

John M. Lachin, III, Sc.D.

Research Professor of Biostatistics and Bioinformatics, and of Statistics
Department of Biostatistics and Bioinformatics, Milken Institute School of Public Health.
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1) **Personal Data**

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2) **Education and Training**

a) Undergraduate Education

B.S., Psychology (Experimental), Tulane University, 6/65

b) Graduate Education

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

3) **Professional Employment**

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.

1973-1977 Assistant Research Professor of Statistics, The Biostatistics Center, GWU

1977-1982 Associate Research Professor of Statistics, The Biostatistics Center, GWU

1982-1984 Research Professor of Statistics, The Biostatistics Center, GWU

1984-2002 Professor of Statistics (tenure 1987), The Biostatistics Center and Department of Statistics, GWU

2002-2014 Professor of Biostatistics and Epidemiology, and of Statistics (joint), with tenure, The Biostatistics Center, Department of Epidemiology and Biostatistics, and Department of Statistics.

2014 - 2019 Research Professor of Biostatistics and Epidemiology, and of Statistics (joint), The Biostatistics Center, Department of Epidemiology and Biostatistics,

2019 - Research Professor of Biostatistics and Bioinformatics, and of Statistics (joint), The Biostatistics Center, Department of Biostatistics and Bioinformatics. GWU. Milken Institute School of Public Health.

1980-1985 Assistant Director, The Biostatistics Center, GWU

1985-1988 Co-Director, The Biostatistics Center, GWU

1988-2000 Director, The Biostatistics Center, GWU

2001-2010 Co-Director, The Biostatistics Center, GWU

2010-2012 Interim Director, The Biostatistics Center, GWU.

Teaching Responsibilities:

- Currently not teaching. Taught 1-2 graduate courses per year during 1979-2006. See Section 13 for list of courses taught.

Administrative Responsibilities

- Former Director of the Biostatistics Center, a research facility of the University with 115 employees and total funding of \$60 million annually.
- Program Director for Biostatistics and Chair of the Executive Committee for the graduate degree program in Biostatistics and Epidemiology, jointly administered by the Department of Epidemiology and Biostatistics and the Department of Statistics, 1995 - 2004.

Research Responsibilities (current only)

- Formerly Principal Investigator and Director (1982-2020), now Co-investigator, of the Data Coordinating Center for the study of the *Epidemiology of Diabetes Intervention and Complications* (EDIC), a long-term epidemiologic study of 1441 subjects with Type 1 diabetes originally enrolled in the *Diabetes Control and Complications Trial* (DCCT/EDIC), funded by the National Institute of Diabetes, Digestive and Kidney Diseases. Initiated in 1982. Current funding to July, 2027. Co-Principal Investigators Barbara Braffett and Ionut Bebu
- Principal Investigator and Director of the Coordinating Center for the *Glycemia Reduction Approaches for Diabetes: A Comparative Effectiveness Study* (GRADE). A long-term randomized trial, funded by the National Institute of Diabetes, Digestive and Kidney Diseases. Initiated in 2010 with a planning grant. Current funding to 2023 (no-cost extension to ~July, 2024).

4) Honors and Awards:

- Top 10 Clinical Research Achievement Award. Clinical Research Forum. April 2023. For the GRADE Study. John Lachin Contact Principal Investigator.
- Distinguished Alumni Award for Research. University of Pittsburgh School of Public Health, December 2022
- Lifetime Achievement Award, 25th Anniversary Celebration of the George Washington University Milken Institute School of Public Health, October, 2022.

- Co-recipient with Barbara Braffett and Ionut Bebu, 2020 American Diabetes Association Michaela Modan Memorial Award, presented by the Public Health & Epidemiology Interest Group.
- Second Annual Robert F. Woolson Lecture, Department of Biostatistics, College of Public Health, University of Iowa, 2011.
- 2010 Oscar and Shoshana Trachtenberg Prize for Scholarship, The George Washington University, May, 2010.
- 2010 Distinguished Researcher Award, The George Washington University Medical Center, March, 2010.
- Inaugural Fellow, Society for Clinical Trials, 2006
- 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
- The Charles H. Best Medal for Distinguished Service in the Cause of Diabetes. Awarded to the Diabetes Control and Complications Trial Research Group (J. Lachin, Principal Investigator and Director, Data 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

5) Current Grant Support

Total funding: \$471,569,626 since 1985, no records prior to 1985.

- *Glycemia Reduction Approaches for Diabetes Effectiveness: A Comparative Effectiveness Study (GRADE)* 07/2017 – 07/2022, P.I., Coordinating Center, NIDDK Cooperative Agreement 1 U01 DK-098246, \$115,406,642.
Main Objective: To compare the effectiveness and safety of 4 commonly used anti-hyperglycemic agents, when added to metformin, for maintenance of metabolic homeostatis in 5000 recently diagnosed participants with type II diabetes over a minimum of 5 years of follow-up.
- *Epidemiology of Diabetes Intervention and Complications:* 7/2017 - 04/2022, P.I., Coordinating Center, NIDDK Grant U01-DK094176-02, \$15,998,739. Current Co-P.I.s Barbara Braffett and Ionut Bebu

Main Objective: To assess the role of the level of glycemia on the risk of micro and macro-vascular complications, cardiovascular disease and mortality in a cohort of 1200 survivors of a cohort of 1441 participants originally enrolled into the Diabetes Control and Complications Trial (1983-1993).

6) **Grants Concluded as Principal Investigator (P.I. or Co-P.I.)**

- *Glycemia Reduction Approaches for Diabetes Effectiveness: A Comparative Effectiveness Study (GRADE)*
 - 09/2012 – 06/2017, P.I., Coordinating Center, NIDDK Cooperative Agreement 1 U01 DK-098246, \$134,184,766.
 - 09/2010 - 08/2012, P.I. Statistical Center, Subcontract from Mass. General Hospital under grant U34-DK-088043 from NIDDK. \$437,178.
- *Epidemiology of Diabetes Intervention and Complications:*
 - 8/2012 - 06/2017, P.I., Coordinating Center, NIDDK Grant U01-DK094176-01, \$14,000,778.
 - 4/1996 – 8/2012, P.I., Coordinating Center, NIDDK Contract N01-DK-6-2204, \$44,401,926
- *Type 1 Diabetes TrialNet:* 09/29/2001 - 06/30/2010, Coordinating Center (2001-2008), Analysis Center (2008-2010), P.I., NIDDK Cooperative Agreement 1 U01 DK61055-01. \$93,180,850.
- *Diabetes Prevention Program - 7/94-6/2003, Co-P.I. 1994-1996 (Dr. Raymond Bain, Co-P.I.) and 1999-2002 (Dr. Sarah Fowler, Co-P.I.), Coordinating Center, NIDDK Cooperative Agreement No. 5-U01-DK48489. \$23,224,129 during years as Co-PI.*
- *Statistical Methods for Cancer Clinical Trials:* 9/97-8/2000, P.I., NCI Grant 2R01-CA-55098-04A2. \$563,240.
- *Diabetes Control and Complications Trial:* 2/82-2/98, P.I., Coordinating Center, NIDDK Contract N01-AM-2-2206B. \$29,448,712
- *Statistical Methods for Chronic Disease Clinical Trials:* 7/88-6/91, P.I., NIDDK Grant R01- DK35952. \$110,461.
- *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. \$304,865.
- *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. \$307,340.
- *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).

- *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.

7) Publications (5 books, 399 refereed papers, 30 non-refereed papers/chapters)

Bibliometrics

Overall summary

	Refereed	Non-refereed	Total
Statistical	77	18	95
Medical	322	12	334
Total	399	30	429

5 books

Per Google Scholar as of February 16, 2024: H-Index is 101, i10 Index is 233, with 103,576 Citations.

Per a 2020 report from the Meta-Research Innovation Center at Stanford University (METRICS), among 8 million authors world-wide since 1960, the number of citations to Dr. Lachin’s work was ranked at the 99.94th percentile over his career, or in the top 6/100th of a percent, in the fields of Endocrinology & Metabolism, Clinical Medicine, and Statistics & Probability.

Per Exaly Search Engine 02/24/2023

Most cited author in *Contemporary Clinical Trials* (1981, 1988)

Most cited paper in *Contemporary Clinical Trials* (1981, 1988)

Most published author in *Contemporary Clinical Trials* (1988, Lifetime)

Most cited author in *The New England Journal of Medicine* (2002)

Most cited paper in *The New England Journal of Medicine* (2002, 2015)

Most cited author in *Gastroenterology* (1982)

2nd most published author in *Diabetes Care* (2019)

3rd most published author in *Diabetes Care* (2017, 2018)

a) Articles in Refereed Journals (397 total)

Methodological (77 papers)

Sandoval GJ, Bebu I, Lachin JM. Cost-efficient multiply matched case-control study designs. *Am J Epidemiol* 2022, 191(11):1970-74

Sandoval GJ, Bebu I, Lachin JM. Cost-efficient clinical studies with continuous time survival outcomes. *Statistics in Medicine*. 2021;40:3682–3694.

<https://doi.org/10.1002/sim.8992>

- Lachin JM. Worst-Rank Score Methods—A Nonparametric Approach to Informatively Missing Data. *JAMA*. 2020 Oct 27;324(16):1670-1. doi:10.1001/jama.2020.7709
- Lachin JM. Nonparametric Statistical Analysis. *JAMA*. 2020;323(20):2080–2081. doi:10.1001/jama.2020.5874
- Bebu I, Braffett BH, Lachin JM. The minimum intensity of a mixed exposure that increases the risk of an outcome. *Statistics in Medicine*. 2020;1–9. <https://doi.org/10.1002/sim.8705>
- Lachin JM, Bebu I, Braffett B. Models to assess the association of a semi-quantitative exposure with outcomes. *Am J Epidemiol* 2020, 189(12): 1573–1582, <https://doi.org/10.1093/aje/kwaa071>
- Lachin JM, Nathan DM, Zinman B, Bebu I. Comment on Miller and Orchard: Understanding Metabolic Memory: A Tale of Two Studies. *Diabetes* 2020;69:291-299. *Diabetes*. 2020;69(7):e7-e8. doi:10.2337/db20-0311
- Lachin JM, Bebu I. Closed testing of each group versus the others combined in a multiple group analysis. *Clinical Trials* 2020, Vol. 17(1) 77–86 DOI: 10.1177/1740774519879932
- Lachin JM, Bebu I, Larsen MD, Younes N (2019) Closed testing using surrogate hypotheses with restricted alternatives. *PLoS ONE* 14(7):e0219520. <https://doi.org/10.1371/journal.pone.0219520>
- Bebu I, Lachin JM. Properties of composite time to first event versus joint marginal analyses of multiple outcomes. *Statistics in Medicine*. 2018; 37:3918-30. <https://doi.org/10.1002/sim.7849>
- Bebu I, Lachin JM. Optimal screening schedules for disease progression with application to diabetic retinopathy. *Biostatistics*. 2018;19(1):1-13. doi.org/10.1093/biostatistics/kxx009.
- Dickersin K, Dixon D, Ferris F, Goldberg J, Kimmel S, and Lachin JM. University of Pennsylvania 10th annual conference on statistical issues in clinical trials: Current issues regarding data and safety monitoring committees in clinical trials (afternoon panel session). *Clinical Trials*, 2017, 15(4): 366 – 385. doi.org/10.1177/1740774518781849
- Bebu I, Mathew T and Lachin JM. Probabilistic measures of cost-effectiveness. *Statistics in Medicine*. 2016, 35(22): 3976-3986. DOI 10.1002/sim.6987.
- Bebu I and Lachin JM. Large sample inference for a win ratio analysis of a composite outcome based on prioritized components. *Biostatistics*, 2016, 17(1):178-87.
- Lachin JM. Fallacies of last observation carried forward analyses. *Clinical Trials*, 2016, 13(2), 161-68 doi: 10.1177/1740774515602688. PMC4785044.
- Lachin JM and Bebu I. Application of the Wei–Lachin multivariate one-directional test to multiple event-time outcomes. *Clinical Trials*, 2015, 12: 627-33.
- Ma, Y., Lai, Y., Lachin, J.M. Identifying change points in a covariate effect on time-to-event analysis with reduced isotonic regression. (2014) *PLoS ONE*, 9 (12), art. no. A506.
- Lachin JM. Applications of the Wei-Lachin multivariate one-sided test for multiple outcomes on possibly different scales *PLoS ONE*, 2014; 9(10): e108784.

- Sun W, Larsen MD, Lachin JM. Methods for a longitudinal quantitative outcome with a multivariate Gaussian distribution multi-dimensionally censored by therapeutic intervention (2014) *Statistics in Medicine*, 33:. 1288-1306.
- Lachin JM. Sample size and power for a logrank test and Cox proportional hazards model with multiple groups and strata, or a quantitative covariate with multiple strata. *Statistics in Medicine* 2013; 32:4413–4425. DOI: 10.1002/sim.5839.
- Lachin JM. Reminiscences of Jerry Cornfield. *Clinical Trials* 2013; 10:337-339. DOI: 10.1177/1740774513477932.
- Lachin JM. Power of the Mantel–Haenszel and other tests for discrete or grouped time-to-event data under a chained binomial model. *Statistics in Medicine* 2013; 32:220–229. DOI: 10.1002/sim.5480.
- Lachin JM. Power and sample size evaluation for the Cochran-Mantel-Haenszel mean score (Wilcoxon rank sum) test and the Cochran-Armitage test for trend. *Statistics in Medicine* 2011; 30:3057-66. DOI: 10.1002/sim.4330.
- Lachin JM. Futility interim monitoring with control of type I and II error probabilities using the interim Z-value or confidence limit. *Clinical Trials*, 2009, 6:565-573.
- Lachin JM. 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* 2008; 27:2509–2523. Correction. *Statistics in Medicine*. 2018;1–2.
- Lachin JM, Younes N. A composite design for transition from a preliminary to a full-scale study. *Statistics in Medicine*. 2007; 26:5014-32.
- Sparling YH, Younes N, Lachin JM, and Bautista OM. Parametric survival models for interval-censored data with time-dependent covariates. *Biostatistics* 7, 599-614, 2006.
- Lachin JM. Operating characteristics of sample size re-estimation with futility stopping based on conditional power. *Statistics in Medicine*, 25, 3348-65, 2006.
- Lachin JM. Maximum Information Designs. *Clinical Trials*, 2, 453-464, 2005.
- Lachin JM. A review of methods for futility stopping based on conditional power. *Statistics in Medicine*, 24, 2747-2764, 2005.
- Lachin JM. The role of measurement reliability in clinical trials. *Clinical Trials*, 1, 553 – 566, 2004.
- 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.
- Lachin JM. Conflicts of interest in data monitoring of industry versus publicly financed clinical trials. *Statistics in Medicine*, 23, 1519-1521, 2004.
- 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.
- 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.
- Lachin, JM. A tribute to Samuel W. Greenhouse. *Statistics in Medicine*, 22, 3267-3276, 2003.

- Hu MX and Lachin, JM. Corrections for Bias in Maximum Likelihood Parameter Estimates Due to Nuisance Parameters. *Communications in Statistics*, 32, 619-639, 2003.
- Hu M and Lachin JM. Application of robust estimating equations to the analysis of quantitative longitudinal data, *Statistics in Medicine*, 20, 3411-3428, 2001.
- Bautista OM, Bain RP and Lachin JM. A flexible stochastic curtailing procedure for the log-rank test. *Controlled Clinical Trials*, 21, 428-439, 2000.
- Lachin JM. Statistical Considerations in the Intent-to-treat Principle. *Controlled Clinical Trials*, 21, 167-189, 2000.
- Lachin JM. Worst-rank score analysis with informatively missing observations in clinical trials. *Controlled Clinical Trials*, 20, 408-422, 1999.
- Younes N and Lachin JM. Link-based models for survival data with interval and continuous time censoring. *Biometrics*, 53, 1199-1211, 1997.
- Lachin JM. Group sequential monitoring of distribution-free analyses of repeated measures. *Statistics in Medicine*, 16, 653-668, 1997.
- Lachin JM. Distribution-Free marginal analysis of repeated measures. *Drug Information Journal*, 30, 1017-1028, 1996.
- Lan KKG and Lachin JM. Martingales without tears. *Lifetime Data Analysis*, 1, 361-375, 1995.
- Rosenberger WF, Lachin JM, and Bain RP. Nonparametric test of stochastic ordering for multiple longitudinal measures. *Journal of Biopharmaceutical Statistics*, 5, 235-243, 1995.
- Lan KKG, Rosenberger WF and Lachin JM. Sequential monitoring of survival data with the Wilcoxon statistic. *Biometrics*, 51, 1175-1183, 1995.
- Rosenberger WF and Lachin JM. The use of response-adaptive designs in clinical trials. *Controlled Clinical Trials*, 14, 471-484, 1993.
- 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.
- Palesch YY and Lachin JM. Asymptotically distribution-free multivariate rank tests for multiple samples with partially incomplete observations. *Statistica Sinica*, 4, 373-387, 1994.
- Su JQ and Lachin JM. Group sequential distribution-free methods for the analysis of multivariate observations. *Biometrics*, 48, 1033-1042, 1992.
- 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.
- Lachin JM, Lan SP and the Lupus Nephritis Collaborative Study Group. Termination of a clinical trial with no treatment group difference: The Lupus Nephritis Collaborative Study. *Controlled Clinical Trials*, 1992, 13, 62-79
- 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.

- Lan KKG and Lachin JM. Group sequential logrank tests in a maximum duration trial. *Biometrics*, 1990, 46, 759-770.
- Wei LJ, Su JQ and Lachin JM. Interim analyses with repeated measurements in a sequential clinical trial. *Biometrika*, 1990, 77, 359-64.
- Colton T, Greenhouse SW, Zelen M, Gehan EA, DeMets D, Ware JH, Gordon T, Lachin JM, Wittes J. Remembrances of Max Halperin. *Statistics In Medicine*, 1990, 9: 863-870 (1990). <https://doi.org/10.1002/sim.4780090802>
- Lachin J, Gordon T, Greenhouse S, Lan KK, Wittes J. In memoriam: Max Halperin (1917-1988). *Controlled Clinical Trials*. 1988 9:170-172. DOI: 10.1016/0197-2456(88)90041-4. PMID: 3293910.
- Lachin JM. Properties of randomization in clinical trials: Foreword. *Controlled Clinical Trials*, 1988, 9, 287-288.
- Lachin JM. Statistical properties of randomization in clinical trials. *Controlled Clinical Trials*, 1988, 9, 289-311.
- Lachin JM. Properties of simple randomization in clinical trials. *Controlled Clinical Trials*, 1988, 9, 312-326.
- Matts JP and Lachin JM. Properties of permuted-block randomization in clinical trials. *Controlled Clinical Trials*, 1988, 9, 327-344.
- Wei LJ and Lachin JM. Properties of the Urn randomization in clinical trials. *Controlled Clinical Trials*, 1988, 9, 345-364.
- Lachin JM, Matts JP and Wei LJ. Randomization in clinical trials: Conclusions and recommendations. *Controlled Clinical Trials*, 1988, 9, 365-374.
- 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.
- 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.
- Halperin M, Gilbert PR and Lachin JM. Distribution-free confidence intervals for $\Pr(X_1 < X_2)$. *Biometrics*, 1987, 43, 71-80.
- 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.
- Thall PF and Lachin JM. Assessment of stratum-covariate interactions in Cox's proportional hazards regression model. *Statistics in Medicine*, 1986, 5, 73-83.
- 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.
- Lachin JM. Sequential clinical trials for normal variates using interval composite hypotheses. *Biometrics*, 1981, 37, 87-101.
- Lachin JM. Introduction to sample size determination and power analysis for clinical trials. *Controlled Clinical Trials*, 1981, 2, 93-113.
- Lachin JM. Perceptions of the Coordinating Center: Foreword. *Controlled Clinical Trials*, 1980, 1, 125-126.

- Lachin JM. Informed consent in clinical investigations. *Biometrics*, 1977, 33, 761-762.
- Lachin JM. Sample size determinations for r x c comparative trials. *Biometrics*, 1977, 33, 315-324.
- Lachin JM and Schachter J. On stepwise discriminant analyses applied to physiologic data. *Psychophysiology*, 1974, 11, 703-709.
- Lachin JM. On a stepwise procedure for two population Bayes decision rules using discrete variables. *Biometrics*, 1973, 29, 551-564.

