

CURRICULUM VITAE

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Education:

1965 B.S.	Washington University, St. Louis, Missouri Major: Applied Mathematics
1969 D.Sc.	Washington University, St. Louis, Missouri Major: Applied Mathematics and Computer Science

Additional Training 1996-1997:

Biotechnology Techniques, (18 lecture hours, 20 lab hours) NIH Foundation for Advanced Education in the Sciences
 Advanced Genome Analysis (18 lecture hours, 20 lab hours) NIH-FAES
 Molecular and Cellular Basis of Cancer (18 lecture hours, 20 lab hours) NIH-FAES
 DNA Binding Proteins, Transcriptional Regulators and Homeoboxes 1997 (18 lecture hours) NIH-FAES
 Recombinant DNA (18 lecture hours, 20 lab hours) NIH-FAES
 Cold Spring Harbor 7 day course in Computational Genomics 1997

Brief Chronology of Employment

1967 - 69	Consultant in statistics, General Electric Center for Advanced Studies, Santa Barbara, California
1968 - 69	Consultant in statistics, The Rand Corporation, Santa Monica, California
1969 - 71	Computer Scientist, Division of Computer Research and Technology, National Institutes of Health, Bethesda, Maryland
1971 - 75	Head, Biostatistical Information Systems Unit, Medical Oncology, Division of Cancer Treatment, National Cancer Institute, Bethesda, Maryland

1976 - 78	Head, Biostatistics and Data Management Section, Clinical Oncology Program, Division of Cancer Treatment, National Cancer Institute, Bethesda Maryland
1978 -	Chief, Biometric Research Branch, Division of Cancer Treatment and Diagnosis, National Cancer Institute, Bethesda Maryland
2000 -	Head, Molecular Statistics and Bioinformatics Section, Biometric Research Branch, National Cancer Institute, Bethesda Maryland

Brief Description of Current Position:

Chief Statistician for the Division of Treatment and Diagnosis of the National Cancer Institute (NCI). Provide statistical and mathematical leadership for national programs of drug discovery, molecular diagnosis, biomedical imaging, radiation research and clinical trials. Responsible for statistical review of all NCI sponsored clinical trials, oversight of coordinating centers and representation of NCI in data monitoring committees. Responsible for collaboration and consulting with scientists in NCI Division of Cancer Treatment and Center for Cancer Research. Provide leadership for an active research program in computational genomics applied to understanding the mechanisms of oncogenesis and for the discovery and development of molecular targets and companion diagnostics. Provide leadership for software team developing bioinformatics systems such as BRB-ArrayTools and BRB-CghTools, platform for gene expression and copy number analysis with over 15,000 registered users in 65 countries, cited in over 1500 publications. Bioinformatics software developed includes many tools for the design of molecularly targeted clinical trials available on-line at <http://brb.nci.nih.gov> and used extensively by investigators in many institutions. Conduct a post-doctoral training program in computational genomics and bioinformatics with focus on methodology for analysis of second and third generation DNA sequencing data and use of such data to identify key molecular targets for treatment and for predictive biomarker development.

Societies:

American Association of Immunologists
 American Statistical Association (Elected Fellow)
 Biometric Society
 International Society for Computational Biology

Honors and Awards:

Senior Biomedical Research Service, National Institutes of Health, 1996-present.
 National Institutes of Health Director's Award, 2005.
 NIH Technology Transfer Award, 1994, 1996
 Elected fellow of The American Statistical Association
 Snedecor Prize for Best Publication in Field of Biometry
 Awarded by American Statistical Association, 1986
 Member, National Research Council Committee on Theoretical & Applied Statistics, 1999-20003
 National Science Foundation Fellow 1965-1969
 American Radium Society Award, 1976

Selected Professional Activities:

Editorial Board Statistics in Medicine, 1982-1997.
 Editorial Board Controlled Clinical Trials 1992-1998.
 Editorial Board Cancer Treatment Reports, 1983-1987.
 Editorial Board Journal of the National Cancer Institute, 2001-
 Editorial Board Clinical Cancer Research, 2004-
 Editorial Board BMC Bioinformatics, 2005-2010

