PUBLICATIONS:

<u>Statistical Methods Papers</u>:

1. Ware JH and DeMets DL: Reanalysis of some baboon descent data. *Biometrics* 32:459-464, 1976.

2. DeMets D and Halperin M: Estimation of a simple regression coefficient in samples arising from a sub-sampling procedure. *Biometrics* 33:47-56, 1977.

3. DeMets DL and Ware JH: Group sequential methods for clinical trials with a one-sided hypothesis. *Biometrika* 67(3):651-660, 1980.

4. Wu M, Fisher M, and DeMets D: Sample sizes for long-term medical trials with time-dependent dropout and event rates. *Controlled Clinical Trials* 1:109-121, 1980.

5. DeMets DL and Halperin M: Early stopping in the two-sample problem for bounded variables. *Controlled Clinical Trials* 3:1-11, 1982.

6. Gail MH, DeMets DL, and Slud EV: Simulation studies on increments of the two-sample logrank score test for survival time data, with application to group sequential boundaries. *Survival Analysis*. IMS Lecture Note Series. J. Crowley and R. Johnson, (Eds.), Vol. 2, Hayward, California, 1982.

7. DeMets DL and Ware JH: Asymmetric group sequential boundaries for monitoring clinical trials. *Biometrika* 69(3):661-663, 1982.

8. Halperin M, Lan KKG, Ware J, Johnson NJ, and DeMets DL: An aid to data monitoring in long-term clinical trials. *Controlled Clinical Trials* 3:311-323, 1982.

9. Lan KKG , DeMets DL: Discrete sequential boundaries for clinical trials. *Biometrika* 70(3):659-663, 1983.

10. DeMets DL: Can early stopping procedures impact significantly on the efficiency of clinical trials without serious loss of information? *Statistics in Medicine* 3:445-451, 1984.

11. DeMets DL: Stopping guidelines vs. stopping rules: A practitioner's point of view. *Communications in Statistics-Theory and Methods* 13(19):2395-2417, 1984.

12. DeMets DL and Lan KKG: An overview of sequential methods and their application in clinical trials. *Communications in Statistics-Theory and Methods* 13(19):2315-2338, 1984.

13. Lan KKG, DeMets DL, and Halperin M: More flexible sequential and non-sequential designs in long-term clinical trials. *Communications in Statistics-Theory and Methods* 13(19):2339-2353, 1984.

14. DeMets DL and Gail MH: Use of logrank tests and group sequential methods at fixed calendar times. *Biometrics* 41:1039-1044, 1985.

15. DeMets DL: Practical aspects in data monitoring: A brief review. *Statistics in Medicine* 6:753-760, 1987.

16. DeMets DL: Methods for combining randomized clinical trials: Strengths and limitations. *Statistics in Medicine* 6:341-348, 1987.

17. Kim K and DeMets DL: Design and analysis of group sequential tests based on the type I error spending rate function. *Biometrika* 74:149-154, 1987.

18. Kim K and DeMets DL: Confidence intervals following group sequential tests in clinical trials. *Biometrics* 43:857-864, 1987.

19. Storer B and DeMets D: Current Phase I/II designs: Are they adequate? *Journal of Clinical Research and Drug Development* 1:121-130, 1987.

20. DeMets DL and Lan KKG: Discussion of "Interim analyses: The repeated confidence interval approach" by C. Jennison and B.W. Turnbull. *Journal of the Royal Statistical Society*, B51, p. 344, 1989.

21. Lan KKG and DeMets DL: Changing frequency of interim analyses in sequential monitoring. *Biometrics* 45:1017-1020, 1989.

22. Lan KKG and DeMets DL: Group sequential procedures: Calendar versus information time. *Statistics in Medicine* 8:1191-1198, 1989.

23. Halperin M, DeMets DL, and Ware JH: Early Methodological Developments for Clinical Trials at the National Heart, Lung and Blood Institute. *Statistics in Medicine* 9:881-892, 1990.

24. Lee JW and DeMets DL: Sequential comparison of changes with repeated measurement data. *Journal of the American Statistical Association (JASA)* 86(415):757-762, 1991.

25. Lin DY, Wei LJ, and DeMets DL: Exact statistical inference for group sequential trials. *Biometrics* 47:1399-1408, 1991.

26. Kim K and DeMets DL: Sample size determination for group sequential clinical trials with immediate response. *Statistics in Medicine* 11:1391-1399, 1992.

27. Lee JW and DeMets DL: Sequential rank tests with repeated measurements in clinical trials. *JASA* 87: 136-142, 1992.

28. Albert JM and DeMets DL: On a model-based approach to estimating efficacy in clinical trials. *Statistics in Medicine* 13:2323-2335, 1994.

29. DeMets DL: Book Review - *Fraud and Misconduct in Medical Research*, S. Lock and F. Wells (eds) *Statistics in Medicine* 13, 1994.

30. DeMets DL, Anbar D, Fairweather W, Louis TA, O'Neill RT: Training the next generation of biostatisticians. *The American Statistician* 48(4):280-284, 1994.

31. DeMets DL and Lan KKG: Interim analysis: The alpha spending function approach. *Statistics in Medicine* 13:1341-1352, 1994.

32. Lan KKG, Reboussin DM, DeMets DL: Information and information fractions for design and sequential monitoring of clinical trials. *Communications in Statistics - Theory and Methods* 23(2):403-420, 1994.

33. Lee JW and DeMets DL: Group sequential comparison of changes: Ad-hoc versus more exact method. *Biometrics* 51:21-30, 1995

34. Gange SJ, Linton KLP, Scott AJ, DeMets DL, Klein R: A comparison of methods for correlated ordinal measures with ophthalmic applications. *Statistics in Medicine* 14:1961-1974, 1995.

35. Gange SJ and DeMets DL: Sequential monitoring of clinical trials with correlated categorical responses. *Biometrika* 83(1):157-167, 1996.

36. Reboussin DM and DeMets DL: Exact permutation inference for two sample repeated measures data. *Communications in Statistics* 25(10):2223-2238, 1996.

37. Pinheiro JC and DeMets DL: Estimating and reducing bias in group sequential designs with Gaussian independent structure. *Biometrika* 84: 831-843, 1997.

38. Qu RP and DeMets DL: Bias correction in group sequential analysis with correlated data. *Statistica Sinica* 9(4):939-952, 1999.

39. Li Z and DeMets DL: On the bias of estimation of a Brownian motion drift following group sequential tests. *Statistical Sinica* 9(4): 923-37, 1999.

40. Lee JW and DeMets DL: Estimation following group sequential tests with repeated measurements data. *Computational Statistics and Data Analysis* 32:69-77, 1999.

41. Reboussin DM, DeMets DL, Kim KM, Lan KKG: Computations for group sequential boundaries using the Lan-DeMets spending function method. *Controlled Clinical Trials* 21(3):190-207, 2000.

42. Gong J, DeMets DL, Pinheiro JC: Estimating significance level and power comparisons for testing multiple endpoints in clinical trials. *Controlled Clinical Trials* 21(4): 313-329, 2000.

43. Spiessens B, Lesaffre, Verbeke G, Kim K, and DeMets DL: An overview of group sequential methods in longitudinal clinical trials. *Statistical Methods in Medical Research* 9:497-515, 2000.

44. Lee JW, Jo SJ, DeMets DL, Kim K. Confidence intervals following group sequential tests in clinical trials with multivariate observations. *J Statist Comput Simul* 72(3): 247-59, 2002.

45. Chen JYH, DeMets DL, Lan KKG. Monitoring mortality at interim analyses while testing a composite endpoint at the final analysis. *Controlled Clinical Trials* 24:16-27, 2003.

46. Chen JYH, DeMets DL, Lan KKG. **Increasing the sample size when the unblinded interim result is promising**. *Statistics in Medicine* 23(7): 1023-1038, 2004.

47. Fan X, DeMets DL and Lan KKG. Conditional bias of point estimates following a group sequential test. *Journal of Biopharmaceutical Statistics*, 14:505-530, 2004.

48. Kosorok MR, Shi Y, DeMets DL: Design and analysis of group sequential clinical trials with multiple primary endpoints. *Biometrics* 60(1):134-45, 2004.

49. DeMets DL. Discussion on statistical issues in the Women's Health Initiative. *Biometrics* 61:914-17, 2005.

50. Fan X, DeMets DL. Conditional and unconditional confidence intervals following a group sequential test. *Journal of Biopharmaceutical Statistics* 16:107-122, 2006.

51. Lan KKG and DeMets D. Further comments on the alpha-spending function. *Stat Biosci* 1:95-111, 2009.

52. Chen JYH, DeMets DL, Lan GKK, Some drop-the-loser designs for monitoring multiple doses. *Stat Med* 29(17):1793-807, 2010. PMID:20658548

53. Cook T and DeMets DL. Review of draft FDA adaptive design guidance. *J Biopharmaceutical Statistics* 20(6):1132-42, 2010. PMID:21058109

54. Fleming T, Hennekens C, Pfeffer M, DeMets D; Enhancing trial integrity by protecting the independence of data monitoring committees in clinical trials, J Biopharm Stat, 2014:5,968-975

55. Yang F, Stewart M, Ye B, DeMets DL; Type 2 diabetes development programs in the new regulatory environment with cardiovascular safety requirements, Diabetes, Metabolism and Obesity, Dover Press, July 2015, 8:315-325

56. David L. DeMets, Janet Turk Wittes & Nancy L. Geller (2015) The Influence of Biostatistics at the National Heart, Lung, and Blood Institute, The American Statistician, 69:2, 108-120

Collaborative Scientific Papers

1. Harris EK and DeMets DL: Biological and analytical components of variation in long-term studies of serum constituents in normal subjects. V. Estimated biological variations in ionized calcium. *Clinical Chemistry* 17(10):983-987, 1971.

2. Harris EK and DeMets DL: Effects of intra- and inter-individual variation on distributions of single measurements. *Clinical Chemistry* 18(3):244-249, 1972.

3. Harris EK and DeMets DL: Estimation of normal ranges and cumulative proportions by transforming observed distributions to Gaussian form. *Clinical Chemistry* 18(7):605-612, 1972.

4. Bell W, Black EB, DeMets D, and Simon T (Eds.): Urokinase-Streptokinase pulmonary embolism trial; Phase II results. *Journal of the American Medical Association* 229(12):1606-1613, 1974.

5. Byar DP, Simon RM, Friedewald WT, Schlesselman JJ, DeMets DL, Ellenberg JH, Gail MH, Ware JH: Randomized clinical trials - Perspectives on some recent ideas. *New Engl J Med* 295:74-80, 1976.

6. Henkin R, Schecter PJ, Friedewald WT, DeMets DL, Raff M: A double blind study of the effects of zinc sulfate on taste and smell dysfunction. *American Journal of Medical Sciences* 272(3):285-299, 1976.

7. Bell WR, Simon TL, and DeMets DL: The clinical features of submassive and massive pulmonary emboli. *American Journal of Medicine* 62:355-360, 1977.

8. Bowden et al: Urinary excretion of immunoreactive prostaglandin E: A circadian rhythm and the effect of posture. *Journal of Prostaglandin Research*, 1977.

9. Klein HG, Aledort LM, Bouma BN, Hoyer LW, Zimmerman TS, DeMets DL: A co-operative study for the detection of the carrier state of classic hemophilia. *New Engl J Med*296:959-962, 1977.

10. Garrison RJ, DeMets DL, Fabsitz RR, Feinleib M: A likelihood ratio test for unequal shared environmental variance in twin studies. *Proceedings of the Second International Congress on Twin Studies*, Washington, D.C., August 29, 1977. *Twin Research: Psychology and Methodology* p. 253-259, 1978.

11. Pierce et al: Report of the task force on bilateral carotid body resection. For the Division of Lung Diseases, National Heart, Lung and Blood Institute, DHEW Publication (NIH), 79-1416, March, 1978.

12. DeMets D, Friedman L, and Furberg C: Counting events in clinical trials. Letter to the editor. *New Engl J Med* 302(16):924, 1980.

13. Lenfant C, et al: Epidemiology of respiratory diseases. Task Force Report. Division of Lung Diseases, National Heart, Lung and Blood Institutes, NIH Publication #81-2019, October, 1980.

14. Nocturnal Oxygen Therapy Trial Group: Continuous or nocturnal oxygen therapy in hypoxemic chronic obstructive lung disease - A clinical trial. *Annals of Internal Medicine* 93(3):391-398, 1980.

15. CASS Principal Investigators and their Associates: National Heart, Lung, and Blood Institute Coronary Artery Surgery Study (CASS). *Circulation* 63(Suppl I):I-1-39, 1981.

16. Collaborative Group on Antenatal Steroid Therapy: Effect of antenatal dexamethasone administration on the prevention of respiratory distress syndrome. *American Journal of Obstetrics and Gynecology* 141(3):276-287, 1981.

17. Friedman L and DeMets D: The data monitoring committee: How it operates and why. *Institutional Review Board* 3:6-8, 1981.

18. Howard JM, DeMets D, and BHAT Research Group: How informed is informed consent? The BHAT experience. *Controlled Clinical Trials* 2:287-303, 1981.

19. May GS, DeMets DL, Friedman LM, Furberg C, and Passamani G: The randomized clinical trial: Bias in analysis. *Circulation* 64(4):669-673, 1981.

20. Stein PD, Willis PW, and DeMets DL: History and physical examination in acute pulmonary embolism in patients without preexisting cardiac or pulmonary disease. *Amer Journal of Cardiology* 47:218-23, 1981.

21. Beta-Blocker Heart Attack Trial Research Group: A randomized trial of propranolol in patients with acute myocardial infarction. I. Mortality results. *Journal of the American Medical Association* 247(12):1707-1714, 1982.

22. DeMets DL, Williams GW, Brown BW, and the NOTT Research Group: A case report of data monitoring experience. The nocturnal oxygen therapy trial. *Controlled Clinical Trials* 3:113-124, 1982.

23. May GS, Eberlein KA, Furberg CD, Passamani ER, and DeMets DL: Secondary prevention after myocardial infarction: A review of long-term trials. *Progress in Cardiovascular Diseases* 24:331-52, 1982.

24. CASS Principal Investigators and their Associates: Coronary Artery Surgery Study (CASS): A randomized trial of coronary artery bypass surgery - Quality of life in patients randomly assigned to treatment groups. *Circulation* 68(5):951-960, 1983.

25. CASS Principal Investigators and their Associates: Coronary Artery Surgery Study (CASS): A randomized trial of coronary artery bypass surgery - Survival data. *Circulation* 68(5):939-950, 1983.

26. The Intermittent Positive Pressure Breathing Trial Group: Intermittent positive pressure breathing therapy of chronic obstructive pulmonary disease - A clinical trial. *Annals of Internal Med* 99(5):612-620, 1983.

27. Klein R, Klein BEK, Moss SE, and DeMets D: Inter-observer variation in refraction and visual acuity measurement using a standardized protocol. *Ophthalmology* 90(10):1357-1359, 1983.

28. CASS Principal Investigators and their Associates: Coronary Artery Surgery Study (CASS): A randomized trial of coronary artery bypass surgery. Comparability of entry characteristics and survival in randomized patients and nonrandomized patients meeting randomization criteria. *J Amer Coll Cardiol* 3:114-128, 1984.

29. CASS Principal Investigators and their Associates: Myocardial infarction and mortality in the Coronary Artery Surgery Study (CASS) randomized trial. *New Engl J Med* 310:750-758, 1984.

30. Collaborative Group on Antenatal Steroid Therapy: Effects of antenatal dexamethasone administration in the infant: Long-term follow-up. *Journal of Pediatrics* 104(2):259-267, 1984.

31. Davey RJ, Lenes BL, Casper AJ and DeMets DL: Adequate survival of red cells from units "undercollected" in citrate-phosphate-dextrose-adenine-one. *Transfusion* 24(4):319-322, 1984.

32. DeMets DL, Hardy R, Friedman LM and Lan KKG: Statistical aspects of early termination in the Beta-Blocker Heart Attack Trial. *Controlled Clinical Trials* 5:362-372, 1984.