Medical: Glycemia Reduction Approaches for Diabetes Effectiveness: A Comparative Effectiveness Study (GRADE) (8 papers)

- Garvey WT, Cohen RM, Butera NM, Kazemi EJ, Younes N, Rosin SP, Suratt CE, Ahmann A, Hollander PA, Krakoff J, Martin CL, [Seaquist E](#), [Steffes MW](#), [John M. Lachin](#), [GRADE Research Group](#). Association of Baseline Factors With Glycemic Outcomes in GRADE: A Comparative Effectiveness Randomized Clinical Trial. *Diabetes Care*. 2024 Jan 29;dc231782.
- The GRADE Study Research Group. Glycemia Reduction in Type 2 Diabetes — Glycemic Outcomes. *N Engl J Med*. Sept 22, 2022; 387(12):1063-1074; doi: <https://doi.org/10.1056/NEJMoa2200433>
- The GRADE Study Research Group. Glycemia Reduction in Type 2 Diabetes — Microvascular and Cardiovascular Outcomes. *N Engl J Med*. Sept 22, 2022; 387(12):1075-1088; doi: <https://doi.org/10.1056/NEJMoa2200436>.
- Nathan DM, Krause-Steinrauf H, Braffett BH, Arends VL, Younes N, McGee P, Lund C, Johnson M, Lorenzi G, Gao X, Steffes MW, Lachin JM, the GRADE Research Group, and the DCCT/EDIC Research Group. Comparison of central laboratory HbA1c measurements obtained from a capillary collection versus a standard venous whole blood collection in the GRADE and EDIC studies. *PLOS One*. 2021 Nov 15; 16(11); doi: [10.1371/journal.pone.0257154](https://doi.org/10.1371/journal.pone.0257154) ;
- Utzschneider KM, Younes N, Rasouli N, Barzilay JI, Banerji MA, Cohen RM, Gonzalez EV, Ismail-Beigi F, Mather KJ, Raskin P, Wexler DJ. Shape of the OGTT glucose response curve: relationship with β -cell function and differences by sex, race, and BMI in adults with early type 2 diabetes treated with metformin. *BMJ Open Diabetes Research and Care*. 2021 Sep 1;9(1):e002264
- Utzschneider KM, Younes N, Rasouli N, Barzilay J, Banerji MA, Cohen RM, Gonzalez EV, Mather KJ, Ismail-Beigi F, Raskin P, Wexler DJ, Lachin JM, Kahn SE, the GRADE Research Group. Association of glycemia with insulin sensitivity and β -cell function in adults with early type 2 diabetes on metformin alone. *Journal of Diabetes and its Complications*. 2021 May 1;35(5):107912
- Rasouli N, Younes N, Utzschneider KM, Inzucchi SE, Balasubramanyam A, Cherrington AL, Ismail-Beigi F, Cohen RM, Olson DE, DeFronzo RA, Herman WH, Lachin JM, Kahn SE, GRADE Research Group. Association of baseline characteristics with insulin sensitivity and β -cell function in the glycemia reduction approaches in diabetes: a comparative effectiveness (GRADE) study cohort. *Diabetes Care*. 2021 Feb 1;44(2):340-9.

Nathan, David M., John B. Buse, Steven E. Kahn, Heidi Krause-Steinrauf, Mary E. Larkin, Myrlene Staten, Deborah Wexler, and John M. Lachin. "Rationale and Design of the Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness Study (GRADE)." *Diabetes Care*, 2013 Aug;36(8):2254-61. PMID: PMC3714493.

Medical: Diabetes Control and Complications Trial (DCCT) and study of the Epidemiology of Diabetes Interventions and Complications (EDIC) (181 Papers)

Bebu I, Braffett BH, de Boer IH, Aiello LP, Bantle JP, Lorenzi GM, Herman WH, Gubitosi-Klug RA, Perkins BA, Lachin JM, Molitch ME. Relationships Between the Cumulative Incidences of Long-term Complications in Type 1 Diabetes: The DCCT/EDIC Study. *Diabetes care*. 2023 Feb 1;46(2):361-8.

Khatri M, Ryan CM, Gao X, de Boer IH, Braffett BH, Molitch M, Karger AB, Lorenzi GM, Lee P, Trapani VR, Lachin JM. Chronic Kidney Disease Associates with Cognitive Decline in Middle-aged and Older Adults with Long-standing Type 1 Diabetes. *Kidney360*. 2023 Jun 9:10-34067.

Bebu I, Braffett BH, de Boer IH, Aiello LP, Bantle JP, Lorenzi GM, Herman WH, Gubitosi-Klug RA, Perkins BA, Lachin JM, Molitch ME. Relationships between the cumulative incidences of long-term complications in Type 1 Diabetes: The DCCT/EDIC Study. *Diabetes Care*. 2023 Feb;46(2):361-8.

Perkins BA, Bebu I, de Boer IH, Molitch M, Zinman B, Bantle J, Lorenzi GM, Nathan DM, Lachin JM, and the DCCT/EDIC Research Group. Optimal frequency of urinary albumin screening in type 1 diabetes. *Diabetes Care* 2022, 45(12):2943-49. PMC9763027.

Lachin JM, Bebu I, Gao X, Nathan DM, Zinman B, Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications (DCCT/EDIC) Research Group. Association of estimated time-in-range capillary glucose levels versus HbA1c with progression of microvascular complications in the Diabetes Control and Complications Trial. *Diabetes Care*. 2022 Oct;45(10):2445-8.

Malone JI, Gao X, Lorenzi GM, Raskin P, White NH, Hainsworth DP, Das A, Tamborlane W, Wallia A, Aiello LP, Bebu I, and the DCCT/EDIC Research Group. Retinopathy during the first 5 years of type 1 diabetes and subsequent risk of advanced retinopathy. *Diabetes Care* 2022, 45(12):2943-49.

Bebu I, Braffett BH, de Boer IH, Aiello LP, Bantle JP, Lorenzi GM, Herman WH, Gubitosi-Klug RA, Perkins BA, Lachin JM, Molitch ME, and the DCCT/EDIC Research Group. Relationships between the cumulative incidences of long-term complications in type 1 diabetes: the DCCT/EDIC study. *Diabetes Care* 2022. Online ahead of print.

Perkins BA, Bebu I, de Boer IH, Molitch M, Zinman B, Bantle J, Lorenzi GM, Nathan DM, Lachin JM, and the DCCT/EDIC Research Group. Cardiometabolic risk factors and incident cardiovascular disease events in women vs. men with type 1 diabetes. *Diabetes Care* 2022, 45(12):2943-49. PMC9459657.

Martin CL, Trapani VR, Backlund JYC, Lee P, Braffett BH, Bebu I, Lachin JM, Jacobson AM, Gubitosi-Klug R, Herman WH, and the DCCT/EDIC Research

- Group. Physical function in middle-aged and older adults with type 1 diabetes: Long-term follow-up of the DCCT/EDIC study. *Diabetes Care* 2022, 45(9):2037-45. PMC9472495.
- Schwartz AV, Backlund JYC, de Boer IH, Rubin MR, Barnie A, Farrell K, Trapani VR, Sinha Gregory N, Wallia A, Bebu I, Lachin JM, Braffett BH, Gubitosi-Klug R, and the DCCT/EDIC Research Group. Risk factors for lower bone mineral density in older adults with type 1 diabetes: a cross-sectional study. *Lancet Diabetes Endocrinol* 2022, 10(7):509-518. PMC.
- Jacobson AM, Braffett BH, Erus G, Ryan CM, Biessels GJ, Luchsinger JA, Bebu I, Gubitosi-Klug RA, Desiderio L, Lorenzi GM, Trapani VR, Lachin JM, Bryan N, Habes M, Nasrallah IM, and the DCCT/EDIC Research Group. Brain structure among middle-aged and older adults with longstanding type 1 diabetes in the DCCT/EDIC study. *Diabetes Care* 2022, 45(8):1779-87. PMC9346989.
- Turkbey EB, Backlund JC, Gai N, Nacif M, van der Geest RJ, Lachin JM, Armstrong A, Volpe GJ, Nazarian S, Lima JAC, Bluemke DA. Left ventricular structure, tissues composition, and aortic distensibility in the DCCT/EDIC. *Am J Cardiol* 2022, 174:158-65. PMC9167770.
- Rubin MR, de Boer IH, Backlund JYC, Arends V, Gubitosi-Klug R, Wallia A, Sinha Gregory N, Barnie A, Burghardt AJ, Lachin JM, Braffett BH, Schwartz AV, and the DCCT/EDIC Research Group. Biochemical markers of bone turnover in older adults with type 1 diabetes. *J Clin Endocrinol Metab* 2022, 107(6):e2405-e2416. PMC9113800.
- Gubitosi-Klug RA, Braffett BH, Bebu I, Johnson ML, Farrell K, Kenny D, Trapani VR, Meadema-Mayer L, Soliman EZ, Pop-Busui R, Lachin JM, Bergenstal RM, Tamborlane WV, and the DCCT/EDIC Research Group. Continuous glucose monitoring in adults with type 1 diabetes with 35 years duration from the DCCT/EDIC study. *Diabetes Care* 2022, 45(3):659-65. PMC8918229.
- Perkins BA, Bebu I, Gao X, Karger AB, Hirsch IB, Karanchi H, Molitch ME, Zinman B, Lachin JM, de Boer IH, and the DCCT/EDIC Research Group. Early trajectory of estimated glomerular filtration rate and long-term advanced kidney and cardiovascular complications in type 1 diabetes. *Diabetes Care* 2022, 45(3):585-93. PMC8918200.
- Braffett BH, Bebu I, El ghormli L, et al. Cardiometabolic Risk Factors and Incident Cardiovascular Disease Events in Women vs Men With Type 1 Diabetes. *JAMA Netw Open*. 2022;5(9):e2230710. doi:10.1001/jamanetworkopen.2022.30710
- Pop-Busui R, Backlund JY, Bebu I, Braffett BH, Lorenzi G, White NH, Lachin JM, Soliman EZ, DCCT/EDIC Research Group. Utility of using electrocardiogram measures of heart rate variability as a measure of cardiovascular autonomic neuropathy in type 1 diabetes patients. *Journal of Diabetes Investigation*. 2022 Jan;13(1):125-33. doi:10.1111/jdi.13635. PMID: 34309223; PMCID: PMC8756321.
- Monnier VM, Sell DR, Gao X, Genuth SM, Lachin JM, Bebu I, the DCCT/EDIC Research Group. Plasma advanced glycation end products and the subsequent risk of microvascular complications in type 1 diabetes in the DCCT/EDIC. *BMJ Open Diabetes Research and Care*. 2022 Jan 1;10(1):e002667.

- Polak JF, Backlund JY, Budoff M, Raskin P, Bebu I, Lachin JM, DCCT/EDIC Research Group. Coronary Artery Disease Events and Carotid Intima-Media Thickness in Type 1 Diabetes in the DCCT/EDIC Cohort. *Journal of the American Heart Association*. 2021 Dec 12;10(24):e022922.
- Gubitosi-Klug RA, Braffett BH, Hitt S, Arends V, Uschner D, Jones K, Diminick L, Karger AB, Paterson AD, Roshandel D, Marcovina S, Lachin JM, Steffes M, Palmer JP, and the DCCT/EDIC Research Group. Residual β cell function in long-term type 1 diabetes associates with reduced incidence of hypoglycemia. *The Journal of Clinical Investigation*. 2021 Feb 1;131(3).
- Nathan DN, Krause-Steinrauf H, Braffett BH, Arends VL, Younes N, McGee P, Lund C, Johnson M, Lorenzi G, Gao X, Steffes MW, Lachin JM, the GRADE Research Group, and the DCCT/EDIC Research Group. Comparison of central laboratory HbA1c measurements obtained from a capillary collection versus a standard venous whole blood collection in the GRADE and EDIC studies. *PLoS One* 2021 16(11): e0257154. <https://doi.org/10.1371/journal.pone.0257154>.
- Bebu I, Keshavarzi S, Gao X, Braffett BH, Canty AJ, Herman WH, Orchard TJ, Dagogo-Jack S, Nathan DM, Lachin JM, Paterson AD. Genetic Risk Factors for CVD in Type 1 Diabetes: The DCCT/EDIC Study. *Diabetes Care*. 2021 Jun 1;44(6):1309-16.
- Lachin JM, Bebu I, Nathan DM, and the DCCT/EDIC Research Group. The beneficial effects of earlier versus later implementation of intensive therapy in type 1 diabetes. *Diabetes Care*. 2021 Oct 1;44(10):2225-30.
- Lachin JM, Nathan DM, and the DCCT/EDIC Research Group. Understanding metabolic memory: The prolonged influence of glycemia during the Diabetes Control and Complications Trial (DCCT) on future risks of complications during the study of the Epidemiology of Diabetes Interventions and Complications (EDIC). *Diabetes Care*. 2021 Oct 1;44(10):2216-24..
- Gubitosi-Klug R, Gao X, Pop-Busui R, de Boer IH, White N, Aiello LP, Miller R, Palmer J, Tamborlane W, Wallia A, Kosiborod M, Lachin JM, Bebu I, and the DCCT/EDIC Research Group. Associations of microvascular complications with the risk of cardiovascular disease in type 1 diabetes. *Diabetes Care* 2021, 44(7):1499-1505. PMC8323173.
- Jacobson AM, Ryan CM, Braffett BH, Gubitosi-Klug RA, Lorenzi GM, Luchsinger JA, Trapani VR, Bebu I, Chaytor N, Hitt SM, Farrell K, Lachin JM, and the DCCT/EDIC Research Group. Cognitive performance declines in older adults with type 1 diabetes: results from 32 years of follow-up in the DCCT and EDIC study. *Lancet Diabetes Endocrinol* 2021, 9(7):436-45.
- Jenkins AJ, Braffett BH, Basu A, Bebu I, Dagogo-Jack S, Orchard TJ, Wallia A, Lopes-Virella MF, Garvey WT, Lachin JM, Lyons TJ, and the DCCT/EDIC Research Group. Serum urate and cardiovascular events in the DCCT/EDIC study. *Sci Rep* 2021, 11(1):14182. PMC8271014.
- Bebu I, Keshavarzi S, Gao X, Braffett BH, Canty AJ, Herman WH, Orchard TJ, Dagogo-Jack S, Nathan DM, Lachin JM, Paterson AD, and the DCCT/EDIC Research Group. Genetic risk factors for CVD in type 1 diabetes: the DCCT/EDIC study. *Diabetes Care* 2021, 44(6):1309-16. PMC8247524.

- Gubitosi-Klug RA, Braffett BH, Hitt S, Arends V, Uschner D, Jones K, Diminick L, Karger AB, Paterson AD, Roshandel D, Marcovina S, Lachin JM, Steffes M, Palmer JP, and the DCCT/EDIC Research Group. Residual β cell function in long-term type 1 diabetes associates with reduced incidence of hypoglycemia. *J Clin Invest* 2021, 131(3):e143011. PMC7843223.
- Bebu I, Braffett BH, Orchard TJ, Lorenzi GM, Nathan DM, Herman WH, Lachin JM, and the DCCT/EDIC Research Group. Moderation of the effect of glycemia on the risk of cardiovascular disease in type 1 diabetes: the DCCT/EDIC study. *Diabetes Res Clin Pract* 2021, 171:108591. PMC7854481.
- Hainsworth DP, Gao X, Bebu I, Das A, de Koo LO, Barkmeier AJ, Tamborlane W, Lachin JM, Aiello LP, Diabetes Control and Complications Trial. Refractive Error and Retinopathy Outcomes in Type 1 Diabetes: The Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications Study. *Ophthalmology*. 2020 Sep 14.
- Jaffa MA, Bebu I, Luttrell D, Braffett BH, Lachin JM, Hunt K, Lopes-Virella M, Luttrell L, Lyons TJ, Jaffa AA, and the DCCT/EDIC Research Group. Longitudinal plasma kallikrein levels and their association with the risk of cardiovascular disease outcomes in type 1 diabetes in DCCT/EDIC. *Diabetes*. 2020 Nov 1;69(11):2440-5
- Bebu I, Braffett BH, Schade D, Sivitz W, Malone JJ, Pop-Busui R, Lorenzi GM, Lee P, Trapani VR, Wallia A, Herman WH, Lachin JM, and the DCCT/EDIC Research Group. An observational study of the equivalence of age and duration of diabetes to glycemic control relative to the risk of complications in the combined cohorts of the DCCT/EDIC study. *Diabetes Care* 2020, Epub ahead of print.
- Chen Z, Miao F, Braffett BH, Lachin JM, Zhang L, Wu X, Carless M, Li XA, Tompkins JD, Kaddis JS, Riggs AD, Patterson AD, Natarajan R, and the DCCT/EDIC Research Group. DNA methylation mediates development of HbA1c-associated complications in type 1 diabetes. *Nat Metab* 2020, 2(8):744-62, Epub ahead of print.
- Braffett BH, Gubitosi-Klug RA, Albers JW, Feldman EL, Martin CL, White NH, Orchard TJ, Lopes-Virella M, Lachin JM, Pop-Busui R; DCCT/EDIC Study Group. Risk Factors for Diabetic Peripheral Neuropathy and Cardiovascular Autonomic Neuropathy in the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications (DCCT/EDIC) Study. *Diabetes*. 2020 Feb 12;db191046. doi: 10.2337/db19-1046. Epub ahead of print.
- Bebu I, Schade D, Braffett B, Kosiborod M, Lopes-Virella M, Soliman EZ, Herman WH, Bluemke DA, Wallia A, Orchard T, Lachin JM; DCCT/EDIC Research Group. Risk Factors for First and Subsequent CVD Events in Type 1 Diabetes: The DCCT/EDIC Study. *Diabetes Care*. 2020 43(4):867-874. doi: 10.2337/dc19-2292.
- Braffett BH, Lorenzi GM, Cowie CC, Gao X, Bainbridge KE, Cruickshanks KJ, Kramer JR, Gubitosi-Klug RA, Larkin ME, Barnie A, Lachin JM. Risk factors for hearing impairment in type 1 diabetes. *Endocrine Practice*. 2019, 25(12): 1243-1254. <https://doi.org/10.4158/EP-2019-0193>

- Lopes-Virella MF, Bebu I, Hunt KJ, Virella G, Baker NL, Braffett B, Gao X, Lachin JM, DCCT/EDIC Research Group. Immune Complexes and the Risk of CVD in Type 1 Diabetes. *Diabetes*. 2019 69(9): 1853-1860. Jun 19:db190358.
- Molitch ME, Gao X, Bebu I, de Boer IH, Lachin J, Paterson A, Perkins B, Saenger AK, Steffes M, Zinman B, Diabetes Control and Complications Trial. Early Glomerular Hyperfiltration and Long-Term Kidney Outcomes in Type 1 Diabetes: The DCCT/EDIC Experience. *Clinical Journal of the American Society of Nephrology*. 2019 Jun 7;14(6):854-61. doi: 10.2215/CJN.14831218.
- Gubitosi-Klug RA, Bebu I, White NH, et al. Screening eye exams in youth with type 1 diabetes under 18 years of age: Once may be enough? *Pediatr Diabetes*. 2019;1-7. <https://doi.org/10.1111/pedi.12877>
- Hainsworth DP, Bebu I, Aiello LP, Sivitz W, Gubitosi-Klug R, Malone J, White NH, Danis R, Wallia A, Gao X, Barkmeier AJ, Das A, Patel S, Gardner TW, Lachin JM, Diabetes Control and Complications Trial (DCCT)/Epidemiology of Diabetes Interventions and Complications (EDIC) Research Group. Risk factors for retinopathy in type 1 diabetes: The DCCT/EDIC Study. *Diabetes Care*. 2019 42(5):875-882. doi:10.2337/dc18-2308. PMID: 30833368.
- Budoff M, Backlund JC, Bluemke DA, Polak J, Bebu I, Schade D, Strowig S, Raskin P, Lachin JM. The association of coronary artery calcification with subsequent incidence of cardiovascular disease in type 1 diabetes: The DCCT/EDIC Trials, *JACC: Cardiovascular Imaging*, 2019, 12(7): 1341-1349. doi: 10.1016/j.jcmg.2019.01.014.
- Bebu I, Braffett BH, Orchard TJ, Lorenzi GM, Lachin JM, and the DCCT/EDIC Research Group. Mediation of the effect of glycemia on the risk of CVD outcomes in type 1 diabetes: The DCCT/EDIC Study. *Diabetes Care*. 2019 42(7):1284-1289. doi: 10.2337/dc18-1613.
- Perkins BA, Bebu I, de Boer IH, Molitch M, Tamborlane W, Lorenzi G, Herman W, White NH, Pop-Busui R, Paterson AD, Orchard T, Cowie , Lachin JM, on behalf of the Diabetes Control and Complications Trial (DCCT)-Epidemiology of Diabetes Interventions and Complications (EDIC) Research Group. Risk factors for kidney disease in type 1 diabetes. *Diabetes Care* 2019 42(5):883-890. doi: 10.2337/dc18-2062.
- Braffett BH, Dagogo-Jack S, Bebu I, Sivitz WI, Larkin M, Kolterman O, Lachin JM, and The DCCT/EDIC Research Group. Association of insulin dose, cardiometabolic risk factors, and cardiovascular disease in type 1 diabetes during 30 years of follow-up in the DCCT/EDIC Study. *Diabetes Care* 2019, 42(4): 657-664. doi: 10.2337/dc18-1574.
- Schade DS, Lorenzi GM, Braffett BH, Gao X, Bainbridge KE, Barnie A, Cruickshanks KJ, Dalton D, Diminick L, Gubitosi-Klug R, Kramer JR, Lachin JM, Larkin ME, Cowie CC, and The DCCT/EDIC Research Group. Hearing impairment and type 1 diabetes in the DCCT/EDIC cohort. *Diabetes Care* 2018, 41(12):2495-2501. DOI: 10.2337/dc18-0625. PMC6245203.
- Wilson Tang WH, McGee P, Lachin JM, Li DY, Hoogwerf B, Hazen SL, DCCT/EDIC Research Group. Oxidative stress and cardiovascular risk in type 1 diabetes mellitus: insights from the DCCT/EDIC study. *J Am Heart Assoc*. 2018;7:e008368. DOI: 10.1161/JAHA.117.008368

