

CURRICULUM VITAE**James D. Neaton**

Name: James Dennis Neaton

Title: Professor of Biostatistics, Adjunct Professor of Medicine, Distinguished International Professor

Address: Coordinating Centers for Biometric Research
Division of Biostatistics
School of Public Health
University of Minnesota
2221 University Avenue SE, Suite 200
Minneapolis MN 55414

Birth Date: September 20, 1947

Place of Birth: Galveston, Texas

Citizenship: U.S.A.

<u>Education:</u>		<u>Major Field</u>	<u>Degree</u>
Lamar University	1965-1968	Mathematics	None
University of Minnesota School of Public Health Biometry Division	1968-1969	Biometry	B.A.
University of Minnesota	1969-1970	Biometry	M.S.
University of Minnesota	1984	Biometry	Ph.D.

Honors: B.A. Awarded with Honors
Pi Mu Epsilon
Delta Omega Honorary Public Health Society
Leonard M. Schuman Excellence in Teaching Award (2001)
Fellow, American Statistical Association (1994)
Fellow, Society for Clinical Trials (2009)
Academic Health Center Academy for Excellence in Health Research (2009)
University of Minnesota Global Engagement Award (2010)
Lillehei Heart Institute (2013)

Membership in Professional Societies:

Society for Clinical Trials, President 2006-2007
Biometric Society, ENAR
American Statistical Association
American Heart Association Council on Epidemiology
International Society and Federation of Cardiology, Scientific Section on
Epidemiology and Prevention
International AIDS Society

Professional Experience:

Professor, Biostatistics Division, School of Public Health, University of Minnesota, 1995 - present

Adjunct Professor of Medicine, Infectious Diseases and International Medicine, Department of Medicine, University of Minnesota, 2006-present.

Associate Professor, Biostatistics Division, School of Public Health, University of Minnesota, 1990 - 1995

Assistant Professor, Biostatistics Division, School of Public Health, University of Minnesota, 1985 - 1990

Research Fellow, Biometry Division, School of Public Health, University Minnesota, 1973 - 1985

USPHS Officer Assigned to Biometrics Research Branch, National Heart and Lung Institute, NIH, 1970-1972.

Grant and Contract Support:

Principal Investigator, NIH (NIAID, NHLBI, NIAMS, NIMH, NINDS) International Network for Strategic Initiatives in Global HIV Trials (INSIGHT), 2006 - Present.

Principal Investigator, subcontract to SAIC (NCI prime) Observational studies of pandemic H1N1 influenza, 2009 - Present.

Principal Investigator, subcontract to SAIC (NCI prime) Clinical trial of IVIG for influenza, 2013 - Present.

Principal Investigator, NIH (NHLBI, NCATS) Summer Institute for Training in Biostatistics (SIBS), 2013 – Present.

Co-Director, NIH Roadmap Multidisciplinary Clinical Research Career Development Program (K12), 2005-2011.

Principal Investigator, Coordinating Center for the SILCAAT Study sponsored by Chiron and the National Institutes of Health, 2003 - 2009.

Principal Investigator, NIAID Statistical Center and Data Management Center for Community Programs for Clinical Research on AIDS, 1990 - 2006.

Principal Investigator, NIAID International Trial of IL-2 (ESPRIT), 1999- 2006.

Principal Investigator, NHLBI Extended Mortality and Follow-up and Analyses of Men in the MRFIT, 2001 –2006.

Principal Investigator, Coordinating Center, Pharmacia/Searle CONVINCENCE Study, 1996 - 2004.

Director, Biostatistics Core, NCI Great Lakes Center for AIDS Research, 1998- 2003.

Principal or Co-Principal Investigator, NHLBI Multiple Risk Factor Intervention Trial (MRFIT) Coordinating Center, 1973 - 1999.

Principal Investigator, NHLBI Mortality Surveillance of MRFIT Screenees, 1989-1999.

Co-Principal Investigator and Director of the Coordinating Center for NHLBI Treatment of Mild Hypertension Study (TOMHS), 1985 - 1996.

Co-Investigator of primary grant and Principal Investigator of Statistical Center for a Prospective Study of Blood Pressure and ESRD, 1991 - 1996.

Co-Principal Investigator and Director of Data Coordinating Center for NHLBI Study of Potassium and Sodium to Control Blood Pressure in Hypertensives, 1983 - 1988.

Co-Investigator, NEI Diabetic Retinopathy Vitrectomy Study: 1975-1980

Co-Investigator, NHLBI Granulocyte Transfusion Study, 1977-1979

Editorial and Advisory Committees:

President, Society for Clinical Trials, 2006-2007

Editor in Chief, *Controlled Clinical Trials*, 1999-2003.

Advisory Board, *Clinical Trials*, 2004-2013.

Chair, Society for Clinical Trials Publication Committee, 2012 – present.

Chair, MRFIT Editorial Committee, 1997- 2006.

NHLBI ALLHAT External Advisory Committee, 2011-present.

NIDDK, Diabetes Prevention Trial Outcomes Data and Safety Monitoring Board, 2011-present.

NIDDK, Vitamin D and Type 2 Diabetes Data and Safety Monitoring Board, 2013- present.

U.S. Public Health Service - Infectious Disease Society Joint Task Force on Prevention of Opportunistic Infection in Patients with HIV-Infection, 1994 – 2010.

U.S. Public Health Service - Panel on Clinical Practices for the Treatment of HIV Infection, 1999 - 2011.

External Advisory Committee, Institute for Clinical and Translational Research, University of Wisconsin, 2008-2012.

Consultant, Minimal Standards in the Prevention and Handling of Missing Data in Observational and Experimental Patient Centered Outcomes Research, Johns Hopkins University, PCORI contract, 2012.

External Reviewer of NHLBI Joint National Committee Report on Blood Pressure, 2012.

Cardiovascular and Renal Drugs Advisory Committee, 2007- 2011.

National Academy of Sciences, Committee on National Statistics Oversight Committee for Workshop on Handling Missing Data in Clinical Trials, 2009-2010.

FDA, Clinical Trials Transformation Initiative, Project Team for Effective and Efficient Monitoring, 2009-2010.

NIH Director's Clinical Research Roadmap Meeting, 2003.