33. Klein R, Klein BEK, Moss SE, Davis MD and DeMets DL: The Wisconsin Epidemiologic Study of Diabetic Retinopathy. II. Prevalence and risk of diabetic retinopathy when age at diagnosis is less than thirty. *Archives of Ophthalmology* 102:520-526, 1984.

34. Klein R, Klein BEK, Moss SE, Davis MD and DeMets DL: The Wisconsin Epidemiologic Study of Diabetic Retinopathy. III. Prevalence and risk of diabetic retinopathy when age at diagnosis is thirty or over. *Archives of Ophthalmology* 102:527-532, 1984.

35. Klein R, Klein BEK, Moss SE, Davis MD, and DeMets DL: The Wisconsin Epidemiologic Study of Diabetic Retinopathy. IV. Diabetic macular edema. *Ophthalmology* 91:1464-1474, 1984.

36. Klein R, Klein BEK, Moss SE, DeMets DL: Visual impairment in diabetes. *Ophthalmology* 91:1-9, 1984.

37. Klein R, Klein BEK, Moss SE, DeMets DL, Kaufman I, and Voss PS: Prevalence of diabetes mellitus in southern Wisconsin. *American Journal of Epidemiology* 119(1):54-61, 1984.

38. Hawkins M, Horning S, Konrad M, Anderson S, Schiesel J, Sielaff K, Rosno S, DeMets D, Merigan T, and Borden E: Interferon $Beta_{ser}$: Interim analysis of a Phase I clinical trial. In, *The Biology of the Interferon System 1984*, H. Kirchner and H. Schellekens (eds.), Elsevier Science Publishers B.V., p. 503-508, 1985.

39. Hawkins M, Horning S, Konrad M, Anderson S, Sielaff K, Rosno S, Schiesel J, Davis T, DeMets D, Merigan T, and Borden E: Phase I evaluation of a synthetic mutant of Beta-Interferon. *Cancer Research* 45:5914-5920, 1985.

40. Klein R, Davis MD, Moss SE, Klein BEK and DeMets DL: The Wisconsin Epidemiologic Study of Diabetic Retinopathy. A comparison of retinopathy in younger and older onset diabetic persons. In, *Comparison of Type I and II Diabetes*, M. Vranic, C.H. Hollenberg and G. Steiner (eds.), Plenum Publishing Corporation, pp. 321-335, 1985.

41. Klein R, Klein BEK, Moss SE, Davis MD and DeMets DL: Retinopathy in young onset diabetic patients. *Diabetes Care* 8(4):311-315, 1985.

42. Klein R, Klein BEK, Moss SE, and DeMets DL: Blood pressure and hypertension in diabetes. *American Journal of Epidemiology* 122(1):75-89, 1985.

43. The DCCT Research Group: Diabetes Control and Complications Trial (DCCT): Design and methodologic considerations for the feasibility phase. *Diabetes* 35:530-545, 1986.

44. Klein R, Klein BEK, Moss SE, Davis MD, and DeMets DL: The Wisconsin Epidemiologic Study of Diabetic Retinopathy. V. Proteinuria and retinopathy in a population of diabetic persons diagnosed prior to 30 years of age. In, *Diabetic Renal-Retinal Syndrome*, vol. 3, Friedman, E.A. and L'Esperance, F.A. (eds.), Grune and Stratton, New York, 1986, pp. 245-264.

45. Klein R, Klein BEK, Moss SE, and DeMets D: The validity of a survey question to study diabetic retinopathy. *American Journal of Epidemiology* 124:104-110, 1986.

46. The DCCT Research Group: Diabetes Control and Complications Trial (DCCT): Results of feasibility study. *Diabetes Care* 10(1):1-19, 1987.

47. Klein R, Klein BEK, Moss SE, Davis MD and DeMets DL: The Wisconsin Epidemiologic Study of Diabetic Retinopathy. VI. Retinal photocoagulation. *Ophthalmology* 94(7):747-753, 1987.

48. Klein R, Klein BEK, Moss SE, Davis MD and DeMets DL: The Wisconsin Epidemiologic Study of Diabetic Retinopathy. VII. Diabetic nonproliferative retinal lesions. *Ophthal* 94(11):1389-1400, 1987.

49. Stein PD, Willis PW, DeMets DL and Greenspan RH: Plain chest roentgenogram in patients with acute pulmonary embolism and no preexisting cardiac or pulmonary disease. *American Journal of Noninvasive Cardiology* 1:171-176, 1987.

50. Williams GW, Snedecor SM, DeMets DL, and the NOTT Research Group: Recruitment experience in the Nocturnal Oxygen Therapy Trial. *Controlled Clinical Trials* 8:121S-130S, 1987.

51. Farrell PM, Gutcher GR, Palta M, and DeMets D: Essential fatty acid deficiency in premature infants. *American Journal of Clinical Nutrition* 48:220-29, 1988.

52. Klein R, Klein BEK, Moss SE, Davis MD, and DeMets DL: Glycosylated hemoglobin predicts the incidence and progression of diabetic retinopathy. *JAMA* 260(19):2864-2871, 1988.

53. Klein R, Klein BEK, Moss SE, Davis MD and DeMets DL: Severe retinopathy in insulin-taking children and young adults. *Pediatric and Adolescent Endocrinology* 17:146-152, 1988.

54. Klein R, Klein BEK, Moss S and DeMets DL: Proteinuria in diabetes. *Archives of Internal Medicine* 148:181-186, 1988.

55. Klein R, Moss SE, Klein BEK, Davis MD, DeMets DL: The Wisconsin Epidemiologic Study of Diabetic Retinopathy: VIII. The incidence of retinal photocoagulation. *Diabetic Complications* 2:79-87, 1988.

56. Steering Committee for the Physicians' Health Study Research Group: Preliminary Report: Findings from the Aspirin Component of the Ongoing Physicians' Health Study. *New Engl J Med* 318(4):262-264, 1988.

57. Cardiac Arrhythmia Suppression Trial (CAST) Investigators: Preliminary report: Effect of encainide and flecainide on mortality in a randomized trial of arrhythmia suppression after myocardial infarction. *New Engl J Med* 321(6):406-412, 1989.

58. Kaufman SC, Ferris FL, Seigel DG, Davis MD, DeMets DL, and the DRS Research Group: Factors associated with visual outcome after photocoagulation for diabetic retinopathy. Diabetic Retinopathy Study Report #13. *Investigative Ophthalmology & Visual Science* 30(1):23-28, 1989.

59. Klein R, Klein BEK, Moss SE, Davis MD, and DeMets DL: Is blood pressure a predictor of the incidence of progression of diabetic retinopathy? *Archives of Internal Medicine* 149:2427-2432, 1989.

60. Klein R, Klein BEK, Moss SE, Davis MD, and DeMets DL: The Wisconsin Epidemiologic Study of Diabetic Retinopathy. IX. Four-year incidence and progression of diabetic retinopathy when age at diagnosis is less then 30 years. *Archives of Ophthalmology* 107:237-243, 1989.

61. Klein R, Klein BEK, Moss SE, Davis MD, and DeMets DL: The Wisconsin Epidemiologic Study of Diabetic Retinopathy. X. Four year incidence and progression of diabetic retinopathy when age at diagnosis is 30 years or more. *Archives of Ophthalmology* 107:244-249, 1989.

62. Klein R, Moss SE, Klein BEK, Davis MD, and DeMets DL: The Wisconsin Epidemiologic Study of Diabetic Retinopathy. XI. The incidence of macular edema. *Ophthalmology* 96(10):1501-1510, 1989.

63. Klein R, Moss SE, Klein BEK, and DeMets DL: The relation of ocular and systemic factors to survival in diabetes. *Archives of Internal Medicine* 149:266-272, 1989.

64. Steering Committee of the Physicians' Health Study Research Group: Final report on the aspirin component of the ongoing Physicians' Health Study. *New Engl J Med* 321(3):129-135, 1989.

65. The TIMI Study Group: Comparison of invasive and conservative strategies after treatment with intravenous tissue plasminogen activator in acute myocardial infarction: Results of the Thrombolysis in Myocardial Infarction (TIMI) Phase II Trial. *New Engl J Med* 320:618-627, 1989.

66. Wiley AL Jr., Wirtanen GW, Stephenson JA, Ramirez G, DeMets D, and Lee J-W: Combined hepatic artery 5-fluorouracil and irradiation of liver metastases-A randomized study. *Cancer* 64(9):1783-89, 1989.

67. DeMets DL: Data monitoring and sequential analysis - An academic perspective. *Journal of Acquired Immune Deficiency Syndrome* 3(Suppl 2):S124-S133, 1990.

68. Klein R, Klein BEK, Linton KLP, and DeMets DL: Visual acuity in the Beaver Dam Eye Study: Preliminary findings. *Investigative Ophthalmology & Visual Science* 31(Suppl):432, 1990.

69. Klein R, Moss SE, Klein BEK, Davis MD, and DeMets DL: The Wisconsin Epidemiologic Study of Diabetic Retinopathy. XII. The relationship of C-peptide and diabetic retinopathy. *Diabetes* 39:1445-50, 1990.

70. Love RR, Newcomb PA, Wiebe DA, Surawicz TS, Jordan VC, Carbone PP, and DeMets DL: Effects of tamoxifen therapy on lipid and lipoprotein levels in postmenopausal patients with node-negative breast cancer. *Journal of the National Cancer Institute* 82:1327-1332, 1990.

71. Sitter RR, Hanrahan LP, DeMets D, and Anderson HA: A monitoring system to detect increased rates of cancer incidence. *American Journal of Epidemiology* 132(1 Suppl):S123-130, 1990.

72. Cairns J, Cohen L, Colton T, DeMets DL, Deykin D, Friedman L, Greenwald P, Hutchinson GB, Rosner B: Issues in the early termination of the aspirin component of the Physician's Health Study. Data Monitoring Board of the Physicians' Health Study. *Annals of Epidemiology* 1(5):395-405, 1991.

73. DeMets DL, and Meinert CL: Data Integrity. *Controlled Clinical Trials* 12:727-730, 1991.

74. DeMets DL, Newcomb PA, and Carey P: Design issues for a breast cancer chemoprevention trial. *Preventive Medicine* 20:101-108, 1991.
75. Echt DS, Liebson PR, Mitchell LB, Peters RW, Obias-Manno D, Barker AH, Arensberg D, Baker A, Friedman L, Greene HL, Huther M, Richardson DW, and the CAST Investigators: Mortality and morbidity in patients receiving encainide, flecainide, or placebo. The Cardiac Arrhythmia Suppression Trial. *New Engl J Med* 324(12):781-788, 1991.
76. Klein R, Klein BEK, Linton KLP, DeMets DL: The Beaver Dam Eye Study: Visual acuity. *Ophthalmology* 98(8):1310-1315, 1991.
77. Love RR, Wiebe DA, Newcomb PA, Cameron L, Leventhal H, Jordan VC, Feyzi J, DeMets DL: Effects of tamoxifen on cardiovascular risk factors in postmenopausal women. *Annals of Int Med* 115:860-64, 1991.
78. Packer M, Carver JR, Rodeheffer RJ, Ivanhoe RJ, DiBianco R, Zeldis SM, Hendrix GH, Bommer WJ, Elkayam U, Kukin ML, Mallis GI, Sollano JA, Shannon J, Tandon PK, and DeMets DL for the PROMISE Study Research Group: Effect of oral milrinone on mortality in severe chronic heart failure. *New Engl J Med* 325:1468-1475, 1991.
79. Cashin-Hemphill L, Kramsch DM, Azen SP, DeMets D, DeBoer L, Hwang I, Vailas L, Hirsch LJ, Mack WJ, Hodis HN, Mahrer PR, Selzer RH, Alaupovic P, Blankenhorn DH: The monitored atherosclerosis regression study (MARS) - Design, methods and baseline results. *On Line Journal of Current Clinical Trials* Doc 26, ISSN 1059-2725, October 23, 1992.
80. DeMets DL: Comment on "Evaluating therapeutic interventions: Some issues and experiences" by TR Fleming. *Statistical Science* 7(4):428-456, 1992.
81. Love RR, Mazess RB, Barden HS, Epstein S, Newcomb PA, Jordan VC, Carbone PP, DeMets DL: Effects of tamoxifen on bone mineral density in postmenopausal women with breast cancer. *New Engl J Med* 326(13):852-856, 1992.
82. Diabetes Control and Complications Trial Research Group: The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *New Engl J Med* 329(14):977-986, 1993.

83. Fleming TR and DeMets DL: Monitoring of Clinical Trials: Issues and Recommendations. *Controlled Clinical Trials* 14:183-197, 1993.
84. Friedman LM, Bristow JD, Hallstrom A, Schron E, Proschan M, Verter J, DeMets D, Fisch C, Nies AS, Ruskin J, Strauss H, Walters L: Data Monitoring in the Cardiac Arrhythmia Suppression Trial. *Online Journal of Current Clinical Trials* Doc 79, ISSN 1059-2725, July 31, 1993.
85. Klein R, Klein BEK, Linton KLP, DeMets DL: The Beaver Dam Eye Study: The relation of age-related maculopathy to smoking. *American Journal of Epidemiology* 137(2):190-200, 1993.
86. Simberkoff MS, Hartigan PM, Hamilton JD, Deykin D, Gail M, Bartlett JG, Feorino P, Redfield R, Roberts R, Collins D, DeMets DL, Pritchett W, Spritz N, Wenzel RP, and VA Cooperative Study Group on AIDS Treatment: Ethical dilemmas in continuing a Zidovudine Trial after early termination of similar studies. *Controlled Clinical Trials* 14:6-8, 1993.
87. Alpha-Tocopherol, Beta Carotene Cancer Prevention Study Group (includes DeMets DL): The effect of vitamin E and beta carotene on the incidence of lung cancer and other cancers in male smokers. *New Engl J Med* 330(15):1029-1035, 1994.
88. Task Force of the Working Group on Arrhythmias of the European Society of Cardiology: The Early Termination of Clinical Trials (includes DeMets DL): Causes, Consequences, and Control - With-special reference to trials in the field of arrhythmias and sudden death. *Circulation* 89(6):2892-2907, 1994.
89. DeMets DL, Fleming TR, Whitley RJ, Childress JF, Ellenberg SS, Foulkes M, Mayer KH, O'Fallon J, Pollard RB, Rahal JJ, Sande M, Straus S, Walters L, Whitley-Williams P: The Data and Safety Monitoring Board and acquired immune deficiency syndrome (AIDS) clinical trials. *Contr Clin Trials* 16:408-21, 1995.
90. Fleming TR, Neaton J, Goldman A, DeMets DL, Lauver C, Korvick J, Abrams D and the Community Program for Clinical Research on AIDS (CPCRA): Insights from monitoring the CPCRA ddI/ddC trial. *Journal of Acquired Immune Deficiency* 10 Suppl 2:S9-18, 1995.
91. Freedman L, Anderson G, Kipnis V, Prentice R, Wang CY, Rossouw J, Wittes J, DeMets DL: Approaches to monitoring results of long-term disease prevention trials: examples from the Women's Health Initiative. *Controlled Clinical Trials* 17:509-525, 1996.
92. Fleming TR and DeMets DL: Surrogate endpoints in clinical trials: Are we being mislead? *Annals of Internal Medicine* 125(7): 605-613, 1996.
93. Packer M, O'Connor CM, Ghali JK, Pressler ML, Carson, PE, Belkin RN, Miller, AB, Neuberg GW, Frid D, Wertheimer JH, Cropp AB, DeMets DL for the Prospective Randomized Amlodipine Survival Evaluation Study Group. Effect of amlodipine on morbidity in severe chronic heart failure. *New Engl J Med* 335(15):1107-1114, 1996.
94. DeMets, DL. Discussion of paper: Changes in clinical trials mandated by the advent of meta-analysis. *Statistics in Medicine* 15:1263-68, 1996.
95. Coumadin Aspirin Reinfarction Study (CARS) Investigators (includes DeMets DL): Randomised double-blind trial of fixed low-dose warfarin with aspirin after myocardial infarction. *Lancet* 350: 389-396, 1997.
96. DeMets DL. Distinctions between fraud, bias, errors, misunderstanding, and incompetence. *Controlled Clinical Trials*, 18:637-650, 1997.