Editorial Board Nature Reviews, Clinical Oncology, 2005-
 Editorial Board The Cancer Journal, 2007-
 Editorial Board Cancer Informatics, 2006-2010
 Visiting Professor of Medicine, University of Virginia, 1989.
 Visiting Professor Pro Tempore, Cleveland Clinic Foundation, 1988, 2007.
 Board of Directors, Society for Clinical Trials, 1986 - 1990
 Member, Oncologic Drugs Advisory Committee, Food and Drug Administration (1997-2001)
 Member, Committee on Controlled Therapeutic Trials, International Union for the Control of Cancer (UICC), 1987 -90
 Member of Time Allocation Group for NCI Supercomputer Center.
 Member of International Early Breast Cancer Trialists' Collaborative Group
 Statistical Advisor, National Bone Marrow Donor Registry (1992).
 Member, NIH Epidemiology and Biostatistics Promotion and Tenure Review Panel (1994-Present)
 Member, Data Monitoring Board - VA Cooperative Studies Program Study of
 Systemic Corticosteroids in Chronic Obstructive Pulmonary Disease Exacerbation (1995).
 Advisor to Secretary of Department of HHS, HRSA on modeling the national liver allocation system (1995-1996).
 Member, Blood Products Advisory Committee, Food and Drug Administration, 1994-1996
 Member, National Research Council Advisory Committee on Applied and Theoretical Statistics, 1999-2003
 Architect of BRB-ArrayTools, an integrated software package for microarray data analysis;
 <http://linus.nci.nih.gov/BRB-ArrayTools.html>
 Member, FDA Advisory Panel on Premarketing Risk Assessment, Washington D.C. April 9-11, 2003.
 Member, Translational Research in Clinical Trials Committee, Cancer Research UK, 2004-2007.
 Advisor to Provost, Harvard University for computational biology appointments
 Member of NCI Translational Research Working Group, 2005-2007
 AACR Think-tank on Translational Research, July 2007
 ASCO-FDA-NCI Committee on Innovative Clinical Trial Designs, August 2007.
AACR-FDA-NCI Cancer Biomarkers Collaborative Assay Validation Subcommittee, August 2007.
AACR Grants Advisory Committee, 2007
NCI-FDA Inter-agency Thinktank on Cancer Biomarkers
CALGB Strategic Planning Retreat on Biomarkers and Scientific Opportunities, November 2007
Co-chair, Bioinformatics Committee for Center of Excellence for Integrative Cancer Biology and Genomics, Center for
Cancer Research, National Cancer Institute, 2009-
Member of ASCO Biomarkers Working Group, 2009
Research Advisory Committee for National Grant Competition on the Earlier Detection of Breast Cancer of the Canadian
Breast Cancer Foundation, 2011
Molecular Diagnostics Technical Working Group, Center for Medical Technology Policy, 2011
External Advisory Board, Personalized Cancer Medicine Partnership, Dana-Farber Cancer Institute and Brigham and
Women's Hospital, 2011-

Symposia Organized:

Organizer, AMS/IMS/SIAM Workshop on Statistics in Functional Genomics, Mt. Holyoke Mass, June 2001.
 Organizer, Short Course in Microarray Data Analysis, Biometric Society (ENAR), March 2002.
 Organizer, Short Course in Microarray Data Analysis, Rockefeller University, April 2002, January 2003. .
 Organizer, Short Course in Microarray Data Analysis, University of Florida, December 2003.
 Organizer, International Symposium on Methodologic Issues in Overviews of Randomized Clinical Trials (1986).
 Organizer, International Symposium on Interim Monitoring of Randomized Clinical Trials (1992).
 Organizer, Short Course on Statistical Methods in Genomics and Computational Biology, Heidelberg Germany (1999)
 Organizer, Oberwolfach Conference on Molecular Biostatistics (1999)
 Organizer, Institute of Pure & Applied Mathematics Conference on Expression Arrays, Genetic Networks and
 Diseases, UCLA, Nov. 2000
 Organizing Committee, International Conference on Bayesian Biostatistics, 2008
 Organizing Committee, Drug Information Association Workshop on Pharmacogenomics, December 2007
 Program Committee, International Society of Clinical Biostatistics, Leiden Netherlands, September 2004.
 Program Committee, International Conference on Analysis of Genomic Data, Harvard Medical School, May 2004.

Program Committee, Statistical Methods in Biopharmacy, Paris, September 2005.

Program Committee, Workshop on Pharmacogenomics in Drug Development & Regulatory Decision-Making of DIA, PhRMA & FDA, 2005.

Program Committee, RECOMB Satellite Workshop on Computational Cancer Biology, September 2007

Program Committee, American Association of Cancer Research 2006; Subcommittee chair for computational biology and bioinformatics.

Books

Simon R, Korn E, McShane L, Radmacher M, Wright G, Zhao Y. *Design and Analysis of DNA Microarray Investigations*, Springer-Verlag New York, 2003.

Simon R. *Genomic Clinical Trials and Predictive Medicine*, Cambridge University Press, (In Preparation).

Peer Reviewed Publications

1. Simon, RM.: Optimal cannibalization policies for multicomponent systems. S.I.A.M.J. Appl. Math. 19: 700-711, 1970.
2. Simon, RM, and Lee, RCT.: Optimal solutions to and/or series-parallel graphs. J. Assoc. Comp. Mach. 18: 354-372, 1971.
3. Simon, RM.: Stationary properties of a two-echelon inventory model for low demand items. Operations Res. 19: 761-773, 1971.
4. Simon, RM, and D'Esopo, DA.: Comments on a paper by SG. Allen and DA. D'Esopo: An ordering policy for repairable stock items. Operations Res. 19: 986-988, 1971.
5. Simon, RM.: The reliability of multicomponent systems subject to cannibalization. Naval Res. Logistics Quart. 19: No. 1, 1972.
6. Simon, RM, Stroot, M, and Weiss, G.: Numerical Inversion of Laplace transforms with application to percentage labelled mitoses experiments. Computers & Biomedical Res. 5: 596-607, 1972.
7. Levine, AS, Siegel, SE, Schreiber, AD, Hauser, J, Preisler, H, Goldstein, IM, Seidler, F, Simon, R, Perry, S, Bennett, JE, and Henderson, ES.: Protected environments and prophylactic antibiotics: A prospective controlled study of their utility in the therapy of acute leukemia. N. Engl. J. Med. 288: 477-483, 1973.
8. Simon, R, Weiss, GH, and Hoel, DG.: Sequential analysis of binomial clinical trials. Biometrika 62: 195-200, 1975.
9. Pocock, SJ, and Simon, R.: Sequential treatment assignment with balancing for prognostic factors in the controlled clinical trial. Biometrics 31: 103-115, 1975.
10. Graff, K, Simon, R, Yankee, RA, DeVita, VT, and Rogentine, GN.: HL-A antigens in Hodgkin's disease: Histopathologic and clinical correlations. J. Natl. Cancer Inst. 52: 1087-1090, 1974.
11. Kovacs, CJ, Hopkins, HA, Simon, R, and Looney, WB.: Effects of 5-Fluorouracil on the cell kinetic and growth parameters of hepatoma 3924A. Brit. J. Cancer 32: 42-50, 1975.