- Herman WH, Braffett BH, Kuo S, Lee JM, Brandle M, Jacobson AM, Prosser LA, Lachin JM, Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications (DCCT/EDIC) Research Group. What are the clinical, quality-of-life, and cost consequences of 30 years of excellent vs. poor glycemic control in type 1 diabetes?. *Journal of Diabetes and Its Complications* 2018, 32: 911–915
- Herman WH, Braffett BH, Kuo S, Lee JM, Brandle M, Jacobson AM, Prosser LA, Lachin JM, Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications (DCCT/EDIC) Research Group. The 30-year cost-effectiveness of alternative strategies to achieve excellent glycemic control in type 1 diabetes: an economic simulation informed by the results of the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications (DCCT/EDIC). *Journal of Diabetes and Its Complications* 2018; 32: 934–939.
- de Boer IH, Gao X, Bebu I, Hoofnagle AN, Lachin JM, Paterson A, Perkins BA, Saenger AK, Steffes MW, Zinman B, Molitch ME, and the DCCT/EDIC Research Group. Biomarkers of tubulointerstitial damage and function in type 1 diabetes. *BMJ Open Diabetes Res Care* 2017, 14;5(1):e000461. PMC5687553.
- Bebu I, Braffett BH, Pop-Busui R, Orchard TJ, Nathan DM, Lachin JM, and the DCCT/EDIC Research Group. The relationship of blood glucose with cardiovascular disease is mediated over time by traditional risk factors in type 1 diabetes: the DCCT/EDIC study. *Diabetologia* 2017 60(10):2084-91. PMC5660661.
- Gubitosi-Klug RA, Braffett BH, White NH, Sherwin RS, Service FJ, Lachin JM, Tamborlane WV, and the DCCT/EDIC Research Group. The risk of severe hypoglycemia in type 1 diabetes over 30 years of follow-up in the DCCT/EDIC study. *Diabetes Care* 2017, 40(8):1010-16. PMC5521975. Erratum: *Diabetes Care*. 2020 Nov 6;dc21er01a. doi: 10.2337/dc21-er01a. Online ahead of print.
- The DCCT/EDIC Research Group (Writing Committee: Nathan DM, Bebu I, Hainsworth D, Klein R, Tamborlane W, Lorenzi G, Gubitosi-Klug R, Lachin JM). Frequency of evidence-based screening for retinopathy in type 1 diabetes. *N Engl J Med* 2017, 376(16):1507-16. PMC5557280.
- Lachin JM, Bebu I, Bergenstal RM, Pop-Busui R, Service FJ, Zinman B, Nathan DM, and the DCCT/EDIC Research Group. Association of glycemic variability in type 1 diabetes with progression of microvascular outcomes in the DCCT. *Diabetes Care* 2017, 40(6):777-83. PMC5439414.
- Soliman EZ, Backlund JY, Bebu I, Orchard TJ, Zinman B, Lachin JM, DCCT/EDIC Research Group. Electrocardiographic Abnormalities and Cardiovascular Disease Risk in Type 1 Diabetes: The Epidemiology of Diabetes Interventions and Complications (EDIC) Study. *Diabetes Care*. 2017, 40(6):793-99. . dc162050, PMC5439417..
- Armstrong AC, Ambale-Venkatesh B, Turkbey E, Donekal S, Chamera E, Backlund JY, Cleary P, Lachin J, Bluemke DA, Lima JA. Association of Cardiovascular Risk Factors and Myocardial Fibrosis With Early Cardiac Dysfunction in Type 1 Diabetes: The Diabetes Control and Complications Trial/Epidemiology of

- Diabetes Interventions and Complications Study. *Diabetes Care*. 2017 Mar 1;40(3):405-11.
- de Boer IH, Gao X, Cleary PA, Bebu I, Lachin JM, Molitch ME, Orchard T, Paterson AD, Perkins BA, Steffes MW, Zinman B. Albuminuria changes and cardiovascular and renal outcomes in type 1 diabetes: the DCCT/EDIC study. *Clinical Journal of the American Society of Nephrology*. 2016 Oct 24:CJN-02870316
- DCCT/EDIC Research Group (Gubitosi-Klug RA, Lachin JM, Backlund J-Y C, Lorenzi GM, Brillon DJ, and Orchard TJ). Intensive diabetes treatment and cardiovascular outcomes in type 1 diabetes: The DCCT/EDIC Study 30-year follow-up. *Diabetes Care* 2016;39:686–693 | DOI: 10.2337/dc15-1990.
- DCCT/EDIC Research Group (Lachin JM, Bebu I, Nathan DM, Zinman B, Brillon D, Backlund J-Y C, Cleary P and Orchard TJ). Mortality in type 1 diabetes in the DCCT/EDIC versus the general population. *Diabetes Care*, 2016.39(8): 1378 DOI: 10.2337/dc15-2399.
- The DCCT/EDIC Research Group (Writing Committee: Braffett BH, Dagogo-Jack S, Larkin M, Sivitz W, Bebu I, Kolterman O, Genuth S, Lachin JM). Coprogression of Cardiovascular Risk Factors in Type 1 Diabetes During 30 Years of Follow-up in the DCCT/EDIC Study. *Diabetes Care* 2016, 39(9):1621-30. PMC5001148.
- Chen Z, Miao F, Paterson AD, Lachin JM, Zhang L, Schones DE, Wu X, Wang J, Tompkins JD, Genuth S, Braffett BH, Riggs AD, DCCT/EDIC Research Group, and Natarajan R. Epigenomic profiling reveals an association between persistence of DNA methylation and metabolic memory in the DCCT/EDIC type 1 diabetes cohort *Proceedings of the National Academy of Sciences*. 2016 113 (21) E3002-E3011; published ahead of print May 9, 2016, doi:10.1073/pnas.1603712113
- Orchard TJ, Backlund J-YC, Costacou T, Cleary P, Lopes-Virella M, Levy AP, Lachin JM and the DCCT/EDIC Research Group. Haptoglobin 2–2 genotype and the risk of coronary artery disease in the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications study (DCCT/EDIC). *Journal of Diabetes and its Complications*. 30(8):1577-84. doi.org/10.1016/j.jdiacomp.2016.07.014
- DCCT/EDIC Research Group (Nathan DM, Bebu I, Braffett BH, Orchard TJ, Cowie CC, Lopes-Virella M, Schutta M, and Lachin JM). Risk factors for cardiovascular disease in type 1 diabetes. *Diabetes* 2016; 65(5): 1370-1379; db151517. <http://dx.doi.org/10.2337/db15-1517>
- Darabian S, Backlund J-YC, Cleary PA, Sheidaee N, Bebu I, Lachin JM, et al. Significance of epicardial and intrathoracic adipose tissue volume among type 1 diabetes patients in the DCCT/EDIC: A pilot study. *PLoS ONE* 2016,11(7): e0159958. doi:10.1371/journal.pone.0159958
- Soliman EZ, Backlund JY, Bebu I, Li Y, Zhang ZM, Cleary PA, Lachin JM, DCCT/EDIC Research Group. Progression of electrocardiographic abnormalities in type 1 diabetes during 16 years of follow-up: The Epidemiology of Diabetes Interventions and Complications (EDIC) study. *Journal of the American Heart Association*. 2016 Mar 1;5(3):e002882.

- Sell DR, Sun W, Gao X, Strauch C, Lachin JM, Cleary PA, Genuth S, the DCCT/EDIC Research Group and Monnier VM. Skin collagen fluorophore LW-1 versus skin fluorescence as markers for the long-term progression of subclinical macrovascular disease in type 1 diabetes. *Cardiovascular Diabetology*, 2016, 15(1), 30.
- Nathan DM, Genuth SM, Zinman B, Lachin JM. Data sharing is desirable, but benefits should not be exaggerated. *British Medical Journal*. 2015 Oct 21;351:h5508
- Rajab HA, Baker NL, Hunt KJ, Klein R, Cleary PA, Lachin J, Virella G, Lopes-Virella MF, DCCT/EDIC Group of Investigators. The predictive role of markers of Inflammation and endothelial dysfunction on the course of diabetic retinopathy in type 1 diabetes. *Journal of Diabetes and its Complications*. 2015 Feb 28;29(1):108-14.
- Monnier VM, Sun W, Gao X, Sell DR, Cleary PA, Lachin JM, Genuth S, and the DCCT/EDIC Research Group. Skin collagen advanced glycation endproducts (AGEs) and the long-term progression of sub-clinical cardiovascular disease in type 1 diabetes. *Cardiovasc Diabetol* 2015, 14:118. PMC4560872. Erratum. 2015. 14:138.
- DCCT/EDIC Research Group (Aiello LP, Sun W, Das A, Gangaputra S, Kiss S, Klein R, Cleary PA, Lachin JM, Nathan DM). Intensive diabetes therapy and ocular surgery in type 1 diabetes. *New England Journal of Medicine*. 2015, 372(18):1722-33.
- The DCCT/EDIC Research Group (Orchard TJ, Nathan DM, Zinman B, Cleary P, Brillon D, Backlund JC, Lachin JM). Association between 7 years of intensive treatment of type 1 diabetes and long-term mortality. *JAMA* 2015, 313(1):45-53. PMID:25562265.
- Rajab HA, Baker NL, Hunt KJ, Klein R, Cleary PA, Lachin J, Virella G, Lopes-Virella MF, and the DCCT/EDIC Research Group. The predictive role of markers on inflammation and endothelial dysfunction on the course of diabetic retinopathy in type 1 diabetes. *J Diabetes Complications* 2015, 29(1):108-14. PMID:25441222.
- The DCCT/EDIC Research Group (Lachin JM, White N, Sun W, Cleary PA, Nathan DM). Effect of intensive diabetes therapy on the progression of diabetes retinopathy in patients with type 1 diabetes: 18 years of follow-up in the DCCT/EDIC. *Diabetes* 2015, 64: 631-642. PMID:25204977.
- Genuth S, Sun W, Cleary P, Gao X, Sell DR, Lachin J, and the DCCT/EDIC Research Group. Skin advanced glycation endproducts (AGEs) glucosepane and methylglyoxal hydroimidazolone are independently associated with long-term microvascular complication progress of type 1 diabetes. *Diabetes* 2015, 64(1):266-78. PMC4274803.
- de Boer IH, Afkarian M, Rue TC, Cleary PA, Lachin JM, Molitch ME, Steffes MW, Sun W, Zinman B, and the DCCT/EDIC Research Group. Renal outcomes in patients with type 1 diabetes and macroalbuminuria. *J Am Soc Nephrol* 2014, 25(10):2342-50. PMC4178441.

- McGee P, Steffes M, Nowicki M, Bayless M, Gubitosi-Klug R, Cleary P, Lachin J, Palmer J, and the DCCT/EDIC Research Group. Insulin secretion measured by stimulated C-peptide in long-established type 1 diabetes in the Diabetes Control and Complications Trial (DCCT)/Epidemiology of Diabetes Interventions and Complications (EDIC) cohort: a pilot study. *Diabet Med* 2014, 31(10):1264-8. PMC4167980.
- de Boer IH, Sun W, Gao X, Cleary PA, Lachin JM, Molitch M, Steffes MW, Zinman B, for the DCCT/EDIC Research Group. Effect of intensive diabetes treatment on albuminuria in type 1 diabetes: long-term follow-up of the Diabetes Control and Complications Trial and Epidemiology of Diabetes Interventions and Complications study. *Lancet Diabetes Endocrinol* 2014, 2(10):793-800. PMC4215637.
- Miao F, Chen Z, Genuth S, Paterson AD, Zhang L, Wu X, Li SM, Cleary P, Riggs A, Harlan DM, Lorenzi G, Kolterman O, Sun W, Lachin JM, Natarajan R, and the DCCT/EDIC Research Group. Evaluating the role of epigenetic histone modifications in the Metabolic Memory of Type 1 Diabetes. *Diabetes* 2014, 63(5):1748-62. PMC3994951.
- Lachin JM, McGee P, Palmer JP, DCCT/EDIC Research Group. Impact of C-Peptide preservation on metabolic and clinical outcomes in the diabetes control and complications trial. *Diabetes*. 2014, 63(2):739-48. PMID: 24089509; PMCID: PMC3900540.
- Lachin JM, Orchard TJ, Nathan DM, DCCT/EDIC Research Group. Update on cardiovascular outcomes at 30 years of the diabetes control and complications trial/epidemiology of diabetes interventions and complications study. *Diabetes Care*. 2014, 37(1):39-43. PMID: 24356596; PMCID: PMC3868002.
- Nathan DM, McGee P, Steffes MW, Lachin JM, DCCT/EDIC Research Group. Relationship of glycated albumin to blood glucose and HbA1c values and to retinopathy, nephropathy, and cardiovascular outcomes in the DCCT/EDIC study. *Diabetes*. 2014, 63(1):282-90. PMID: 23990364; PMCID: PMC3868040.
- de Boer IH, Sun W, Cleary PA, Lachin JM, Molitch ME, Zinman B, Steffes MW, for the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications Study Research Group. Longitudinal Changes in Estimated and Measured GFR in Type 1 Diabetes. *J Am Soc Nephrol* 2014, 25(4):810-818. PMC3968500. PMID: 24309189.
- Nathan DM, Bayless M, Cleary P, Genuth S, Gubitosi-Klug R, Lachin JM, Lorenzi G, Zinman B, DCCT/EDIC Research Group. Diabetes control and complications trial/epidemiology of diabetes interventions and complications study at 30 years: advances and contributions. *Diabetes*. 2013, 62(12):3976-86. PMID: 24264395; PMCID: PMC3837056.
- Grassi MA, Sun W, Gangaputra S, Cleary PA, Hubbard L, Lachin JM, Gao X, Kiss S, Barkmeier AJ, Almony A, Davis M, Klein R, Danis RP, DCCT/EDIC Research Group. Validity of self-report in type 1 diabetic subjects for laser treatment of retinopathy. *Ophthalmology*. 2013, 120(12):2580-6. PMID: 23890420; PMCID: PMC3818390.

- Genuth SM, Backlund JY, Bayless M, Bluemke DA, Cleary PA, Crandall J, Lachin JM, Lima JA, Miao C, Turkbey EB, DCCT/EDIC Research Group. Effects of prior intensive versus conventional therapy and history of glycemia on cardiac function in type 1 diabetes in the DCCT/EDIC. *Diabetes*. 2013 Oct;62(10):3561-9. PMID: 23520132; PMCID: PMC3781466.
- Orchard T, Sun W, Cleary P, Genuth S, Lachin J, McGee P, Paterson A, Raskin P, Anbinder Y, Levy A. Haptoglobin Genotype and the rate of Renal Function Decline in the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications Study. *Diabetes* 2013, 62(9):3218-3223. PMCID:3749329.
- Sachs MC, Brunzell JD, Cleary PA, Hoofnagle AN, Lachin JM, Molitch ME, Steffes MW, Zinman B, de Boer IH, and the DCCT/EDIC Research Group. Circulating vitamin D metabolites and subclinical atherosclerosis in type 1 diabetes. *Diabetes Care* 2013, 36(8):2423-2429. PMCID:3714470.
- Purnell JQ, Hokanson JE, Cleary PA, Nathan DM, Lachin JM, Zinman B, Brunzell JD, and the DCCT/EDIC Research Group. The effect of excess weight gain with intensive diabetes treatment on cardiovascular disease risk factors and atherosclerosis in type 1 diabetes mellitus: Results from the Diabetes Control and Complications Trial / Epidemiology of Diabetes Interventions and Complications Study (DCCT/EDIC). *Circulation* 2013, 127(2):180-187. PMID:23212717.
- Turkbey EB, Redheuil A, Backlund JY, Small AC, Cleary PA, Lachin JM, Lima JAC, Bluemke DA, and the DCCT/EDIC Research Group. Aortic Distensibility in type 1 diabetes. *Diabetes Care* 2013, 36 (8):2380-2387. PMCID:3714531.
- Monnier VM, Sell DR, Strauch C, Sun W, Lachin JM, Cleary PA, Genuth S, the DCCT Research Group, The association between skin collagen glucosepane and past progression of microvascular and neuropathic complications in type 1 diabetes, *Journal of Diabetes and its Complications*. 2013, 27(2):141-149. PMCID:3577949, 10.1016/j.jdiacomp.2012.10.004.
- Lopes-Virella MF, Carter RE, Baker NL, Lachin J, Virella G and the DCCT/EDIC Research Group. High levels of oxidized LDL in circulating immune complexes are associated with increased odds of developing abnormal albuminuria in Type 1 diabetes *Nephrol. Dial. Transplant*. 2012; 27: 1416-1423 DOI: 10.1093/ndt/gfr454.
- de Boer IH, Sachs MC, Cleary PA, Hoofnagle AN, Lachin JM, Molitch ME, Steffes MW, Sun W, Zinman B, and Brunzell JD. Circulating Vitamin D Metabolites and Kidney Disease in Type 1 Diabetes *J Clin Endocrin Metab*. 2012, 97:4780-4788. DOI: 10.1210/jc.2012-2852
- Hotaling JM, Waggott DR, Goldberg J, Jarvik G, Paterson AD, Cleary PA, Lachin J, Sarma A, Wessells H, DCCT/EDIC Research Group. Pilot Genome-Wide Association Search Identifies Potential Loci for Risk of Erectile Dysfunction in Type 1 Diabetes Using the DCCT/EDIC Study Cohort, *The Journal of Urology*, 2012, 188: 514-520 DOI: 10.1016/j.juro.2012.04.001.
- de Boer IH, Rue TC, Cleary PA, Lachin JM, Molitch ME, Steffes MW, Sun W, Zinman B, Brunzell JD, DCCT/EDIC Research Group. Long-term Renal Outcomes of Patients With Type 1 Diabetes Mellitus and Microalbuminuria: An