97. The International Steering Committee on Behalf of the MERIT-HF Study Group (includes DeMets DL): Rationale, design, and organization of the metoprolol CR/XL randomized intervention trial in heart failure (MERIT-HF). *Amer J Cardiol* 80(9B):54J-58J, 1997.
98. DeMets DL, Woolson R, Brooks C, Qu R: Where the jobs are: A study of AMSTAT news job advertisements, *American Statistician* 52(4):303-307, 1998.
99. DeMets DL: Sequential designs in clinical trials. *Cardiac Electrophysiology Review* 2(1):57-60, 1998.
100. Cohn JN, Goldstein SO, Greenberg BH, Lorell BH, Bourge RC, Jaski BE, Gottlieb SO, McGrew F, DeMets DL, White BG for the Vesnarinone Trial Investigators: A dose-dependent increase in mortality with vesnarinone among patients with severe heart failure. *New Engl J Med* 339(25)1810-1816, 1998.
101. DeMets DL: Statistics and ethics in medical research. *Science & Engineering Ethics* 5(1):97-117, 1999.
102. O'Connor CM, Carson PE, Miller AB, Pressler ML, Belkin RN, Neuberg GW, Wertheimer JH, Frid DJ, Cropp AB, Anderson S, DeMets DL for the PRAISE Investigators. Effect of Amlodipine on mode of death among advanced heart failure patients in the PRAISE trial. *Amer J Cardiol* 82(7): 881-7, 1998.
103. MERIT-HF Study Group (includes DeMets DL): Effect of metoprolol CR/XL in chronic heart failure: Metoprolol CR/XL randomised intervention trials in congestive heart failure (MERIT-HF). *Lancet* 353: 2001-2007, 1999.
104. DeMets DL, Pocock S, Julian DG: The agonising negative trend in monitoring clinical trials. *Lancet* 354: 1983-1988, 1999.
105. DeMets DL: Commentary: Relationships between data monitoring committees. *Controlled Clinical Trials* 21: 54-55, 2000.
106. 106, DeMets DL: Design of Phase II trials in congestive heart failure. *Amer Heart J* 139:S207-S210, 2000.

107. DeMets DL: The role of surrogate outcome measures in evaluating medical devices. *Surgery* 128(3):379-385, 2000.

108. Fisher M, Roecker EB, DeMets D: The role of an independent statistical analysis center in the industry-modified National Institutes of Health model. *Drug Information Journal* 35(1):115-29, 2001.

109. DeMets DL and Yusuf S: The data and safety monitoring committee: some final thoughts. *American Heart Journal* 141(4):548-49, 2001.

110. Gong J, Pinheiro JC, DeMets DL: Letter to the Editor. *Controlled Clinical Trials* 22(2):192-94, 2001.

111. Atkinson AJ, Colburn WA, DeGruttola VG, DeMets DL, Downing GJ, Hoth DF, Oates JA, Peck CC, Schooley RT, Spilker BA, Woodcock J, Zeger SL: Biomarkers and surrogate endpoints: Preferred definitions and conceptual framework. *Clinical Pharmacology and Therapeutics* 69:89-95 2001.

112. Packer M, Coats AJS, Fowler MB, Katus HA, Krum H, Mohacsi P, Rouleau JL, Tendera M, Castaigne A, Staiger C, Curtin EL, Roecker EB, Schultz MK and DeMets DL for the Carvedilol Prospective Randomized Cumulative Survival (COPERNICUS) Study Group. Effect of Carvedilol on survival in severe chronic heart failure. *New Engl J Med* 334(22):1651-58, 2001.

113. DeGruttola VG, Clax P, DeMets DL, Downing GJ, Ellenberg SS, Friedman L, Gail MH, Prentice R, Wittes J, Zeger SL. Considerations in the evaluation of surrogate endpoints in clinical trials: Summary of a National Institutes of Health Workshop. *Controlled Clinical Trials* 22:485-502, 2001.

114. O'Shea C, DeMets D: Statistical issues relating to international differences in clinical trials. *American Heart Journal* 142(1): 21-28, 2001.

115. Wedel H, DeMets D, Deedwania P, Fagerberg B, Goldstein S, Gottlieb S, Hjalmarson Å, Kjekshus J, Waagstein F, Wikstrand J on behalf of the MERIT-HF Study Group: Challenges of subgroup analyses in multinational clinical trials: Experiences from the Merit-HF trial. *Amer Heart Journal* 142(3):502-11, 2001.

116. Love RR, Ba Duc N, Van Dinh N, Shen TZ, Havihurst TC, Allred DC, DeMets DL. Mastectomy and oophorectomy by menstrual cycle phase in women with operable breast cancer. *JNCI* 94(9):662-669, 2002.

117. DeMets DL and Califf RM. Lessons learned from recent cardiovascular clinical trials: Part I. *Circulation* 106:746-51, 2002.

118. DeMets DL and Califf RM. Lessons learned from recent cardiovascular clinical trials: Part II. *Circulation* 106:880-86, 2002.

119. Califf RM and DeMets DL. Principles from clinical trials relevant to clinical practice: Part I. *Circulation* 106: 1015-1021, 2002.

120. Califf RM and DeMets DL. Principles from clinical trials relevant to clinical practice: Part II. *Circulation* 106: 1172-1175, 2002.

121. DeMets DL: Clinical trials in the new millennium. *Statistics in Medicine* 21:2779-2787, 2002.

122. Love RR, Duc NB, Allred DC, Binh NC, Dinh NV, Kha NN, Thuan TV, Mohsin SK, Roanh le D, Khang HX, Tran TL, Quy TT, Thuy NV, The PN, Cau TT, Tung ND, Huong DT, Quang le M, Hien NN, Thuong L, Shen tz, Xin Y, Zhang Q, Havighurst TC, Yang YF, Hillner BE, DeMets DL. Oophorectomy and tamoxifen adjuvant therapy in premenopausal Vietnamese and Chinese women with operable breast cancer. *Journal of Clinical Oncology* 94(10):2559-66, 2002.

123. Fleming TR, Ellenberg S, DeMets DL. Monitoring clinical trials: issues and controversies regarding confidentiality. *Statistics in Medicine*. 21:2843-51, 2002.

124. Packer M, Fowler MB, Roecker EB, Coats AJS, Katus HA, Krum H, Mohacsi P, Rouleau JL, Tendera M, Staiger C, Holcslaw T, Amann-Zalan I, DeMets DL. Effect of carvedilol on the morbidity of patients with severe chronic heart failure -Results of the Carvedilol Prospective Randomized Cumulative Survival (COPERNICUS) study. *Circulation* 106(17):2194-2199, 2002.

125. DeMets DL and Califf RM. Combining composite endpoints: Counterintuitive or a mathematical impossibility? Response [Letter] *Circulation* 107(9): E70, 2003.

126. Love RR, Duc NB, Havighurst TC, Mohsin SK, Zhang Q, DeMets DL, Allred DC. HER-2/neu oerexpression and response to oopherectomy plus tamoxifen adjuvant therapy in estrogen receptor-positive premenopausal women with operable breast cancer. *Journal of Clinical Oncology* 21(3): 453-57, 2003.

127. Califf RM, Morse MA, Wittes J, Goodman SN, Nelson DK, DeMets DL, Iafrate RP, Sugarman J. Toward protecting the safety of participants in clinical trials. *Controlled Clinical Trials* 24:256-71, 2003.

128. Liu G, Oettel K, Bailey H, Van Ummersen L, Tutsch K, Staab MJ, Horvath D, Alberti D, Arzoomanian R, Rezazadeh H, McGovern J, Robinson E, DeMets D, Wilding, G. Phase II trial of perillyl alcohol (NSC 641066) administered daily in patients with metastatic androgen independent prostate cancer. *Inv New Drugs* 21:367-372, 2003.

129. DeMets DL. Statistical issues in interpreting clinical trials. *Journal of Internal Medicine* 255:529-37, 2004.

130. DeMets, DL, Califf R, Dixon D, Ellenberg S, Fleming T, Held P, Julian D, Kaplan R, Levine R, Neaton J, Packer M, Pocock S, Rockhold F, Seto B, Siegel J, Snapinn S, Stump D, Temple R, Whitley. Issues in regulatory guidelines for data monitoring committees. *Clinical Trials* 1:162-69, 2004.

131. DeMets DL and Fleming TR. The independent statistician for data monitoring committees. *Statistics in Medicine* 23:1513-1517, 2004.

132. Bristow MR, Saxon LA, Boehmer J, Boehmer J, Krueger S, Kass D, DeMarco T, Carson P, DiCarlo L, DeMets D, White BG, DeVries DW, Feldman AM for the Comparison of Medical Therapy, Pacing and Defibrillation in Heart Failure (COMPANION) Investigators. Cardiac resynchronization therapy with or without an implantable defibrillator in advanced chronic heart failure. *New Engl J Med* 350:2140-50, 2004.

133. DeMets DL, Fleming TR, Rockold F, Massie B, Merchant T, Meisel A, Mishkin B, Wittes J, Stump D, Califf R. Liability issues for data monitoring committee members. *Clinical Trials* 1:525-31, 2004.

134. Antman EM, DeMets D, Loscalzo J. Cyclooxygenase inhibition and cardiovascular risk. *Circulation* 112(5): 759-70, 2005.

135. Packer M, McMurray J, Massie BM, Caspi A, Charlon V, Cohen-Solal A, Kiowski W, Kostuk W, Krum H, Levine B, Rizzon P, Soler J, Swedberg K, Anderson S, DeMets DL. Clinical effects of endothelin receptor antagonism with bosentan in patients with severe chronic heart failure: results of a pilot study. [see comment]. *Journal of Cardiac Failure* 11(1):12-20, 2005.

136. Gheorghiade M, Orlandi C, Burnett JC Jr, DeMets D, Grinfeld L, Maggioni A, Swedberg K, Udelson JE, Zannad F, Zimmer C, Konstam MA. Rationale and design of the multicenter, randomized, double-blind, placebo-controlled studyto evaluate the efficacy of vasopressin antagonism in heart failure: Outcome study with tolvaptan (EVEREST). *J Cardiac Failure* 11(4):260-269, 2005.

137. DeMets, DL. Discussion on Statistical Issues in the Women's Health Initiative. *Biometrics* 61(4):914-18, 2005.

138. Lowes BD, Shakar SF, Metra M, Feldman AM, Eichhorn E, Freytag JW, Gerber MJ, Liard JF, Hartman C, Gorczynski R, Evans G, Lineseman JV, Stewart J, Robertson AD, Roecker EB, DeMets DL, Bristow MR. Rationale and design of the Enoximone clinical trials program. *J Cardiac Failure* 11(9):659-69, 2005

139. DeMets DL, Fost N, Powers M. An Institutional Board Dilemma: Responsible for safety monitoring but not in control. *Clinical Trials* 3:142-148, 2006.

140. Society for Clinical Trials Board of Directors (Begg CB, Brawley O, Califf RM, DeMets DL, Ellenberg SS, Kaplan RS, Rockhold RW on behalf of the Society for Clinical Trials). The Society for Clinical Trials opposes US legislation to permit marketing of unproven medical therapies for seriously ill patients. *Clinical Trials* 3:154-57, 2006.

141. DeMets DL, Stormo G, Boehnke M, Louis TA, Taylor J, Dixon D. Training of the next generation of biostatisticians: a call to action in the U.S. *Stat Med* 25:3415-29, 2006.

142. DeMets DL. Futility approaches to interim monitoring by data monitoring committees. *Clinical Trials*, 3: 522-529, 2006.

143. Wittes J, Barrett-Connor E, Braunwald E, Chesney M, Cohen HJ, DeMets D, Dunn L, Dwyer J, Heaney RP, Vogel CV, Walters L, Yusuf, S. Monitoring the randomized trials of the Women's Health Initiative: the experience of the Data and Safety Monitoring Board. *Clinical Trials* 4:218-34, 2007

144. Kjekshus J, Apetrei E, Barrios V, Böhm M, Cleland JG, et al for the CORONA Group (DeMets DL, and Feyzi J). Rosuvastatin in Older Patients with Systolic Heart Failure. *NEJM* 357: 2248-2264, 2007.

145. Baron JA, Sandler RS, Bresalier RS, Lanas A, Morton DG, Riddell R, Iverson ER, DeMets DL. Cardio-vascular events associated with rofecoxib: final analysis of the APPROVe trial. *Lancet* 372(9651):1756-64, 2008.

146. Hennekens CH, DeMets DL, Bairey Merz CN, Borzak SL, Borer JS. Doing more good than harm: need for a cease fire. *Am J Med*. 122(4):315-6, 2009. PMID:19332222[no PMCID#]

147. Anand IS, Carson P, Galle E, Song R, Bochmer J, Ghali JK, Jaski B, Lindenfeld J, O'Connor C, Steinberg JS, Leigh J, Yong P, Kosorok MR, Feldman AM, DeMets D, and Bristow MR. Cardiac resynchronization therapy reduces the risk of hospitalizations in patients with advanced heart failure. Results from the Comparison of Medical Therapy, Pacing and Defibrillation in Heart Failure (COMPANION) Trial. *Circulation*119(7):969-77, 2009.

148. Metra M, Eichhorn E, Abraham WT, Linseman J, Böhm M, Corbalan R, DeMets D, DeMarco T, Elkayam U, Gerber M, Komajda M, Liu P, Mareev V, Perrone SV, Poole-Wilson P, Roecker E, Stewart J, Swedberg K, Tendera M, Wiens B, Bristow MR for the ESSENTIAL Investigators (DL DeMets). Effects of low-dose oral enoximone administration on mortality, morbidity and exercise capacity in patients with advanced heart failure: the randomized, double-blind, placebo-controlled, parallel group ESSENTIAL trials. *Eur Heart J* 30(24):3015-26, 2009. PMCID: 2792716.

149. Hennekens CH and DeMets D. The need for large-scale randomized evidence without undue emphasis on small trials, meta-analysis or subgroup analysis. *JAMA* 302(21):2361-62, 2009.

150. Bailey H, Agger W, Baumgardner D, Burmester JK, Cisler RA, Evertsen J, Glurich I, Hartman D, Yale SH, DeMets D. The Wisconsin Network for Health Research (WiNHR): a statewide, collaborative, multi-disciplinary, research group. *Wisconsin Medical J*. 108(9):453-8, 2009.

151. Ellenberg SS, DeMets DL, Fleming TR. Bias and trials stopped early for benefit. Comment on "Stopping randomized trials early for benefit and estimation of treatment effects: systematic review and meta-regression analysis" in *JAMA* 2010 303:1180. *J Amer Med Assoc* 304:158-159, 2010.

152. Hennekens CH, Schneider WR, Pokov A, Hetzel S, DeMets D, Serebruany V, Schröder H. A randomized trial of aspirin at clinically relevant doses and nitric oxide formation in humans. *J Cardiovasc Pharmaol Ther* 15(4):344-8, 2010.

153. Hennekens CH, Hebert PR, Schneider WR, O'Brien P, DeMets D, Borer JS. Academic perspectives on the United States Food and Drug Administration's guidance for industry on diabetes mellitus. *Contemp Clin Trials*. 31(5):411-3, 2010.

154. Komajda M, Carson PE, Hetzel S, McKelvie R, McMurray J, Ptaszynska A, Zile MR, DeMets D, Massie BM. Factors Associated with Outcome in Heart Failure with Preserved Ejection Fraction: Findings from the Irbesartan in Heart Failure with Preserved Ejection Fraction Study (I-PRESERVE). *Circ Heart Fail.* Nov 10, 2010. [Epub ahead of print]

155. DeMets DL, Califf RM. A historical perspective on clinical trials innovation and leadership: where have the academics gone? *JAMA* 305(7):713-714, 2011. PMID: 21325190[no PMCID#]

156. Hennekens CH and DeMets D. Statistical association and causation. Contributions of different types of evidence. JAMA 305(11):1134-35, 2011.