NIH Director's Meeting for Investigators on Open Access, 2004.

NHLBI Strategic Planning Group, 2006.

NIDDK, Extramural Advisory Committee, Special Statutory Funding Program for Type 1 Diabetes Research, 2008 and 2013

NHLBI Working Group on Clinical Use of Ventricular Assist Devices, 2008.

TrialNet External Advisory Committee, NIDDK, NIH, 2006-2011.

Consultant, South Africa PHIDISA Project, NIH, 2003 - Present.

Data Monitoring Committee, Centers for Disease Control Clinical Trials on the Treatment of Tuberculosis, 1996 - Present.

Data and Safety Monitoring Board, Bill and Melinda Gates Foundation Study of Pre-Exposure Prophylaxis to Prevent HIV-1 Acquisition within HIV-1 Discordant Couples, 2008-2013.

Data and Safety Monitoring Board, NIAID (HPTN 039) Acyclovir for the Reduction of HIV Acquisition, 2002 - 2008.

Data and Safety Monitoring Committee, Harvard Clinical Research Institute Dual Antiplatelet Therapy (DAPT) Trial, 2009 - 2014.

Data and Safety Monitoring Committee, NCI, NIH Polyp Prevention Study, 2005 - 2013.

Data and Safety Monitoring Committee, Pfizer Phase 3 Program of PCSK9 Inhibition and Reduction in Risk of Vascular Events, 2013 - present.

Data and Safety Monitoring Board, NIDDK, NIH D2d Study of Diabetes Prevention, 2013 - present.

Data and Safety Monitoring Board, Trevena Phase 2 Study of TRV027 for Acute Decompensated Heart Failure, 2013 - present.

Data and Safety Monitoring Board, NIDDK Wisconsin Cystic Fibrosis Neonatal Screening Project, 2003 - 2011.

Data and Safety Monitoring Board, NHLBI Systolic Blood Pressure Intervention Trial (SPRINT), 2010 - Present.

Steering Committee, Yale University Open Data Access Project (YODA), 2011 - present.

- External Data Monitoring Committee, Merck, V212, Inactivated Varicella Zoster Virus Vaccine, Studies, 2010- present.
- Data and Safety Monitoring Board, Bristol-Myers Squibb I-Preserve Heart Failure Trial, 2003-2007.
- Data Monitoring Committee, Astellas Phase 2 Study of ASKP1240 for Kidney Transplant Recipients, 2013- present.
- Data and Safety Monitoring Board, Amgen, Etanercept in Pediatric Patients with Plaque Psoriasis, 2004-2012.
- Data and Safety Monitoring Board, St. Jude Medical, Left Atrial Pressure Monitoring to Optimize Heart Failure (LAPTOP), 2010-2014.
- Data and Safety Monitoring Board, Takeda, Cardiovascular outcomes in patients with type 2 diabetes, 2011-present.
- Data and Safety Monitoring Committee, Astra-Zeneca, Inhaled corticosteroids and serious asthma-related events, 2011-present.
- Executive Committee, Phentermine/Topirmate Outcomes Trial, Vivus, 2011 - present.
- External Reviewer, Institute of Medicine Report, Methodological Challenges in Biomedical HIV Prevention Trials, 2008.
- Data and Safety Monitoring Committee, Bristol Myers Squibb, Clinical trial of IL-6 blocker for Crohn's Disease, 2012-2014.
- Data and Safety Monitoring Board, Biocontrol, INNOVATE Heart Failure Trial, 2009-present.
- Framingham Heart Study, Observational Study Monitoring Board, NIH, NHLBI, 2001 - present.
- Steering Committee, Merck Research Laboratories Losartan HEAAL Study, 2001 - 2010.
- Member, DSMB, Medtronic REDUCE HF Trial, 2007 - 2009.
- Chair, DSMB, Merck Phase IV Clinical Trial to Evaluate the Safety and Tolerability of ZOSTAVAX, 2007-2009
- Advisory Committee, Inventory and Evaluation of Clinical Research Networks (IECRN), NIH Roadmap Project, Westat, 2005-2006.
- Member, DSMB, Medtronic COMPASS Heart Failure Trial, 2004-2005.
- Chair, Data and Safety Monitoring Board, Merck Research Laboratories APPROVe Trial, 2001-2004.
- Chair, Data and Safety Monitoring Board, Merck Research Laboratories VIOXX Prostate Cancer Trial and Combined Analysis of CV Events, 2003 - 2004.
- Data and Safety Monitoring Board, Acorn Medical Device Trial, 2002 - 2004.

Data Monitoring Committee, Veterans Administration Trial on Varicella Vaccine for the Prevention of Herpes Zoster and its Complications, 1999 - 2004.

Steering Committee, Searle/Pharmacia EPHESUS Study, 1999 - 2003.

NIH Gene Transfer Clinical Trials Design Working Group, 2004 - 2005.

Data Monitoring Committee, Abbott Laboratories Trial of Depakote in the Elderly, 1999 - 2002.

Data and Safety Monitoring Board, St. Jude Medical Trial on SJM Regent/Epic Heart Valve, 2000 - 2006.

Data and Safety Monitoring Board, St. Jude Prospective Study of Trifecta Valve, 2007 - 2011.

Steering Committee, Merck Research Laboratories Losartan ELITE II Study, 1997 - 2000.

Data Monitoring Committee, Regeneron Pharmaceuticals Trial of r-methHuBDNF for ALS, 1998 - 2001.

Data and Safety Monitoring Committee, Merck Research Laboratories Vioxx Gastrointestinal Outcomes Research Study (VIGOR), 1999 - 2000.

HIVNET Prevention Research Review Group, NIAID, 1995 - 1998.

Data Monitoring and Safety Committee, NICHD Maternal-Fetal Medicine Units Network, 1991 - 1996.

Data and Safety Monitoring Board, NHLBI Dietary Approaches to Stop Hypertension (DASH) trial, 1994 - 1996.

Data and Safety Monitoring Committee, Merck Research Laboratories Losartan ELITE Study, 1994 - 1996.

Data and Safety Monitoring Committee, Glaucoma Research Foundation Trial of Intraocular pressure reduction in normal-tension glaucoma, 1996-1998.