- Analysis of the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications Cohort. *Arch Intern Med.* 2011; 171:412-420. doi:10.1001/archinternmed.2011.16.
- Chahal H, Backlund J-Y, Cleary PA, Lachin JM, Polak JF, Lima JAC, Bluemke DA, DCCT/EDIC Research Group, Relation Between Carotid Intima–Media Thickness and Left Ventricular Mass in Type 1 Diabetes Mellitus (from the Epidemiology of Diabetes Interventions and Complications [EDIC] Study), *The American Journal of Cardiology*; 2012; 110: 1534-1540. DOI: 10.1016/j.bbr.2011.03.031.
- The DCCT/EDIC Research Group (de Boer IH, Sun W, Cleary PA, Lachin JL, Molitch ME, Steffes MW, Zinman B.). Intensive Diabetes Therapy and Glomerular Filtration Rate in Type 1 Diabetes. *The New England Journal of Medicine* 2011, 365:2366-2376. PMID: 22077236
- Turkbey EB, Backlund JY, Genuth S, Jain A, Miao C, Cleary PA, Lachin JM, Nathan DM, van der Geest RJ, Soliman EZ, Liu CY, Lima JA, Bluemke DA; the DCCT/EDIC Research Group. Myocardial Structure, Function, and Scar in Patients With Type 1 Diabetes Mellitus. *Circulation.* 2011; 124:1737-1746.
- Wessells H, Penson DF, Cleary P, Rutledge BN, Lachin JM, McVary KT, Schade DS, Sarma AV; Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications Research Group. Effect of intensive glycemic therapy on erectile function in men with type 1 diabetes. *J Urol.* 2011; 185:1828-34.
- Sacks DB, Nathan DM, Lachin JM. Gaps in the glycation gap hypothesis. *Clinical Chemistry* 2011, 57:150-152. PMID: 21127149.
- de Boer IH, Rue TC, Cleary PA, Lachin JL, Molitch ME, Steffes MW, Sun W, Zinman B, Brunzell JD, for the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications Study Research Group. Long-term Renal Outcomes of Patients With Type 1 Diabetes Mellitus and Microalbuminuria: An Analysis of the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications Cohort. *Arch Intern Med.* 2011, 171(5), 412-420. doi:10.1001/archinternmed.2011.16.
- Polak JF, Backlund J-YC, Cleary PA, Harrington AP, O’Leary DH, Lachin JM, Nathan DM for the DCCT/EDIC Research Group. Progression of Carotid Artery Intima-Media Thickness During 12 Years in the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications (DCCT/EDIC) Study *Diabetes*, 2011, 60, 607-61.
- Nathan DM, Steffes MW, Sun W, Rynders GP and Lachin JM. Determining Stability of Stored Samples Retrospectively: The Validation of Glycated Albumin. *Clinical Chemistry* 2011, 57, 286-290.
- Lopes-Virella MF, Hunt KJ, Baker NL, Lachin J, Nathan DM, Virella G; the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications Research Group. Levels of Oxidized LDL and Advanced Glycation End Products-Modified LDL in Circulating Immune Complexes Are Strongly Associated With Increased Levels of Carotid Intima-Media Thickness

- and Its Progression in Type 1 Diabetes. *Diabetes*. 2011, 60, 582-589.
10.2337/db10-0915
- Lopes-Virella MF, Baker NL, Hunt KJ, Lachin JM, Nathan DM, Virella G, The DCCT/EDIC Research Group . Oxidized LDL immune complexes and coronary artery calcification in type 1 diabetes. *Atherosclerosis*, 2011, 214, 462-467.
- Younes N, Cleary PA, Steffes MW, deBoer IH, Molitch ME, Rutledge BN, Lachin JM, Dahms W and the DCCT/EDIC Research Group. Comparison of Urinary Albumin-Creatinine Ratio and Albumin Excretion Rate in the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications Study *CJASN*, 2010, 5, 1235-1242.
- Molitch ME, Steffes M, Sun W, Rutledge B, Cleary P, de Boer IH, Zinman B, Lachin J; Epidemiology of Diabetes Interventions and Complications Study Group. Development and Progression of Renal Insufficiency With and Without Albuminuria in Adults With Type 1 Diabetes in the Diabetes Control and Complications Trial and the Epidemiology of Diabetes Interventions and Complications Study. *Diabetes Care* , 2010, 33, 1536-1543
- Pop-Busui R, Herman WH, Feldman EL, Low PA, Martin CL, Cleary PA, Waberski BH, Lachin JM, Albers JW for the DCCT/EDIC Research Group. DCCT and EDIC Studies in Type 1 Diabetes: Lessons for Diabetic Neuropathy Regarding Metabolic Memory and Natural History, *Curr Diab Rep*, 2010, 10:276–282
- Albers JW, Herman WH, Pop-Busui R, Feldman EL, Martin CL, Cleary PA, Waberski BH, Lachin JM; Diabetes Control and Complications Trial /Epidemiology of Diabetes Interventions and Complications Research Group. Effect of prior intensive insulin treatment during the Diabetes Control and Complications Trial (DCCT) on peripheral neuropathy in type 1 diabetes during the Epidemiology of Diabetes Interventions and Complications (EDIC) Study. *Diabetes Care*. 2010, 33(5): 1090-6.
- Paterson AD, Waggott D, Boright AP, Hosseini SM, Shen E, Sylvestre M-P, Wong I, Bharaj B, Cleary PA, Lachin JM, MAGIC, Below JE, Nicolae D, Cox NJ, Canty AJ, Sun L, Bull SB, and The Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications Research Group. A genome-wide association study identifies a novel major locus for glycemic control in type 1 diabetes, as measured by both HbA1c and glucose. *Diabetes*, 2010, 59: 539-549.
- Pop-Busui R, Low PA, Waberski BH, Martin CL, Albers JW, Feldman, EL, Sommer, C, Cleary PA, Lachin JM, Herman WH for the DCCT/EDIC Research Group. Effects of Prior Intensive Insulin Therapy on Cardiac Autonomic Nervous System Function in Type 1 Diabetes Mellitus: The Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications Study (DCCT/EDIC). *Circulation*, 2009, 119: 2886-2893.
- Delahanty LM, Nathan DM, Lachin JM, Hu FB, Cleary PA, Ziegler GK, Wylie-Rosett J, Wexler DJ for the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications. Association of Diet with Glycated Hemoglobin During Intensive Treatment of Type 1 Diabetes

- in the Diabetes Control and Complications Trial. *American Journal of Clinical Nutrition*, 2009, 89:518-524
- de Boer IH, Kestenbaum B, Rue TC, Steffes MW, Cleary PA, Molitch ME, Lachin JM, Weiss NS, Brunzell JD; Diabetes Control and Complications Trial (DCCT)/Epidemiology of Diabetes Interventions and Complications (EDIC) Study Research Group. Insulin therapy, hyperglycemia, and hypertension in type 1 diabetes mellitus. *Arch Intern Med.*, 2008 168:1867-73.
- White NH, Sun W, Cleary PA, Danis RP, Davis MD, Hainsworth DP, Hubbard L, Lachin JM, Nathan DM for the DCCT/EDIC Research Group. Prolonged Effect of Intensive Therapy on the Risk of Retinopathy Complications in Patients with Type 1 Diabetes Mellitus: 10 years after the Diabetes Control and Complications Trial, *Archives of Ophthalmology*, 2008, 126:1707-1715.
- Lachin JM, Genuth S, Nathan DM, Zinman, Rutledge B, for the DCCT/EDIC Research Group. Effect of glycemic exposure on the risk of microvascular complications in the Diabetes Control and Complications Trial—Revisited. *Diabetes* 2008; 57: 995-1001
- Al-Kateb H, Boright AP, Mirea L, Xie X, Sutradhar R, Mowjoodi A, Bharaj B, Liu M, Buckska JM, Arends VL, Steffes MW, Cleary PA, Sun W, Lachin JM, Thorner PS, Ho M, McKnight AJ, Maxwell AP, Savage DA, Kidd KK, Kidd JR, Speed WC, Orchard TJ, Miller RG, Sun L, Bull SB, Paterson AD; Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications Research Group. Multiple superoxide dismutase 1/splicing factor serine alanine 15 variants are associated with the development and progression of diabetic nephropathy: the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications Genetics study. *Diabetes*. 2008;57:218-28.
- Paterson AD, Rutledge BN, Cleary PA, Lachin JM, Crow RS; Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications Research Group. The effect of intensive diabetes treatment on resting heart rate in type 1 diabetes: the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications study. *Diabetes Care*. 2007; 30:2107-12.
- Lachin JM, Genuth S, Nathan DM and Rutledge B. The Hemoglobin Glycation Index Is Not an Independent Predictor of the Risk of Microvascular Complications in the Diabetes Control and Complications Trial. *Diabetes*, 2007, 56:1913-21.
- The DCCT/EDIC Research Group. Long-term effect of diabetes and its treatment on cognitive function. *The New England Journal of Medicine*, 2007; 356:1842-52.
- Cleary PA, Orchard TJ, Genuth S, Wong ND, Detrano R, Backlund JC, Zinman B, Jacobson A, Sun W, Lachin JM, Nathan DM for the DCCT/EDIC Research Group The Effect of Intensive Glycemic Treatment on Coronary Artery Calcification in Type 1 Diabetic Participants of the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications (DCCT/EDIC) Study. *Diabetes*, 2006, 55:3556-3565.
- Martin CL, Albers J, Herman WH, Cleary P, Waberski B, Greene DA, Stevens MJ, Feldman EL and the DCCT/EDIC Research Group . Neuropathy Among the

- Diabetes Control and Complication Trial Cohort 8 Years After Trial Completion. *Diabetes Care*, 2006, 29: 340-4.
- Nathan DM, Cleary PA, Backlund JY, Genuth SM, Lachin JM, Orchard TJ, Raskin P, Zinman B and the DCCT/EDIC Research Group. Intensive diabetes treatment and cardiovascular disease in patients with type 1 diabetes. *The New England Journal of Medicine*, 2005; 353:2643-53.
- Steffes MW, Chavers BM, Molitch ME, Cleary PA, Lachin JM, Genuth S, Nathan DM and the DCCT/EDIC Research Group. Sustained effect of intensive treatment of type 1 diabetes mellitus on development and progression of diabetic nephropathy. *Journal of the American Medical Association*; 2003, 290, 2159-67.
- The DCCT/EDIC Research Group (J. Lachin, member, Writing Committee). Intensive diabetes therapy and carotid intima-media thickness in type 1 diabetes mellitus. *The New England Journal of Medicine*; 2003, 348, 2294-303.
- The DCCT/EDIC Research Group (J. Lachin, member, Writing Committee). The effect of intensive therapy on the microvascular complications of type 1 diabetes mellitus. *Journal of the American Medical Association*, 2002, 287, 2563-2569.
- The DCCT/EDIC Research Group . The beneficial effects of intensive therapy of diabetes during adolescence: Outcomes after the conclusion of the Diabetes Control and Complications Trial (DCCT). *The Journal of Pediatrics*, 2001, 139, 804-812.
- The DCCT Research Group . Influence of Intensive Diabetes Treatment on Body Weight and Composition of Adults with Type 1 Diabetes in the Diabetes Control and Complications Trial. *Diabetes Care*, 2001, 24, 1711-1721
- The DCCT Research Group (J. Lachin, member, Writing Committee). The effect of pregnancy on microvascular complications in the Diabetes Control and Complications Trial (DCCT). *Diabetes Care*, 2000, 23, 1084-1091.
- The DCCT/EDIC Research Group (J. Lachin, Chair, Writing Committee). Retinopathy and nephropathy in patients with type 1 diabetes four years after a trial of intensive therapy. *The New England Journal of Medicine*, 2000, 342, 381-9.
- The EDIC Research Group. The effect of intensive diabetes treatment on carotid artery wall thickness in the Epidemiology of Diabetes Interventions and Complications (EDIC). *Diabetes*, 1999, 48, 383-90.
- The EDIC Research Group .Epidemiology of Diabetes Interventions and Complications (EDIC): design, implementation, and preliminary results of a long-term follow-up of the Diabetes Control and Complications Trial cohort. *Diabetes Care*, 1999, 117, 99-111.
- Monnier VM, Bautista O, Kenny D, Sell DR, Fogarty J, Dahms W, Cleary P, Lachin J, Genuth S and the DCCT 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: Relevance of glycated collagen products versus HbA1c as markers of diabetic complications. *Diabetes*, 1999, 48, 870-880

- The DCCT Research Group (J. Lachin, member, Writing Committee). Early worsening of diabetic retinopathy in the Diabetes Control and Complications Trial. *Archives of Ophthalmology*, 1998, 116, 874-86.
- The DCCT Research Group . Effect of intensive diabetes therapy on measures of autonomic nervous system function in the Diabetes Control and Complications Trial. *Diabetologia*, 1998, 41, 416-23.
- The DCCT Research Group . Effect of intensive therapy on residual β -cell function in patients with Type I diabetes in the Diabetes Control and Complications Trial. *Annals of Internal Medicine*, 1998, 128, 517-523.
- The DCCT Research Group . Effect of intensive diabetes therapy on measures of autonomic nervous system function in the Diabetes Control and Complications Trial. *Diabetologia*, 1998, 41, 416-23.
- The DCCT Research Group (J. Lachin, member, Writing Committee). Clustering of long-term complications in families with diabetes in the Diabetes Control and Complications Trial. *Diabetes*, 1997, 46, 1829-1839.
- The DCCT Research Group (J. Lachin, Chairman, Writing Committee). Hypoglycemia in the Diabetes Control and Complications Trail. *Diabetes*, 1997, 46, 271-286
- The DCCT Research Group. Lifetime benefits and costs of intensive therapy as practiced in the Diabetes Control and Complications Trial. *Journal of the American Medical Association*, 1996, 276, 1409-1415.
- The DCCT Research Group (J. Lachin, Chairman, Writing Committee). The absence of a glycemic threshold for the development of long-term complications: the perspective of the Diabetes Control and Complications Trial. *Diabetes*, 1996, 45, 1289-1298.
- The DCCT Research Group (J. Lachin, member, Writing Committee). Effects of intensive diabetes therapy on neuropsychological function in adults in the Diabetes Control and Complications Trial. *Annals of Internal Medicine*, 1996, 124, 379-388.
- The DCCT Research Group (J. Lachin, member, Writing Committee). Influence of intensive diabetes treatment on quality-of-life outcomes in the Diabetes Control and Complications Trial. *Diabetes Care*, 1996, 19, 195-203.
- The DCCT Research Group. Pregnancy outcomes in the Diabetes Control and Complications Trial. *American Journal of Obstetrics and Gynecology*, 1996, 174, 1343-1353.
- Leiter LA and the DCCT Research Group. Use of Bioelectrical Impedance Analysis Measurements in Patients with Diabetes. *American Journal of Clinical Nutrition*, 1996, 64 supplement 515S-518S
- The DCCT Research Group (J. Lachin, member, Writing Committee). Effect of intensive diabetes treatment on nerve conduction in the Diabetes Control and Complications Trial. *Annals of Neurology*, 1995, 38, 869-880.
- The DCCT Research Group (J. Lachin, member, Writing Committee). Adverse events and their association with treatment regimens in the Diabetes Control and Complications Trial. *Diabetes Care*, 1995, 18, 1415-1427.

- The DCCT Research Group . Resource utilization and costs of care in the Diabetes Control and Complications Trial. *Diabetes Care*, 1995, 18, 1468-1478.
- The DCCT Research Group (J. Lachin, Chairman, Writing Committee). The relationship of glycemic exposure (HbA1c) to the risk of development and progression of retinopathy in the Diabetes Control and Complications Trial. *Diabetes*, 1995, 44, 968-983.
- The DCCT Research Group . The effect of intensive diabetes therapy on macrovascular disease and its risk factors in the Diabetes Control and Complications Trial. *American Journal of Cardiology*, 1995, 75, 894-903.
- The DCCT Research Group (J. Lachin, member, Writing Committee). The effect of intensive therapy on the development and progression of diabetic nephropathy in the Diabetes Control and Complications Trial. *Kidney International*, 1995, 47, 1703-1720.
- The DCCT Research Group and Klein R. Comparison of study populations in the Diabetes Control and Complications Trial and the Wisconsin Epidemiologic Study of Diabetic Retinopathy. *Archives of Internal Medicine*, 1995, 155, 745-754.
- The DCCT Research Group (J. Lachin, member, Writing Committee). The effect of intensive diabetes therapy on the development and progression of neuropathy in the Diabetes Control and Complications Trial. *Annals of Internal Medicine*, 1995, 122, 561-68.
- The DCCT Research Group (J. Lachin, member, Writing Committee). Progression of retinopathy with intensive versus conventional treatment in the Diabetes Control and Complication Trial. *Ophthalmology*, 1995, 102, 647-661.
- The DCCT Research Group (J. Lachin, member, Writing Committee). Implementation of treatment protocols in the Diabetes Control and Complications Trial. *Diabetes Care*, 1995, 18, 361-76.
- The DCCT Research Group (J. Lachin, member, Writing Committee). The effect of intensive diabetes treatment on the development and progression of diabetic retinopathy in insulin-dependent diabetes mellitus: the Diabetes Control and Complications Trial. *Archives of Ophthalmology*, 1995, 113, 36-51.
- Leiter LA, Lukaski HC, Kenny DJ, Barnie A, Camelon K, Ferguson RS, MacLean S, Simkins S, Zinman B and Cleary PA for the DCCT Research Group. The use of Bioelectrical Impedance Analysis (BIA) to estimate body composition in the Diabetes Control and Complications Trial (DCCT). *International Journal of Obesity*, 1994, 18, 829- 835
- Schmidt LE, Cox MS, Buzzard IM, and Cleary PA, for the DCCT Research Group. Reproducibility of a comprehensive diet history in the Diabetes Control and Complications Trial. *Journal of the American Dietetic Association*, 1994, 94, 1392-1397
- The DCCT Research Group . A screening algorithm to identify clinically significant changes in neuropsychological function in the Diabetes Control and Complications Trial. *Journal of Clinical and Experimental Neuropsychology*, 1994, 16, 303-316.

- The DCCT Research Group (J. Lachin, member, Writing Committee). The effect of intensive diabetes treatment on the development and progression of long-term complications in adolescents with IDDM: the DCCT. *Journal of Pediatrics*, 1994, 125, 177-88.
- The DCCT Research Group. The impact of the trial coordinator in the Diabetes Control and Complications Trial. *Diabetes Educator*, 1993, 19, 509-512
- Levey AS, Greene T, Schluchter MD, Cleary PA, Teschan PE, Lorenz RA, Molitch ME, Mitch WE, Siebert C, Hall PM, and Steffes MW, for the Modification of Diet in Renal Disease Study Group and the Diabetes Control and Complications Trial Research Group. Glomerular filtration rate measurements in clinical trials. *Journal of the American Society of Nephrology*, 1993, 4, 1159-1171
- The DCCT Research Group. Nutrition interventions for intensive therapy in the Diabetes Control and Complications Trial. *The Journal of the American Dietetic Association*, 1993, 93, 768-772
- The DCCT Research Group. Expanded role of the dietitian in the Diabetes Control and Complications Trial: Implications for clinical practice. *The Journal of the American Dietetic Association*, 1993, 93, 758-767
- The DCCT Research Group (J. Lachin, member, Writing Committee). The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *The New England Journal of Medicine*, 1993, 329, 977-986.
- The DCCT Research Group . Baseline analysis of renal function in the Diabetes Control and Complications Trial. *Kidney International*, 1993, 43, 668-674.
- The DCCT Research Group . Lipid and lipoprotein levels in patients with IDDM. The Diabetes Control and Complications Trial Experience. *Diabetes Care*, 1992, 15, 886-894.
- The DCCT Research Group, (J. Lachin, member, Writing Committee). Epidemiology of severe hypoglycemia in the Diabetes Control and Complications Trial. *The American Journal of Medicine*, 1991, 90, 450-459.
- The DCCT Research Group . The Diabetes Control and Complications Trial (DCCT): Update. *Diabetes Care*, 1990, 13, 427-433.
- The DCCT Research Group. The Diabetes Control and Complications Trial: The trial coordinator perspective. *Diabetes Educator*, 1989, 15, 236-241.
- The DCCT Research Group. Implementation of a multi-component process to obtain informed consent in the Diabetes Control and Complications Trial. *Controlled Clinical Trials*, 1989, 10, 83-96.
- The DCCT Research Group. The Diabetes Control and Complications Trial: Update. *Diabetes Spectrum*, 1988, 1, 187-190.
- The DCCT Research Group. Weight gain associated with intensive therapy in the Diabetes Control and Complications Trial (DCCT). *Diabetes Care*, 1988, 11, 567-573.
- Schumer M, Burton G, Burton C, Crum D, Pfeifer MA, and The DCCT Study Group. Diabetic autonomic neuropathy-Part I. Autonomic nervous system data analysis

- by a computerized central unit in a multicenter trial. *The American Journal of Medicine*, 1988, 85, Supplement 5A, 137-143
- The DCCT Research Group. Is there a need for a continuation of the DCCT in 1988? *Diabetes Nutrition and Metabolism*, 1988, 1, 151-159.
- The DCCT Research Group. Reliability and validity of a diabetes quality-of-life measure for the Diabetes Control and Complications Trial (DCCT). *Diabetes Care*, 1988, 11, 725-732.
- The DCCT Research Group. Factors in the development of diabetic neuropathy: Baseline analysis in the feasibility phase of the Diabetes Control and Complications Trial (DCCT). *Diabetes*, 1988, 37, 476-481.
- The DCCT Research Group. Are continuing studies of metabolic control and microvascular complications in IDDM justified?: The Diabetes Control and Complications Trial (DCCT). *The New England Journal of Medicine*, 1988, 318, 246-250.
- The DCCT Research Group. Color photography vs. fluorescein angiography in the detection of diabetic retinopathy in the Diabetes Control and Complications Trial. *Archives of Ophthalmology*, 1987, 105, 1344-1351.
- The DCCT Research Group. Feasibility of centralized measurements of glycated hemoglobin in the Diabetes Control and Complications Trial: A multicenter study. *Clinical Chemistry*, 1987, 33, 2267-71.
- The DCCT Research Group. Effects of age, duration and treatment of insulin-dependent diabetes mellitus on residual Beta-cell function: Observations during eligibility testing for the Diabetes Control and Complications Trial (DCCT). *Journal of Clinical Endocrinology and Metabolism*, 1987, 65, 30-36.
- The DCCT Research Group. The Diabetes Control and Complications Trial (DCCT): Results of the feasibility study (Phase II). *Diabetes Care*, 1987, 10, 1-19.
- The DCCT Research Group, (J. Lachin, Director, Coordinating Center; chairman, writing team). The Diabetes Control and Complications Trial (DCCT): Design and methodological considerations for the feasibility phase. *Diabetes*, 1986, 35, 530-545.