157. Hennekens CH and DeMets DL. Data and safety monitoring boards of randomized trials: evolving principles and practical suggestions. Clinical Investigation 1(1):53-57, 2011.

158. DeMets DL & Friedman L. Some thoughts on non-inferiority designs. *Drug Information Journal* 46(4):420-27, 2012.

159. DeMets DL. Current development in clinical trials: issues old and new. *Stat Med* (31)25: 2944-54, 2012. PMID: 22736410

160. Zheng G, Wu CO, Yang S, Waclawiw MA, DeMets DL, Geller NL. NHLBI clinical trials workshop: an executive summary. *Stat Med* 31(25):2938-43, 2012. PMID: 22733431

161. D'Agostino R Sr, DeMets D, Friedewald W, Goodman S, Witte J, Geller NL. The future of clinical trials: A panel discussion. *Stat Med* 31(25): 3068-72, 2012.

162. Hennekens CH, Hetzel S, Pfeffer M, Schneider R, Borzak S, Schneider W, Serebruany V, DeMets D: Low dose enteric coated aspirin does not inhibit thromboxane B2 or prostaglandin E2: Data derived hypothesis formulation. Clin Invest. 2012, 2: 747-752.

163. Hennekens CH, Schneider WR, Pokov A, Hetzel S, DeMets D, Serebruany V, Schroder H. A randomized trial of aspirin at clinical relevant doses and nitric oxide formation in humans. *J Cardiovascular Pharmacol & Therapeutics*, in press, 2013.

164. Jacobs AK, Kushner FG, Ettinger SM, Guyton RA, Anderson JL, Ohman EM, Albert NM, Antman EM, Arnett DK, Bertolet M, Bhatt DL, Brindis RG, Creager MA, DeMets DL, et al. ACCF/AHA clinical practice guideline methodology summit report: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol* 61(2): 213-65, 2013.

165. Jacobs AK, Kushner FG, Ettinger SM, Guyton RA, Anderson JL, Ohman EM, Albert NM, Antman EM, Arnett DK, Bertolet M, Bhatt DL, Brindis RG, Creager MA, DeMets DL, et al. ACCF/AHA clinical practice guideline methodology summit report: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation* 127(2): 268-310, 2013.

166. Hetzel S, DeMets D, Schneider R, Borzak S, Schneider W, Serebruany V, Schroder H and Hennekens CH. Aspirin increases nitric oxide formation in chronic stable coronary disease. J Cardiovasc Pharmacol Ther 18: 217, 2013 (http://cpt.sagepub.com/content/18/3/217)

167. Jacobs AK, Kushner FG, Ettinger SM, Guyton RA, Anderson JL, Ohman EM, Albert NM, Antman EM, Arnett DK, Bertolet M, Bhatt DL, Brindis RG, Creager MA, **DeMets** DL, Dickersin K, Fonarow GC, Gibbons RJ, Halperin JL, Hochman JS, Koster MA, Normand SL, Ortiz E, Peterson ED, Roach WH Jr, Sacco RL, Smith SC Jr, Stevenson WG, Tomaselli GF, Yancy CW, Zoghbi WA. ACCF/AHA clinical practice guideline methodology summit report: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2013 Jan 15;127(2):268-310. doi: 10.1161/CIR.0b013e31827e8e5f. Epub 2012 Dec 10. PubMed PMID: 23230312.

168. Jacobs AK, Kushner FG, Ettinger SM, Guyton RA, Anderson JL, Ohman EM, Albert NM, Antman EM, Arnett DK, Bertolet M, Bhatt DL, Brindis RG, Creager MA, **DeMets** DL, Dickersin K, Fonarow GC, Gibbons RJ, Halperin JL, Hochman JS, Koster MA, Normand SL, Ortiz E, Peterson ED, Roach WH Jr, Sacco RL, Smith SC Jr, Stevenson WG, Tomaselli GF, Yancy CW, Zoghbi WA, Harold JG, He Y, Mangu PB, Qaseem A, Sayre MR, Somerfield MR. ACCF/AHA clinical practice guideline methodology summit report: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2013 Jan 15;61(2):213-65. doi: 10.1016/j.jacc.2012.09.025. Epub 2012 Dec 10. PubMed PMID: 23238451.

169. O'Gara PT, Kushner FG, Ascheim DD, Casey DE Jr, Chung MK, de Lemos JA, Ettinger SM, Fang JC, Fesmire FM, Franklin BA, Granger CB, Krumholz HM, Linderbaum JA, Morrow DA, Newby LK, Ornato JP, Ou N, Radford MJ, Tamis-Holland JE, Tommaso CL, Tracy CM, Woo YJ, Zhao DX, Anderson JL, Jacobs AK, Halperin JL, Albert NM, Brindis RG, Creager MA, **DeMets** D, Guyton RA, Hochman JS, Kovacs RJ, Kushner FG, Ohman EM, Stevenson WG, Yancy CW; American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2013 Jan 29;127(4):e362-425. doi: 10.1161/CIR.0b013e3182742cf6. Epub 2012 Dec 17. Erratum in: Circulation. 2013 Dec 24;128(25):e481. PubMed PMID: 23247304.

170. American College of Emergency Physicians; Society for Cardiovascular Angiography and Interventions, O'Gara PT, Kushner FG, Ascheim DD, Casey DE Jr, Chung MK, de Lemos JA, Ettinger SM, Fang JC, Fesmire FM, Franklin BA, Granger CB, Krumholz HM, Linderbaum JA, Morrow DA, Newby LK, Ornato JP, Ou N, Radford MJ, Tamis-Holland JE, Tommaso CL, Tracy CM, Woo YJ, Zhao DX, Anderson JL, Jacobs AK, Halperin JL, Albert NM, Brindis RG, Creager MA, **DeMets** D, Guyton RA, Hochman JS, Kovacs RJ, Kushner FG, Ohman EM, Stevenson WG, Yancy CW. 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: executive summary: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2013 Jan 29;61(4):485-510. doi: 10.1016/j.jacc.2012.11.018. Epub 2012 Dec 17. Erratum in: J Am Coll Cardiol. 2013 Sep 10;62(11):1039. PubMed PMID: 23256913.

171. American College of Emergency Physicians; Society for Cardiovascular Angiography and Interventions, O'Gara PT, Kushner FG, Ascheim DD, Casey DE Jr, Chung MK, de Lemos JA, Ettinger SM, Fang JC, Fesmire FM, Franklin BA, Granger CB, Krumholz HM, Linderbaum JA, Morrow DA, Newby LK, Ornato JP, Ou N, Radford MJ, Tamis-Holland JE, Tommaso CL, Tracy CM, Woo YJ, Zhao DX, Anderson JL, Jacobs AK, Halperin JL, Albert NM, Brindis RG, Creager MA, **DeMets** D, Guyton RA, Hochman JS, Kovacs RJ, Kushner FG, Ohman EM, Stevenson WG, Yancy CW. 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2013 Jan 29;61(4):e78-140. doi: 10.1016/j.jacc.2012.11.019. Epub 2012 Dec 17. PubMed PMID: 23256914.

172. Anderson JL, Halperin JL, Albert NM, Bozkurt B, Brindis RG, Curtis LH, **DeMets** D, Guyton RA, Hochman JS, Kovacs RJ, Ohman EM, Pressler SJ, Sellke FW, Shen WK. Management of patients with peripheral artery disease (compilation of 2005 and 2011 ACCF/AHA guideline recommendations): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2013 Apr 2;127(13):1425-43. doi: 10.1161/CIR.0b013e31828b82aa. Epub 2013 Mar 1. PubMed PMID: 23457117.

173. Anderson JL, Halperin JL, Albert NM, Bozkurt B, Brindis RG, Curtis LH, **DeMets** D, Guyton RA, Hochman JS, Kovacs RJ, Ohman EM, Pressler SJ, Sellke FW, Shen WK, Wann LS, Curtis AB, Ellenbogen KA, Estes NA 3rd, Ezekowitz MD, Jackman WM, January CT, Lowe JE, Page RL, Slotwiner DJ, Stevenson WG, Tracy CM, Fuster V, Rydén LE, Cannom DS, Crijns HJ, Curtis AB, Ellenbogen KA, Le Heuzey JY, Kay GN, Olsson SB, Prystowsky EN, Tamargo JL, Wann S. Management of patients with atrial fibrillation (compilation of 2006 ACCF/AHA/ESC and 2011 ACCF/AHA/HRS recommendations): a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2013 May 7;61(18):1935-44. doi: 10.1016/j.jacc.2013.02.001. Epub 2013 Apr 1. Review. PubMed PMID: 23558044.

174. Anderson JL, Adams CD, Antman EM, Bridges CR, Califf RM, Casey DE Jr, Chavey WE 2nd, Fesmire FM, Hochman JS, Levin TN, Lincoff AM, Peterson ED, Theroux P, Wenger NK, Wright RS, Jneid H, Ettinger SM, Ganiats TG, Philippides GJ, Jacobs AK, Halperin JL, Albert NM, Creager MA, **DeMets** D, Guyton RA, Kushner FG, Ohman EM, Stevenson W, Yancy CW. 2012 ACCF/AHA focused update incorporated into the ACCF/AHA 2007 guidelines for the management of patients with unstable angina/non-ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2013 Jun 11;61(23):e179-347. doi: 10.1016/j.jacc.2013.01.014. Epub 2013 Apr 29. Review. Erratum in: J Am Coll Cardiol. 2013 Sep 10;62(11):1040-1. PubMed PMID: 23639841.

175. Milton Packer, MD, Peter Carson, MD, Uri Elkayam, MD, Marvin A. Konstam, MD, Gordon Moe, MD, Christopher O'Connor, MD, Jean-Lucien Rouleau, MD, Douglas Schocken, MD, Susan A. Anderson, MS, David L. DeMets, PHD, for the PRAISE-2 Study Group, Effect of Amlodipine on the Survival of Patients With Severe Chronic Heart Failure Due to a Nonischemic Cardiomyopathy. Results of the PRAISE-2 Study (Prospective Randomized Amlodipine Survival Evaluation 2), Journal of the American College of Cardiology (JACC): Heart Failure Vol. 1, No. 4, 2013
176. Antman E, Benjamin E, Harrington R et al, A conference report from the American Heart Association data summit conference proceeding, J Am Heart Association, Nov 2015
177. DeMets DL & Ellenberg S, Data monitoring committees: expect the unexpected, NEJM, Oct 2016
178. Bristow MR, Saxon LA, Feldman AM, Mei C, Anderson SA, DeMets DL: Lessons learned and insights gained in the design, analysis and outcomes of the COMPANION trial, J Am College Cardiology, 2016
179. Lo B & DeMets DL, Incentives for sharing their clinical trial data, NEJM, October 6, 2016
180. Collins R, Reith C, Emberson J, et al, Interpretation of the evidence for the efficacy and safety of statin therapy, Lancet Online Sept 8, 2016 http://dx/doi.org/10.1016/S0140-6736(16)3157-5
181. Fasula K, Evans C, et al, Randomized trial of plaque identifying toothpaste: dental plaque and inflamation, Am J Medicine (accepted 2016)
182. Lewis R, Calis K & DeMets DL, Enhancing the Scientific Integrity and Safety of Clinical Trials: Recommendations for Data Monitoring Committees from the Clinical Trials Transformation Initiative, JAMA (accepted Oct 2016)
183. Calis K, Archdeacon P, Bain R, Forrest A, Perlmutter J, DeMets D, Understanding the Functions and Operations of Data Monitoring Committees: Survey and Focus Group Findings" to Clinical Trials: Journal of the Society for Clinical Trials (accepted Nov 2016) http://ctj.sagepub.com/content/early/2016/11/23/1740774516679665.abstract
184. Fleming T, DeMets D et al, Data Monitoring Committees: Promoting Best Practices to Address Emerging Challenges, Journal of the Society for Clinical Trials, 2017, p1-9
185. DeMets D, Fleming T, Geller G & Ransohoff D, Institutional Responsibility and Flawed Genomic Predictors at Duke University, J of Ethics in Science and Engineering, Nov 24, 2016

186. Calis K, Archdeacon P, Bain B, DeMets D, Donohue M, Elzarrad MK, Forest A, McEachern J, Pencina M, Perlmutter J, Lewis R, Recommendations for Data Monitoring Committees from the Clinical Trials Transformation Initiative, submitted 2017

187. Packer M, McMurray J, Krum JH, Kiowski W, Massie B, Caspi A, Pratt C, Petrie M, DeMets D, Kobrin I, Roux S, Swedberg K on behalf of the ENABLE Investigators, Long-Term Effect of Endothelin Receptor Antagonism With Bosentan on the Morbidity and Mortality of Patients with Severe Chronic Heart Failure: Primary Results of the ENABLE Trials, submitted 2017 AHJ

188. Packer M, Pitt B, Rouleau JL, Swedberg K, Armstrong P, DeMets D: Long-term Effects of Flosequinan on the Morbidity and Mortality of Patients With Severe Chronic Heart Failure: Primary Results of the PROFILE Trial After 24 Years, submitted 2017 AHJ

Books

1. Friedman L, Furberg C, and DeMets D: *Fundamentals of Clinical Trials*. Springer Science+Business Media, LLC, New York, NY 5th edition, 2015.

2. Ellenberg S, Fleming T and DeMets D: *Data Monitoring Committees in Clinical Trials: A Practical Perspective*. John Wiley & Sons, Ltd., West Sussex, England, 2002.

3. DeMets DL, Friedman L, Furberg CD. *Data Monitoring in Clinical Trials: A Case Studies Approach*. Springer Science+Business Media, New York, NY, 2005.

4. Cook T and DeMets DL. *Introduction to Statistical Methods for Clinical Trials*, Chapman & Hall/CRC; Taylor & Francis Group, LLC, Boca Raton, FL, 2008.

Book Chapters

1. DeMets DL: Data and safety monitoring (Chapter 10). In: *Nutrition and Cancer Prevention*. M. Micozzi and T. Moon (Eds.), Marcel Dekker, New York, NY, 1989.

2. DeMets DL and Lan KKG: The Alpha Spending Function Approach to Interim Data Analyses. In: *Recent Advances in Clinical Trial Design and Analysis*. P. Thall (Ed.), Kluver Academic Publishers, Boston, 1995. pp.1-27.

3. Fleming TR, DeGruttola V, DeMets DL: Surrogate Endpoints. In: *AIDS Clinical Review 1997/1998*. PA Volberding and MA Jacobson (Eds.) Marcel Dekker, Inc. New York, NY, 1998, pp. 129-143.

4. DeMets DL: Data and Safety Monitoring Boards. In: *Encyclopedia of Biostatistics*. L. Freedman (section ed.), P. Armitage, T. Colton (editors in chief), John Wiley and Sons, West Sussex, England, 1998,Volume 2, pp. 1067-71.

5. DeMets DL: Principles of Data and Safety Monitoring Boards. In: *Clinical Trials in Cardiovascular Disease*.

6. C.H. Hennekens (editor), W.B. Saunders Co., Philadelphia, PA, 1999, pp.31-42.

7. DeMets D, Fisher M. Fundamentals of Biostatistics. In: *A Physician's Guide to Healthcare Management*.

8. D. Albert (ed.), Blackwell Science, Inc., Oxford, England, 2002, pp. 122-130.

9. DeMets DL: Principles of Data and Safety Monitoring Boards in Randomized Trials. In: *Clinical Trials in Heart Disease,2nd edition*. JE Manson, JE Buring, PM Ridker, JM Gaziano (Eds), Elsevier Saunders, Philadelphia, PA, 2004, pp. 22-32.

10. DeMets, DL: Evidence-Based Medicine and Clinical Practice. In: *Controversies in Science and Technology: From Maize to Menopause*. DL Kleinman, AJ Kinchy, J Handelsman (Eds), The University of Wisconsin Press, Madison, WI, 2005.