Data and Safety Monitoring Committee, Glaxo 3TC Clinical Endpoint Protocol NUCB3007, 1995 - 1996.

Data Monitoring Board, NHLBI Prevention and Treatment of Hypertension Study, 1988 - 1994

Data and Safety Monitoring Committee, VA-NHLBI Trial of Reduction of Alcohol Intake in Lowering Blood Pressure, 1989 - 1995

Data Monitoring Committee, NHLBI Sodium and Hypertension in Blacks, 1992 - 1995.

Data Monitoring Committee, NHLBI Women's Healthy Lifestyle Project, 1992 - 1995.

Data Monitoring Committee, NIDDK African American Study of Kidney Disease and Hypertension, 1992 - 1994

NIH Ad Hoc Data and Safety Monitoring Review Committee on Human Growth Hormone in Turner Syndrome, 1992 - 1993

Data Monitoring Committee, Children and Adolescent Blood Pressure Program, 1986-1990.

Special Review Committee, NCI National Bladder Cancer Project, Collaborative Group A, 1976 - 1982.

Policy Advisory Committee, NICHD Sudden Infant Death Syndrome Study, 1977 - 1984.

Participant, Keystone Dialogue (initiated by Vice-President Gore) on Establishment of Studies to Optimize Medical Management of HIV Infection, 1996.

NIH gp160 Trial Design Team, NIAID, 1992.

Member, Joint National Committee V on Detection, Evaluation and Treatment of High Blood Pressure (Subcommittee No. 1 on Definition, Prevalence, Evaluation, Screening and Goals of Therapy), 1992.

Consultant, Minnesota Department of Health, Impact of Vaccination on Haemophilus Disease Incidence, 1986 - 1992.

Consultant, Minnesota Department of Health, Smoking Cessation Protocol for Primary Care Physician Offices, 1987 - 1990.

Seminar Committee and Faculty Member, International Teaching Seminar on Cardiovascular Disease Epidemiology and Prevention, 1987 - 1994.

Scientific Program Committee, American Heart Association, 1984 - 1987.

Scientific Program Committee, 2nd Joint Meeting of the Society for Clinical Trials and the International Society for Clinical Biostatistics, 1997.

Scientific Program Committee, XIth, XIIth, XIIIth, XIVth, XVth and XIXth International Conferences on AIDS, 1996, 1998, 2000, 2002, 2004, 2012 and 2013.

Plus ad hoc committee assignments with NIH and consultations with the Food and Drug Administration and the pharmaceutical industry.

Publications, including Peer-Reviewed Papers, Letters, Commentaries, and Book Chapters:

1. Urokinase Pulmonary Embolism Trial Group. The Urokinase Pulmonary Embolism Trial: a national cooperative study. Circulation 47:1-108, 1973.
2. Urokinase-Streptokinase Pulmonary Embolism Trial Group. Urokinase-Streptokinase Pulmonary Embolism Trial JAMA 229:1606-1613, 1974.
3. Multiple Risk Factor Intervention Trial Group. Design Considerations in the NHLI Multiple Risk Factor Intervention Trial (MRFIT). J. Chronic Diseases, 30:261-275, 1977.
4. Multiple Risk Factor Intervention Trial Group. The MRFIT Behavior Pattern Study. I. Study Design, Procedures, and Reproducibility of Behavior Pattern Judgements. J. Chronic Diseases, 32:293-305, 1978.
5. Kuller L, Neaton JD, Caggiula A, Falvo-Gerard L. Primary Prevention of Heart Attacks: The Multiple Risk Factor Intervention Trial. Am J Epidemiol, 112:185-199, 1980.
6. Neaton JD, Broste S, Cohen L, Fishman E, Kjelsberg M. The Multiple Risk Factor Intervention Trial (MRFIT) VII. A Comparison of Risk Factor Changes Between the Two Study Groups. Prev Med 10:519-543, 1981.
7. Multiple Risk Factor Intervention Trial Research Group. Multiple Risk Factor Intervention Trial: Risk Factor Changes and Mortality Results. JAMA, 248:1465-1477, 1982.
8. Kuller L, Hulley SB, Laporte R, Neaton JD, Dai W. Environmental determinants, liver function and high density lipoprotein cholesterol levels. Am J Epidemiol, 117:406-418, 1983.
9. Wentworth D, Neaton JD, Rasmussen W. An Evaluation of the Social Security Administration MBR File and the National Death Index in the Ascertainment of Vital Status. Am. J. Public Health, 73:1270-1274, 1983.
10. Neaton JD, Kuller L, Wentworth D., Borhani N. Total and Cardiovascular Mortality in Relation to Cigarette Smoking, Serum Cholesterol Concentration and Diastolic Blood Pressure Among Black and White Men Followed 5 Years. American Heart Journal, 108:759-770, 1984.
11. Multiple Risk Factor Intervention Trial Research Group. Exercise Electrocardiogram and Coronary Heart Disease Mortality in the Multiple Risk Factor Intervention Trial. Amer. J. Cardiology, 5:16-23, 1985.
12. Multiple Risk Factor Intervention Trial Research Group. Relationship Among Baseline Resting Electrocardiographic Abnormalities, Antihypertensive Treatment, and Mortality in the Multiple Risk Factor Intervention Trial. Amer. J. Cardiology, 5:1-15, 1985.
13. Grimm RH, Cohen JD, Smith W, Falvo-Gerard L, Neaton JD. Hypertension Management in the Multiple Risk Factor Intervention Trial (MRFIT): Six Year Intervention Results for Special Intervention and Usual Care Men. Archives of Internal Medicine, Vol. 145, July, 1985.
14. Grimm RH, Neaton JD, McDonald M, et al. Beneficial Effects from Systematic Dosage Reduction of the Diuretic Chlorthalidone: A Randomized Study Within a Clinical Trial. American Heart Journal, 109:858-864, 1985.