12. Simon, R, Weiss, GH, and Hoel, DG.: A class of sampling schemes for selecting the better of two binomial populations. *J. Statistical Computation and Simulation* 4: 37-47, 1975.
13. Primack, A, Vogel, CL, Kyalwazi, SK, Ziegler, JL, and Simon, R.: A staging system of hepatocellular carcinoma: Prognostic factors in Ugandan patients. *Cancer* 35: 1357-1364, 1975.
14. Simon, R.: Application of optimization methods to the hematological support of patients with disseminated malignancies. *Mathematical Bio-sciences* 25: 125-138, 1975.
15. Brereton, HD, Simon, R, and Pomeroy, TC.: Pretreatment serum lactate dehydrogenase predicting metastatic spread in Ewing's sarcoma. *Ann. Int. Med.* 83: 352-354, 1975.
16. Leventhal, B, Levine, A, Graw, R, Simon, R, Freireich, EJ, and Henderson, E.: Long-term second remissions in acute lymphatic leukemia. *Cancer* 35: 1136-1140, 1975.
17. Ziegler, JL, Magrath, IT, Nkrumah, FK, Perkins, IV, and Simon, R.: Evaluation of 1- (2-chloroethyl)-3-cyclohexyl 1-nitrosourea (CCNU) for the prevention of CNS involvement in Burkitt's lymphoma. *Cancer Chemotherapy Rept.* 59: 1155-1156, 1975.
18. Sacks, KL, Olweny, C, Mann, DL, Simon, R, Johnson, GE, Poplack, DG, Leventhal, BL.: A clinical trial of chemotherapy and RAJI immunotherapy in advanced acute lymphatic leukemia. *Cancer Res.* 35: 3715-3720, 1975.
19. Looney, WB, Mayo, AA, Kovacs, CJ, Hopkins, HA, Simon, R, and Morris, HP.: Solid tumor models for the assessment of different treatment modalities: II, Rapid, intermediate, and slow growing transplantable rat hepatomas. *Life Sciences* 18: 377-390, 1976.
20. Byar, DP, Simon, R, Friedwald, WT, Schlesselman, JJ, DeMets, DL, Ellenberg, JH, Gail, MH, and Ware, JH.: Randomized clinical trials: Perspectives on some recent ideas. *New Engl. J. Med.* 295: 74-79, 1976.
21. Hoel, DG, Weiss, GH, and Simon, R.: Sequential tests for composite hypotheses with two binomial populations. *J. Royal Stat. Society, Series B* 38: 302-308, 1976.
22. Oster, MW, Margileth, DA, Simon, R, and Leventhal, BG.: Lack of prognostic value of lymphoblast size in acute lymphoblastic leukemia. *Brit. J. Hematol.* 33: 131-136, 1976.
23. Kenady, DE, Simon, R, and Chretien, PB.: Effect of thymosin *in vitro* on T cell levels during radiation therapy. Correlations with radiation portal and dose, tumor histology, and initial T cell levels. *Cancer* 39: 642-652, 1977.
24. Hansen, HH, Selawry, OS, Simon, R, Carr, DT, Van Wyk, CH, Tucker, RD, and Sealy, RE.: Combination chemotherapy of advanced lung cancer: A randomized trial. *Cancer* 38: 2201-2207, 1976.
25. Fisher, RI, DeVita, VT, Johnson, BL, Simon, R, and Young, RC.: Prognostic factors for advanced diffuse histiocytic lymphoma following treatment with combination chemotherapy. *Am. J. Med.* 63: 177-182, 1977.
26. Magrath, II, and Simon, RM.: Immunosuppression in Burkitt's lymphoma II. Peripheral blood lymphocyte populations related to clinical status. *Intern. J. Cancer* 18: 399-408, 1976.
27. Tormey, DC, Simon, R, Falkson, G, Bull, J, Band, P, Perlin, E, and Blom, J.: Evaluation of adriamycin and dibromodulcitol in metastatic breast carcinoma. *Cancer Res.* 37: 529-534, 1977.
28. Norton, L, Simon, R, Brereton, HD, and Bodgen, AE.: Predicting the course of Gompertzian growth. *Nature* 264: 542-544, 1976.