11. Lan, KK and DeMets, DL. Lan-DeMets Alpha Spending Function. In: *Wiley Encyclopedia of Clinical Trials*. John Wiley and Sons, Raritan, New Jersey, accepted, 2008.

12. Gallo P, DeMets D & Lavange LL, Considerations for interim analyses in adaptive trials and perspectives on the use of DMCs-chapter 14, In: Practical Considerations for Adaptive Trial Design and Implementation, Eds He W, Pinheiro J & Kuznetsova OM, Springer 2014

Technical Reports

(*denotes reports later published)

1. DeMets DL and Harris EK: Transformation of observed distributions to Gaussian form. Technical Report #8. Division of Computer Research and Technology, National Institutes of Health, July 1972.

2. *Lan KKG, DeMets DL, and Halperin M: More flexible sequential and non-sequential designs in long-term clinical trials. UW Biostatistics Center, Technical Report No. 25, July 1984.

3. *DeMets DL: Stopping guidelines vs. stopping rules: A practitioner's point of view. UW Biostatistics Center, Technical Report No. 26, August 1984.

4. *DeMets DL and Lan KKG: An overview of sequential methods and their application in clinical trials. UW Biostatistics Center, Technical Report No. 27, August 1984.

5. Kim K and DeMets DL: Group sequential monitoring in clinical trials. UW Biostatistics Center, Technical Report No. 31, April 1985.

6. Kim K and DeMets DL: Estimation following group sequential tests in clinical trials. UW Biostatistics Center, Technical Report No. 32, June 1985.

7. *DeMets DL and Gail MH: Logrank tests and group sequential methods. UW Biostatistics Center, Technical Report No. 33, November 1985.

8. *Lan KKG and DeMets DL: Changing frequency of interim analyses in sequential monitoring. UW Biostatistics Center, Technical Report No. 43, May 1988.

9. *Lan KKG and DeMets DL: Group sequential procedures: Calendar vs information time. UW Biostatistics Center, Technical Report No. 44, May 1988.

10. *Lee JW and DeMets DL: Sequential comparison of change with repeated measurement data. UW Biostatistics Center, Technical Report No. 53, October 1989.

11. *Lee JW and DeMets DL: Sequential rank tests with repeated measurements in clinical trials. UW Biostatistics Center, Technical Report No. 58, September 1990.

12. Lee JW, Reboussin DM, and DeMets DL: Rank tests for multivariate linear models in the presence of missing data. UW Biostatistics Center, Technical Report No. 59, August 1990.

13. *Kim K and DeMets DL: Sample size determination for group sequential clinical trials with immediate response. UW Department of Biostatistics, Technical Report No. 67, January 1992.

14. Reboussin DM, DeMets DL, Kim K, Lan KKG: Programs for computing group sequential bounds using the Lan-DeMets method. UW Department of Biostatistics, Technical Report No. 60, June 1992.

15. *Lee JW and DeMets DL: Group Sequential Comparison of Changes: Ad-hoc vs. More Exact Methods. UW Department of Biostatistics, Technical Report No. 68, June 1992, revised October 1992.

16. Reboussin DM and DeMets DL: Exact inference for multivariate linear rank statistics with missing data. UW Department of Biostatistics, Technical Report No. 69, August 1992.

17. *Reboussin DM and DeMets DL: Permutation based inference on ranks for two sample repeated measures. UW Department of Biostatistics, Technical Report No. 70, August 1992.

18. Reboussin DM and DeMets DL: Some shortcut methods for computation of permutation distributions. UW Department of Biostatistics, Technical Report No. 71, August 1992.

19. Reboussin DM, Lan KKG, DeMets DL: Group sequential testing of longitudinal data. UW Department of Biostatistics, Technical Report No. 72, August 1992.

20. *Lan KKG, Reboussin DM, DeMets DL: Information and Information Fractions for Design and Sequential Monitoring of Clinical Trials. UW Department of Biostatistics, Technical Report No. 73, August 1992.

21. Gange SJ, Linton KLP, Scott AJ, DeMets DL, Klein R: Analysis of correlated ordinal measures with ophthalmic applications. UW Department of Biostatistics, Technical Report No. 77, April 1993.

22. *Gange SJ, Linton KLP, Scott AJ, DeMets DL, Klein R: A Comparison of Methods for Correlated Ordinal Measures with Ophthalmic Applications. UW Department of Biostatistics, Technical Report No. 81, Sept 1993.

23. *Gange SJ and DeMets DL: Sequential Monitoring of Clinical Trials with Correlated Categorical Responses. UW Department of Biostatistics, Technical Report No. 86, July 1994.

24. Reboussin DM, DeMets DL, Kim KM, Lan KKG: Programs for computing group sequential bounds using the Lan-DeMets method, Version 2, UW Department of Biostatistics, Technical Report No. 95, October 1995.

25. *Pinheiro JC and DeMets DL: Estimating and reducing bias in group sequential designs with Gaussian independent increment structure. UW Department of Biostatistics and Medical Informatics, Technical Report No. 96, October 1995.

26. Li Z and DeMets DL: On the bias of estimation of a Brownian motion drift following group sequential tests. UW Department of Biostatistics and Medical Informatics, Technical Report No. 103, June 1996.

27. Li Z and DeMets DL: On the bias of estimation of a treatment effect following group sequential tests for survival data, UW Department of Biostatistics and Medical Informatics, Technical Report No. 104, June 1996.

28. Li Z and DeMets DL: A Repeated Significance Test of the Proportional Hazards Assumption, UW Department of Biostatistics and Medical Informatics, Technical Report No. 107, September 1996.

29. Qu RP, DeMets DL: On the bias correction in group sequential analysis with correlated data. UW Department of Biostatistics and Medical Informatics, Technical Report No. 130, December 1998.

30. Chen JYH, DeMets DL: Switching endpoint in clinical trials with simple and composite outcomes. UW Department of Biostatistics and Medical Informatics, Technical Report No. 140, November 1999.

31. Li Z and DeMets DL: Checking model adequacy for sequentially monitored survival trials. UW Department of Biostatistics and Medical Informatics, Technical Report No. 143, March 2000.

32. Chen JHY, DeMets DL: "Dropping-the-Loser" Designs: Monitoring multiple doses in a combined phase II/II trial. University of Wisconsin Department of Biostatistics and Medical Informatics, Technical Report No. 146, April 2000.

33. Fan X, DeMets DL, Lan GKK: Bias of point estimation following a group sequential test. University of Wisconsin Department of Biostatistics and Medical Informatics, Technical Report No. 157, June 2000.

34. Fan X, DeMets DL: Application of conditional estimation to the survival analysis with interim monitoring. University of Wisconsin Department of Biostatistics and Medical Informatics, Technical Report No. 159, June 2000.

35. Pinheiro JC, DeMets DL: Sequential Testing of Model Fitting with Longitudinal Data. University of Wisconsin Department of Biostatistics and Medical Informatics, Technical Report No. 150, June 2000.

36. Lee JW, Jo SJ, DeMets DL, Kim KM: Confidence Intervals following group sequential tests in clinical trials with multivariate observations. University of Wisconsin Department of Biostatistics and Medical Informatics, Technical Report No. 154, February 2001.

37. Kosorok MR, Shi Y, DeMets DL: Design and analysis of group sequential clinical trials with multiple primary endpoints. University of Wisconsin Department of Biostatistics and Medical Informatics, Technical Report No. 165, September 2001.

Abstracts

1. Klein R, Klein BEK, Moss SE, and DeMets DL: Visual impairment in a population-based study of diabetes. *Diabetes* 32(Suppl.):424, 1983.

2. Klein R, Klein BEK, Moss SE, Davis MD, and DeMets DL: Risk factors for diabetic retinopathy. *Investigative Ophthalmology & Visual Science* 24(Suppl.):80, 1983.

3. Hawkins MJ, Borden EC, Storer B, DeMets DL, Sielaff KM, Konrad M: Phase I repetitive dose trial of recombinant interferon beta with a serine substitution. *Clinical Research* 33:452A, 1985.

4. Klein R, Klein BEK, Moss SE, Davis MD, and DeMets DL: Proteinuria and retinopathy in a population of diabetic persons diagnosed prior to 30 years of age. *Investigative Ophthalmology & Visual Science* 26(Suppl.):86, 1985.

5. Klein R, Klein BEK, Moss SE, and DeMets DL: The validity of survey questions as an estimation of prevalence of diabetic retinopathy. *American Journal of Epidemiology* 122:540, 1985.

6. Klein R, Klein BEK, Moss SE, DeMets DL, and Davis MD: Lens changes, diabetic retinopathy, and survival in a population-based study: Preliminary report. *Investigative Ophthalmology & Visual Science* 27(Suppl.):6, 1986.

7. Klein R, Klein BEK, Moss SE, and DeMets DL: Are ocular factors independent risk factors for survival in diabetic patients. *Diabetes* 35(Suppl.):133A, 1986.

8. Klein R, Klein BEK, Moss SE, and DeMets DL: Are lens changes and diabetic retinopathy independent predictors of survival in diabetes mellitus? *American Journal of Epidemiology* 124:524, 1986.

9. Klein R, Klein BEK, Moss SE, Davis MD, and DeMets DL: Epidemiology of panretinal photocoagulation in a population-based study of diabetes. *Ophthalmology* 93(Suppl.):98, 1986.

10. Klein R, Klein BEK, Moss SE, Davis MD, and DeMets DL: Photocoagulation for diabetic retinopathy. *Diabetes* 36(Suppl.):207A, 1987.

11. Klein R, Klein BEK, Moss SE, Davis MD, and DeMets DL: The incidence and progression of diabetic retinopathy in younger onset persons. *Investigative Ophthalmology & Visual Science* 29(Suppl.):259, 1988.

12. Klein BEK, Klein R, Moss SE, Davis MD, and DeMets DL: Incidence and progression of retinopathy in older onset persons with diabetes. *Investigative Ophthalmology & Visual Science* 29(Suppl.):260, 1988.

13. Klein R, Klein BEK, Moss SE, and DeMets DL: The incidence of diabetic retinopathy and its relation to control. *American Journal of Epidemiology* 128:895, 1988.

14. Klein R, Klein BEK, Moss SE, and DeMets DL: Blood pressure predicts the four-year incidence and progression of diabetic retinopathy in insulin-taking younger onset persons. *Diabetes* 38(Suppl. 2):53A, 1989.

15. Klein R, Klein BEK, Moss SE, and DeMets DL: The incidence of diabetic retinopathy and its relationship to blood pressure. *American Journal of Epidemiology* 129: , 1989.

16. Klein R, Klein BEK, Linton KLP, and DeMets DL: Visual acuity in the Beaver Dam Eye Study: Preliminary findings. *Investigative Ophthalmology & Visual Science* 30(Suppl.):433, 1990.

17. Love RR, Mazess RB, Epstein S, Wiebe DA, DeMets DL: Bone mineral density (BMD) preservation with tamoxifen treatment in postmenopausal women: Results of a placebo-controlled trial. *Breast Cancer Research & Treatment* 16(2):145, 1990.

18. Love RR, Wiebe DA, Newcomb PA, Jordan VC, Carbone PP, Feyzi J, DeMets DL: Cardiovascular risk factor effects of tamoxifen in postmenopausal women. *Preventive Medicine* (1991).

19. Klein R, Klein BEK, Moss SE, and DeMets DL: Diabetes Mellitus and the Prevalence of Age-Related Maculopathy in the Beaver Dam Eye Study. *ARVO Abstracts*, 1992.

20. Kwiatkowski K, Brennan PF, DeMets D, Dahlen K, Buchanan J: University of Wisconsin IAIMS planning: organizational challenges within a faculty governance model. *Proceedings/AMIA Annual Symposium*: 448-52, 2000.

21. Fan X and DeMets DL. Confidence intervals following a group sequential test: conditional or unconditional? *Joint Statistical Meetings*, August 2004.

Presentations or Lectures (1980-present)

1. *Data Monitoring in Multicenter Clinical Trials - A Case Report*. Spring Regional Meeting - Biometric Society, Richmond, VA 1980.

2. *Introducing Bias in the Analysis of Clinical Trials*. Society for Clinical Trials, San Francisco, CA, 1980.

3. *Group Sequential Methods in Clinical Trial Data Monitoring*. University of Wisconsin, Department of Statistics, Madison, WI, 1981.

4. *Early Termination of the Beta-Blocker Heart Attack Trial*. Society for Clinical Trials Meeting, Pittsburgh, PA 1982.

5. Lecturer on design and analysis of clinical trials, Sahlgrenske Hospital, Goteborg, Sweden, 1982.

6. *Design and Analysis of Clinical Trials*. Marshfield Clinic, Marshfield, WI 1983.

7. *Introduction to Survival Analysis*. Wisconsin Tumor Registry Association, Madison, WI, 1983.

8. *Guidelines to Decision Making for Early Termination of a Clinical Trial*. Northwestern University and the Northern Illinois Statistics Meeting, Chicago, IL, 1983.

9. *Stopping Guidelines vs. Stopping Rules: A Practitioner's View*. Northwestern University Conference on Sequential Methods, Chicago, IL, 1983.

10. *An Overview of Sequential Methods and Their Application in Clinical Trials*. Northwestern University Conference on Sequential Methods, Chicago, IL, 1983.

11. *Can Early Stopping Procedures Impact Significantly on the Efficiency of Clinical Trials Without Serious Loss of Information?* NIH Workshop on the Evaluation of Therapy, Bethesda, MD, 1983.

12. *The Anatomy of a Fraud: The Darsee Dog Story*. Stanford Univ. Department of Biostatistics, Stanford, CA 1984.

13. *Decision for Early Termination in Multicenter Clinical Trials*. Symposium on Current Issues in the Design, Conduct and Interpretation of Clinical Trials, Bethesda, MD, 1984.

14. Discussant on General Issues Session, Symposium on Methodology and Quality Assurance in Cancer Clinical Trials, Bethesda, MD, 1984.

15. *Sequential Analysis of Data in Clinical Trials*. Sterling-Winthrop Research Institute, Rensselaer, NY 1984.

16. Organizer and Moderator for Panel Discussion in *Surrogate Outcome Measures*. Society for Clinical Trials Meeting, New Orleans, LA, May, 1985.

17. *Practical Aspects in Applying Group or Pseudo-Sequential Data Monitoring Procedures*. Invited talk at American Statistical Association Meeting, Las Vegas, NV, 1985.

18. *Estimation Following Group Sequential Tests* (with Kyung-Mann Kim). American Statistical Association Meeting, Las Vegas, NV, August, 1985.

19. *Fundamentals of Clinical Trials*. Biostatistics Symposium, Diabetes Research Center, University of Washington, Seattle, WA, September, 1985.

20. Short three day course on Clinical Trials, CIBA-GEIGY Corporation. Summit, NJ, January and June, 1986.

21. Discussant at *Cancer Therapy - Today and Tomorrow*. Burroughs-Wellcome, Research Triangle Park, NC, February, 1986.

22. Introductory Presentation at NCI/NHLBI Workshop on Pooling of Clinical Trials, Bethesda, MD, May, 1986.

23. *Reanalysis of Anturane Reinfarction Trial*. Presented at the Nordic Biometric Society Meeting, Sigtuna, Sweden, May, 1986.

24. Short course on clinical trials, Annual meeting of the American Statistical Association, Chicago, August, 1986.

25. *Reasons for Stopping*. International Society for Clinical Biostatistics, Cardiff, Wales, September, 1986.

26. *Group Sequential Methods in Randomized Clinical Trials*. Workshop on Sequential Experimentation, Cornell University, October, 1986.

27. Workshop on Clinical Trial Data Monitoring, Society for Clinical Trials, Atlanta, May, 1987.

28. *Group Sequential Procedures for Early Termination*. Dept of Statistics, University of Chicago, November, 1987.

29. *Impact of Compliance on the Design and Analysis of Prevention Clinical Trials*. Presented in Helsinki, Finland, June, 1988.