15. Grimm RH, Elmer PH, Neaton, JD, Segal MS, Prineas RJ. Role of Potassium Supplementation and Sodium Reduction in Controlling Blood Pressure in Hypertensive Men: Design and Methods of the Mt. Sinai Hypertension Trial. Edited by Paul K Whelton and Andrew Whelton, Marcel Dekker, Inc, New York, 1985.
16. Tillotson J, Neaton JD. Forms designed for implementation or evaluation of the MRFIT intervention process. In Materials and Methods for a cardiovascular disease risk factor reduction program. Edited by Jeanne Tillotson and SB Hulley. NIH Publication No. 85-1267, DHEW, March, 1985.
17. Grimm RH, Neaton JD, Ludwig B. The Prognostic Importance of Total White Blood Cell Count for All Cause, Cardiovascular and Cancer Mortality. JAMA, 254:1932-1937, 1985.
18. Cutler JA, Neaton JD, Hulley SB, Stamler J. Coronary Heart Disease and All Cause Mortality in the Multiple Risk Factor Intervention Trial: Overall and Subgroup Findings. Preventive Medicine, 14:293-311, 1985.
19. Shekelle RB, Hulley SB, Neaton JD, Billings J, Borhani N, et al. The MRFIT Behavior Pattern Study. II. Type A Behavior and Incidence of Coronary Heart Disease. Amer. J. Epid., 122:559-570, 1985.
20. Kuller LH, Hulley SB, Cohen JD, Neaton JD. Unexpected Effects of Treating Hypertension in Men with ECG Abnormalities: A Review of the Evidence. Circulation, 73:114-123, 1986.
21. Stamler J, Wentworth D, Neaton JD. Prevalence and prognostic significance of hypercholesterolemia in men with hypertension. Am. J. Med., 80:33-39, 1986.
22. Watkins LO, Neaton JD, Kuller, LH. Racial Differences in High-Density Lipoprotein Cholesterol and Coronary Heart Disease Incidence in the Usual Care Group of the Multiple Risk Factor Intervention Trial. Am. J. Cardio., 57:538-545, 1986.
23. Rautaharju PM, Prineas RJ, Furburg CD, Neaton JD, Crow RS, Stamler J. The prognostic value of exercise ECG in men at high risk of future coronary heart disease: Multiple Risk Factor Intervention Trial (MRFIT) Experience. J. Amer. College Cardio., 8:668-686, 1986.
24. Multiple Risk Factor Intervention Trial Research Group. Multiple Risk Factor Intervention Trial (MRFIT): Coronary Death, Non-Fatal Myocardial Infarction, and Other Clinical Outcomes. Amer. J. Cardio., 58:1-13, 1986.
25. Multiple Risk Factor Intervention Trial Research Group. Relationship Between Baseline Risk Coronary Heart Disease and Total Mortality in the Multiple Risk Factor Intervention Trial (MRFIT). Prev. Med., 15:254-273, 1986.
26. Kannel WB, Neaton JD, Wentworth D, Thomas HE, Stamler J, Hulley SB, Kjelsberg MO. Overall and coronary heart disease mortality rates in relation to major risk factors in 325,348 men screened for the MRFIT. Amer. Heart J., Vol. 112, No. 4, 825-836, 1986.
27. Stamler J, Wentworth D, Neaton J. Is relationship Between Serum Cholesterol and Risk of Premature Death From Coronary Heart Disease Continuous and Graded? JAMA, Vol. 256, No. 20, 2823-2828, 1986.
28. Shekelle RB, Hulley SB, Neaton JD, et al. Type A behavior and risk of coronary heart disease in the Multiple Risk Factor Intervention Trial. In Biological and Psychological Factors in

Cardiovascular Disease. Edited by T.H. Schmidt, T.M. Dembroski and G. Blumenchen, Springer-Verlag, Berlin 1986.

29. DuChene AG, Hultgren DH, Neaton JD, Grambsch PV, et al. Forms Control and Error Detection Procedures Used at the Coordinating Center of the Multiple Risk Factor Intervention Trial. Controlled Clinical Trials (Suppl.), Vol. 7, No. 3, 345-455, 1986.
30. Neaton JD, Kannel WB, Wentworth D et al. Smoking plus hyper-cholesterolemia and coronary risk. Letter to the Editor. Amer. Heart J., 1527-1528, 1987.
31. Grimm RH, Tillinghast L, Daniels K, Neaton JD, Mascioli S, Crow R, Pritzker M, Prineas R. Unrecognized myocardial infarction: Experience in the Multiple Risk Factor Intervention Trial (MRFIT). Circulation, Vol. 75 (Suppl. II), II-6 - II-8, 1987.
32. MacMahon SW, Cutler JA, Neaton JD, et al. Relationship of blood pressure to coronary and stroke morbidity and mortality in clinical and epidemiological studies. J. Hypertension, 4 (Suppl. 6), S14-S17, 1987.
33. Stamler J, Prineas RJ, Neaton JD, Grimm RH, et al. Background and design of the new U.S. trial on diet and drug treatment of "mild" hypertension (TOMHS). Am J. Cardiology, 59:512-602, 1987.
34. Grimm RH, Neaton JD, Prineas RJ. Primary prevention trials and the rationale for treating mild hypertension. Clinical Therapeutics, Vol. 9, Suppl. D, 20-30, 1987.
35. Cohen JD, Neaton JD, Prineas RJ, Daniels KA. Diuretics, serum potassium and ventricular arrhythmias in the Multiple Risk Factor Intervention Trial. Am. J. Cardiology, 60:548-554, 1987.
36. Rautaharju PM, Neaton JD. Electrocardiographic abnormalities and coronary heart disease mortality among hypertensive men in the Multiple Risk Factor Intervention Trial. Clinical and Investigative Med, 10:606-615, 1987.
37. Abdalla ISH, Prineas RJ, Neaton JD, et al. Relation between ventricular premature complexes and sudden cardiac death in apparently healthy men. Am. J. Cardiology, 60:1036-1042, 1987.
38. Rutan GH, Kuller LH, Neaton JD, et al. Mortality associated with diastolic and isolated systolic hypertension among men screened for the Multiple Risk Factor Intervention Trial. Circulation 77:504-514, 1988.
39. Neaton JD, Grimm RH, Cutler JA. Recruitment of participants for the Multiple Risk Factor Intervention Trial (MRFIT). Cont Clinical Trials 8:41S-53S, 1988.
40. Osterholm MT, Rambeck JH, White KE, Jacobs JL, Pierson LM, Neaton JD, Hedberg CW et al. Lack of efficacy of Haemophilus b polysaccharide vaccine in Minnesota. JAMA 260:1423-1428, 1988.
41. Shekelle RB, Hulley SB, Neaton JD, Borhani NO et al. Type A behavior (Letters to the Editor) Amer. Heart J 115:1348-1350, 1988.
42. Gordon DJ, Probstfield JL, Garrison, RJ, Neaton JD, et al. High-density lipoprotein cholesterol and cardiovascular disease. Four prospective American studies. Circulation 79:8-15, 1989.
43. MacMahon S, Collins G, Rautaharju P, Cutler JW, Neaton, JD, Prineas R, Crow R, Stamler J. Electrocardiograph left ventricular hypertrophy and the effects of antihypertensive drug therapy in