Medical: Diabetes Prevention Program (DPP) and Outcome Study (DPPOS) (24 papers)

- The Diabetes Prevention Program (DPP) Research Group, Hamman RF, Horton E, Barrett-Connor E, Bray GA, Christophi C, Crandall J, Florez JC, Fowler S, Goldberg R, Kahn SE, Knowler WC, Lachin J, Murphy MB, Venditti E. Factors Affecting the Decline in Incidence of Diabetes in the Diabetes Prevention Program Outcome Study (DPPOS). *Diabetes*. 2015, 64(3), 989-998.
- Herman WH, Ma Y, Uwaifo G, Haffner S, Kahn SE, Horton ES, Lachin JM, Montez MG, Brenneman T, Barrett-Connor E; Diabetes Prevention Program Research Group. Differences in A1C by race and ethnicity among patients with impaired

- glucose tolerance in the Diabetes Prevention Program. *Diabetes Care*. 2007;30:2453-7.
- Lachin JM, Christophi CA, Edelstein SL, Ehrmann DA, Hamman RF, Kahn SE, Knowler WC, Nathan DM on behalf of the Diabetes Prevention Program Research Group. Factors associated with diabetes onset during metformin versus placebo therapy in the Diabetes Prevention Program. *Diabetes*. 2007 56:1153-9.
- Hamman RF, Wing RR, Edelstein SL, Lachin JM, Bray GA, Delahanty L, Hoskin M, Kriska AM, Mayer-Davis EJ, Pi-Sunyer X, Regensteiner J, Venditti B, Wylie-Rosett J, for the Diabetes Prevention Program Research Group. Effect of weight loss with lifestyle intervention on risk of diabetes. *Diabetes Care*. 2006 29:2102-7.
- The DPP Research Group. (J. Lachin, member, Writing Committee). Lipid, lipoproteins, C-reactive protein, and hemostatic factors at baseline in the Diabetes Prevention Program. *Diabetes Care*. 2005, 28(10): 2472-9.
- The DPP Research Group.. Role of insulin secretion and sensitivity in the evolution of type 2 diabetes in the diabetes prevention program: effects of lifestyle intervention and metformin. *Diabetes*. 2005, 54(8): 2404-14
- The DPP Research Group.. Intensive lifestyle and metformin on inflammation and coagulation in participants with impaired glucose tolerance. *Diabetes* 2005, 54(5):1566-1572.
- The DPP Research Group. Effect of metformin and lifestyle intervention on the metabolic syndrome: The Diabetes Prevention Program Randomized Trial. *Ann Int Med* 2005; 142: 611-19.
- The DPP Research Group. Depression symptoms and antidepressant medicine use in Diabetes Prevention Program (DPP) participants. *Diabetes Care* 2005, 28: 830-37.
- The DPP Research Group. Impact of intensive lifestyle and metformin therapy on cardiovascular (CVD) risk factors in the Diabetes Prevention Program. *Diabetes Care* 2005, 28: 888-94.
- The DPP Research Group. Prevention of type 2 diabetes with troglitazone in the Diabetes Prevention Program. *Diabetes* 2005, 54: 1150-1156
- The DPP Research Group. The cost-effectiveness of lifestyle modification or metformin in preventing type 2 diabetes in adults with impaired glucose tolerance. *Ann Intern Med*. 2005, 42:323-32
- The DPP Research Group. Strategies to identify adults at high risk for type 2 diabetes. *Diabetes Care* 2005, 28: 138-44.
- The DPP Research Group. Dietary intake in the diabetes prevention program cohort: Baseline and 1-year post-randomization. *Annals of Epidemiology* 2004, 14: 763-72
- Wing RR, Hamman RF, Bray GA, Delahanty L, Edelstein SL, Hill JO, Horton ES, Hoskin MA, Kriska A, Lachin J, Mayer-Davis EJ, Pi-Sunyer X, Regensteiner JG, Venditti B, Wylie-Rosett J; Diabetes Prevention Program Research Group.. Achieving weight and activity goals among diabetes prevention program lifestyle participants. *Obesity Research* 2004; 12: 1426-34

- The DPP Research Group. (J. Lachin, member, Writing Committee). Within trial cost-effectiveness of lifestyle intervention or metformin for the primary prevention of type 2 diabetes. *Diabetes Care* 2003; 26: 2518-23
- Herman WH, Brandle M, Zhang P, Williamson DF, Matulik MJ, Ratner RE, Lachin JM, Engelgau MM; Diabetes Prevention Program Research Group. Cost associated with the primary prevention of type 2 Diabetes Mellitus in the Diabetes Prevention Program. *Diabetes Care*, 2003, 26, 36-47.
- The DPP Research Group. Effects of withdrawal from metformin on the development of diabetes in the diabetes prevention program. *Diabetes Care*, 2003, 26, 977-80.
- The DPP Research Group. The Diabetes Prevention Program: recruitment methods and results. *Controlled Clinical Trials*, 2002; 23, 157-171.
- The DPP Research Group. The Diabetes Prevention Program (DPP): Description of lifestyle intervention. *Diabetes Care*, 2002, 25, 2165-2171.
- The DPP Research Group (J. Lachin, member, Writing Committee). Hypertension, Insulin, Proinsulin in participants with impaired glucose tolerance. *Hypertension*, 2002, 40, 679-686.
- The DPP Research Group (J. Lachin, member, Writing Committee). Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *The New England Journal of Medicine*, 2002; 346, 393-403.
- The DPP Research Group. The Diabetes Prevention Program: baseline characteristics of the randomized cohort. *Diabetes Care*, 2000, 23, 1619-29.
- The DPP Research Group. The Diabetes Prevention Program. Design and methods for a clinical trial in the prevention of type 2 diabetes. *Diabetes Care*, 1999, 22, 623-34.

Medical: Type 1 Diabetes Trial Network (TrialNet) (16 papers)

- Greenbaum CJ, Beam CA, Boulware D, Gitelman SE, Gottlieb PA, Herold KC, Lachin JM, McGee P, Palmer JP, Pescovitz MD, Krause-Steinrauf H, Skyler JS, Sosenko JM, and on behalf of the Type 1 Diabetes TrialNet Study Group. Fall in C-peptide during first 2 years from diagnosis: evidence of at least two distinct phases from composite type 1 diabetes TrialNet data *Diabetes*, 2012; 61:2066-2073; doi:10.2337/db11-1538.
- Lachin JM, McGee PL, Greenbaum CJ, Palmer J, Pescovitz MD, et al. 2011 Sample Size Requirements for Studies of Treatment Effects on Beta-Cell Function in Newly Diagnosed Type 1 Diabetes. *PLoS ONE* 2011; 6(11): e26471. doi:10.1371/journal.pone.0026471
- Pescovitz MD, Torgerson TR, Ochs HD, Ocheltree E, McGee P, Krause-Steinrauf H, Lachin JM, Canniff J, Greenbaum C, Herold KC, Skyler JS, Weinberg A; Type 1 Diabetes TrialNet Study Group. Effect of rituximab on human in vivo antibody immune responses. *J Allergy Clin Immunol*. 2011, 128, 1295-1302. PMID: 21908031

- Herold KC, Pescovitz MD, McGee P, Krause-Steinrauf H, Spain LM, Bourcier K, Asare A, Liu Z, Lachin JM, Dosch HM; Type 1 Diabetes TrialNet Anti-CD20 Study Group. Increased T cell proliferative responses to islet antigens identify clinical responders to anti-CD20 monoclonal antibody (rituximab) therapy in type 1 diabetes. *J Immunol.* 2011; 187:1998-2005.
- Sosenko JM, Mahon J, Rafkin L, Lachin JM, Krause-Steinrauf H, Krischer JP, Cuthbertson D, Palmer JP, Thompson C, Greenbaum CJ, Skyler JS; Diabetes Prevention Trial-Type 1 and TrialNet Study Groups. A comparison of the baseline metabolic profiles between Diabetes Prevention Trial-Type 1 and TrialNet Natural History Study participants. *Pediatr Diabetes.* 2011;12:85-90. doi: 10.1111/j.1399-5448.2010.00662.x.
- Gottlieb PA, Quinlan S, Krause-Steinrauf H, Greenbaum CJ, Wilson DM, Rodriguez H, Schatz DA, Moran AM, Lachin JM, Skyler JS; Type 1 Diabetes TrialNet MMF/DZB Study Group. Failure to preserve beta-cell function with mycophenolate mofetil and daclizumab combined therapy in patients with new-onset type 1 diabetes. *Diabetes Care.* 2010, 33(4):826-32.
- Pescovitz MD, Greenbaum CJ, Krause-Steinrauf H, Becker DJ, Gitelman SE, Goland R, Gottlieb PA, Marks JB, McGee PF, Moran AM, Raskin P, Rodriguez H, Schatz DA, Wherrett D, Wilson DM, Lachin JM, Skyler JS for the Type 1 Diabetes TrialNet Anti-CD20 Study Group. Rituximab, B-Lymphocyte Depletion, and Preservation of Beta-Cell Function. *New Engl J. Med.*, 2009, 361:2143-2152.
- Mahon JL, Sosenko JM, Rafkin-Mervis L, Krause-Steinrauf H, Lachin JM, Thompson C, Bingley PJ, Bonifacio E, Palmer JP, Eisenbarth JS, Wolfsdorf J, Skyler JS, the TrialNet Natural History Committee and Type 1 Diabetes TrialNet Study Group. The TrialNet Natural History Study of the Development of Type 1 Diabetes: objectives, design, and initial results. *Pediatric Diabetes.* 10(2), 2009: 97–104, DOI: 10.1111/j.1399-5448.2008.00464.x
- Chase P, Leschek E, Krause-Steinrauf H, Chritton S, Asare S, Adams S, Skyler S, Clare-Salzler M. Nutritional Intervention to Prevent (NIP) Type 1 Diabetes A Pilot Trial. *Infant, Child, and Adolescent Nutrition 2009; 99-107.*
- Herold KC, Brooks-Worrell B, Palmer J, Dosch HM, Peakman M, Gottlieb P, Reijonen H, Arif S, Spain LM, Thompson C, Lachin JM; Type 1 Diabetes TrialNet Research Group. Validity and reproducibility of measurement of islet autoreactivity by T-cell assays in subjects with early type 1 diabetes. *Diabetes.* 2009, 58:2588-95.
- Skyler JS, Greenbaum CJ, Lachin JM, Leschek E, Rafkin-Mervis L, Savage P, Spain L, and the Type 1 Diabetes TrialNet Study Group. Type 1 Diabetes TrialNet—An International Collaborative Clinical Trials Network. *Annals of the New York Academy of Sciences*, 2008 1150: 14-24.
- Mahon JL, Sosenko JM, Rafkin-Mervis L, Krause-Steinrauf H, Lachin JM, Thompson C, Bingley PJ, Bonifacio E, Palmer JP, Eisenbarth GS, Wolfsdorf J and Skyler JS for the TrialNet Natural History Committee* and Type 1 Diabetes TrialNet Study Group. The TrialNet Natural History Study of the Development of Type 1 Diabetes: objectives, design, and initial results. *Pediatric Diabetes*, 2008 10: 97-104.

- Skyler JS, Greenbaum CJ, Lachin JM, Leschek E, Rafkin-Mervis L, Savage P, Spain L, and the Type 1 Diabetes TrialNet Study Group. Type 1 Diabetes TrialNet—An International Collaborative Clinical Trials Network. *Annals of the New York Academy of Sciences*, 2008 1150: 14-24.
- Skyler JS and the Type 1 Diabetes TrialNet Study Group. Update on Worldwide Efforts to Prevent Type 1 Diabetes. *Annals of the New York Academy of Sciences* 2008; Dec;1150:190-6.
- Greenbaum CJ, Mandrup-Poulsen T, McGee PF, Battelino T, Haastert B, Ludvigsson J, Pozzilli P, Lachin JM, Kolb H; Type 1 Diabetes Trial Net Research Group; European C-Peptide Trial Study Group. Mixed-meal tolerance test versus glucagon stimulation test for the assessment of beta-cell function in therapeutic trials in type 1 diabetes. *Diabetes Care*. 2008, 31:1966-71.
- Sosenko JM, Krischer JP, Palmer JP, Mahon J, Cowie C, Greenbaum CJ, Cuthbertson D, Lachin JM, Skyler JS; Diabetes Prevention Trial-Type 1 Study Group. A risk score for type 1 diabetes derived from autoantibody-positive participants in the diabetes prevention trial-type 1. *Diabetes Care*. 2008; 31:528-33

Medical: Captopril Treatment of Diabetic Nephropathy (10 papers)

- Breyer JA, Bain RP, Evans JK, Nahman NS, Lewis EJ, Cooper M, McGill J, Berl T and the Collaborative Study Group. Predictors of the progression of renal insufficiency in patients with insulin-dependent diabetes and overt diabetic nephropathy. *Kidney International*. 1996, 50,1651-8
- Rodby RA, Lewis EJ, Firthe LM, and the Collaborative Study Group. An Economic analysis of Captopril in the treatment of diabetic nephropathy. *Diabetes Care*, 1996 19, 1051-61
- Rodby RA, Rohde RD, Sharon Z, Pohl M, Bain RP and Lewis EJ for the Collaborative Study Group. The urine protein to creatinine ratio as a predictor of 24-hour urine protein excretion in type 1 diabetic patients with nephropathy. *American Journal of Kidney Diseases* 1995, 26, 904-9
- Rodby RA, Rohde R, Evans J, Bain RP, Mulcahy WS, Lewis EJ and the Collaborative Study Group, The study of the effect of intensity of blood pressure management on the progression of type 1 diabetic nephropathy: study design and baseline patient characteristics. *Journal American Society of Nephrology* 1995; 5, 1775-81
- Breyer JA, Hunsicker LG, Bain RP, Lewis EJ, and the Collaborative Study Group. Angiotensin converting enzyme inhibition in diabetic nephropathy. *Kidney International*, 1994, 45, S156-60.
- Herbert LA, Verme D, Bain RP, Cattran DC, Whittier FC, Tolchin N, Lewis EJ, Rohde R, and the Collaborative Study Group. Remission of nephrotic range proteinuria in type I diabetes. *Kidney International* 1994 46, 1688-93
- Lewis EJ, Hunsicker LG, Bain RP and Rohde RD and the Collaborative Study Group. The effect of angiotensin-converting-enzyme inhibition in diabetic nephropathy. *The New England Journal of Medicine*, 1993, 329, 1456-1462.

- Bain R, Rohde R, Hunsicker LG, McGill J, Kobrin S, Lewis EJ, and the Collaborative Study Group. A controlled clinical trial of angiotensin-converting enzyme inhibition in Type I diabetic nephropathy: Study design and patient characteristics. *Journal of the American Society of Nephrology*, 1992, 3, 97-103.
- Rodby R, Ali J, Rohde RD, Lewis EJ, and the Collaborative Study Group for the Study of Angiotensin Converting Enzyme Inhibition in Diabetic Nephropathy. Renal scanning Tc-DTPA GFR determination compared to iothalamate clearance GFR in diabetics. *American Journal of Kidney Diseases*, 1992, XX, : 569-573
- Lemann J, Jr., Bidani AK, Bain RP, Lewis EJ, Rohde RD, and the Collaborative Study Group of Angiotensin Converting Enzyme Inhibition in Diabetic Nephropathy. Use of the serum creatinine to estimate glomerular filtration in rate in health and early diabetic nephropathy. *American Journal of Kidney Diseases*, 1990, 16, 236-243.

Medical: Lupus Nephritis Collaborative Study (LNCS) (14 Papers)

- Najafi CC, Korbet SM, Lewis EJ, Schwartz MM, Reichlin M and Evans J, for the Collaborative Study Group. Significance of histologic patterns of glomerular injury upon long-term prognosis in severe lupus glomerulonephritis. *Kidney International* 2001, 59, 2156-63
- Korbet SM, Lewis EJ, Schwartz MM, Reichlin M, Evans J, and Rohde RD for the Collaborative Study Group. Factors predictive of outcome in severe lupus nephritis. *American Journal of Kidney Diseases*, 2000, 35, 904-914
- Sloan RP, Schwartz MM, Korbet SM, Borok RZ and the Lupus Nephritis Collaborative Study Group. Long term outcome in systemic lupus erythematosus membranous glomerulonephritis. *Journal of American Society of Nephrology* 1996, 7, 299-305.
- Herbert LA, Dillon JJ, Middendorf DF, Lewis EJ, Peter JB, and the Lupus Nephritis Collaborative Study Group. Relationship between appearance of urinary red blood cell/white blood cell casts and the onset of renal relapse in systemic lupus erythematosus. *American Journal of Kidney Diseases* 1995, 26, 432-8
- Schwartz MM, Lan SP, Bernstein J, Hill GS, Holley K, Lewis EJ, and the Lupus Nephritis Collaborative Study Group. Irreproducibility of the activity and chronicity indices limits. Their utility in the management of Lupus Nephritis. *American Journal of Kidney Diseases*, 1993, 21, 374-377.
- 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.
- 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.
- Schwartz MM, Lan SP, Bernstein J, Hill GS, Holley K, Lewis EJ, and the Lupus

- Nephritis Collaborative Study Group. Role of pathology indices in the management of severe lupus glomerulonephritis. *Kidney International*, 1992, 42, 743-748.
- Ricker DM, Hebert LA, Rohde R, Sedmak D, Lewis EJ, Clough JD and the Lupus Nephritis Collaborative Study Group, Serum C3 Levels are diagnostically more sensitive and specific for SLE activity than are serum C4 levels. *American Journal of Kidney Diseases*, 1991, XVIII, 678-685
- Pohl MA, Lan SL, Berl T, and the Lupus Nephritis Collaborative Study Group. Plasmapheresis does not increase the risk for infection in immunosuppressed patients with severe lupus nephritis. *Annals of Internal Medicine*, 1991, 114, 924-929.
- Clough J. Proceedings of the Second International Congress of the World Apheresis Association 1988, Treatment protocols of the lupus nephritis collaborative study of plasmapheresis in severe lupus nephritis. *Progress in Clinical and Biological Research*, 1990, 337, 301-307
- Schwartz MM, Lan SP, Bonsib SM, Gephardt GN, Sharma HM, and the Lupus Nephritis Collaborative Study Group. Clinical outcome of three discrete histologic patterns of injury in severe lupus glomerulonephritis. *American Journal of Kidney Diseases*, 1989, XIII, 273-283.
- Sasse EA, Doumas BT, Lemann J, Jr. and the Collaborative Study Group. Urinary albumin in relation to urinary total protein in patients with established diabetic nephrology. *Annals of Internal Medicine*, 1989, III, 343-4.
- Schwartz ML, Bernstein J, Hill GS, Holley K, Phillips EA, and the Lupus Nephritis Collaborative Study Group. Predictive value of renal pathology in diffuse proliferative lupus glomerulonephritis. *Kidney International*, 1989, 36, 891-896.