30. *Data Monitoring for Prevention Trials*. Presented in Helsinki, Finland, June, 1988.

31. *Methodologic Contributions of the NHLBI to Clinical Trials: The Early Years*. (with M Halperin M and J. Ware), 1988 American Statistical Association Meeting, New Orleans, LA.

32. Discussant at the "Quality of Life" Session. 1988 American Statistical Association Meeting, New Orleans

33. *Design of Group Sequential Clinical Trials with Immediate Responses* (with K Kim). 1988 American Statistical Association Meeting, New Orleans, LA.

34. *Data Monitoring in Industry Trials*. Presented at CIBA-Geigy, December, 1988.

35. Discussant at *Missing Data Problems in Clinical Trials* session. 1989 ENAR Meeting, Lexington, KY.

36. Chair and discussant at *What if the Data Doesn't Look Right* session. 1989 Society for Clinical Trials Meeting in Minneapolis, MN.

37. *Issues in Data Monitoring and Interim Analyses in the Pharmaceutical Industry - An Academic Perspective*. Presented at the Pharmaceutical Manufacturers Association Biostatistics Subsection Annual Meeting, Tempe, AZ, October 1989.

38. *Statistical Guidelines in Early Stopping of Clinical Trials*. Presented at the American Public Health Association Annual Meeting, Chicago, Illinois, October 1989.

39. *Interim Analyses and Sequential Analysis*. Presented at AIDS Clinical Trials Symposium on Methodological Issues, Hyatt Regency, Bethesda, MD, November 1989.

40. *Data Monitoring for Longitudinal Follow up Studies*. University of Pittsburgh, March 1990.

41. *Sequential Comparison of Changes with Repeated Measurements Data*. Contributed paper (with J. W. Lee) at ENAR Meeting, Baltimore, MD, 1990.

42. *Sequential Rank Tests with Repeated Measurements in Clinical Trials*. Contributed paper (with J. W. Lee) at the ENAR Meeting, Baltimore, MD, 1990.

43. *Termination of the Physicians' Health Study - A Case Report*. Invited paper at the Data Monitoring session, Society for Clinical Trials, Toronto, 1990.

44. FDA Data Monitoring Workshop Organized and Presented. Bureau of Drugs, Rockville, 1991.

45. Discussant, Group Sequential Session. ENAR/ASA meeting, Houston, TX, 1991.

46. FDA Data Monitoring Workshop Co-organized and Presented. Bureau of Biologies, Bethesda, MD, 1991.

47. *Why Clinical Trials*. Johns Hopkins Center for Clinical Trials, 1991.

48. *Stopping Rules and Data Monitoring*. Society of Clinical Trials meeting, Brussels, Belgium 1991.

49. *Data Monitoring in the Industry Setting*." Syntex Corporation, Palo Alto, CA, 1991.

50. *Data Monitoring in the Industry Setting."* Sandoz Corporation, East Hannow, 1991.

51. *Recent Thrombolytic Therapy Trials*. Department of Preventive Medicine, Madison, WI, 1991.

52. *Discussant: "Data Monitoring in the Industry Setting*. FDA/PMA Workshop, Washington, DC, Feb 1992.

53. *A Bayesian Interim Analyses for the CAST early termination*. University of Minnesota, Department of Biostatistics, April 1992.

54. *Flexible Group Sequential Methods for Data Monitoring*. Midwest Biopharmaceutical Meeting, Muncie, IN, May 1992.

55. *Statistical Consulting*. A two day workshop (with Clayton) at Merck, Sharpe, and Dohme, Washington, DC, July 1992.

56. *Perspectives and Pitfalls of Clinical Trials*. Fourth International Conference on Dose, Time, and Fractionation in Radiation Oncology. September 1992.

57. *Issues in Data Monitoring and Quality Assurance*. National Eye Institute Conference, Washington, DC, October 1992.

58. *A Statistician's View of Interim Monitoring*. Fifteenth AIDS Clinical Trials Group Meeting. Washington, DC, November 1992.

59. *Interim Analyses in Longitudinal Studies*. University of Alabama-Birmingham, Department of Biostatistics. Birmingham, AL, November 1992.

60. *Interim Analyses in Longitudinal Studies*. University of Iowa, Department of Biostatistics. Iowa City, IA, November 1992.

61. *Pitfalls in the Design and Analysis of Clinical Trials*. Centocor Corporation, Minneapolis, MN, January 1993.

62. Training the Next Generation of Biostatisticians: A View from Academia." Invited. Eastern North American Region (ENAR) Spring Meeting, Philadelphia, PA. March 1993.

63. *Overview of Stopping Rules: The Alpha Spending Approach*. Invited. Cambridge (UK). Workshop on Data Monitoring. April 1993.

64. *Ethical Issues in the Statistical Design and Analysis*. Invited. University of Wisconsin Conference on Fraud and Integrity. Madison, WI, May 1993.

65. *Data Monitoring Committees*. Invited. Harvard School of Public Health Workshop: Interim Analysis of Clinical Trials: Beyond Stopping Rules. Boston, MA. June 1993.

66. *Interim Analysis: The Alpha Spending Function*. Invited Session. Statistical Society of Canada Annual Meeting. Arcadia University, Newfoundland. June 1993.

67. *The Design, Monitoring, and Analysis of Clinical Trials*. Northeastern Illinois Chapter of American Statistical Association. Chicago, IL. June 1993.

68. *Recent Developments and Applications of Data Monitoring and Interim Analysis in Drug Research*. Hoechst-Roussel Pharmaceuticals. Newark, NJ, July 1993.

69. *Issues and Insights in Grantsmanship for Statistical Research*. Invited Session. American Statistical Association Annual Meeting. San Francisco, CA. August 1993.

70. *Interim Analysis for Clinical Trials in the Industry Setting*. Alcon Laboratories. Fort Worth, TX. September 1993.

71. Control Selection, Patient Comparability, and Treatment - An Academic Perspective. Invited Talk. FDA Device Clinical Trial Workshop, Hernden,VA. September 1993.

72. Biostatistics: At the Frontier of Medical Research. Gustavus Adolphus College, St. Peter, MN, April 1994.

73. *Bias in the Analysis*. UW Veterinary School, Madison, WI. May 1994.

74. *Bias in the Design and Analysis*. Teaching Research Ethics Workshop. Indiana University, Bloomington, IN, May 1994.

75. *Compliance Issues in Clinical Trials*. Workshop at National Cancer Institute. Bethesda, MD. May 1994.

76. *Conflicts of Interest in Clinical Investigations*. Invited Session. Society for Clinical Trials Annual Meeting. Houston, TX. May 1994.

77. *Data Monitoring and Clinical Trials*. Short Course (w/ A. Tsiatis). Temple University, May 1994.

78. Discussant. *Evaluation of Devices: Past, Present, and Future*. Society for Clinical Trials Annual Meeting. Houston, TX. May 1994.

79. *Introducing Bias with Statistical Analysis - Intentional or Otherwise*. Training Research Ethics Workshop. Poynter Center, Indiana University, Bloomington, IN, May 1994.

80. Discussant. *Role of Meta-analysis in Monitoring Clinical Trials*. National Institute of Child Health and Human Development\National Institutes of Health, Bethesda, MD, June 1994.

81. Presenter. FDA Conference on Design of Device Trials. Food and Drug Administration, September 1994.

82. *Designing Clinical Research and Results*. UW GCRC Clinical Trials Training Workshops, Madison, WI, Oct 1994

83. Keynote Address. *Current Issues in Clinical Trials*. Procter & Gamble Statistics Short Course & Symposium, Cincinnati, OH, October 1994.

84. *Rights and Obligations Associated with the Proper Monitoring of Clinical Trials*. American College of Cardiology Meeting, New Orleans, LA, March 1995.

85. *Surprises in Monitoring Clinical Trials*. Biometric Society, Eastern North American Region Meeting, Birmingham, AL, March 1995.

86. *Data Integrity in Clinical Trials: Looking Back at 25 Years*. Biometric Society, Eastern North American Region Meeting, Birmingham, AL, March 1995.

87. *Establishing a Biostatistics Department in a Medical School and Living to Tell About It*. Biometric Society, Eastern North American Region Meeting, Birmingham, AL, March 1995.

88. Short Course, Society of Clinical Trials Seattle, WA, April 1995.

89. *Nutritional Supplements, Observational Studies, and RCTs: The Finnish Beta Carotene Study as an Example*. Maryland Medical Research Institute Clinical Trials Seminar, Baltimore, Maryland, May 1995.

90. *Ethical Issues in Statistical Design and Analysis*. Training Research Ethics Workshop. Poynter Center, Indiana University, Bloomington, IN, May 1995.

91. *Distinctions Between Fraud, Errors, Incompetence, Misunderstandings, and Bias*. Eighth International Symposium on Long-Term Clinical Trials, Toronto, Ontario, Canada, September 1995.

92. *Role of Surrogate Outcomes in Clinical Trials*. Rush Medical College, Chicago, IL. October, 1995.

93. *Are Surrogate Outcome Measures our Surrogate?* Cardiology Conference, University of Wisconsin, Madison, WI, January 1996.

94. *The Role of Surrogate Outcome Measures in Clinical Trials*. UWCCC Grand Rounds, University of Wisconsin, Madison, WI, January 1996.

95. *The Importance of Clinical Trials to Progress in Breast Cancer Control*. The International Breast Cancer Research Foundation, Inc. Board of Directors Meeting, Madison, WI, March 1996.

96. *The Use of Surrogate Outcomes in Cardiovascular Clinical Trials*. The International Biometric Society, Eastern North American Region Spring Meeting, Richmond, VA, March 1996.

97. *Statistics and Ethics in Research*. Undergraduate Data Analysis Contest, Winona State University, Winona, MN, April 1996.

98. *Data Monitoring Board Practicum*. Workshop at Society for Clinical Trials Annual Meeting, Pittsburgh, PA, May, 1996.

99. *Equal Risk for Equal Blood Pressure?* Plenary Session at Society for Clinical Trials Annual Meeting, Pittsburgh, PA, May 1996.

100. *Statistical Analysis and the Responsible Use of Data*. Graduate Research Ethics Education Workshop. Poynter Center, Indiana University, Bloomington, IN, June 1996.

101. *Where are the Jobs: Summary of an AMSTAT News Employment Advertisement Survey*. Joint Statistical Meeting, Chicago, IL, August 1996.

102. *Appropriate Use of Statistics*. Research in Physical Activity course (742-991), Department of Kinesiology, University of Wisconsin, October 1996.

103. *Use of surrogate outcome measures: Are we being misled?* Duke University, Raleigh-Durham, Oct 1996.

104. *Clinical Trials in the 21st Century: Academic Perspective*. Contemporary Issues in Clinical Trials Conference, Harvard School of Public Health, Boston, MA. May 1997.

105. *An Overview of the Use of Surrogate Markers in Clinical Trials*. Drug Information Association 33rd Annual Meeting, Montréal, Quebec, Canada, June 1997.

106. Keynote Address, Society for Clinical Trials Meeting, Boston, MA, July 1997.

107. Discussant, *The Impact of External Events on Ongoing Clinical Trials*. Society for Clinical Trials Meeting, Boston, MA, July 1997.

108. *Surrogate Markers*. Society for Clinical Trials Meeting, Boston, MA, July 1997.

109. *Surrogate Endpoints in Clinical Trials: Are We Being Misled?* (with T. Fleming), Joint Statistical Meetings, Anaheim, CA, August 1997.

110. *Bias Evaluation and Reduction in Group Sequential Analysis with Correlated Data*. (with Roger Qu), Joint Statistical Meetings, Anaheim, CA, August 1997.

111. *"Scientific Fraud: What is the Role of Statistics?* David DeMets, Chair; Joint Statistical Meetings, Anaheim, CA, August 1997.

112. *Statistics and Ethics in Research*. Research in Physical Activity (Kinesiology 742-991), Department of Kinesiology, University of Wisconsin, Madison, WI, October 1997.

113. *Phase II Design: Congestive Heart Failure*. David DeMets (with Milton Packer), How Should We Design Phase II Trials in Cardiovascular Disease? Sponsor: Duke Clinical Research Institute; Hilton Head, SC, October 1997.

114. *Statistics and Ethics in Research* (Statistics 932-998) Department of Statistics, University of Wisconsin, Madison, WI, October 1997.

115. *Statistics and Ethics in Research*. MD/PhD Program, Medical School, University of Wisconsin, Madison, WI, November 1997.

116. *Statistics and Ethics in Research*. Statistics 998, Department of Statistics, University of Wisconsin, Madison, WI, April 1998.

117. *Statistics and Ethics in Research*. Department of Oncology-McArdle Laboratory, University of Wisconsin, Madison, WI, April 1998.

118. *The Fundamentals of an Investigator-Initiated Clinical Trial*. Grand Rounds, Department of Neurology, University of Wisconsin Medical School, Madison, WI, April 1998.

119. *Overview of Interim Analysis for Pivotal Clinical Trials Using Group Sequential Methods*. Tap Pharmaceuticals, Deerfield, IL, May 1998.

120. Discussant: Medical Device Clinical Trials, Society for Clinical Trials, Atlanta, GA, May 1998.

121. *Statistical Analysis and the Responsible Use of Data*. GREE Conference, Indiana University, Bloomington, IN, June 1998

122. Plenary Session: *Current Issues in Clinical Trials - Stopping Trials*. Heart Failure Society, Boca Raton, FL, September 1998.

123. *Role of Data Monitoring Committees in Multicenter Clinical Trials*. ACRP of Southern WI, Ltd., Madison, WI, October 1998.

124. *Statistics and Ethics in Research*. MD/PhD Program, Medical School, University of Wisconsin, Madison, WI, November 1998.

125. *Statistics and Ethics in Research*. Statistics 641, Department of Statistics, University of Wisconsin, Madison, WI, October 1998.

126. *Statistics and Ethics in Research*. Statistics 998, Department of Statistics, University of Wisconsin, Madison, WI, November 1998.

127. *Ethics in Research*. Human Oncology 770, Department of Human Oncology, University of Wisconsin, Madison, WI, March 1999.

128. *Statistics and Ethics in Research*. Statistics 998, Department of Statistics, Univ of Wisconsin-Madison,March 1999.

129. *Surrogate Endpoints in Clinical Trials: Are we Being Misled?* 1999 Charles L. Odoroff Memorial Lecture, University of Rochester Medical Center, Rochester, NY, April 1999

130. *Statistics and Ethics in Research*. Department of Oncology-McArdle Laboratory, University of Wisconsin, Madison, WI, April 1999.

131. *When and How to Report on Studies Indicating No Benefit or Harm*. Society of Clinical Trials Workshop (with Frederick Ferris-Chair, Janet Wittes, Brenda Gallie, Kay Dickersin, & Michael Spino), Anaheim, CA, May 1999.

132. *The Overuse of Surrogate Outcomes in Phase III Clinical Trials*. World Wide Biometrics Advisory Meeting, Harlow, England, October 1999.

133. *One Large, Well-Designed Study as an Alternative to the Usual FDA Paradigm*" Discussant (with Lloyd Fisher & Stuart Pocock), World Wide Biometrics Advisory Meeting, Harlow, England, October 1999.

134. *Statistics and Ethics in Research*. Statistics 998, Department of Statistics, University of Wisconsin-Madison, November 1999.

135. *Sequential Monitoring of Clinical Trials*. Population Health Faculty and Network for Health Policy Research Joint Seminar, January 2000.

136. *Issues in Data Monitoring of Industry-Sponsored Trials*. Roundtable Discussion Leader, ENAR Meeting, Chicago, IL. March 2000.

137. *Interim Data" Who Should be Privy to What and When*. Plenary Session, Society for Clinical Trials, Toronto, Canada. April 2000.

138. *Clinical Trials in the New Millennium*. Keynote Address, 9th International Symposium on Long-Term Clinical Trials, London, England. June 2000.

139. *The Data and Safety Monitoring Board (DSMB)*. Drug Information Association, San Diego, June 2000.