- hypertensive participants in the Multiple Risk Factor Intervention Trial. Am. J. Cardiology 63:202-210, 1989.
44. Grimm RH, Kofran PM, Neaton JD et al. Effect of potassium supplementation combined with dietary sodium reduction on blood pressure in men taking antihypertensive medication. J. Hypertension 6 (Suppl. 4), S591-S593, 1989.
 45. Stamler J, Neaton JD, Wentworth, DN. Blood pressure (systolic and diastolic) and risk of fatal coronary heart disease. Hypertension, 13 (Suppl. I), 2-12, 1989.
 46. Iso H, Jacobs DR, Wentworth D, Neaton JD, Cohen J. Serum cholesterol levels and six-year mortality from stroke in 350,977 men screened for the Multiple Risk Factor Intervention Trial. N Engl J Med 320:904-910, 1989.
 47. Grimm RH, Neaton JD, Elmer PJ, Svendsen KH, et al. The influence of potassium on blood pressure in hypertensive men on a low sodium diet: Results of a double-blind randomized trial. N Engl J Med 322:571-574, 1990.
 48. Neaton JD, DuChene AG, Svendsen, KH, Wentworth D. An examination of the efficiency of some quality assurance methods commonly employed in clinical trials. Statistics in Medicine, 9:115-124, 1990.
 49. MacMahon S, Peto R, Cutler J, Collins R, Sorlie P, Neaton J, Abbott R et al. Blood pressure, stroke and coronary heart disease, Part I: Effects of prolonged differences in blood pressure - evidence from nine prospective observational studies corrected for the regression dilution bias. Lancet, 335:765-774, 1990.
 50. Multiple Risk Factor Intervention Trial Research Group. Mortality rates after 10.5 years for participants in the Multiple Risk Factor Intervention Trial. Findings related to a priori hypothesis of the trial. JAMA 263:1795-1801, 1990.
 51. Hung J, Huang T, Wu D, Yen M, Tsai S, Dahl H, Neaton JD, Dahl JC. The impact of dietary sodium, potassium and calcium on blood pressure. J. Formosan Med. Assoc 89:17-22, 1990.
 52. Multiple Risk Factor Intervention Trial Research Group. Mortality after 10.5 years for hypertensive participants in the Multiple Risk Factor Intervention Trial. Circulation, 82:1616-1628, 1990.
 53. Mascioli S, Grimm RH, Neaton JD, Stamler J, et al. The Treatment of Mild Hypertension Study (TOMHS): Characteristics of participants at baseline. Amer. J. Cardiol, 66:32C-35C, 1990.
 54. Hanson LK, Grimm RH, Neaton JD. The relationship of white blood cell count to other cardiovascular risk factors. Int J Epid, 19:881-888, 1990.
 55. Mascioli S, Grimm RH, Launer C, Svendsen K, Flack J, Gonzalez N, Elmer P, Neaton JD. Sodium chloride raises blood pressure in normotensives: The Study of Sodium and Blood Pressure. Hypertension, 17:I21-I26, 1991.
 56. Treatment of Mild Hypertension Research Group. The Treatment of Mild Hypertension Study (TOMHS): A randomized, placebo controlled trial of a nutritional-hygienic regimen along with various drug monotherapies. Arch Int. Med., 151:1413-1423, 1991.
 57. Neaton JD, Bartsch G, Broste S, Cohen J, Simon N. A case of data alteration in the Multiple Risk Factor Intervention Trial. Cont Clin Trials, 12:731-740, 1991.

58. Ruth KE, Neaton JD. Evaluation of two biological markers of tobacco exposure. Prev Med 20:574-589, 1991.
59. Kuller L, Ockene J, Meilahn E, Wentworth D, Svendsen K, Neaton J. Cigarette smoking and mortality. Prev Med 20:638-654, 1991.
60. Shaten BJ, Kuller L, Neaton JD. Association between baseline risk factors, cigarette smoking and CHD mortality after 10.5 years. Prev Med 20:655-669, 1991.
61. Stamler J, Neaton JD, Wentworth D, Shih J et al. Lifestyles and life-style related risk factors: their combined impact in producing epidemic cardiovascular disease and the potential for prevention (in "Multiple Risk Factors for Cardiovascular Disease," edited by A.M. Gotto, C. Lenfant, R. Paoletti and M. Some), Norwell; Kluwer, 19-25, 1992.
62. Phillips AN, Neaton JD, Cook DG, Grimm RH, Shaper AG. The white blood cell count and risk of lung cancer. Cancer 69:681-684, 1992.
63. Davey-Smith G, Neaton JD, Ben-Shlomo Y, Shipley M, Wentworth D. Serum Cholesterol Concentration and Primary Brain Tumors: A Prospective Study. Amer J Epid, 135:259-265, 1992.
64. Neaton JD, Wentworth D. Influence of serum cholesterol, blood pressure, and cigarette smoking on death from coronary heart disease in 316,099 white men age 35-57 years: Overall findings and differences by age. Arch Int Med 152:56-64, 1992.
65. Neaton JD, Blackburn H, et al. Serum cholesterol level and mortality findings for men screened in the Multiple Risk Factor Intervention Trial. Arch Int Med 152:1490-1500, 1992.
66. Pearce KA, Grimm RH, Rao S, Svendsen K, Liebson PR, Neaton JD. Population-derived comparisons of ambulatory and office blood pressures; implications for the determination of usual blood pressure and the concept of white coat hypertension. Arch Int Med 152:750-756, 1992.
67. Phillips AN, Neaton JD, Cook DG, Grimm RH, Shaper AG. Leukocyte count and risk of major coronary heart disease events. Amer. J. Epid., 136:59-70, 1992.
68. Davey Smith G, Phillips AN, Neaton JD. Smoking as "independent" risk factor for suicide: Illustration of an artifact from observational epidemiology? Lancet, 340:709-712, 1992.
69. Jacobs D, Blackburn H, Higgins M, Reed D, Iso H, McMillan G, Neaton J et al. Report of the conference on low blood cholesterol: Mortality associations. Circulation, 86:1046-1060, 1992.
70. Stamler J, Stamler R, Neaton JD. National high blood pressure education program 20 years of achievement. Chapter 6: Blood pressure and cardiovascular risks: U.S. population data. NHLBI, 1992.
71. Neaton JD, Bartsch GE. Impact of measurement error and temporal variability on the estimation of event probabilities for risk factor intervention trials. Stat Med, 11: 1719-1729, 1992.
72. Walker WG, Neaton JD, Cutler JA, Neuwirth R, Cohen JD. Changes in serum creatinine in hypertensive participants in the Multiple Risk Factor Intervention Trial (MRFIT): Evidence that lowering blood pressure protects renal function in mild to moderate hypertensives. JAMA 268:3085-3091, 1992.