Medical: National Cooperative Gallstone Study (NCGS) (19 papers)

- 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.
- 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.
- Marks JW, Lan SP, the Steering Committee and the NCGS Group. Low-dose Chenodiol to prevent gallstone recurrence after dissolution therapy. *Annals of Internal Medicine*, 1984, 100, 376-381.
- 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.
- 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.
- 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.
- Hofmann AF and Lachin JM. Biliary bile acid composition and cholesterol saturation. *Gastroenterology*, 1983, 84, 1075-1077.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- Albers JJ, Grundy SM, Cleary PA, Small DM, Lachin JM, Schoenfield LJ, for the NCGS Group. National Cooperative Gallstone Study: The effect of chenodeoxycholic acid on lipoproteins and apolipoproteins. *Gastroenterology*, 1982, 82, 638-646.
- Schoenfield LJ, Lachin JM, the Steering Committee and the NCGS Group. Chenodiol (chenodeoxycholic acid) for dissolution of gallstones: The National Cooperative Gallstone Study. A controlled trial of efficacy and safety *Annals of Internal Medicine*, 1981, 95, 257-282.
- Lasser EC, Amberg JR, Baily NA, Varady P, Lachin JM, Okun R, and Schoenfield LJ. Validation of a computer-assisted method for estimating the number and volume of gallstones visualized by cholecystography. *Investigative Radiology*, 1981, 16, 342-347.
- Marks JW, Sue SO, Pearlman BJ, Banorris GG, Varady P, Lachin JM and Schoenfield LJ. Sulfation of lithocholate as a possible modifier of

- chenodeoxycholic acid-induced elevations of serum transaminase in patients with gallstones. *Journal of Clinical Investigation*, 1981, 68, 1190-1196.
- Lachin JM, Marks J, and Schoenfield LJ, the Protocol Committee and the NCGS Group. Design and methodological considerations in the National Cooperative Gallstone Study: A multi-center clinical trial. *Controlled Clinical Trials*, 1981, 2, 177-230.
- Marks JW, Bonorris GG, Chung A, Coyne MJ, Okun R, Lachin JM and Schoenfield LJ. Feasibility of low dose and intermittent chenodeoxycholic acid therapy of gallstones. *American Journal of Digestive Diseases*, 1977, 22, 856-860.

Miscellaneous Medical (51 papers)

Empa-Reg Outcome Study

- Fitchett D, Inzucchi SE, Zinman B, Wanner C, Schumacher M, Schmoor C, Ohneberg K, Ofstad AP, Salsali A, George JT, Hantel S, Bluhmki E, Lachin JM, Zannad F. Mediators of the improvement in heart failure outcomes with empagliflozin in the EMPA-REG OUTCOME trial. *ESC Heart Failure* 2021; **8**: 4517–4527 doi: 10.1002/ehf2.13615.
- Claggett B, Lachin J, Hantel S, Fitchett D, Inzucchi S.E., Woerle H.J., George J.T., Zinman B. Long-Term Benefit of Empagliflozin on Life Expectancy in Patients with Type 2 Diabetes and Established Cardiovascular Disease: Survival Estimates from the EMPA-REG OUTCOME Trial . *Circulation*. 2018;138(15):1599-1601.
- Fitchett D, Inzucchi SE, Lachin JM, Wanner C, van de Borne P, Mattheus M, Johansen OE, Woerle HJ, Broedl UC, George JT, Zinman B; EMPA-REG OUTCOME investigators. Cardiovascular mortality reduction with empagliflozin in patients with type 2 diabetes and cardiovascular disease. *J Am Coll Cardiol* 2018;71:364–67.
- Inzucchi SE, Zinman B, Fitchett D, Wanner C, Ferrannini E, Schumacher M, Schmoor C, Ohneberg K, Johansen OE, George JT, Hantel S. How Does Empagliflozin Reduce Cardiovascular Mortality? Insights From a Mediation Analysis of the EMPA-REG OUTCOME Trial. *Diabetes Care*. 2018 Feb 1;41(2):356-63.
- Fitchett, D., Butler, J., van de Borne, P., Zinman, B., Lachin, J., Wanner, C., Woerle, H., Hantel, S., George, J., Johansen, O., & Inzucchi, S. Effects of Empagliflozin on Risk for Cardiovascular Death and Heart Failure Hospitalization Across the Spectrum of Heart Failure Risk in the EMPA-REG OUTCOME® Trial.. *European Heart Journal*, 2018;39(5):363-370. doi: 10.1093/eurheartj/ehx511.
- Wanner C, Lachin JM, Inzucchi SE, Fitchett D, Mattheus M, George JT, Woerle HJ, Broedl UC, von Eynatten M, Zinman B. Empagliflozin and clinical outcomes in patients with type 2 diabetes, established cardiovascular disease and chronic kidney disease. *Circulation*. 2018; 137: 119-29.
- Wanner C, Inzucchi S, Lachin JM, Fitchett D, von Eynatten M, Mattheus M, Johansen OE, Woerle HJ, Broedl UC, Zinman B. Reduced progression of kidney

- disease with empagliflozin: results from EMPA-REG OUTCOME. *Diabetic Medicine* 2017; 34: 80-81.
- Zinman B, Inzucchi SE, Lachin JM, Wanner C, Fitchett D, Kohler S, Mattheus M, Woerle HJ, Broedl UC, Johansen OE, Albers GW. Empagliflozin and cerebrovascular events in patients with type 2 diabetes mellitus at high cardiovascular risk. *Stroke*. 2017 48(5): 1218-1225.
- Wanner C, Inzucchi SE, Lachin JM, Fitchett D, von Eynatten M, Mattheus M, Johansen OE, Woerle HJ, Broedl UC, and Zinman B for the EMPA-REG OUTCOME Investigators. Empagliflozin and progression of kidney disease in type 2 diabetes *N Engl J Med* 2016;375:323-34.DOI: 10.1056/NEJMoa1515920
- Fitchett D, Zinman B, Wanner C, Lachin JM, Hantel S, Salsali A, Johansen OE, Woerle HJ, Broedl UC, Inzucchi SE. Heart failure outcomes with empagliflozin in patients with type 2 diabetes at high cardiovascular risk: results of the EMPA-REG OUTCOME® trial. *European Heart Journal*. 2016;37(19):1526-34.:ehv728.
- Zinman B, Wanner C, Lachin JM, Fitchett D, Bluhmki E, Hantel S, Mattheus M, Devins T, Johansen OE, Woerle HJ, Broedl UC. Empagliflozin, cardiovascular outcomes, and mortality in type 2 diabetes. *New England Journal of Medicine*. 2015; 373(22):2117-28
- Zinman B, Inzucchi SE, Lachin JM, Wanner C, Ferrari R, Fitchett D, Bluhmki E, Hantel S, Kempthorne-Rawson J, Newman J, Johansen O-E, Woerle H-J., Broedl UC. Rationale, design, and baseline characteristics of a randomized, placebo-controlled cardiovascular outcome trial of empagliflozin (EMPA-REG OUTCOME™). *Cardiovascular Diabetology*, 2014, 13 (1), art. no. 102.

Trial Evaluating Cardiovascular Out- comes with *Sitagliptin* (TECOS)

- Navar AM, Gallup DS, Lokhnygina Y, Green JB, McGuire DK, Armstrong PW, Buse JB, Samuel S, Engel SS, Lachin JM, Standl E, Van de Werf F, Holman RR, Peterson ED on behalf of the TECOS Study Group. Hypertension control in adults with diabetes and recurrent cardiovascular events: Global results from the TECOS Trial *Hypertension*. 2017;70:907–914.
- Standl E, Stevens SR, Armstrong PW, Buse JB, Chan JC, Green JB, Lachin JM, Scheen A, Travert F, Van de Werf F, Peterson ED. Increased Risk of Severe Hypoglycemic Events Before and After Cardiovascular Outcomes in TECOS Suggests an At-Risk Type 2 Diabetes Frail Patient Phenotype. *Diabetes Care*. 2018, 41(3):596-603. doi: 10.2337, dc171778.
- Sharma A, Green JB, Dunning A, Lokhnygina Y, Al-Khatib SM, Lopes RD, Buse JB, Lachin JM, Van de Werf F, Armstrong PW, Kaufman KD. Causes of death in a contemporary cohort of patients with type 2 diabetes and atherosclerotic cardiovascular disease: insights from the TECOS Trial. *Diabetes Care*. 2017; 40(12):1763-1770. doi: 10.2337:dc171091.
- Buse JB, Bethel MA, Green JB, Stevens SR, Lokhnygina Y, Aschner P, Grado CR, Tankova T, Wainstein J, Josse R, Lachin JM, Engel SS, Patel K, Peterson ED,

- Holman RR. Pancreatic Safety of Sitagliptin in the TECOS Trial. *Diabetes Care* 2017;40(2):164-170. doi: 10.2337/dc15-2780.
- McGuire DK, Van de Werf F, Armstrong PW, Standl E, Koglin J, Green JB, Bethel MA, Cornel JH, Lopes RD, Halvorsen S, Ambrosio G, Buse JB; Josse RG; Lachin JM, Pencina MJ, Garg J, Lokhnygina Y, Holman RR, Peterson ED for the TECOS Study Group. Association between sitagliptin use and heart failure hospitalization and related outcomes in type 2 diabetes mellitus: secondary analysis of a randomized clinical trial. *JAMA Cardiol.* 2016;1(2):126-135. doi:10.1001/jamacardio.2016.0103.
- Green JB, Bethel MA, Armstrong PW, Buse JB, Engel SS, Garg J, Josse R, Kaufman KD, Koglin J, Korn SH, Lachin J, McGuire D, Pencina M, Standl E, Stein P, Suryawanshi S, Van de Werf F, Peterson E, Holman RR. Effect of sitagliptin on cardiovascular outcomes in type 2 diabetes. *N Engl J Med*, 2015, 373:232-242

A Diabetes Outcome Prevention Trial (ADOPT)

- Kahn SE, Lachin JM, Zinman B, Haffner SM, Aftring RP, Paul G, Kravitz BG, Herman WH, Viberti G, Holman RR; ADOPT Study Group. Effects of rosiglitazone, glyburide, and metformin on β -cell function and insulin sensitivity in ADOPT. *Diabetes*. 2011, 60:1552-60.
- Lachin JM, Viberti G, Zinman B, Haffner SM, Aftring RP, Paul G, Kravitz BG, Herman WH, Holman RR, Kahn SE; ADOPT Study Group. Renal function in type 2 diabetes with rosiglitazone, metformin, and glyburide monotherapy. *Clin J Am Soc Nephrol*. 2011, 6:1032-40.
- Zinman B, Haffner SM, Herman WH, Holman RR, Lachin JM, Kravitz BG, Paul G, Jones NP, Aftring RP, Viberti G, Kahn SE and the A Diabetes Outcome Progression Trial Study Group Effect of Rosiglitazone, Metformin, and Glyburide on Bone Biomarkers in Patients with Type 2 Diabetes. *J Clin Endocrinol Metab*, 2010, 95: 134-142
- Kahn SE, Haffner SM, Viberti G, Herman WH, Lachin JM, Kravitz BG, Yu D, Paul G, Holman RR, Zinman B; Diabetes Outcome Progression Trial (ADOPT) Study Group. Rosiglitazone decreases C-reactive protein to a greater extent relative to glyburide and metformin over 4 years despite greater weight gain: observations from a Diabetes Outcome Progression Trial (ADOPT). *Diabetes Care*, 2010, 33:177-83.
- Kahn SE, Zinman B, Lachin JM, Haffner SM, Herman WH, Holman RR, Kravitz BG, Yu D, Heise MA, Aftring RP, Viberti G; Diabetes Outcome Progression Trial (ADOPT) Study Group. Rosiglitazone-associated fractures in type 2 diabetes: an Analysis from A Diabetes Outcome Progression Trial (ADOPT). *Diabetes Care*, 2008, 31:845-51.
- Kahn SE, Haffner SM, Heise MA, Herman WH, Holman RR, Jones NP, Kravitz BG, Lachin JM, O'Neill MC, Zinman B, Viberti G for the ADOPT Study Group. Glycemic Durability of Rosiglitazone, Metformin, or Glyburide Monotherapy.

- The New England Journal of Medicine* 355: 2427-43, 2006. Correction (356: 1387-8, 2007).
- Viberti G, Lachin JM, Holman RR, Zinman B, Haffner SM, Heise MA, Jones NP, Kravitz BG, O'Neill MC, Freed MI, Kahn SE, Herman WH for the ADOPT Study Group. A Diabetes Outcome Progression Trial (ADOPT): baseline characteristics of Type 2 diabetic patients in North America and Europe. *Diabetic Medicine* 23: 1289-1294, 2006
- Kahn SE, Zinman B, Haffner SM, O'Neill C, Kravitz BG, Yu D, Freed MI, Herman WH, Holman RR, Jones NP, Lachin JM, Viberti GC and the ADOPT Study Group. Obesity is a major determinant of the association of C-reactive protein levels and the metabolic syndrome in type 2 diabetes. *Diabetes*, 55: 2357-2364, 2006
- 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.

Other Medical

- Riddle MC, Blonde L, Gerstein HC, Gregg EW, Holman RR, Lachin JM, Nichols GA, Turchin A, Cefalu WT. Diabetes Care Editors' Expert Forum 2018: Managing Big Data for Diabetes Research and Care. *Diabetes Care* 2019 Jun; 42(6): 1136-1146. <https://doi.org/10.2337/dci19-0020>
- Braffett BH, Rice MM, Young HA, Lachin JM. Mediation of the association of smoking and microvascular complications by glycemic control in type 1 diabetes. *PLoS ONE* 2019 Jan. 14(1):e0210367. <https://doi.org/10.1371/journal.pone.0210367>
- Sacks DB, Bebu I, Lachin JM. Refining Measurement of Hemoglobin A1c. *Clinical Chemistry*. 2017 Sep 1;63(9):1433-5.
- Guglielmi C, Del Toro R, Lauria A, Maurizi AR, Fallucca S, Cappelli A, Angeletti S, Lachin JM, Pozzilli P. Effect of GLP-1 and GIP on C-peptide secretion after glucagon or mixed meal tests: Significance in assessing B-cell function in diabetes. *Diabetes/metabolism Research and Reviews*. Sep 2017; 33(6), e2899 .
- Nikolaus Marx, Julio Rosenstock, Steven E Kahn, Bernard Zinman, John J Kastelein, John M Lachin, Mark A Espeland, Erich Bluhmki, Michaela Mattheus, Bart Ryckaert, Sanjay Patel, Odd Erik Johansen, Hans-Juergen Woerle. Design and baseline characteristics of the CARdiovascular Outcome Trial of LINAgliptin Versus Glimepiride in Type 2 Diabetes (CAROLINA®). *Diabetes and Vascular Disease Research*, 1479164115570301, 2015/3/15.
- Rosenstock J, Marx N, Kahn SE, Zinman B, Kastelein JJ, Lachin JM, Bluhmki E, Patel S, Johansen O-E, Woerle H-J. Cardiovascular outcome trials in type 2 diabetes and the sulphonylurea controversy: Rationale for the active-comparator

- CAROLINA trial. *Diabetes and Vascular Disease Research*, 2013, 10 (4), pp. 289-301.
- Sacks DB, Nathan DM, Lachin JM. Gaps in the glycation gap hypothesis. *Clin Chem*. 2011, 57, 150-2.
- Lachin JM. Point: Intensive Glycemic Control and Mortality in ACCORD—A Chance Finding? *Diabetes Care*, 2010, 33, 2719-2721.
- 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.
- American Diabetes Association (Work Group: Genuth S, Eastman R, Kahn R, Klein R, Lachin J, Liebovitz H, Nathan D, Vinicor F). Implications of the United Kingdom Prospective Diabetes Study, *Diabetes Care*, 1998, 21, 2180-84.
- 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.
- 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.
- 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.
- American Diabetes Association and American Academy of Neurology, (J. Lachin, participant). Consensus statement: Report and recommendations of the San Antonio conference on diabetic neuropathy. *Diabetes Care*, 1988, 11, 592-597.
- The NIH. (J. Lachin, member, Consensus Panel). Consensus development conference on diet and exercise in non-insulin dependent diabetes mellitus. *Diabetes Care*, 1987, 10, 639-644.
- Schachter J, Elmer E, Ragins N, Wimberly F, Lachin JM. Assessment of mother-infant interaction: schizophrenic and non-schizophrenic mothers. *Merrill-Palmer Quarterly of Behavior and Development*, 1977. 23(3), 193-206. <http://www.jstor.org/stable/23084551>.
- Schachter J, Lachin JM, Kerr J, and Wimberly F. Measurement of electroencephalic evoked response: Comparison of univariate and multivariate. *Psychophysiology*, 1976, 13, 261-268.
- Schachter J, Lachin JM, and Wimberly F. Newborn heart rate and blood pressure: Relation to race and socioeconomic class. *Psychosomatic Medicine*, 1976, 38, 390-398.

- Schachter J, Lachin JM, Kerr J, Wimberly F, and Patey J. Heart rate and blood pressure in black newborns and in white newborns. *Pediatrics*, 1976, 58, 283-286.
- Schachter J, Kerr J, Lachin JM, and Faer M. Newborn offspring of schizophrenic parent: Cardiac reactivity to auditory stimuli. *Psychophysiology*, 1975, 12, 483-492.
- Schachter J, Kerr J, Wimberly F, and Lachin J. Phasic heart rate responses: Different patterns in black and in white newborns. *Psychosomatic Medicine*, 1975, 37, 326-332.
- Schachter J, Kerr J, Wimberly F, and Lachin J. Heart rate levels of black and white newborns. *Psychosomatic Medicine*, 1974, 36, 513-524.
- Bell AH, Weingold HP, and Lachin J. Measuring adjustment in patients disabled with alcoholism. *Quarterly Journal of Studies on Alcohol*, 1969, 30, 634-639.
- Weingold HP, Lachin JM, Bell AH, and Coxe RC. Depression as a symptom of alcoholism: Search for a phenomenon. *Journal of Abnormal Psychology*, 1968, 73, 195-197.

b) Articles in Non-Refereed Journal Articles, including letters (14 papers)

- Lachin JM, Bebu I, Gao X, Nathan DM, Zinman B. Response to Comment on Lachin et al. Association of Estimated Time-in-Range Capillary Glucose Levels Versus HbA1c With Progression of Microvascular Complications in the Diabetes Control and Complications Trial. *Diabetes Care* 2022; 45: 2445-2448. *Diabetes care*. 2023 Jan 1;46(1):e13.
- Braffett BH, Dagogo-Jack S, Bebu I, Sivitz WI, Larkin M, Kolterman O, Lachin JM; DCCT/EDIC Research Group. Response to Comment on Braffett et al. Association of Insulin Dose, Cardiometabolic Risk Factors, and Cardiovascular Disease in Type 1 Diabetes During 30 Years of Follow-up in the DCCT/EDIC Study. *Diabetes Care* 2019 42:657-664. *Diabetes Care* 2019 Aug;42(8):e137. doi: 10.2337/dci19-0026.
- Home P, Lachin JM. Comment on Novodvorsky et al. Diurnal Differences in Risk of Cardiac Arrhythmias During Spontaneous Hypoglycemia in Young People With Type 1 Diabetes. *Diabetes Care* 2017;40:655–662 *Diabetes Care* Apr 2018, 41 (4) e64; DOI: 10.2337/dc17-2405.
- Lachin JM. Sample size evaluation for a multiply matched case-control study using the score test from a conditional logistic(discrete Cox PH) regression model. Correction. *Statistics in Medicine*. 2018;37:1765–1766.
- John M. Lachin, Ionut Bebu, Richard M. Bergenstal, Rodica Pop-Busui, F. John Service, Bernard Zinman, David M. Nathan. Response to Comment on Lachin et al. Association of Glycemic Variability in Type 1 Diabetes With Progression of Microvascular Outcomes in the Diabetes Control and Complications Trial. *Diabetes Care* 2017;40:777–783. e165-e166; DOI: 10.2337/dci17-0038
- Nathan DM, Genuth SM, Zinman B, Lachin JM. Data sharing is desirable, but benefits should not be exaggerated. *British Medical Journal* 2015; 351:h5508