29. Ingle, JN, Tormey, DC, Bull, JM, and Simon, RM.: Bone marrow involvement in breast cancer: Effect on response and tolerance to combination chemotherapy. *Cancer* 39: 104-111, 1977.
30. Tormey, DC, Waalkes, TP, and Simon, RM.: Biological markers in breast carcinoma. III. Clinical correlations with carcinoembryonic antigen. *Cancer* 39: 2397-2404, 1977.
31. Kenady, DE, Potvin, C, Simon, RM, and Chretien, PB.: Thymosin reconstitution of T cell deficits *in vitro* in cancer patients. *Cancer* 39: 575-580, 1977.
32. Norton, L, and Simon, R.: The growth curve of an experimental solid tumor following radiotherapy. *J. Natl. Cancer Inst.* 58: 1735-1741, 1977.
33. Cohen, MH, Ketcham, AS, Felix, EL, Li, SH, Tomaszewski, MM, Costa, J, Rabson, AS, Simon RM, and Rosenberg, SA.: Prognostic factors in patients undergoing lymphadenectomy for malignant melanoma. *Annals of Surgery* 186: 635-642, 1977.
34. Tormey, DC, Simon, RM, Lippman, ME, Bull, JM, and Myers, CCE.: Evaluation of Tamoxifen dose in advanced breast cancer: a progress report. *Cancer Treatment Rep.* 60: 1451-1459, 1976.
35. Bull, JM, Tormey DC, Li, SH, Carbone, PP, Falkson, G, Blom, J, Perlin, E, and Simon, R.: A randomized comparative trial of adriamycin versus methotrexate in combination drug therapy. *Cancer* 41: 1649-1657, 1978.
36. Norton, L, and Simon, R.: Tumor size, sensitivity to therapy, and the design of treatment schedules. *Cancer Treatment Rep.* 61: 1307-1317, 1977.
37. Simon, R, Hoel, DG and Weiss, GH.: The use of covariate information in the sequential analysis of dichotomous response experiments. *Communications in Statistics -Theory and Methods* A6: 777-788, 1977.
38. Strauss, BL, Matthews, MJ, Cohen, MH, Simon, R, and Tejada, F.: Cardiac metastases in lung cancer. *Chest* 71: 607-611, 1977.
39. Simon, R.: Adaptive treatment assignment methods and clinical trials. *Biometrics* 33: 743-749, 1977.
40. Simon, R.: Clinical prognostic factors in osteosarcoma. *Cancer Treatment Rep.* 62: 193-198, 1978.
41. Simon, R, Norton, L, and Katz, R.: Statistical considerations in the determination of ventricular volume from echocardiographic and angiographic data. *Am. J. of Cardiology* 41: 351, 1978.
42. Goldberg, NH, Lipson, SD, Kenady, DE, Simon, RM, Cohen, MH, and Chretien, PB.: T cell levels and response to thymosin *in vitro* during intensive chemotherapy in cancer patients receiving thymosin. *Surgical Forum* 28: 151-152. American College of Surgeons. Chicago, Illinois, 1977.
43. Spence, RJ, Simon, RM, and Baker, AR.: Failure of immunotherapy with neuraminidase-treated tumor cell vaccine in mice bearing established methylcholanthrene sarcoma. *J. Natl. Cancer Inst.* 60: 451-459, 1978.
44. Tormey, DC, Falkson, G, Simon, RM, Blom, J, Bull, JM, Lippman, ME, Li, S, Cassidy, JG, and Falkson, H.: A randomized comparison of two sequentially administered combination regimens to a single combination regimen in metastatic breast cancer. *Cancer Clinical Trials* 2: 247-256, 1979.
45. Pizzo, PA, Ladisch, S, Simon, RM, Gill, F, and Levine, AS.: Increasing incidence of gram-positive sepsis in the cancer patient. *Med. and Pediat. Oncology* 5: 241-244, 1978.

46. Simon, R.: Patient heterogeneity in clinical trials. *Cancer Treatment Rep.* 64: 405-410, 1980.
47. Belling, D, Kelley, RR, and Simon, R.: Use of the swivel adaptor aperture during suctioning to prevent hypoxemia in the mechanically ventilated patient. *Heart and Lung* 7: 320-322, 1978.
48. Rosenberg, SA, Kent, CH, Costa, J, Webber, BL, Young, RC, Chabner, BA, Baker, AR, Brennan, MF, Chretien, PB, Cohen, MH, DeMoss, EV, Sears, HF, Seipp, C, and Simon, R.: Prospective randomized evaluation of the role of limb sparing surgery, radiation therapy and adjuvant chemo-immunotherapy in the treatment of adult soft-tissue sarcomas. *Surgery* 84: 62-69, 1978.
49. Lippman, ME, Allegra, JC, Thompson, EB, Simon, R, Barlock, A, Green, L, Huff, KK, Do, HMT, Aitken, SC, Warren, R.: Lack of estrogen receptor is associated with an increased response rate to cytotoxic chemotherapy in metastatic breast cancer. *N. Engl. J. Med.* 298: 1223-1228, 1978.
50. Makuch, R, and Simon, R.: Sample size requirements for evaluating a conservative therapy. *Cancer Treatment Rep.* 62: 1037-1040, 1978.
51. Bender, RA, Nichols, AP, Norton, L, and Simon, RM.: Lack of therapeutic synergism between vincristine and methotrexate in L1210 murine leukemia *in vivo*. *Cancer Treatment Rep.* 62: 997-1003, 1978.
52. Nemoto, T, Rosner, D, Diaz, R, Dao, T, Sponzo, R, Cunningham, T, Horton, J, and Simon, R.: Combination chemotherapy for metastatic breast cancer: comparison of multiple drug therapy with 5-fluorouracil, cytoxan and prednisone with adriamycin or adrenalectomy. *Cancer* 41: 2073-2077, 1978.
53. Simon, R.: Comment on "New methodology in clinical trials". *Biometrics* 34: 710-712, 1978.
54. Makuch, R, and Simon, R.: Recommendations for the analysis of the effect of treatment on the development of second malignancies. *Cancer* 44: 250-253, 1979.
55. Simon, R.: Prognostic factors in osteosarcoma. *J.C.E. Orthopedics*, December 1978: 32-33.
56. Norton, L, and Simon, R.: Comments on an alternate view of tumor growth kinetics, therapeutic differentials, and design of treatment schedules. *Cancer Treatment Rep.* 62: 846-847, 1978.
57. Baker, AR, Ward, JM, Simon, RM, Stinson, SF, and Devereux, DF.: Gut transit time is an important factor in the pathogenesis of DMH induced rat colon cancer. Surg. Forum, 1978.
58. Tejada, F, Eisenberger, MA, Broder, LE, Cohen, MH, and Simon, R.: 5-Fluorouracil versus CCNU in the treatment of metastatic prostatic carcinoma. *Cancer Treatment Rep.* 61: 1589-1590, 1977.
59. Young, RC, Chabner, BA, Hubbard, SP, Fisher, RI, Bender, RA, Anderson, T, Simon, RM, Canellos, GP, and DeVita, VT.: Advanced ovarian adenocarcinoma: A prospective clinical trial of melphalan (L-PAM) vs. combination chemotherapy (HEXA-CAF). *New Engl. J. of Med.* 299: 1261-1266, 1978.
60. Lippman, ME, Simon, R, Thompson, EB, and Allegra, J.: Response to correspondence concerning "The relation between estrogen receptors and response rate to cytotoxic chemotherapy in metastatic breast cancer". *New Engl. J. of Med.* 298: 1223-1228, 1978.
61. Li, SH, Simon, RM, and Gart, JJ.: Small-sample properties of the Mantel-Haenszel test. *Biometrika* 66: 181-183, 1979.
62. Daly, PA, Simon, R, Schiffer, CA, Aisner, J, Terasaki, PI, and Wiernik, PH.: A study of HL-A antigens and haplotypes in a population of caucasians with acute nonlymphocytic leukemia. *Leukemia Res.* 3: 75-82, 1979.