73. Eichner JE, Kuller LH, Orchard TJ, Grandits GA, McCallum LM, Ferrell RE, Neaton JD. The relationship of apolipoprotein E phenotype to myocardial infarction and CHD mortality. Amer. J. Cardiology, 71:160-165, 1993.
74. Stamler J, Vaccaro O, Neaton JD, Wentworth D. Diabetes, other risk factors, and 12 year cardiovascular mortality for men screened for the Multiple Risk Factor Intervention Trial. Diabetes Care, 16:434-444, 1993.
75. Stamler J, Stamler R, Neaton JD. Blood pressure, systolic and diastolic, and cardiovascular risks; U.S. Population Data. Archives Int. Med., 153:598-615, 1993.
76. Stamler J, Dyer AR, Shekelle RB, Neaton JD, Stamler R. Relationship of baseline major risk factors to coronary and all cause mortality, and to longevity: Findings from long-term follow-up of Chicago cohorts. Cardiology, 82(2-3):191-222, 1993.
77. Flack JM, Neaton JD, Daniels B, Esunge P. Ethnicity and renal disease. Lessons from MRFIT and TOMHS. Amer. J. Kidney Diseases, 21 (Suppl):31-40, 1993.
78. Neaton JD, Grimm RH, Prineas RJ, Grandits G, et al for the Treatment of Mild Hypertension Study Research Group. Treatment of Mild Hypertension Study (TOMHS): Final Results JAMA 270:713-724, 1993.
79. Stamler R, Stamler J, Brown WV, Gotto AM, Greenland P, Grundy S, Hegsted M, Leupker RV, Neaton JD, Steinberg D, Stone NJ, Van Horn L, Wissler RW. Serum Cholesterol: Doing the right thing. Circulation, 88:1954-1960, 1993.
80. Stamler R, Stamler J, Brown WV, Gotto AM, Greenland P, Grundy S, Hegsted M, Leupker RV, Neaton JD, Steinberg D, Stone NJ, Van Horn L, Wissler RW. Reply to Letters to the Editor on Editorial, "Serum Cholesterol: Doing the right thing". Circulation, 90:2573-2577, 1993.
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Presentations at Scientific Meetings, NIH/FDA Workshops and Scientific Symposia:

Design, implementation and field experience with the use of computer terminals in clinical centers in the Multiple Risk Factor Intervention Trial, Ninth International Biometric Society Conference, August, 1976, Boston, MA.

The "Oslo-like" cohort in the Multiple Risk Factor Intervention Trial. NHLBI Workshop on Primary Prevention of Coronary Heart Disease: Implications of the MRFIT. February, 1982, Bethesda, MD.

Total and CHD mortality in relation to smoking, serum cholesterol and diastolic blood pressure among Black and White men followed five years, AHA Cardiovascular Epidemiology Conference, March, 1983, San Diego, CA.

MRFIT subgroup findings, Sydenham Society, April 1983, Washington D.C. Do multiple risk factors explain racial differences and CHD mortality trends in Black populations? Symposium on recent Advances in Hypertension and Coronary Heart Disease in Black Populations, October, 1983, Baltimore, MD.

Use of logistic model in the design of intervention studies. Fifth Annual Meeting Society of Clinical Trials, May 1984, Miami, FL.

Monitoring of drug associated adverse reactions in a multiclinic trial. Eighty-ninth Annual Meeting of the American Society for Clinical Pharmacology and therapeutics, March, 1985, San Antonio, Texas.

Recruitment experience in the Multiple Risk Factor Intervention Trial. NIH Workshop on Recruitment of Patients in Cardiovascular Trials, April, 1986. Bethesda, MD.

Estimation of event rates for clinical trials, Spring Meetings of the Biometric Society (ENAR), March, 1988.

An examination of the efficiency of some quality assurance methods commonly employed in clinical trials, NIH Workshop on Cost and Efficiency in Clinical Trials, February, 1989.

Statistical design of the Treatment of Mild Hypertension Study (TOMHS). Tenth Annual Meeting Society of Clinical Trials, May, 1989, Minneapolis, MN.

What do you do when the data don't look right? Panel Discussion. Tenth Annual Meeting Society of Clinical Trials, May, 1989, Minneapolis, MN.

Facilitating critical evaluation of clinical trial reports. Annual Meeting. Council of Biology Editors, May 1989, Rochester, MN.

Comparison of 10 year coronary and cerebrovascular disease mortality rates by hypertensive status for black and white men screened in the MRFIT. American Heart Association, November 1989, New Orleans, Louisiana.

Quality control issues in multicenter clinical trials (Discussant), Society for Clinical Trials, May, 1990, Toronto, Canada.

Low serum cholesterol: risk of disease and determinants. NIH Workshop on Low Blood Cholesterol Levels and Disease, October, 1990, Bethesda, MD.