- Nathan DM, Genuth S, Rutledge B and Lachin JM. Response to Comment on: Lachin et al. (2007) The Hemoglobin Glycation Index Is Not an Independent Predictor of the Risk of Microvascular Complications in the Diabetes Control and Complications Trial: *Diabetes* 56:1913–1921, 2007. *Diabetes* 2008, 57:e5.
- Lachin JM and Greenhouse, J. Sam Greenhouse: 1918-2000. *AmStat News*, September, 4-5, 2001.
- Hu, MX and Lachin, JM. Likelihood-based Approaches for Handling Nuisance Parameters. *ASA Proceedings of the Section on Bayesian Statistical Science*, 1999, 108-113.
- Lachin JM. Discussion: Adaptive designs in clinical trials: the Lilly experience. *Biopharmaceutical Report*, 3: 6,1995.
- The DCCT Research Group. Psychological aspects of the DCCT. The Technology of Diabetes Care, *Converging Medical and Psychosocial Perspectives*, 1994, 122-139
- 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.
- The DCCT Research Group. Treatment regimen design in the Diabetes Control and Complications Trial (DCCT). *Transplantation Proceedings*, 1986, 28, 1678-80.
- Kerr J, Tobin M, Milkman N, Kjoletto B, Khachaturian Z, Williams T, Schachter J, and Lachin J. A PDP-12 System for on-line acquisition of heart rate data. *PDP-12 Biomedical User Application Report*, Digital Equipment Corporation, Maynard, Mass., 1971.

c) Chapters in Books (16 papers)

- Lachin, JM. Intention-to-Treat: Overview. *Wiley StatsRef: Statistics Reference Online*. 2018; 1–10. John Wiley & Sons, Ltd. DOI: 10.1002/9781118445112.stat07131.pub2
- Lachin JM. Intention-to-Treat Analysis, in *Methods and Applications of Statistics in Clinical Trials: Planning, Analysis, and Inferential Methods*, 2014 Volume 2 (ed N. Balakrishnan), John Wiley & Sons, Inc., Hoboken, NJ, USA. doi: 10.1002/9781118596333.ch16
- Mahmoud HM, Gastwirth JL, Lachin J, Modarres R. The Department of Statistics at The George Washington University, In. *Strength in Numbers: The Rising of Academic Statistics Departments in the U. S.* (Agresti A and Meng X-L, Eds.), 2013, pp 65-76.
- Lachin JM. Intention to Treat Analysis. In *Wiley Encyclopedia of Clinical Trials*. RB D'Agostino, L Sullivan, J Massaro (Editors). John Wiley & Sons, 2008.
- Lachin JM. The National Cooperative Gallstone Study. In *Wiley Encyclopedia of Clinical Trials*. RB D'Agostino, L Sullivan, J Massaro (Editors). John Wiley & Sons, 2008.
- 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, pp 93-108, 2006.
- 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
- Lachin JM. Sample size determination. In *Encyclopedia of Biostatistics*, P. Armitage and T. Colton (Eds.), Wiley, New York, 3892-3903, 1998.
- 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. Reprinted as *Cancer Treat Res.* 1995; 75:203-23.
- 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.
- Lachin JM. Sample size considerations for clinical trials of potentially hepatotoxic drugs. In *Guidelines for Detection of Hepatotoxicity Due to Drugs and Chemicals*, CS Davidson, CM Leevy, and EC Chamberlayne, eds., U.S. Department of H.E.W., National Institutes of Health, NIH Publication No. 79-313, 1979, 119-130.
- Lachin JM. "Prog. Lachin", a computer program for the Lachin (1973) procedure; In *Discrete Discriminant Analysis*, by M Goldstein and WR Dillon, Wiley, New York, 1978, 153-168.
- Ryan CM, Adams KA, Heaton RK, Grant I, Jacobson AM and the DCCT Research Group. Neurobehavioral assessment of medical patients in clinical trials: The DCCT Experience. In Mohr E and Brouwers P, editors, *Handbook of Clinical Trials; The Neurobehavioral Approach*. Amsterdam/Lisse: Swets and Zeitlinger, 1991, 215-240
- The DCCT Research Group. The DCCT: Will it answer the questions? In Larkin R, Zimmer P, Chisolm D, editors, *Diabetes 1988*. Amsterdam: Elsevier: 1989, 847-855
- Siebert C for The DCCT Research Group. The Diabetes Control and Complications Trial (DCCT): Results of the feasibility study and design of the full-scale clinical trial. In Laron Z, Kamp M, editors, *Pediatric and Adolescent Endocrinology*, Tel Aviv, Basel, Karger, 1989, 18, 15-21
- 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.

d) Books Edited or Written

Rosenberger, W. and Lachin J.M. *Randomization in Clinical Trials: Theory and Practice*. Second Edition. John Wiley and Sons, 2016. (ISBN: 978-1-118-74224-2, 269 pages)

Lachin, J.M. *Biostatistical Methods: The Assessment of Relative Risks*. Second Edition. John Wiley and Sons, 2011. (ISBN: 978-0-470-50822-0; 659 pages). Also, published in Japanese.

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.

e) Letters

See Section 7.b above

f) Book Reviews

None

g) Peer Reviewed Reports

None

h) Non-Peer Reviewed Reports

None

i) Abstracts (Last Three Years)

None

8) Scholarly Presentations at Scientific Meetings (122). Others, e.g. seminars, are not shown.

Invited (86). All National or International

Lachin JM. Applications of the Wei-Lachin multivariate one-directional test to multiple outcomes. *International Conference on Recent Advances in Statistical*

- Methodology With Applications in Clinical and Official Statistics*. Jan. 3-5, 2018 Kerala, India.
- Lachin JM. Discussion to: Choosing Monitoring Boundaries: Balancing Risks and Benefits. *10th Annual Conference on Statistical Issues in Clinical Trials*. University of Pennsylvania, Philadelphia. April 19, 2017.
- Lachin JM. Statistical considerations in design and analysis. *World Congress on Clinical Trials in Diabetes*. Berlin, Germany. Nov. 30 – Dec. 1, 2016.
- Lachin JM. A multivariate one-directional test of multiple event-time outcomes. *Joint Statistical Meetings. American Statistical Association*. Chicago. August 1-4, 2016.
- Lachin JM. Further insights into the findings – Mediation Analysis (Methods). *American Diabetes Association*. New Orleans. June 10-14, 2016.
- Lachin JM. The Design and Baseline Data from the EMPA-REG Outcome Study. *European Association for the Study of Diabetes*. Stockholm, Sweden, 9, September 14-18, 2015
- Lachin JM. Data monitoring committee decision making: Behind Closed Doors. *Joint Statistical Meetings. American Statistical Association*. Seattle. August 10-13, 2015.
- Lachin JM. Statistical Practice and Challenges in Chronic Disease Clinical Trials: Diabetes and Cardiovascular. Keynote Address. *Sixth Annual International Symposium on the Evaluation of Clinical Trials (Methodologies and Applications)*. Renmin University, Beijing, China. July 11-12, 2015.
- Lachin JM. Avoiding Rigid and Legalistic Procedures for Data Monitoring Committees. *Data Monitoring Committee Think Tank*. June 4-5, 2015. Duke Clinical Research Institute, Tyson's Corner, VA.
- Lachin JM. Cardiovascular Results from the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications study (DCCT/EDIC): Analysis of Risk Factors for Cardiovascular Disease. *Cardiovascular Disease and Type 1 Diabetes*. National Institutes of Health. October 8-9 2014
- Lachin JM. Evidence of metabolic memory from the Diabetes Control and Complications Trial and the Epidemiology of Diabetes Interventions and Complications study. *American Diabetes Association*. June 13-17, 2014.
- Lachin JM. Update on cardiovascular disease outcomes over 30 years of follow-up in the Diabetes Control and Complications Trial and the Epidemiology of Diabetes Interventions and Complications study. *American Diabetes Association*. June 21-25, 2013.
- Lachin JM. Statistical practice and challenges in chronic disease clinical trials – Diabetes and Cardiovascular Diseases. *Pharmaceutical and Regulatory Sciences Workshop: Revitalizing Clinical Trial Methodology and Translational Statistics*. Department of Biostatistics, Harvard School of Public Health. May 23-24, 2013.
- Lachin JM. DCCT/EDIC Research Group Update. *Annual Rachmiel Levine Diabetes and Obesity Symposium*. City of Hope (Duarte, CA). March 13-16, 2013.

- Lachin JM. What should the clinician know about statistics in clinical trials? *International Diabetes Federation*. December 5-8, 2011.
- Lachin JM. Definition of Biomarkers, Criteria for Biomarker Appraisal. *Retinal Vessels as Biomarkers; Seeing the Development of Diabetes Complications*. National Institutes of Health. October 3-4, 2011.
- Lachin JM. Comparative Effectiveness Research: Randomized Trials Versus Epidemiologic Evidence and the Role of Registries. *Second Annual Robert F. Woolson Lecture*, Department of Biostatistics, College of Public Health, University of Iowa. March 28, 2011.
- Lachin JM. Levels of evidence from diabetes registries. *European Best Information through Regional Outcomes in Diabetes, International Diabetes Federation Science Taskforce*. January 23-25, 2011. Brussels, Belgium.
- Lachin JM. Why good trials go bad. *Clinical Trials in Acute Kidney Injury: Current Opportunities and Barriers*, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, December 2-3, 2010.
- Lachin JM. Insulin glargine and cancer: Facts and Fallacies. *American Diabetes Association*. June 26-30, 2010, Orlando, Florida
- Lachin JM. Intensive glycemic control and mortality in ACCORD. *American Diabetes Association*. June 26-30, 2010, Orlando, Florida
- Lachin JM. Design considerations for outcome studies in type 1 diabetes. Juvenile Diabetes Research Foundation International, *Symposium on Prevention Trials for Complications of Type 1 Diabetes*, April 15-16, 2010, Crystal City, Virginia.
- Lachin JM. The statistical evaluation of observational studies and an evaluation of the evidence. Symposium on Glucose Lowering Drugs and Cancer. *International Diabetes Federation*, October 18-22, 2009, Montreal, CA.
- Lachin JM. Interpreting statistics from clinical trials in diabetes: The intention-to-treat principle and beyond. *International Diabetes Federation*, October 18-22, 2009, Montreal, CA.
- Lachin JM. Intention-to-treat and missing data. *Workshop on the Handling of Missing Data in Clinical Trials*. September 9, 2009. Institute of Medicine, National Academy of Sciences, Washington DC.
- Lachin JM. Outcome trials in type 1 diabetes – The Diabetes Control and Complications Trial. *American Statistical Association*. August 2-6, 2009. Washington DC.
- Lachin JM. Current controversies in clinical trials: Perspectives from SCT Fellows. *Society for Clinical Trials*. May 3-6, 2009. Atlanta.
- Lachin JM. Interpreting Statistics From Clinical Trials In Diabetes: The Intention-To-Treat Principle And Beyond. *American Diabetes Association Post-Graduate Course*, San Francisco, February, 2008.
- Lachin JM. The impact of HbA1c and other indices of glycemia on the risk of microvascular complications in the Diabetes Control and Complications Trial and the Epidemiology of Diabetes Interventions and its Complications (DCCT/EDIC) Study. *Diabetes Technology Society Meeting*, San Francisco, October 2007.

- Lachin JM. The challenge of designing outcomes studies from the vantage of a statistician. *European Diabetes Expert Forum: The Cambridge Symposium*, Cambridge University, UK, 2007.
- Kahn SE, Haffner SM, Herman WH, Holman RR, Lachin JM, Zinman B, Viberti G. The ADOPT Study Results. *International Diabetes Federation*, Cape Town South Africa, 2006.
- Lachin JM. Obstacles to the use of randomization-based inference in randomized clinical trials. *International Biometric Society, Eastern North American Region*, Tampa FL. 2006
- Lachin JM. Long-term Effects of Improved Glucose Control on Cardiovascular Disease in Type 1 Diabetes – The Diabetes Control and Complications Trial (DCCT) Epidemiology of Diabetes Interventions and Complications (EDIC) Study. *First Swiss Update on Key Clinical Trials in Diabetes and Metabolic Disorders*. Bern, Switzerland, February, 2006
- Lachin JM. Sample Size Considerations In Trialnet: POPPII-1 And Other Studies. National Institutes of Health Symposium on *Biostatistical Issues and the Design of Type 1 Diabetes TrialNet Protocols*, Bethesda, MD, 2005.
- Lachin JM. The Intent-To-Treat Design and The Intent-To-Treat Analysis. *Drug Information Association*, Washington DC, 2004.
- Lachin JM. Futility Monitoring Based on Conditional Power. *Society for Clinical Trials*, 2004.
- Lachin JM. Differences in HbA1c Levels During DCCT Explain Persistent Effects of DCCT Intensive Therapy on Vascular Complications During Subsequent 8 years of Follow-up in EDIC. *International Diabetes Epidemiology Group*, Tours, France, 2003.
- Lachin JM. Long Lasting Effects of DCCT Intensive Therapy on Microvascular Complications and Early Atherosclerosis During EDIC. *American Diabetes Association*, 2003.
- Lachin JM. The Effect of Glycemic Exposure on Microvascular Complications During the DCCT and its Persistent Long-Term Effects in EDIC. *Metabolic Imprinting and the Long-term Complications of Diabetes Mellitus: Bench to Bedside and Back*. April 10-11, 2003. National Institutes of Health, Bethesda MD.
- Lachin JM. Biostatistical Methods: The Assessment of Relative Risks. *The Fifty-Eighth Annual Deming Conference on Applied Statistics*, Atlantic City, NJ, 2002.
- Lachin JM. Potential for Selection Bias in Randomized Clinical Trials. *American Statistical Association*, Atlanta, GA, 2001.
- Lachin JM. Highlights of the Career of Sam Greenhouse. *Perspectives on the Biostatistical Sciences: A Symposium in Memory of Samuel W. Greenhouse*. June 11, 2001, National Institutes of Health, Bethesda MD.
- Lachin JM. Sam Greenhouse, the GWU years. *International Biometric Society, Eastern North American Region*, Charlotte NC, 2001.
- Lachin, JM. Biostatistical Methods: The Assessment of Relative Risks. *Annual Deming Conference on Applied Statistics and Management*, Newark NJ, 2000.

- Lachin JM. Design of Studies to Evaluate Preservation of C-Peptide Function Based on the DCCT Results. *Workshop on Future Directions in Prevention of Type I Diabetes*, Miami, 2000.
- Lachin JM. Interim analysis and Data-safety Monitoring Boards. *FDA/Industry statistical Workshop: Statistical Issues for the New Millennium*, Crystal City, Virginia, 1999.
- Lachin JM. Evaluation of the association of blood glucose levels with the risk of diabetes complications and hypoglycemia in the Diabetes Control and Complications Trial. *Joint Statistical Meetings, the American Statistical Association*, Baltimore, 1999.
- Lachin JM. Ruminations on being an academic biostatistician. *Biostatistics in the Future*. Department of Biostatistics, University of Pittsburgh, 1999.
- Lachin JM. Risk of microvascular complications of type 1 diabetes mellitus as a function of glycemic exposure (hba1c) in the diabetes control and complications trial. National Institutes of Health Workshop: *Research Needs for the Design and Analysis of Surrogate Endpoints in Clinical Trials*, Potomac, MD, 1998.
- Lachin JM. Design and interim monitoring of clinical trials. *Drug Information Association: Models for Launching and Coordinating Multi-Center Trials*. New Orleans, 1988.
- Lachin JM. Discussion to “The Role of DSMBs and the Accumulating Evidence in the Conduct of Clinical Trials”. *International Biometric Society, Eastern North American Region*, 1998.
- Lachin JM. Role of data and safety monitoring boards in phase 3 clinical trials. *Drug Information Association: Clinical Trials and Drug Development in Biotechnology*, Dana Point, CA, 1998.
- Lachin JM. Statistical considerations in the intention-to-treat principle. *Biopharmaceutical Applied Statistics Symposium*. Hilton Head, South Carolina, 1997.
- Lachin JM. Is there a glycemic threshold in type 1 diabetes mellitus for development of microvascular complications: the Diabetes Control and Complications Trial (DCCT) perspective. *American Diabetes Association*, 1997.
- Lachin JM. Trial design and other considerations. *American Diabetes Association Research Symposium on Prevention of Type I Diabetes in the General Population*. Estes Park, Colorado, 1996.
- Lachin JM. Selection, definition, and measurement of outcomes. *American Diabetes Association Satellite Symposium on “Clinical Trials: Understanding Design, Management and Analysis - A Workshop for Researchers in Diabetes”*. San Francisco, 1996.
- Lachin JM. Analysis strategies and issues. *American Diabetes Association Satellite Symposium on “Clinical Trials: Understanding Design, Management, and Analysis - A Workshop for Researchers in Diabetes”*. San Francisco, 1996.
- Lachin JM. Experience and perspectives of the monitoring committee in NIH and industry sponsored trials. *Harvard University Shering-Plough workshop on “Flexible Strategies for Clinical Trials”*. Boston, May 30-31, 1996.

- Lachin JM. The role of a central statistical center in multi-center collaborative studies: the role of the George Washington University Biostatistics Center in the Diabetes Control and Complications Trial (DCCT). *Department of Epidemiology and Biostatistics of the School of Health Sciences and Nursing of the University of Tokyo, Japan, 1995.*
- Lachin JM. The effects of intensive vs. conventional treatment and exposure to hyperglycemic (HbA1c) on the risk of retinopathy progression in the Diabetes Control and Complications Trial (DCCT). *The Tokyo Society of Medical Sciences and the Faculty of Medicine at the University of Tokyo, and the Japanese Diabetes Society, 1995.*
- Lachin JM. Distribution-free marginal analyses of repeated measures. *Drug Information Association's Second Annual Biostatistics Meeting in Tokyo, 1995.*
- Lachin JM. Exposure to hyperglycemia and risk of complications in insulin dependent diabetes mellitus: time-dependent covariate analyses in the DCCT. *John C. Forbes Graduate Student Honors Colloquium. Medical College of Virginia, 1995. Distinguished guest lecturer.*
- Lachin JM. Some considerations in monitoring pharmaceutical trials. *International Biometric Society, Eastern North American Region, 1995.*
- The DCCT Study Group (J. Lachin presenting). Glycemic exposure and the risk of progression of complications in the DCCT. *American Diabetes Association, 1994.*
- Lachin JM. A review of methods for sample size evaluation based on power and precision. *Symposium on Sample Size Methodology, Temple University, 1991.*
- Lachin JM. A review of some distribution-free methods for analysis of repeated measures from two populations. Conference on *Moving Clinical Trials Into the Twenty-first Century*, the Delaware Chapter of the American Statistical Association, 1991.
- Lachin JM. Sample size Evaluation. Workshop organized for the *International Clinical Epidemiology Network*, Ninth Annual Meeting, Mombassa, Kenya, 1991.
- Lachin JM. Sample size, precision and power. Paper presented to the *International Clinical Epidemiology Network*, Ninth Annual Meeting, Mombassa, Kenya, January 21-25, 1991.
- Lachin JM. Randomization in clinical trials: Some statistical considerations. *Associates of Clinical Pharmacology, 1988.*
- Lachin JM. The statistical properties of clinical indices for diabetic neuropathy. *American Diabetes Association Conference on Peripheral Neuropathy in Diabetes, 1988.*
- Lachin JM. Study size and trial duration. (Pre-conference course: Some considerations in clinical trial design and analysis.) *Society for Clinical Trials, 1987.*
- Lachin JM. Statistical considerations in the design of clinical trials in peripheral neuropathy. *Peripheral Neuropathy Association of America, 1986.*
- Lachin JM. Simple randomization in clinical trials. *Society for Clinical Trials, 1986.* (In workshop organized by J. Lachin: The role of randomization in clinical trials).

- Lachin JM. Randomization in clinical trials. *Delaware Chapter of the American Statistical Association*, 1986.
- Lachin JM and Wright EC. Statistical considerations in the design and analysis of clinical trials of causal therapy in cirrhosis of the liver. *Fifth Advanced Course in Gastroenterology*, San Miniato, Italy, 1985.
- Lachin JM. Design and analysis of an intervention trial to assess the effects of control of blood glucose on early vascular complications. *Biostatistics Symposium*, Diabetes Research Center, University of Washington, September 12, 1985.
- Lachin JM. The design and analysis of clinical trials: Perspectives on recent developments. *Fortieth Annual Conference on Applied Statistics*, 1984.
- Lachin JM. Ursodeoxycholic acid treatment of gallstones--International results. Symposium: *Update on treatment of gallstones: Role of ursodeoxycholic acid*, Nov. 29 - Dec. 2, 1984.
- Lachin JM. Historically and randomized controlled clinical trials in nephritis. *International Congress of Nephrology*, 1984.
- Lachin JM. Design of clinical trials in peripheral neuropathy. *Peripheral Neuropathy Association of America*, 1984.
- Lachin JM. External monitoring of data coordinating center performance: Assessment of the biostatistical monitoring team in the National Cooperative Gallstone Study. *Society for Clinical Trials*, 1984.
- Lachin JM. Design of clinical trials in apheresis. *International Society for Artificial Organs*, 1984.
- Lachin JM. Statistical aspects of clinical trials of the effects of insulin pump therapy on microvascular disease. *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.
- Lachin JM. Utilization of results from quality control programs: measurement of gallstone number and volume from cholecystograms. *Society for Clinical Trials*, 1981.
- Lachin JM. Utilization of results from quality control programs: evaluation of morphological changes from liver biopsies. *Society for Clinical Trials*, 1981.
- Anderson D and Lachin JM. Statistical reports in the National Cooperative Gallstone Study. *Sixth Annual Symposium on Coordinating Clinical Trials*, 1979.
- Lachin JM. Some criteria for evaluating information systems in mental health. *Southern Regional Conference on Mental Health Statistics*, 1973.