140. *Introductory Commentary on Meta Analysis*. UWCCC Grand Rounds, October 2000.

141. *What do DMC's Actually Do?* Drug Information Association (DIA) Workshop on Data Safety Monitoring Boards, Washington DC, October 2000.

142. *Statistics and Ethics in Research*. Statistics 998, Department of Statistics, University of Wisconsin-Madison, November 2000.

143. *Short Courses in Clinical Trials*. Frontier Science & Technology Research Foundation (FSTRF) St. Petersburg, FL, December 2000.

144. *Scientific Ethics*. Chemistry 901, Department of Bacteriology/Chemistry, UW, March 2001.

145. *Clinical Trial Safety and Efficacy Monitoring: Coronary Heart Disease Trials*. Department of Nutritional Sciences, University of Wisconsin-Madison, April 2001.

146. *The Next Generation: NEI-Sponsored Training Programs-University of Wisconsin*. Symposium: A Randomized Trial in Ophthalmology: Past Present and Future; Johns Hopkins University, Baltimore, April 2001.

147. *Statistics and Ethics in Research."* Oncology 675, Department of Oncology-McArdle Laboratory, University of Wisconsin, April 2001.

148. *Managing and Monitoring Multicenter Clinical Trials: Who is in Charge of What?* The 2001 Robert S. Gordon Lecture in Epidemiology, National Institutes of Health, Bethesda, MD, April 2001.

149. *Clinical Trials*. Short Course in Clinical Research sponsored by Clinical Investigator Preparatory Program (CIPP), University of Wisconsin, July 2001.

150. *Managing and Monitoring Clinical Trials*. (with Norm Fost, M.D.), Combined Annual Meeting of Central Society for Clinical Research/Midwest Region Society of General Internal Medicine/Midwestern Section American Federation for Medical Research/Midwest Society for Pediatric Research, Chicago, IL, September 2001.

151. *Analysis and Interpretation of Subgroups*. Heart Failure Society of America Scientific Meeting, Washington, DC, September 2001.

152. *Roles and Organization of Data Monitoring Committees* (with Marian Fisher). Frontier Science & Technology Research Foundation (FSTRF) Short Courses in Clinical Trials; King of Prussia, PA, October 2001

153. *Statistics and Ethics in Research*. Statistics 998, Department of Statistics, University of Wisconsin-Madison, November 2001.

154. *Data and Safety Monitoring Boards*. Clinical Research and Compliance-A Guide for Investigators, CME, University of Washington, Seattle, April 2002.

155. *Data Monitoring Committees and Methods with Example Scenarios* (with Marian Fisher). Mock DSMB, GlaxoSmith Kline, King of Prussia, PA, May 2002.

156. *Data and Safety Monitoring*. Clinical Gene Transfer Comprehensive Review Course, American Society of Gene Therapy Meeting, Boston, MA, June 2002.

157. *The Role of Data Monitoring Committees (DMCs) and Clinical Trials*. European Society of Cardiology, Berlin, Germany, September 2002.

158. *Data Monitoring Committees: Role, Organization & Function*. Statistics 641, Department of Statistics, University of Wisconsin-Madison, September 2002.

159. *Keynote Lecture: Issues in Interpreting Clinical Trials*. Fifth ICF International Experts' Meeting, Cannes, France, October 2002.

160. *What You Observe Is Not Always What You Get*. Shapiro Guest Lecture, First Annual Medical Student Summer Research Forum, UW Medical School, October 2002.

161. *One Confirmatory Trial to Support Evidence of Effectiveness*. Glaxo Smith Kline Biomedical Data Sciences Statistical Advisory Board Conference, Cary, NC, October 2002.

162. *Are We Monitoring Our Trials To Death?* Mayo Clinic Grand Rounds, Rochester, MN, October 2002

163. *Are We Monitoring Our Trials To Death?* Cardiology Grand Rounds, St. Luke's-Roosevelt Hospital, New York, November 2002.

164. *Statistics and Ethics in Research*. Statistics 998, Department of Statistics, University of Wisconsin-Madison, November 2002.

165. *Clinical Trials and Drug Development: A Long Complicated Journey from Bench to the Bedside*, Conversations in Science, Wisconsin Initiative for Science Literacy/Madison Metropolitan School District/Edgewood High School, December 2002.

166. *Industry/Academia Model*, Issues in Data Monitoring Committees, Washington, DC, January 2003

167. *Statistics and Ethics in Research*. Statistics 641, Department of Statistics, Univ of Wisconsin-Madison, March2003.

168. *Data and Safety Monitoring*, Clinical Gene Transfer Comprehensive Review Course, American Society of Gene Therapy, Washington, DC, June 2003.

169. *Emerging Issues in Clinical Trial Data Monitoring*, Joint meeting of International Society for Clinical Biostatistics and the Society for Clinical Trials, London, England, July 2003.

170. *Origins and Rationale of Clinical Trials Data Monitoring, Keynote Address*, Drug Information Association Workshop, "Clinical Trial Data Monitoring Committees: Policies, Practices and Controversies," Bethesda, September 2003.

171. *Genomics, Bioinformatics and Clinical Research,* Visiting Professor, Korea Univ, Seoul, Korea, October 2003.

172. *Statistics and Ethics in Research*. Statistics 641, Department of Statistics, University of Wisconsin-Madison, October 2003.

173. *Statistics and Ethics in Research*. Statistics 998, Department of Statistics, University of Wisconsin-Madison, November 2003.

174. *Fundamentals of Data Monitoring Short Course*. BASS X (Biopharmaceutical Applied Statistics Symposium), Savannah, GA, December 2003.

175. *Heart Failure over the Past 20 years – Have We Improved Trial Design to Include Novel Endpoints?* Heart Failure Trial Endpoints Conference sponsored by Duke Clinical Research Institute, Washington, DC, January 2004.

176. *Clinical Trials*. Medical College of Wisconsin. Milwaukee, WI. February 2004.

177. *Statistics and Ethics in Research*. Statistics 998, Department of Statistics, Univ of Wisconsin-Madison, April 2004.

178. *Practical Approaches to Data Monitoring of Clinical Trials*, FDA Clinical & Statistical Reviewers Course (with Susan Ellenberg & Fleming), April 2004.

179. *Fundamental Issues in Clinical Trials,* Toward Evidence Based Practice in Geriatric Dysphagia: A Multidisciplinary Approach, GRECC, University of Wisconsin, May 2004.

180. *Workshop: Independence in Data Monitoring of Clinical Trials: Can it Be Carried To Far?* Society for Clinical Trials Annual Meeting, New Orleans, LA, May 2004.

181. *Clinical Trials*, CIPP Short Course in Clinical Research, University of Wisconsin, Madison, July 2004.

182. *An IRB Data Monitoring Dilemma: Responsible, but Not in Control,* New York Society of Health-System Pharmacists Meeting, New York, NY, Sept 2004.

183. *Statistics and Ethics in Research*. Statistics 641, Department of Statistics, University of Wisconsin-Madison, November 2004.

184. *Lessons Learned: Surrogates and Immediate Endpoints*. NIH Symposium, Bethesda, MD; January 2005.

185. *Short Course* sponsored by Scios, Inc., Fremont CA; March 2005.

186. *An IRB Safety Monitoring Dilemma: Responsible But Not in Control*. Visiting Professor, Boston University School of Public Health; April 2005.

187. *Data Monitoring Committees: Role, Organization and Function*. Frontier Science, Technology and Research Foundation Retreat, Edinburgh, Scotland; April 2005.

188. *Case Studies in Data and Safety Monitoring Committees*. Society for Clinical Trials Annual Meeting, Portland, Oregon; May 2005.

189. *Causation & Evidence Based Medicine*. Summer Institute for Biostatistics (SIBS) funded by the National Institutes of Health (NIH) & National Heart Lung & Blood Institute (NHLBI), Madison, June 2005.

190. *Design, Bias & Surrogate Outcomes*. SIBS program funded by the NIH & NHLBI, Madison, June 2005

191. *Analysis and Interpretation of Subgroups*. SIBS program funded by the NIH & NHLBI, Madison, June 2005

192. *Issues in Analysis of Randomized Clinical Trials*. SIBS program funded by the NIH & NHLBI, Madison, June 2005

193. *Data Analysis and Ethics*. SIBS program funded by the NIH & NHLBI, Madison, June 2005

194. *Fundamentals of Clinical Trials,* CIPP Short Course in Clinical Research, Univof Wisconsin, Madison, July 2005.

195. *Statistical Issues Arising in the Women's Health Initiative (WHI),* Joint Statistical Meetings, Minneapolis, MN August 2005.

196. *Data Monitoring Committees: Futility Approaches to Monitoring,* International Symposium on Long-Term Clinical Trials: Advanced Issues in the Design and Conduct of Randomized Clinical Trials, Oxford, England; Sept 2005.

197. *Statistics and Ethics in Research*. Statistics 641, Department of Statistics, University of Wisconsin-Madison, November 2005.

198. *Panel Discussion: Introducing Innovative Techniques/Thinking in to the Design of Trials*. Glaxo Smith Kline Biomedical Data Sciences Statistical Advisory Board Conference, King of Prussia, PA, October 2005.

199. *Experimental Design and Statistical Analysis*. AHABS 873, Research Ethics and Survival Skills, University of Wisconsin-Madison, November 2005.

200. *Statistics and Ethics in Research*. Statistics 641, Department of Statistics, University of Wisconsin-Madison, December 2005.

201. *Stopping Trials for Futility* (Speaker), *Changing Endpoints During the Trial* (Discussant), *Co-Variate Analysis:, Why & How To Do It*. (Discussant). Eighth CardioVascular Clinical Trialists CVCT – Workshop, Versailles, France, December 2005.

202. *Challenges and Opportunities in Clinical Research*. University of Minnesota Visiting Lecturer, Minneapolis, January 2006

203. Diversity Workshop, Junior Investigators Workshop; ENAR Invited Session: *Inference in Randomized Multi-Center Clinical Trials* - Organizer: Marvin Zelen; ENAR, March 2006

204. *Challenges and Opportunities in Future Clinical Research*. Visiting Professor, Duke Clinical Research Institute, Durham, North Carolina, April 2006

205. *The Future of Clinical Trials*. Session 5 – Clinical Trials and Statistics: A Glance at the Past and Present and a Look to the Future, 2006 FDA Science Forum, A Century of FDA Science: Pioneering the Future of Public Health, Washington, DC, April 2006.

206. *Challenges and Opportunities in Future Clinical Research*. Northwestern University Visiting Professor, Chicago, IL, April 2006.

207. *Invited Session 11: The Link Between Meta-Analysis and Clinical Practice: how to Interpret Meta-Analyses and the Evidence They Provide*. Co-Chair with Jorn Wettersley. Society for Clinical Trials Annual Meeting, Orlando, FL, May 2006.

208. *Fundamentals of Clinical Trials*, Seventh Biannual William Magrane Basic Science Course in Veterinary & Comparative Ophthalmology & Histologic Basis of Occular Disease Short Course, University of Wisconsin, Madison, June 2006.

209. *Fundamentals of DSMB*, *Development of software to produce NDA and DSMB reports*, Johnson and Johnson Pharmaceuticals, Raritan, NJ, June 2006.

210. *Court is in Session: Randomized Clinical Trials on Trial* (Defense Team Witness), Heart Failure Society 10th Annual Scientific Meeting, Seattle, WA, September 2006.

211. *Session I: Standardization of DES definitions, issues of data poolability and information technology transfer* (with Drs. Krucoff, Pocock, Mehran, Cutlip, Friedman, Larkin, Boam, Fink, Uchida, Van Es), Health & Human Services Town Hall Meting at TCT 2006 (Transcatheter Cardiovascular Therapeutics), Washington, DC, October 2006.

212. *Session II: Accelerating DES clinical trials: Surrogate endpoints, composite endpoints and adaptive designs* (with Drs. Krucoff, Pocock, Geller, Shurin, Mauri, Campbell, Donohoe, Yue, Fiorentino, Agler), Health & Human Services Town Hall Meting at TCT 2006 (Transcatheter Cardiovascular Therapeutics), Washington, DC, October 2006.

213. *Session III: Specific DES issues – Preclinical evaluation, device iteration, non-inferiority trials, label expansion, next generation devices, speed to market vs. safety, etc.* (with Drs. Stone, Leon, Kaplan, Lenarz, Somberg, Maisel, Domanski, Koglin, Pocock, Farb & Pinto), Health & Human Services Town Hall Meting at TCT 2006 (Transcatheter Cardiovascular Therapeutics), Washington, DC, October 2006.

214. *Evolving Roles of safety reporting and the DSMC in the clinical trial process* – Discussion with Drs. Mehran, Krucoff, Gersh, Russell, Gordon, Shurin,Pocock, Zuckerman & Sapirstein), Health & Human Services Town Hall Meting at TCT 2006 (Transcatheter Cardiovascular Therapeutics), Washington, DC, October 2006..

215. *Statistics and Ethics in Research*. Statistics 998, Department of Statistics, University of Wisconsin-Madison, November 2006.

216. *Developing a Statistical Plan: The Key to Success*, Harvard Medical School, Clinical Trials Course: Principles and Practice, Boston, MA November 2006.

217. *Data Monitoring Committees, Methods and Examples*, Clinical Trials Course: Principles and Practice, Harvard Medical School, Boston, MA November 2006.

218. *Panel X: Data & Safety Monitoring in Research* (with Robert Levine, Susan Ellenberg and Lawrence Friedman), 2006 Annual HRPP Conference: A Commitment to Ethical Research: Advancing the Mission of Human Research Protection Programs, Washington, DC, November 2006.

219. *Lessons Learned from multi-center collaborations in heart disease and cancer: What can we apply to Parkinson Disease?* National Parkinson Foundation, Collaboration for Care 2006 Leadership Conference, Chicago, IL, December 2006.

220. *Data Monitoring Committees and Related Issues,* 62nd Annual Deming Conference on Applied Statistics, Atlantic City, NJ, December 2006.

221. *Enhancing the Public's Trust in the Industry through the Use of Independent DMCs,* Data Monitoring Committees, sponsored by EXL Pharma, Philadelphia, PA, February 2007.

222. *Statistical Methodology for Non-Inferiority Clinical Trials,* Panelist (HM James Hung & Steven Snapinn, Co-Chairs), FDA/DIA Statistics Forum, Bethesda, MD, March 2007.

223. *Challenges in Clinical Research Includng Adaptive Designs and Non-Inferiority Designs*, Biostatistics Seminar Series at Memorial Sloan Kettering Cancer Center, New York, NY, March 2007.

224. *Statistics and Ethics in Research*. Statistics 998, Department of Statistics, Univ of Wisconsin-Madison, April 2007.

225. *Workshop: Implementing Quality: Design & Measurement,* HSP/Bioresearch Workshop, Defining and Implementing Quality in Clinical Investigations: from Design to Completion, sponsored by the Drug Information Association, May 2007

226. *Clinical Trials: The Zelen Era*, Marvin Zelen's 80th Birthday Celebration, Harvard School of Public Health and Schering-Plough Research Institute, Boston,, MA, June 2007.

227. *Data Monitoring and Group Sequential Methods* and *Adaptive Designs and Non Inferiority Designs*, Roche, Nutley, NJ, June 2007.

228. *Traditional vs. Group-Sequential Designs,* Exploratory Workshop: Methodological Issues in Randomized Clinical Trials in the Elderly, sponsored by National Institute on Aging, Washington, DC, September 2007.

229. *Data Monitoring Overview for Phase III Clinical Trials*, NINDS DMC Workshop: Someone to Watch Over Me—Data and Safety Monitoring of NIH Supported Clinical Trials, Washington, DC, November 2007.

230. *Statistics and Ethics in Research*. Statistics 998, Department of Statistics, University of Wisconsin-Madison, November 2007.