63. Allegra, JC, Lippman, ME, Thompson, EB, Simon, R, Barlock, A, Green, L, Huff, KK, Hoan, MTD, Aitken, SC, and Warren, R.: Association between steroid hormone receptors and response rate to cytotoxic chemotherapy in metastatic breast cancer. *Cancer Treatment Rep.* 62: 1281-1286, 1978.
64. Allegra, JC, Lippman, ME, Thompson, EB, and Simon, R.: An association between steroid hormone receptors and response to cytotoxic chemotherapy in patients with metastatic breast cancer. *Cancer Res.* 38: 4299-4304, 1978.
65. Allegra, JC, Lippman, ME, Green, L, Barlock, A, Simon, R, Thompson, EB, Huff, KK, and Griffin, W.: Estrogen receptor values in patients with benign breast disease. *Cancer* 44: 228-231, 1979.
66. Allegra, JC, Lippman, ME, Thompson, EB, Simon, R, Barlock, A, Green, L, Huff, KK, Do, HMT, and Aitken, SC.: The distribution, frequency, and quantitative analysis of estrogen, progesterone, androgen and glucocorticoid receptors in human breast cancer. *Cancer Res.* 39: 1447-1454, 1979.
67. Allegra, JC, Lippman, ME, Thompson, EB, Simon, R, Barlock, A, Green, L, Huff, KK, Do, HMT, Aitken, SC, and Warren, R.: The relationship between the progesterone, androgen and glucocorticoid receptor and response rate to endocrine therapy in metastatic breast cancer. *Cancer Res.* 39: 1973-1979, 1979.
68. Makuch, RW, and Simon, R, M: A note on the design of multi-institution three-treatment studies. *Cancer Clinical Trials* 1: 301-303, 1978.
69. Fisher, RI, DeVita, VT, Hubbard, SP, Simon, R, and Young, RC.: Prolonged disease-free survival in Hodgkin's disease following reinduction with MOPP after first relapse. *Ann. of Int. Med.* 90: 761-763, 1979.
70. Ozols, RF, Garvey, AJ, Costa, J, Simon, RM, and Young, RC.: Advanced ovarian cancer: Correlation of histologic grade with response to therapy and survival. *Cancer* 45: 572-581, 1980.
71. Rosenberg, SA, Chabner, B, Young, R, Seipp, C, Levine, AS, Costa, J, Hanson, TA, Head, G, and Simon, R.: Treatment of osteogenic sarcoma. I. Effect of adjuvant high-dose methotrexate after amputation. *Cancer Treatment Rep.* 63: 739-752, 1979.
72. Rosenberg, SA, Flye, MW, Conkle, D, Seipp, C, Levine, AS, and Simon, R.: Treatment of osteogenic sarcoma. II. Aggressive resection of pulmonary metastases. *Cancer Treatment Rep.* 63: 753-756, 1979.
73. Simon, R.: Restricted randomization designs in clinical trials. *Biometrics* 35: 503-512, 1979.
74. Ozols, RF, Garvin, AJ, Costa, J, Simon, RM, and Young RC.: Histologic grade in advanced ovarian cancer. *Cancer Treatment Rep.* 63: 255-264, 1979.
75. Allegra, JC, Lippman, ME, Simon, R, Thompson, EB, Barlock, A, Green, L, Huff, KK., Do, HMT, Aitken, SC, and Warren, R.: The association between steroid hormone receptor status and disease-free interval in breast cancer. *Cancer Treatment Rep.* 63: 1271-1277, 1979.
76. Lee, YJ, Catane, R, Rozenzweig, M, Bono, VH Jr, Muggia, FM, Simon, R, and Staquet, MJ.: Analysis and interpretation of response rates for anticancer drugs. *Cancer Treatment Rep.* 63: 1713-1720, 1979.
77. Lee, YJ, Staquet, M, Simon, R, Catane, R, and Muggia, FM.: Two-stage plans for patient-accrual in phase II clinical trials. *Cancer Treatment Rep.* 63: 1721-1726, 1979.
78. Magrath, I, Lee, YJ, Anderson, T, Henle, W, Ziegler, J, Simon, R, and Shein, P.: Prognostic factors in Burkitt's lymphoma: Importance of total tumor burden. *Cancer* 45: 1507-1515, 1980.

