with no treatment group difference: The Lupus Nephritis Collaborative Study. *Controlled Clinical Trials*, 13, 62-79, 1992.

* 54. Levey AS, Lan SP, Corwin HL, Kasinath BS, Lachin JM, Neilson EG, Hunsicker LG, Lewis EJ and the Lupus Nephritis Collaborative Study Group. Progression and remission

of renal disease in the Lupus Nephritis Collaborative Study. Results of treatment with prednisone and short-term oral cyclophosphamide. *Annals of Internal Medicine*, 1992, 116, 114-123.

* 53. Lan KKG and Lachin JM. Group sequential logrank tests in a maximum duration trial. *Biometrics*, 1990, 46, 759-770.

* 52. Wei LJ, Su JQ and Lachin JM. Interim analyses with repeated measurements in a sequential clinical trial. *Biometrika*, 1990, 77, 359-64.

51. Clough JD, Lewis EJ, Lachin JM and the Lupus Nephritis Collaborative Study Group (LNCSG) (1990). Treatment protocols of the Lupus Nephritis Collaborative Study of plasmapheresis in severe nephritis. In: *Apheresis*, Ed. Alan R. Liss, Inc., New York, pp. 301-307.

*50. Lachin JM, Matts JP and Wei LJ. Response to Letter to the Editor. Permutation tests following restricted randomization procedures. *Controlled Clinical Trials*, 1990, 11, 150-152.

* 49. Lachin JM. Properties of randomization in clinical trials: Foreword. *Controlled Clinical Trials*, 1988, 9, 287-288.

* 48. Lachin JM. Statistical properties of randomization in clinical trials. *Controlled Clinical Trials*, 1988, 9, 289-311.

* 47. Lachin JM. Properties of simple randomization in clinical trials. *Controlled Clinical Trials*, 1988, 9, 312-326.

* 46. Matts JP and Lachin JM. Properties of permuted-block randomization in clinical trials. *Controlled Clinical Trials*, 1988, 9, 327-344.

* 45. Wei LJ and Lachin JM. Properties of the Urn randomization in clinical trials. *Controlled Clinical Trials*, 1988, 9, 345-364.

* 44. Lachin JM, Matts JP and Wei LJ. Randomization in clinical trials: Conclusions and recommendations. *Controlled Clinical Trials*, 1988, 9, 365-374.

* 43. Lachin JM and Wei LJ. Estimators and tests in the analysis of nonindependent 2 x 2 tables with partially missing observations. *Biometrics*, 1988, 44, 513-528.

* 42. Thall PF and Lachin JM. Analysis of recurrent events: Nonparametric methods for random interval count data. *Journal of the American Statistical Association*, 1988, 83, 339-347.

* 41. Canner PL, Gatewood LC, White C, Lachin JM and Schoenfield LJ. External monitoring of a data coordinating center: Experience of the National Cooperative Gallstone Study. *Controlled Clinical Trials*, 1987, 8, 1-11.

* 40. Halperin M, Gilbert PR and Lachin JM. Distribution-free confidence intervals for $Pr(X_1 < X_2)$. *Biometrics*, 1987, 43, 71-80.

39. Lachin JM and Wright EC. Statistical considerations in the design and analysis of clinical trials of causal therapy in cirrhosis of the liver. In Tygstrup N and Orlandi F. (eds.), *Cirrhosis of the Liver: Methods and Fields of Research*, Elsevier, Amsterdam, 1987, 461-482.

* 38. Lachin JM and Foulkes MA. Evaluation of sample size and power for analyses of survival with allowance for non-uniform patient entry, losses to follow-up, non-compliance and stratification. *Biometrics*, 1986, 42, 507-519.

* 37. Thall PF and Lachin JM. Assessment of stratum-covariate interactions in Cox's proportional hazards regression model. *Statistics in Medicine*, 1986, 5, 73-83.

* 36. Stellard F, Klein PD, Hofmann A and Lachin JM. Mass spectrometry identification of biliary bile acids in bile from gallstone patients before and during treatment with chenodeoxycholic acid. *Journal of Laboratory and Clinical Medicine*, 1985, 105, 504-513.

* 35. Thistle JL, Cleary PA, Lachin JM, Tyor MP, Hersh T, and the NCGS Group. The natural history of untreated cholelithiasis during the National Cooperative Gallstone Study (NCGS).*Annals of Internal Medicine*, 1984, 100, 171-175.

* 34. Wei LJ and Lachin JM. Two-sample asymptotically distribution-free tests for incomplete multivariate observations. *Journal of the American Statistical Association*, 1984, 79, 653-661.

* 33. Marks J, Croke G, Gochman N, Hofmann AF, Lachin JM, Schoenfield LJ and Tyor MP, and the NCGS Group. Major issues in the organization and implementation of the National Cooperative Gallstone Study (NCGS). *Controlled Clinical Trials*, 1984, 5, 1-12.

* 32. Grundy SM, Lan S, Lachin JM, the Steering Committee and the NCGS Group. The effects of chenodiol on biliary lipids and their association with gallstone dissolution in the National Cooperative Gallstone Study (NCGS). *Journal of Clinical Investigation*, 1984, 73, 1156-1166.

* 31. Hofmann AF and Lachin JM. Biliary bile acid composition and cholesterol saturation. *Gastroenterology*, 1983, 84, 1075-1077.

* 30. Schoenfield LJ, Grundy SM, Hofmann AF, Lachin JM, Thistle JL and Tyor MP, for the NCGS. The National Cooperative Gallstone Study viewed by its investigators. *Gastroenterology*, 1983, 84, 644-648.

* 29. Habig RL, Thomas P, Lippel K, Anderson D and Lachin JM. Central laboratory quality control in the National Cooperative Gallstone Study. *Controlled Clinical Trials*, 1983, 4, 101-123.

* 28. Lachin JM, Schoenfield LJ, the Steering Committee and the NCGS Group. Effects of dose relative to body weight in the National Cooperative Gallstone Study, a fixed-dose clinical trial. *Controlled Clinical Trials*, 1983, 4, 125-131.

* 27. Phillips MJ, Fisher RL, Anderson DW, Lan S, Lachin JM, Boyer JL, and the Steering Committee for the NCGS Group. Ultrastructural evidence of intrahepatic cholestasis before

and after chenodeoxycholic acid (CDCA) therapy in patients with cholelithiasis: The National Cooperative Gallstone Study (NCGS). *Hepatology*, 1983, 3, 209-220.

* 26. Hofmann AF, Grundy SM, Lachin JM, Lan, SP, et al. Pretreatment biliary lipid composition in white patients with radiolucent gallstones in the National Cooperative Gallstone Study. *Gastroenterology*, 1982, 83, 738-752.

* 25. Fisher RL, Anderson DW, Boyer JL, Ishak K, Klatskin G, Lachin JM, and Phillips MJ, and the Steering Committee for the NCGS Group. A prospective morphologic evaluation of hepatic toxicity of chenodeoxycholic acid in patients with cholelithiasis: The National Cooperative Gallstone Study. *Hepatology*, 1982, 2, 187-201.

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