231. *Are patients better off inside than outside randomized clinical trials?* (Discussant); *DSMB Issues: DSMB Conflicts* (Discussant), CVCT 2007 -- CardioVascular Clinical Trialists Workshop, Paris, France, December 2007

232. *Statistical Views of "Reasonable Assurance of Safety and Effectiveness* (Discussant), CRT 2008, Washington, DC, February 2008.

233. *Challenges in Outcomes, Implementation and Health Services Research,* NHLBI Biomedical Lecture, Washington, DC, February 2008.

234. *DMC Charter: How to Write a DMC Charter: Step-by-Step Guide through a Sample Charter,* Data Monitoring Committees Conference, sponsored by Exl Pharma, Philadelphia, PA, Feb 2008.

235. *Education of Clinical Trial Statisticians* (Panel with Scott Evans, Naitee Ting, Karl Pearce, Walter Offen & Marvin Zelen), ENAR, Crystal City, VA, March 2008.

236. *Implementing Quality in Clinical Trials: Design and Measurement,* FDA CDER Workshop Session #2 with Robert Temple, Glenn Gormley, Dale Hammerschmidt, Brude Wagman, Judy Racoosin, Jason Woo, Washington, DC, March 2008

237. *Data Integrity: Data Standard, Data Management, Data Clean-up,* FDA CDER Workshop Session #3 with Ed Cox, Becky Dusch, Christine Pierre, Leslie Ball, Tom Marciniak, & Rod Usher, Washington, DC, March 2008

238. *Statistics and Ethics in Research*. Statistics 998, Department of Statistics, University of Wisconsin-Madison, April 2008.

239. *Interim Look(s): Practical Recommendations*, Invited Session 5 with Paul Wakim, John Lachine & Peter Ouyang, Society for Clinical Trials, St Louis, May 2008.

240. CTSA Plenary Session, Society for Clinical Trials, St Louis, May 2008.

241. *Analysis of Clinical Safety: Current Practices and Challenges*, *Challenges for Clinical Research: Something New and Something Old,* The 17th Annual ICSA Applied Statistics Symposium, Piscataway, NJ, June 2008.

242. *Session 4: Safety Boundaries for Data Monitoring Committees* (with Steve Snappin), DIA/FDA/PhRMA Drug Safety Conference: Planning the Lifecycle of Safety Evaluation, Arlington, VA, October 2008.

243. *Statistics and Ethics in Research*. Vet Med/Surgical Sci 812: Research Ethics & Career Development, Department of Veterinary Medicine, University of Wisconsin-Madison, October 2008.

244. Discussant, Invited Session: *Role of Meta-Analysis in Drug Development* (with Sue Jane Wang, KKG Lan, HMJ Hung, MA Proschan), ENAR Meeting, San Antonio, TX, March 2009.

245. Panelist, FDA/DIA Stat Forum, *Adaptive Design* Panel, Arlington, VA, April 2009

246. *Statistics and Ethics in Research. N*ursing 802: Ethics and Responsible Conduct of Research, Nursing School, University of Wisconsin, April 2009.

247. Discussant, Invited Session #5: *Current Controversies in Clinical Trials: Perspectives from SCT Fellows* (with Barbara Hawkins, Marc Buyse, Frank Rockhold, & Janet Wittes), SCT Meeting, Atlanta, GA, May 2009.

248. *Challenges in Clinical Trials: Some Old and Some New*. Marvin Zelen Leadership Award Lecture, Harvard School of Public Health, Boston, MA, May 2009.

249. *Statistics and Ethics in Research*. Vet Med/Surgical Sci 812: Research Ethics & Career Development, Department of Veterinary Medicine, University of Wisconsin-Madison, October 2009.

250. *Statistics and Ethics in Research*. Statistics 998, Department of Statistics, Univ of Wisconsin-Madison, Oct 2009.

251. *Choosing the Best Study Design*. Clinician Scientist Training Workshop. Univ of Wisconsin-Madison, Oct 2009.

252. *Challenges in Clinical Trials: Some Old and Some New*. North Carolina State University, Raleigh, NC, Nov 2009.

253. *Challenges in Clinical Trials: Some Old and Some New*. Wake Forest University, Winston-Salem, NC, Nov 2009.

254. *Challenges in Clinical Trials: Some Old and Some New*. Duke University, Durham, NC, November 2009.

255. *Challenges in Clinical Trials: Some Old and Some New*. Univ of North Carolina-Chapel Hill, November 2009.

256. *Health Informatics at the University of Wisconsin-Madison*. Duke University Health Informatics Center, Durham, NC, November 2009.

257. *Evolution of Statistical Methods and Principles in Clinical Trials*. Duke Clinical Research Institute, Durham, NC, November 2009.

258. *Issues in Data Analysis*. Food and Drug Administration Clinical Trials Training Course, Silver Spring, Nov 2009.

259. *Challenges in Clinical Trials: Some Old and Some New*. Keynote Address, Innovations in Design, Analysis, and Dissemination: Frontiers in Biostatistical Methods Symposium, The University of Kansas, Kansas City, April 2010.

260. *Meta Analysis: Setting the Stage* (with Jim Hung, Christy Chuang-Stein & Armin Koch, Fourth Annual FDA/DIA Statistics Forum – Integrating Knowledge in Clinical Development: Meta-Analysis, Non-Inferiority, and Related Topics, Bethesda, MD, April 2010.

261. *Health Informatics at the University of Wisconsin-Madison*. Department of Population Health Sciences, University of Wisconsin-Madison, April 2010.

262. *Challenges in Clinical Trials: Some Old and Some New*. Cardiovascular Medicine Grand Rounds, Department of Medicine, University of Wisconsin, Madison, June 2010.

263. *Challenges in Clinical Trials: Some Old and Some New*. Naval Medical Research Center (NMRC) Clinical Investigation Lecture Series, Silver Spring, MD, September 2010.

264. *Statistics and Ethics in Research*. Vet Med/Surgical Sci 812: Research Ethics & Career Development, Department of Veterinary Medicine, University of Wisconsin-Madison, September 2010.

265. *Industry MRCT KIT Workstream: Consistency Assessments of Treatment Effects in MRCTs* (with Bruce Binkowitz, Joshua Chen, H.M. James Hung). Ensuring Quality and Balancing Risks for Multiregional Clinical Trials: Statistical, Clinical, Regulatory, and Ethical Factors, Drug Information Association Meeting, October 2010.

266. *Defining the Path Forward: Time for Action* (with Bruce Binkowitz and Ekopimo Okon Ibia Session Co-Chairs; Panelists: David DeMets, Cynthia Girman, Ian Marschner, Fergus Sweeney, Agnes Klein, Mark Paxton, Francois Bompart, et al.), Ensuring Quality and Balancing Risks for Multiregional Clinical Trials: Statistical, Clinical, Regulatory, and Ethical Factors, Drug Information Association Meeting, October 2010.

267. *Challenges in Adaptive and Non-Inferiority Designs for Clinical Trials*. Tow-day symposium honoring Steve Lagakos: Impact of Biostatistics Science – Advances in Research: AIDS, Cancer, Environment, Athens, Greece, October 2010.

268. *The Analysis of Investigator Data, Sources of Bias and Error*. FDA/CTTI Short Course, Washington, DC, November 2010.

269. *Data Monitoring Committees: A Practical Approach*. Short Course with Susan Ellenberg and Tom Fleming. Fourth Seattle Symposium in Biostatistics: Clinical Trials. Seattle, WA, November 2010.

270. *Role and Potential of Surrogate Outcomes*. Fourth Seattle Symposium in Biostatistics: Clinical Trials. Seattle, WA, November 2010.

271. *Statistics and Ethics in Research*. Statistics 998, Department of Statistics, University of Wisconsin-Madison, March 2011.

272. *Clinical Trials and the Growth of Regulations*. Eastern Mediterranean Region/IBS Conference, Crete, Greece, May 2011.

273. *Challenges in Subgroup Analyses in Multi-Regional Clinical Development* (with Joshua Chen, Yoko Adachi,), FDA/Industry Statistics Workshop, Washington, DC, September 2011.

274. *The Role of a Data Safety Monitoroing Board in Research,* IRB Seminar, Meriter Hospital, Madison, WI October 2011.

275. *How important is robust UW enrollment in global trials? Real or perceived heterogeneity, differences in practice context, etc.* (with Doug Weber, Doug Throckmorton, Jonathan Fox), Rescuing Clinical Trials in the U.S.: A Call to Action. McLean, VA, October 2011.

276. *Statistics and Ethics in Research*. Statistics 998, Department of Statistics, University of Wisconsin-Madison, November 2011.

277. *Clinical Trials and the Impact of Regulations*, Tufts Grand Rounds, Boston, MA, January 2012

278. *Panel Discussion 1* (with Phyllis Gimotty/U Penn and Jay Siegel/Johnson), Fifth Annual Conference on Statistical Issues in Clinical Trials, University of Pennsylvania, Philadelphia, PA, April 2012

279. *Data Monitoring, Committee Concepts, Practices and Controversies* (with Susan Ellenberg), FDA/DIA Statistics Forum, Bethesda, MD, April 2012

280. *Safety Assessment during the Pre-Marketing Phase Session,* (Session Chairs: Aloka Chakravarty & Christy Chuang-Stein; Speakers: Hong Amy Xia, Mat Soukup & David DeMets), FDA/DIA Statistics Forum, Bethesda, MD, April 2012

281. *What Matters in Terms of Clinical Trial Quality*, 2012 Sensible Guidelines Symposium, Toronto, Ontario, Canada, May 2012, FL, May 2012

282. *Data Monitoring Committees in Randomized Trials: Emerging Principles and Practical Suggestions*, Eli Lilly, Indianapolis, IN, October 2012

283. *Clinical Trials and Growth of Regulations,* EAST User Group Meeting, Cytel, Boston, MA, October 2012

284. *Data Monitoring Committees: Best Practices and Future Directions,* DIA Adaptive Design in Clinical Trials: Overcoming Persistent Barriers meeting, Washington, DC, November 2012

285. *This Could Happen Anywhere: Evolution of Translational "Omics" and Lessons Learned from the Duke Saga,* UW ICTR Research Learning Series, Madison, WI, November 2012.

286. *Challenges in Clinical Trials: Some Old & Some New*, Medical College of Wisconsin, Milwaukee, WI, April 2013.

287. *Randomized Clinical Trial Short Course*, Hadassah Hospital, Jerusalem, Israel, April 2013.

288. *Statistical Issues in Trial Reporting: Revised US FDA Regulations*, Eastern Mediterranean Region of Biometric Society Conference, Tel Aviv, April 2013

289. *Plenary Session(DeMets Chair): Personalized Medicine/Pharmacogentics*, *Plenary Session: Statistical Issues in Clinical Trials, Talk: Statistical Issues in Clinical Trial* Reporting; Eastern Mediterranean Region, International Biometric Society, Tel Aviv, Israel, April 2013.

290. *Origins & Development of Clinical Trials Data Monitoring Committees (DMCs) 1965-2013*, Amgen Speakers Symposium, Thousand Oaks, CA, May 2013.

291. *Causation & Evidence Based Medicine, Design, Bias & Surrogate Outcomes, Analysis and Interpretation of Subgroups, Issues in Analysis of Randomized Clinical Trials, Data Analysis and Ethics*. Summer Institute for Biostatistics (SIBS) funded by the National Institutes of Health (NIH) & National Heart Lung & Blood Institute (NHLBI), Madison, June 2013.

292. *Collaboration & Team Science*. Family Medicine 701. Department of Family Medicine, University of Wisconsin-Madison, September 2013.

293. *This Could Happen Anywhere: Evolution of Translational 'OMICS' & Lessons Learned from the Duke Saga*. Computation and Informatics in Biology Seminar, University of Wisconsin-Madison, September 2013.

294. *Recent Issues and Development in Clinical Trials,* Merck Conference, Philadelphia, PA, September 2013

295. *Adverse Event Reporting & Monitoring*. Biostatistics and Medical Informatics 544. University of Wisconsin-Madison, November 2013.

296. *Data Monitoring Committees: History (1965-2013) & Future*. Clinical Trials Methodology Conference, Edinburgh, Scotland, November 2013.

297. *This Could Happen Anywhere: Evolution of Translational "Omics"*. Biostatistics and Medical Informatics 544. University of Wisconsin-Madison, December 2013.

298. *Statistics and Ethics in Research*. Statistics 998, Department of Statistics, University of Wisconsin-Madison, December 2013.

299. *Challenges in Adaptive Clinical Trials Based on Emerging Trends,* Society for Clinical Trials, Philadelphia, May 18, 2014

300. *LSTs & CER in Learning Health Care Systems,* Discussant, Society for Clinical Trials, Philadelphia, May 18, 2014

301. *Master Clinical Trial Protocols*: presented at NIH FDA meeting on Antibiotics, Washington DC, July 30, 2014

302. *Biostatistics at NIH: The early years/NHLBI - Reduction in mortality from cardiovascular disease,* Joint Statistical Meetings, Montreal, August 2014

303. *Multi-Regional Clinical Trials, Session on Global Clincal Trials:* Joint Statistical Meetings, Montreal, August 2014

304. *Challenges in Clinical Trials: Some Old & Some New:* Presented at AbbVie Pharmaceuticals, August 27, 2014

305. *This Could Happen Anywhere: Evolution of Translational "Omics" & Lessons Learned from the Duke Saga* Presented at AbbVie Pharmaceuticals, August 27, 2014

306. *Value and Feasibility of Large Simple Trials for Answering Practical Questions of Public Health Importance*,

307. Institute of Medicine Annual Meeting, Washington DC, October 2014

308. *Challenges in Clinical Trial Design and Analysis*, Mayo Clinic- Scottsdale, Grand Rounds, Jan 2015

309. AAAS Organized and Chaired Session on Training Quantitative Sciences Feb 2015 San Jose CA

310. *Challenges in Clinical Trials: Some Old, Some New*, Stanford Grand Rounds, Palo Alto, CA Feb 2015

311. *Challenges in Clinical Trial: Some Old, Some New*, Portola, San Francisco, Feb 2015

312. *IOM Report on Responsible Clinical Trial Data Sharing*, AHA Big Data SUMMIT, Baltimore April 2015

313. *Superiority, Noninferiority, and Equivalence Designs,* AHA Meeting - Clinical Trials Session 201 , Orlando Nov 2015

314. *Adaptive Designs*, AHA Meeting - Clinical Trials Session 301, Orlando Nov 2015

315. *Statistics and Ethics Lecture*, Stat 998 Lecture, Nov 17, 2015

316. *Adverse Events Lecture*, BMI 544, Nov 19, 2015

317. *IOM Report: Sharing Clinical Trial Data*, AbbVie Pharmaceuticals, N Chicago, Nov 20 2015

318. *DMC Issues,* AbbVie Pharmaceuticals, N Chicago, Nov 20 2015

319. *IOM Report on Genomic Predictors: Lessons from Duke Experience*, 5th Seattle Conference, Nov 22 2015

320. *Omics Lecture*, BMI 544, Dec 1, 2015

321. *IOM Report: Sharing Clinical Trial Data*, CardioVascular Clinical Trials (CVCT) Forum, Washington DC, Dec 3, 2015

322. *Meta Analysis: Getting More Complex, Are Standards Possible?* CardioVascular Clinical Trials (CVCT) Forum, Washington DC, Dec 5, 2015

323. *Early Lessons from Randomized Clinical Trials: NHLBI Early Contributions:* NHBLI Workshop, Bethesda September 26, 2016

324. *Biostatistics: Past, Present & Future:* Colin White Lecture, Department of Biostatistics, Yale University, October 11, 2016

325. *Biostatistics: Past, Present & Future:* 50th Anniversary, Department of Biostatistics, Washington University, November 7, 2016

326. *Data Monitoring Committee Short Course,* American Heart Association Annual Meeting, New Orleans, Nov 15, 2016

327. *Adaptive Designs: Are they more efficient*: American Heart Association Annual Meeting, New Orleans, Nov 15, 2016

328. Top Ten Break Throws in Cardiology in Past 40 Years: Grand Rounds, Mayo Clinic Scottsdale, March 2016