79. Pizzo, PA, Robichaud, KJ, Gill, FA, Witebsky, FG, Levine, AS, Deisseroth, AB, Glaubiger, DL, MacLowry, JD, Magrath, IT, Poplack, DG, and Simon, RM.: Duration of empiric antibiotic. *Medicine* 67: 194-200, 1979.
80. Simon, R.: Reassessing effects of confounding variables. *Am. J. of Epidemiology* 111: 127-128, 1980.
81. Simon, R.: Statistical methods for evaluating pregnancy outcomes in patients with Hodgkin's disease. *Cancer* 45: 2890-2892, 1980.
82. Baker, AR, Ward, GM, Simon, RM, Stinson, SF, and Devereux, D.: Dietary fiber added to an elemental diet speeds gut transit time, increases stool bulk, and protects against the induction of rat colon tumors by dimethylhydrazine. *Surgical Forum* 1979.
83. Makuch, RW, and Simon, RM.: Sample size considerations for non-randomized comparative studies. *J. Chron. Dis.* 33: 175-181, 1980.
84. Allegra, JC, Lippman, ME, Thompson, EB, Simon, R, Barlock, A, Green, L, Huff, KK, Do, HMT, Aitken, SC, and Warren, R.: Estrogen receptor status is the most important prognostic variable in predicting response to endocrine therapy in metastatic breast cancer. *European J. of Cancer* 16: 323-331, 1980.
85. Simon, R.: Length biased sampling in etiologic studies. *Am. J. of Epidemiology* 111: 444-452, 1980.
86. Chang, AE, Shiling, DJ, Stillman, RC, Goldberg, NH, Seipp, CA, Barofsky, I, Simon, RM, and Rosenberg, SA.: Delta-9-tetra-hydrocannabinol as an antiemetic in cancer patients receiving high dose methotrexate. A prospective, randomized evaluation. *Ann. of Int. Med.* 91: 819-824, 1979.
87. Simon, R.: Antileukemic effect of graft-versus-host disease? *New Engl. J. of Med.* 301: 1006, 1979.
88. Sears, HF, and Simon, R.: Cryopreserved lymphocytes-decreased response in immune assays of a population of sarcoma patients. *Cryobiology* 17:93-99, 1980.
89. Sears, HF, Simon, R, and Rosenberg, SA.: Longitudinal studies of cellular immunity of patients with osteogenic sarcoma during chemotherapy. *Cancer Treatment Rep.* 64: 589-597, 1980.
90. Garvin, AJ, Simon, R, Young, RC, DeVita, VT, and Berard, CW.: The Rappaport classification of non-Hodgkin's lymphomas: A closer look using other proposed classifications. *Seminars in Oncology* 7: 234-243, 1980.
91. Popp, MB, Fisher, RI, Simon, RM, and Brennan, MF.: A prospective randomized study of adjuvant parenteral nutrition in the treatment of diffuse lymphoma: I. Effect on drug to tolerance. *Cancer Treatment Rep.* 65: 129-135, 1981.
92. DeVita, VT, Simon, RM, Hubbard, SM, Young, RC, Berard, CW, Moxley, JH III, Frei, E III, Carbone, PP, and Canellos, GP.: On the curability of advanced Hodgkin's disease with chemotherapy: Long-term follow-up of MOPP treated patients at the National Cancer Institute. *Ann. of Int. Med.* 92: 587-595, 1980.
93. DeWys, WD, Allegra, JC, Simon, R, and Lippman, ME.: Prediction of response to endocrine therapy in breast cancer from the estrogen receptor status of one site and the number of metastatic sites: A hypothesis. *Cancer Res.* 40: 2423-2427, 1980.
94. Fisher, RI, Jones, RB, DeVita, VT Jr, Simon, RM, Garvin, AJ, Berard, CW, and Young, RC.: Natural history of malignant lymphomas with divergent histologies at staging evaluation. *Cancer* 47: 2022-2025.

95. Simon, RM, and Makuch, RW.: On a qualitative discrepancy between censored data rank tests. *Biometrics* 36: 353-354, 1980.
96. Osborne, C K, Norton, L, Young, RC, Garvin, AJ, Simon, RM, Berard, CW, and DeVita, VT Jr.: Nodular histiocytic lymphoma: An aggressive nodular lymphoma with potential for prolonged disease-free survival. *Blood* 56: 98-103, 1980.
97. Simon, R.: Composite randomization designs for clinical trials. *Biometrics* 37:723-731, 1981.
98. Nemoto, T, Horton, J, Simon, R, Dao, TL, Rosner, D, Cunningham, T, Sponzo, R, and Snyderman, M.: Comparison of four combination chemotherapy programs in metastatic breast cancer. *Cancer* 49: 1988-1993, 1982.
99. DeVita, VT, Simon, RM, Hubbard, SM, and Young, RC.: Combination chemotherapy for Hodgkin's disease. *Ann. of Int. Med.* 94: 713-714 (Letter), 1981.
100. Simon, R.: Patient subsets and variation in therapeutic efficacy. *Br. J. Clin. Pharmacol.* 14: 473-482, 1982.
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82. Simon R. Evaluating prognostic factor studies. pp49-56 in *Prognostic Factors in Cancer*, Gospodarowicz, Henson, Hutter, O'Sullivan, Sobin and Wittekind (eds.) Wiley-Liss, New York, 2001.
83. Simon R. Bioinformatics and whole genome technologies. In *Strategies for Cancer Chemoprevention*, Kelloff GJ, Hawk ET, Sigman CC (eds.), Humana Press, Totowa New Jersey, 2002.
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87. Simon R. Guidelines for the design of clinical studies for development and validation of therapeutically relevant biomarkers and biomarker based classification systems. In *Biomarkers in Breast Cancer: Molecular Diagnostics for Predicting and Monitoring Therapeutic Effect*, Hayes DF and Gasparini G (eds), Humana Press, pp 3-15, 2005.