Contributed (36). All National or International

- Bebu I and Lachin JM. Longitudinal models with an interval censored binary covariate. *Population-based Time-to-event Analyses International Conference*. London University School of Hygiene and Tropical Medicine. London, 2016.

- Lachin JM and Younes N. Phase II to Phase III Designs. Symposium on *Statistical Innovations in Clinical Trials, Statistical Methods in Biopharmacy, Societe Francaise de Statistique*, Paris, 2005.
- Bautista OM and Lachin JM. Preserving alpha and power when over-ruling a group sequential boundary. *Society for Clinical Trials*, Toronto, 2000.
- Lachin JM, Genuth S, Nathan DM, Davis MD, Cleary P and The EDIC Research Group. Prolonged Effects of DCCT Intensive Therapy on Complications After Four Years Of EDIC Follow-up. *American Diabetes Association*, San Diego, 1999.
- Lachin JM, Cleary P, Davis MD, Molitch M, Nathan DM and The EDIC Research Group. Progression of retinopathy in the DCCT cohort after 4 years of follow-up in the Epidemiology of Diabetes Interventions And Complications (EDIC) study. *European Association for the Study of Diabetes*. Barcelona, 1998.
- Lachin JM, Cleary P, Molitch M, Nathan DM and the DCCT Research Group. Pregnancy increases the risk of complications in the DCCT. *American Diabetes Association*, Chicago, 1998.
- Lachin JM, Genuth S, Cleary P, Spielman R and the Diabetes Control and Complications Trial (DCCT) Research Group. Familial clustering of insulin dependent diabetes mellitus (IDDM) complications in the Diabetes Control and Complications Trial (DCCT). *Sixteenth International Diabetes Federation Congress*, Helsinki, 1997.
- Lachin JM, Lorenz R, Cleary P, Nathan D and the DCCT Research Group. Risk factors for hypoglycemia in the Diabetes Control and Complications Trial (DCCT). *International Diabetes Epidemiology Group*, satellite meeting to the Sixteenth International Diabetes Federation Congress, Savonlinna, Finland, 1997.
- Lachin JM. Poisson regression direct adjustment comparison of lifetables. Joint meeting of the *Society for Clinical Trials and International Society for Clinical Biostatistics*, Boston, 1997.
- Lachin JM. Group sequential monitoring of distribution-free analyses of repeated measures. *International Biometric Conference*, Hamilton, New Zealand, 1992.
- Lachin JM. Some useful distribution-free multivariate estimators and tests for the analysis of repeated measures in a clinical trial. *International Society for Clinical Biostatistics and the Society for Clinical Trials*, Brussels, Belgium, 1991.
- Bain RP, Lachin JM, Keen H, Viberti GC. Designing longitudinal studies in progressive renal disease. *Society for Clinical Trials*, 1989.
- Lachin JM and Wei LJ. Methods for the analysis of multiple nonindependent 2 x 2 tables with partially missing observations. *International Biometric Conference*, 1988.
- Lachin JM, Lan SP and the Lupus Nephritis Collaborative Study Group. Termination of a clinical trial with no treatment group difference: the Lupus Nephritis Collaborative Study. *Controlled Clinical Trials*, 1987, 8, 280 (abstract). *Society for Clinical Trials*, 1987.

- Thall PF and Lachin JM. Analysis of recurrent events based on random interval count data. *Controlled Clinical Trials*, 1986, 7, 237 (abstract). *Society for Clinical Trials*, 1986.
- Foulkes MA and Lachin JM. Sample size and survival for survival time studies with non-uniform entry, losses to follow-up, non-compliance and stratification. *Controlled Clinical Trials*, 1985, 6, 230 (abstract). *Society for Clinical Trials*, 1985.
- Thall PF and Lachin JM. Assessment of stratum-covariate interactions in Cox's proportional hazards regression model. *Society for Clinical Trials*, 1983.
- Wei LJ and Lachin JM. Two sample distribution-free tests for censored multivariate observations, *Biometrics*, 1983, 39, 813 (abstract). *International Biometric Society (ENAR)*, 1983.
- Schwartz SJ, Lan SP, Soloway RD, and Lachin JM, et al. Predicting dissolution in patients treated with chenodiol. *Gastroenterology*, 1982, 82, 1173 (abstract). *American Gastroenterology Association*, 1982.
- Thistle JL, Cleary PA, Lachin JM, Tyor MP, Hersh T, et al. The natural history of untreated cholelithiasis in the National Cooperative Gallstone Study. *Gastroenterology*, 1982, 82, 197 (abstract). *American Gastroenterology Association*, 1982.
- Grundy SM, Lan SP, Lachin JM, et al. Biliary lipid determinants of gallstone dissolution among patients in the National Cooperative Gallstone Study. *Gastroenterology*, 1982, 82, 1073 (abstract). *American Gastroenterology Association*, 1982.
- Schoenfield LJ, Lachin JM et al. The National Cooperative Gallstone Study: A controlled trial of the efficacy and safety of chenodeoxycholic acid for dissolution of gallstones. *Gastroenterology*, 1981, 80, (abstract). *American Gastroenterology Association*, 1981.
- Fisher RL, Anderson D, Boyer JL, Ishak K, Klatskin G, Lachin JM, Phillips MJ, et al. National Cooperative Gallstone Study: A prospective morphologic evaluation of hepatic toxicity of chenodeoxycholic acid (CDCA) in patients with cholelithiasis. *Gastroenterology*, 1981, 80, 1332 (abstract). *American Gastroenterology Association*, 1981.
- Fisher RL, Anderson D, Boyer JL, Ishak K, Klatskin G, Lachin JM, Phillips MJ, et al. National Cooperative Gallstone Study: Abnormal hepatic morphology in patients with cholelithiasis--light (LM) and electron (EM) microscopic interpretation. *Gastroenterology*, 1981, 80, 1332 (abstract). *American Gastroenterology Association*, 1981.
- Lachin JM and Rogers JS. Managing laboratory data in multicenter trials. *Fifth Annual Symposium on Coordinating Clinical Trials*, 1978.
- Shaw LW, Ellenberg SS, Lachin JM, and Schlesselman SE. Constraints employed in randomization procedures. *Fifth Annual Symposium on Coordinating Clinical Trials*, 1978.
- Lachin JM and Wong E. Data entry using the Datapoint 1100. *Fifth Annual Symposium on Coordinating Clinical Trials*, 1978.

- Schachter J, Lachin JM and Wimberly FC. Newborn heart rate: relation to race and socioeconomic status. *American Psychosomatic Society*, 1976.
- Lachin JM. Bayes extensions of some F and Chi-square tests, *Biometrics*, 1975, 31, 1005 (abstract). *International Biometric Society (ENAR)*, 1975.
- Schachter J, Patey J, Wimberly F, and Lachin JM. Maternal weight gain and newborn blood pressure level. *Psychophysiology*, 1975, 12, (abstract). *Society for Psychophysiological Research*, 1974.
- Schachter J, Kerr J, Wimberly F and Lachin JM. Racial differences in newborn heart rate level. *Psychophysiology*, 1974, 11, (abstract). *Society for Psychophysiological Research*, 1973.
- Lachin JM. Two population discriminant functions under prior logical constraints. *Statistics Section, Virginia Academy of Sciences*, 1973.
- Lachin JM and Schachter J. On the interpretation of stepwise discriminant function analyses applied to evoked physiologic data. *Psychophysiology*, 1973, 10, 199 (abstract). *Society for Psychophysiological Research*, 1972.
- Schachter J, Kerr J, Lachin JM, Khachaturian Z, Williams T, and Faer M. Heart rate reactivity of newborn offspring of schizophrenic parents. *Psychophysiology*, 1972, 9, 273 (abstract). *Society for Psychophysiological Research*, 1971.
- Williams TA, Lachin JM, and Schachter J. The multiphasic heart rate response to auditory clicks in neonates: Sources of variance in response to repetitive stimuli. *Psychophysiology*, 1971, 8, 277 (abstract). *Society for Psychophysiological Research*, 1970.
- Khachaturian Z, Kruger R, Schachter J, Williams T, and Lachin JM. A comparison of two methods of analyzing cardiac activity; R-R interval vs. heart rate. *Psychophysiology*, 1970, 6, 647-648 (abstract). *Society for Psychophysiological Research*, 1969.

9) **University Service** (Specify names and dates)

a) Committee service: Department, School, Senate, University

- 2016-7. Member, Search Committee, Professor and Director of the Biostatistics Center. Department of Epidemiology and Biostatistics, Milken Institute School of Public Health.
- 2013, Member, Oscar and Shoshana Trachtenberg Prize for Scholarship selection committee.
- 2012, member, review committee for GWU Research Facilitating Funds for the Medical Center.
- 1998-9. Member, Search Committee, Professor and Director of the Biostatistics Center Medical Center Unit. Department of Epidemiology and Biostatistics.
- 1995-1999, Chair, Executive Committee. The Biostatistics Center Medical Center Unit. GWU Medical Center
- 1996-8, member, search committee, Professor and Chair, Department of Epidemiology and Biostatistics, School of Public Health and Health Services.

1997-8, member, Task Force on an Associate Vice President for Research, GWU Medical Center
 1997-8, member, search committee, Associate Vice President for Research, GWU Medical Center.
 1996-7, Chair, search committee, Associate to Full Professor of Statistics
 1995-6, Chair, search committee, Associate to Full Research Professor of Statistics, to direct the Biostatistics Center Medical Center Unit.
 1993-6, member, Advisory Council on Research, Office of the Associate Vice-President for Academic Affairs and Research.
 1993-5, member, Department of Economics Self-study Evaluation Review Committee.
 1993-5, Chair, Committee for the establishment of graduate programs in biostatistics and epidemiology.
 1993-4, member, Special Review Committee, by appointment to the Vice President for Academic Affairs.
 1986-7, member, Committee on Sponsored Research
 1986-7, member, Middle States Subcommittee on Academic Computing.
 1986-7, member, Junior Scholar Incentive Program Committee
 1986-7, member, Committee on Scholarly and Creative Awards.

- b) Administrative assignments: Department, School, University
 1980-1985 Assistant Director, The Biostatistics Center, GWU
 1985-1988 Co-Director, The Biostatistics Center, GWU
 1988-2000 Director, The Biostatistics Center, GWU
 2001-2010 Co-Director, The Biostatistics Center, GWU
 2010-2012 Interim Director, The Biostatistics Center, GWU.
 1995 – 2004 Program Director for Biostatistics and Chair of the Executive Committee for the graduate degree program in Biostatistics and Epidemiology, jointly administered by the Department of Epidemiology and Biostatistics and the Department of Statistics.
- c) Mentoring to a member of the faculty. None
 d) Service to admissions, alumni, or student groups. None
 e) Community service (other than public health practice activities listed below).
 None

10) Professional Society Membership and Leadership

a) Societies

American Statistical Association

Biometric Society

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

Institute of Mathematical Statistics

Royal Statistical Society

International Statistical Institute

International Chinese Statistical Association

Society for Clinical Trials

Committee on Fellows (Chair, 2011-12, member 2007-8)

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.

Society for Epidemiologic Research

International Society for Clinical Biostatistics

American Diabetes Association (Professional Section, Council on Epidemiology and Statistics)

2010-2013, Member, Editorial Board, *Diabetes*,

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

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

European Association for the Study of Diabetes

International Diabetes Epidemiology Group

International Diabetes Federation

2010-2014, Member, Science Task Force

Drug Information Association

b) Symposia and Conferences (Partial List) as Participant (*Presentations listed separately in Section 8 above*)

International Conference on Recent Advances in Statistical Methodology With Applications in Clinical and Official Statistics. Jan. 3-5, Kerala, India

10th Annual Conference on Statistical Issues in Clinical Trials. University of Pennsylvania, Philadelphia. April 19, 2017.

World Congress on Clinical Trials in Diabetes. Berlin, Germany. Nov. 30 – Dec. 1, 2016.

Sixth Annual International Symposium on the Evaluation of Clinical Trials (Methodologies and Applications). Renmin University, Beijing, China. July 11-12, 2015.

Data Monitoring Committee Think Tank. Duke Clinical Research Institute, Tyson's Corner, VA. June 4-5, 2015.

Cardiovascular Disease and Type 1 Diabetes. National Institutes of Health. October 8-9 2014.

Pharmaceutical and Regulatory Sciences Workshop: Revitalizing Clinical Trial Methodology and Translational Statistics. Department of Biostatistics, Harvard School of Public Health. May 23-24, 2013.

Annual Rachmiel Levine Diabetes and Obesity Symposium. City of Hope (Duarte, CA). March 13-16, 2013.

Retinal Vessels as Biomarkers; Seeing the Development of Diabetes Complications. National Institutes of Health. October 3-4, 2011.

Clinical Trials in Acute Kidney Injury: Current Opportunities and Barriers, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, December 2-3, 2010.

Symposium on Prevention Trials for Complications of Type 1 Diabetes, Juvenile Diabetes Research Foundation International, April 15-16, 2010, Crystal City, Virginia.

Workshop on the Handling of Missing Data in Clinical Trials. September 9, 2009. Institute of Medicine, National Academy of Sciences, Washington DC.

Regulatory Review of Drugs for Type 2 Diabetes and Cardiovascular Risk: Beyond HgbA1c. June 13-15, 2007. Duke Clinical Research Institute, Washington DC.

European Diabetes Expert Forum: The Cambridge Symposium, Cambridge University, UK, 2007.

First Swiss Update on Key Clinical Trials in Diabetes and Metabolic Disorders. Bern, Switzerland, February, 2006

Issues in Data Monitoring Committees. January 16-18, 2003. Duke Clinical Research Institute, Washington DC.

Metabolic Imprinting and the Long-term Complications of Diabetes Mellitus: Bench to Bedside and Back. April 10-11, 2003. National Institutes of Health, Bethesda MD.

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.

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).

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

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 books below.)

11) **Editorial Peer Review Activities** (grant review activities, journals, etc.)

Numerous reviews of grant applications and journal article submissions.

12) **External Activities/Partnerships** (List all external professional activities including consultancies, the name of the company, government agency, organization, private or public foundation or other entity involved, your relationship to it, and dates of service. Also list all visiting professorships).

Numerous past consultancies to government agencies, and the private sector including service on pharmaceutical Scientific Advisory Boards, Steering Committees and Data and Safety Monitoring Boards. All activities conducted on my own time and not as an employee of GWU. See 14.a below.

No Visiting Professorship.

13) **Teaching/Learning Portfolio** (Include dates of participation for all categories.)

a) **Educational Program Leadership**

1993-1995, Chair, Committee for the Establishment of a PhD Program in Biostatistics and in Epidemiology.

1995-2004, Chair, Executive Committee, Graduate Program in Biostatistics and Epidemiology; and Program Director for Biostatistics.

b) **Courses Taught**

Department of Statistics

Introduction to Biostatistics (Statistics 1127), lecturer

Data Analysis (Statistics 6210), developer and lecturer

Design of Medical Studies (formerly Statistics 224, now PH 6247), developer and lecturer;

Biostatistical Methods (formerly Statistics 225, now PH 6266), lecturer

Advanced Biostatistical Methods (formerly Statistics 226), lecturer

Survival Analysis (Statistics 6227), developer and lecturer.

Department of Epidemiology and Biostatistics

Biostatistical Methods (PH 6266), developer and lecturer

c) **Students and Trainees: Advising/Mentoring**

Undergraduate (number by year)

None

Master's (number by year)

None

Capstone advisor (name, degree program, year)

None

Doctoral dissertation/primary thesis advisor (name, degree program, year)

Milton Fan, Ph.D. Statistics, 1986, *Estimation of Parameters for the Logistic Regression Model with Partial Incomplete Observations..*

Yuko Palesch, Ph.D. Statistics, 1990, *R-Sample($R > 2$) Multivariate Rank Tests and Related Estimators of Population Differences.*

Naji Younes, Ph.D. Statistics, 1994, *A Family of Event-Time Models with Smooth Baseline Hazards.*

Oliver Bautista, Ph.D. Statistics, 1996, (Co-Advisor with K.K. Gordon Lan), *Analysis of Overdispersed Poisson Count Data..*

Mingxiu Hu, Ph.D. Statistics, 1997, *Robust Estimating Functions with Nuisance Parameters..*

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

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

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

Ainong Zhou, Ph.D. Biostatistics, 2006, (Co-Advisor with Giovanni Parmigiani), *Bayes Factors Comparing Two Multi-Normal Covariance Matrices and Their Application to Microarray Data Analysis*

Mark VanRaden, Ph.D. Biostatistics, 2007, *Cumulative Logit - Poisson and Cumulative Logit - Negative Binomial Compound Regression Models for Count Data*

Ruthanna Davi, PhD Biostatistics, 2008, *Methods to Jointly Evaluate Sensitivity, Specificity, and Kappa in Diagnostic Imaging Studies.*

Yong Ma, PhD Biostatistics, 2010 (Co-advisor with Yinglei Lai), *Flexible Isotonic Regression in Survival Data Analysis*

Marinella Temprosa, PhD Biostatistics, 2012, *An Imputation-Estimation Algorithm Using Time-Varying Auxiliary Covariates for a Longitudinal Model When Outcome is Missing by Design.*

Wanjie Sun, PhD Biostatistics, 2012 (Co-advisor with Michael Larsen), *Models for a Longitudinal Quantitative Outcome with Multivariate Normal (MVN) Distribution Censored by Therapeutic Intervention.*

Barbara Braffett, PhD Epidemiology, 2013, *The Effects of Smoking on Metabolic Control and Diabetes-Related Complications in Type 1 Diabetes.*

Gregory Sandoval, PhD Biostatistics, 2021 (Co-advisor with Ionut Bebu). *A Cost-Efficient Design for Clinical Trials*

Doctoral dissertation/research committee (name, degree program, year)

Numerous, not recorded

Doctoral preliminary oral examination (name, degree program, year)

Numerous, not recorded

Doctoral thesis reader/final oral examination (name, degree program, year)

Numerous, not recorded

Postdoctoral fellows mentored

None

Supervision of students in internships, practicum experience, mentored research.

None

14) Public Health Practice Portfolio

a) Participation on Advisory Panels (all paid)

Scientific Advisory Board (member). Tolerion Inc. Development of pharmaceuticals for induction of immune tolerance in auto-immune diseases. 2015 - 2019

Steering Committee (member). EMPA-REG Outcomes Study, Boehringer-Ingelheim, 2010 - 2017

Data and Safety Monitoring Board (member). Time to Reduce Mortality in End-Stage Renal Disease (TiME) Trial. National Institute of Diabetes, Digestive and Kidney Diseases, 2013 - 2016

Steering Committee (member). Trial Evaluating Cardiovascular Outcomes with Sitagliptin (TECOS), Duke Clinical Research Institute, University of Oxford Diabetes Trials Unit, Merck, 2009 - 2017.

Data and Safety Monitoring Board (member). Apnea Positive Pressure Long-term Efficacy Study (APPLES). National Heart, Lung and Blood Institute, 2003 - 2010.

Data and Safety Monitoring Board (Vice-chair). Look AHEAD: Action for Health in Diabetes. National Institute of Diabetes, Digestive and Kidney Diseases, 2001-2012

Steering Committee (member). A Diabetes Outcomes Progression Trial (ADOPT), Glaxo SmithKline, 2000 - 2010.

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' Tolerations 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.

Member of Data, Safety Monitoring Boards for various studies in industry.

b) Program or Project Development

None

c) Consultations

Many, no record retained.

d) Testimony

Many, no record retained.

e) Clinical Practice Activities

Not applicable

f) Governmental (e.g., IPA) Assignments

None.