Lessons from Epidemiological Studies on the Prevention of Cardiovascular Disease, 5th Annual Meeting of Spanish Society of Preventive Cardiology, April, 1991, Jaca, Spain.

Long-term follow-up results of MRFIT, 5th Annual Meeting of Spanish Society of Preventive Cardiology, April, 1991, Jaca, Spain.

Issues in the design and conduct of AIDS trials. FDA Conference on the Role of Alternative Data Sources in AIDS Drug Development, May, 1991, Rockville, MD.

Ethnicity and renal disease: lessons from MRFIT and TOMHS. NIH Workshop on the Biology of Kidney Disease and Hypertension in Blacks, Washington D.C., December, 1991.

The challenges and opportunities of large, simple, community-based clinical trials: Four perspectives, organizer/chair of invited session, Biometric Society (ENAR), March, 1992, Cincinnati, Ohio.

Relative efficiency of taking research to the patient versus the patient to research, 13th Annual Meeting for Society for Clinical Trials, May, 1992, Philadelphia, PA.

Determinants of death from stroke. NIH Workshop on the Decline in Stroke Mortality, November 1992, Bethesda, MD.

Overview of toxoplasma prophylaxis studies. International Consensus Conference on Toxoplasma Prophylaxis, June, 1993, Berlin, Germany.

Is disease progression the optimal endpoint for AIDS Clinical Trials? IXth International Conference on AIDS, June 1993, Berlin, Germany.

Considerations in choice of a clinical endpoint for AIDS clinical trials. Societal Institute of the Mathematical Sciences 1993 AIDS Conference, June 1993, Blaubeuren, Germany.

What is going on at the lower end of the blood cholesterol distribution? 3rd International Conference on Preventive Cardiology, June 1993, Oslo, Norway.

Statistical design considerations for a large, simple trial (LST) on timing of combination nucleoside treatment, Joint Statistical Meetings, August, 1993, San Francisco, CA.

How to evaluate HIV/AIDS drugs. Japanese Health Foundation, March, 1994, Tokyo, Japan.

In search of the optimal endpoint for AIDS clinical trials. Journée d'Animation Scientifique. ANRS, April, 1994, Paris, France.

Considerations in specifying the duration of followup of antiretroviral trials. 2nd National Conference on Human Retroviruses and Related Infections, February, 1995, Washington,

Can it work? Does it work? Differing expectations for clinical trials. Arguments for pragmatic clinical trials for persons with HIV. American Association for the Advancement of Science, February, 1995, Atlanta, Georgia.

Relationship of serum cholesterol and blood pressure with risk of death from AIDS. American Epidemiological Society, March, 1995, Tampa, Florida.

- How much on-site auditing of clinical trials should be performed? Chairperson, 16th Annual Meeting of the Society of Clinical Trials, May, 1995, Seattle, Washington.
- How does one measure change in chronic disease? Encounters in Glaucoma Research, June, 1995, Vancouver, British Columbia.
- How should clinical endpoints be defined in antiretroviral trials? FDA, AIDS Task Force Workshop: Current Issues in AIDS Clinical Trials: Clinical Endpoint Confirmation Studies, September, 1995, Bethesda, Maryland.
- Considerations in specifying the duration of follow-up of antiretroviral trials. Overview and status of HIV: Conference on the Disease Prevention and Control, October, 1995, Pavia, Italy.
- Design issues for clinical endpoint trials: Cambridge Healthtech Institute's Second Annual Conference on Surrogate Markers of HIV, October, 1995, Tysons Corners, Virginia.
- Role of data and safety monitoring boards. American Academy of Neurology, April 1998, Minneapolis, Minnesota.
- Design and analysis issues for equivalence trials. 19th Annual Meeting, Society for Clinical Trials, May, 1998, Atlanta, Georgia.
- Making it work: Experience with a centralized biostatistics unit in an academic setting, Joint Statistical Meetings, August, 2000, Indianapolis, Indiana
- Challenges to clinical trial design in the setting of HAART (Invited State-of-the-Art Mini-lecture). 40th Interscience Conference on Antimicrobial Agents and Chemotherapy, October, 2000, Toronto, Ontario.
- Combined endpoints for HIV trials, NIH Endpoint Workshop, February, 2001, Bethesda, Maryland.
- Role of the sponsor in data management, steering committee, DSMB, stopping trials and publication, Fourth Cardiovascular Clinical Trials Workshop, December, 2001, Monte Carlo, Monaco.
- Practical issues in establishing and operating a data monitoring committee, Drug Information Association Workshop, January, 2002, Bethesda, Maryland.
- Predictors of cardiovascular disease: Implications for future HIV clinical trial design, 4th International Workshop on Adverse Drug Reactions and Lipodystrophy, September, 2002, San Diego, California.
- Issues in Data Monitoring Committees - Role of Independent Statistician, Duke Clinical Research Institute Symposia, January 2003, Washington D.C.
- Prevention of CVD events: 30 years of MRFIT, Festschrift Honoring Dr. Lewis H. Kuller, March 2003, Pittsburgh, PA.
- The collection and monitoring of drug safety data, Tools for Pre-Approval of Drug Safety Evaluation, FDA course, May 2003, Washington D.C.

A new generation of clinical endpoint trials in HIV, 3rd Joint Meeting of the Society for Clinical Trials and the International Society for Clinical Biostatistics, July 2003, London

Case Study: CPCRA TOXO Study: Stopped twice, maybe three times. Clinical trial data monitoring committees. Policies, practices and controversies. Drug Information Association, September 2003, Washington D.C.

Rationale, design, and implementation issues for large, long-term international trials in HIV. 6th Congresso Argentino de Sida, November 2003, Buenos Aires, Argentina.

International Research in HIV/AIDS: Challenges and opportunities in the new millennium, Center for Public Health Education, February 2004, Minneapolis, Minnesota.

Composite endpoints. Key issues in endpoint selection and measurement for devices in heart failure. Heart Failure Society of America, April 2004, Washington D.C.

Socioeconomic status, ethnicity, risk factors & cardiovascular disease, Festschrift Honoring the Life and Achievements of Jeremiah Stamler, MD, October 2004, Chicago, Illinois.

Trials in AIDS: lessons for future MS trials? National Multiple Sclerosis Society, December 2004, Washington D.C.