88. Simon R. Using gene expression profile based diagnostic classification in clinical oncology. American Society of Clinical Oncology Education Book, 2004.
89. Simon R. Panel discussion, FDA-NIH Conference on Bayesian Methods in Clinical Trials, *Clinical Trials* 2:352-358, 2005.
90. Irony T and Simon R. Bayesian methods for the design and analysis of clinical trials. In *Clinical Evaluation of Medical Devices*, 2nd Edition, KB Witkin editor, pp 99-116, Humana Press , Totowa New Jersey, 2006.
91. Simon R. Targets for treatment success (Editorial), *Nature Clinical Practice-Oncology* 3:1, 2006.
92. Simon R. New approaches to phase II development for molecularly targeted agents. American Society of Clinical Oncology Education Book, 2006.
93. Simon R. Transforming correlative science to predictive science: New approaches to the interface of laboratory and clinic in cancer therapeutics development. American Society of Clinical Oncology Meeting Education Book, 2006.
94. Dobbin KK and Simon RM. Statistical issues in the design and interpretation of Microarray experiments, Chapter 2 in *Bioinformatics in Cancer and Cancer Therapy*, Gordon GG editor, Humana Press, 2009.
95. Simon RM. Challenges of Microarray data and the evaluation of gene expression profile signatures, Chapter 3 in *Translational Therapeutic Strategies in Breast Cancer*, Lyman GH and Burstein HJ editors, Taylor & Franchis Publishers, Chapter 3, pp 27-36, 2007.
96. Simon R. Identification of pharmacogenomic biomarker classifiers in cancer drug development, In *Pharmacogenomics, Anticancer Drug Discovery and Response*, F Innocenti editor, Humana Press, Chapter 19, pp 327-338, 2008.
97. Simon R. Resampling strategies for model assessment and selection, Chapter 8 In *Fundamentals of Data Mining in Genomics and Proteomics*, pp 173-186, W Dubitzky, M Granzow and DP Berrar editors, Springer, 2007.
98. Simon R. Use of predictive biomarker classifiers in the design of pivotal clinical trials. In *Pharmacogenomics and Personalized Medicine* (N Cohen ed.), Chapter 11, pp 239-238, Humana Press, 2008.
99. Simon R. Drug and pharmacodiagnostic co-development: Statistical Considerations. pp 207-226 in *Molecular Diagnostics* (JT Jorgensen and H Winther, eds), Pan Stanford Publishing, 2010.
100. Simon R. Use of genomics in therapeutic clinical trials. Chapter 24 in *Fundamentals of Oncology Clinical Trials*, (WK Kelly and S Halabi), Devos Medical Publishing , 2010.
101. Simon R. Statistical considerations in the development and validation of cancer biomarkers. In *Molecular Biology of Cancer* (Garcia-Foncillas ed), (In Press).
102. Simon R. Designing genomics based clinical studies. In *Genomic and Personalized Medicine* (G Ginsburg and H Williard eds), Elsevier, 2nd edition (In Press).

Invited Presentations

1. Adaptive Treatment Assignment and Clinical Trials. Biometric Society, (ENAR), Chapel Hill, NC, March 1977.
2. Restricted Randomization Designs in Clinical Trials. Joint National Meeting of Biometric Society and American Statistical Association, Chicago, IL, August 1977.
3. Effect of Stratification on the Analysis of Clinical Trials. Meeting of Cancer Cooperative Group Statisticians, Bethesda, MD, October 1977.
4. Patient Heterogeneity in Clinical Trials. Symposium on Designs for Clinical Cancer Research. New Orleans, LA, April 1978.
5. Heterogeneity and Standardization in Clinical Trials. E.O.R.T.C. Symposium on Controversies in Cancer Treatment. Brussels, Belgium, April 1978.
6. Adaptive Sampling and Clinical Trials. Mathematical Association of America. November 1979.
7. Comments of Chairman for Working Group on Biostatistics and Trial Design in Head and Neck Cancer Research. International Head and Neck Oncology Research Conference. September 1980.
8. Length Biased Sampling in Etiologic Studies. Joint Meeting of Biometric Society (ENAR) and American Statistical Association. Richmond, VA, March 1981.
9. Early Stopping for Clinical Trials. Joint Meeting of Biometric Society (ENAR) and American Statistical Association. Richmond, VA, March 1981.
10. Experimental Randomization and Clinical Trials. Midwest Biopharmaceutical Symposium. Muncie, IN, May 1981.
11. Simple Confidence Intervals for Quantiles of a Survival Distribution. American Statistical Association. Detroit, MI, August 1981.
12. Biostatistics and Data Management Considerations for Multi-Center Clinical Trials. Third Annual Meeting of the collaborative Cancer Treatment Research Program, Pan American Health Organization. Washington, DC, April 1981.
13. Stochastically Curtailed Tests in Long-term Clinical Trials. Joint Meeting of the Biometric Society (ENAR) and the American Statistical Association. San Antonio, TX, March 1982.
14. Theoretical Considerations in Designing Effective Therapy for Patients with Acute Myelogenous Leukemia. National Cancer Institute Workshop on Acute Myelogenous Leukemia. Bethesda, MD, December 1981.
15. An Evaluation of Clinical Trial Designs that Randomize Composite Units Rather than Individual Patients. Second International Meeting on Clinical Trials in Early Breast Cancer. Heidelberg, West Germany, December 1981.