Biostatistical issues in the design of type 1 diabetes trials (Co-chair of workshop), NIDDK, March 2005, Washington D.C.

Importance of follow-up in clinical trials, 2nd Annual PHIDISA Conference, August 2005, Capetown, South Africa.

Alternatives to randomized controlled trials for VAD development, HFSA/FDA Workshop, March 2006, Rockville, Maryland

Data Monitoring Board perspective on the Shingles Prevention Study, Society for Clinical Trials, May 2006, Orlando, Florida

Challenges in the design, implementation, and monitoring of HIV treatment trials, Statistical Society of Canada, May 2006, London, Ontario.

Results of the SMART study, HAART Oversight Committee, June 2006, Paris, France,

The dark side of composite endpoints, European Heart Failure Society, June 2006, Helsinki, Finland.

Randomized Clinical Trials: Designs for the future and obstacles to overcome. Current Issues in Clinical Research, Mayo Clinical Trials Services and the Academic Health Center, University of Minnesota, October 2006, Minneapolis, MN.

When to start HAART. Why an RCT can, and should, be performed. 11th International Workshop on HIV Observational Databases, March 2007, Monte Carlo.

Statistical considerations in interpreting non-randomized trials. Heart Failure Society of America Workshop on Regulatory Issues Surrounding Heart Failure Devices, May 2007, Bethesda, MD.

- Changing patterns of morbidity and mortality in HIV disease. 4th IAS Conference on HIV Pathogenesis, Treatment and Prevention, July 2007, Sydney, Australia.
- Considerations in clinical trial design with LVADs. 11th Annual Scientific Meeting, Heart Failure Society of America, September 2007, Washington D.C.
- Challenges in the design, organization and conduct of multi-center trials. Current Issues in Clinical Research, Mayo Clinical Trials Services and the Academic Health Center, University of Minnesota, September 2007, Minneapolis, MN.
- Practical challenges to keeping the simple in large, simple trials. International Biometric Society, Eastern North American Region, March 2008, Arlington, Virginia.
- Interpreting data in the medical literature, Minnesota Academy of Family Physicians, April 2008, St. Paul, Minnesota.
- Developing a career in clinical trials: a biostatistician's perspective. 29th Annual Meeting of the Society for Clinical Trials, May 2008, St. Louis, Missouri.
- Formation of the INSIGHT Clinical Trials Network – a Case History. Midwest Consortium for Training Clinical Researchers, June 2008, Rochester, Minnesota.
- Establishing an infrastructure for a clinical trial network in South Africa. NIAID Workshop on Strengthening Biostatistical Resources in South Africa, September 2009, Bethesda, Maryland.
- Commentary on long-term follow-up in clinical trials – ALLHAT experience. American Heart Association Scientific Sessions, November 2009, Orlando, Florida.
- Lessons from the field, Collaborative Leadership Development Series, Legal and Regulatory Issues in International Research Collaborations, April 2010, Minneapolis.
- Perspectives from SCT Fellows. Society for Clinical Trials, May 2010, Baltimore, MD.
- Handling of missing data in clinical trials: findings of a National Research Council Study. Choice of estimand, trial design, and trial conduct. Joint Statistical Meetings, August 2010, Vancouver, British Columbia.
- Strategies for preventing cardiovascular disease among individuals infected with HIV. Grand Rounds, University of Rochester School of Medicine and Dentistry, October 2010, Rochester, New York.
- Current issues and controversies for clinical trial data monitoring committees. International Biometric Society, Eastern North American Region, March 2011, Miami, Florida.
- Emerging statistical issues in the conduct and monitoring of clinical trials, discussant. University of Pennsylvania Annual Conference on Statistical Issues in Clinical Trials, April 2011, Philadelphia, PA.
- Missing data in clinical trials. 32nd Annual Meeting of Society for Clinical Trials, May 2011, Vancouver, British Columbia.

A proposal: The establishment of regional data coordinating centers in sub-Saharan Africa for the conduct of large trials. NIAID, NIH Workshop for Biostatistics Capacity Building in Sub-Saharan Africa, June 2011, Gaborone, Botswana.

Compensation for research-related injuries: transforming obligations into action? The START trial: a case example of regulatory impediments to the conduct of publically funded trials. American Society for Bioethics and Humanities, October 2011, Minneapolis, MN.

Prevention of missing data: trial conduct strategies. Short course on the prevention and treatment of missing data in clinical trials, November 2011, Newark, New Jersey.

Rationale and design of two early treatment trials for HIV: START and START-Survival, NIAID, NIH, December 2011, Bethesda.

Incorporating new data and changing standards of care into clinical trials. 19th Conference on Retroviruses and Opportunistic Infections, March 2012, Seattle.

Streamlining regulatory issues: challenges from recent international trials. 2012 Sensible Guidelines Symposium, May 2012, Toronto.

Estimates of CVD mortality risk associated with drug-induced BP elevations. Duke-FDA Cardiac Safety Research Consortium Think Tank, July 2012, Bethesda, Maryland.

The search for missing data: The impact of the National Academies of Science report (Discussant). Joint Statistical Meetings, July 2012, San Diego, California.

Prevention of CVD: Time for a polypill for HIV+ persons. The Global Summit on Combination Polypharmacy for Cardiovascular Disease, September 2012, Hamilton, Ontario.

Prevention of cardiovascular disease in HIV+ individuals: time for a polypill? 1st International Symposium. Present and future of applied sciences in HIV infection, October 2012, Buenos Aires.

Missing data in outcome trials: implications and prevention. Duke FDA Cardiac Safety Research Consortium Annual Meeting, December 2012, Bethesda, Maryland.

Data and safety monitoring boards: current issues and challenges. How blind should the investigators and sponsors be? Joint Statistical Meetings, August 2013, Montreal, Canada.

Considerations in defining and summarizing composite outcomes in clinical trials. ASA Biopharmaceutical Section. FDA-Industry Statistics Workshop, September 2013, Washington, D.C.

Strategies to prevent missing data. Johns Hopkins Symposium and on Handling and Preventing Missing Data, October 2013, Baltimore, MD.

Plus numerous co-authored abstracts and departmental seminars at other institutions.