16. Statistical Monitoring of Clinical Trials for Early Termination in the Absence of Apparent Treatment Differences. Department of Biomathematics, M. D. Anderson Hospital and Tumor Institute, Houston, TX, November 1982.
17. Cell Kinetic and Genetic Considerations in the Deliver of Therapy. U.S.- Japan Cooperative Cancer Research Treatment Program Review Meeting. Bethesda, MD, November 1982.
18. Design Considerations for Clinical Trials in Oncology. U.S.-Japan Cooperative Cancer Research Treatment Program Review Meeting. Bethesda, MD, November 1982.
19. Observational Studies and Clinical Trials in Cancer Therapeutics. Board of Scientific Counselors, Division of Cancer Treatment, National Cancer Institute, Bethesda, MD, January 1983.
20. Methodological Developments in Clinical Trials. Session Organizer and Chairman. Biometric Society, ENAR. Nashville, TN, March 1983.
21. Survival Curves with Time-Dependent Covariates. School of Public Health, University of North Carolina, Chapel Hill, NC, April 1983.
22. The Microprocessor Revolution and the Cooperative Oncology Group Program - Closing Remarks of Co-Chairman. Workshop on New Computer Applications in Clinical Trials. Bethesda, MD, July, 1983.
23. Critique of Study Endpoints for Clinical Trials of Solid Tumors. Symposium on Response Criteria. National Prostatic Cancer Project, Buffalo, NY, August 1983.
24. Organizer of Symposium on Methodology for Evaluating Therapy. Sponsored by the National Cancer Institute and National Heart, Lung and Blood Institute, Bethesda, MD, September 1983. Editor of Proceedings published in Stat. in Med. 3: 4, 1984.
25. Issues in the Design, Conduct and Analyses of Phase I and Phase II Studies of Drugs. Plenary Session of Pediatric Oncology Group Meeting. St. Louis, MO, October 1983.
26. Microcomputers and Cancer Clinical Trials: Speaker and Panel Chairman, Meeting of Community Cancer Oncology Program Participants, Bethesda, MD, October 1983.
27. New Approaches for Evaluating Treatment by Subset Interactions for Clinical Trials. Society for Clinical Trials, Miami, FL, May 1984.
28. Two-stage Designs of *In Vitro* Screening Assays. Workshop on the Application of the Human Tumor Colony Forming Assay to Drug Screening. University of Arizona, Tucson, AZ, January 1984.
29. Testing for Qualitative Interactions in Clinical Trials. Washington Statistical Society, May 1984.
30. Methodologic Standards for Reporting the Results of Clinical Trials. Combined Oncology/Radiation Conference. NYU Medical Center, NY, May 1984.
31. New Methodology for Subset Analysis in Clinical Trials. Symposium of Cancer Cooperative Group Statisticians, Philadelphia, PA, August 1984.
32. Composite Randomization Designs in Clinical Trials. Biopharmaceutical Section Roundtable. American Statistical Association National Meeting. Philadelphia, PA, August 1984.

33. The Design of Comparative Studies to Evaluate Nuclear Magnetic Resonance Imaging. Collaborative NMR Evaluation Group, Bethesda, MD, July 1984.
34. Subset Analysis in Clinical Trials. Workshop on Subgroup Analyses and Interpretation in Clinical Trials. National Heart, Lung and Blood Institute, Bethesda, MD, September 1984.
35. The Size of Cancer Clinical Trials. Symposium on Methodology and Quality Assurance in Cancer Clinical Trials, Washington, DC, October 1984.
36. Organizer of Symposium on Methodology and Quality Assurance in Cancer Clinical Trials, Washington, DC, October 1984. Editor of Proceedings in Volume 69, Number 10, Cancer Treatment Reports, 1985.
37. Comment on "Phase II Trials in Cancer: Present Status and Analysis Methods." Discussant at Washington Statistical Society Seminar. Washington, DC, February 1985.
38. The Design of Phase II Clinical Trials. Seminar, Department of Biostatistics, Memorial Sloan Kettering Cancer Institute, New York, NY, April 1985.
39. New Sequential Design for Phase III Clinical Trials. Meeting of Cancer and Leukemia Group B. Cambridge, MA, April 1985.
40. Methodologic Considerations in Combining Results of Clinical Trials. Invited Presentation, Society of Clinical Trials, New Orleans, LA, May 1985.
41. An Evaluation of "Pre-randomization" in Cancer Clinical Trials. FDA Oncologic Advisory Committee, Rockville, MD, June 1985.
42. The Design of Cancer Clinical Trials. Cancer Control Science Workshop, Bethesda, MD, July 1985.
43. Equivalence Trials in Cancer Therapeutics. National Science Foundation Symposium on Sequential Analysis. Columbia University, New York, NY, October 1985.
44. The Design of Cancer Clinical Trials. American College of Physicians Course on Current Concepts in Internal Medicine. Letterman Army Medical Center, San Francisco, CA, October 1985.
45. Prognostic Factors in Head and Neck Cancer. International Symposium on Head and Neck Cancer. Genoa, Italy, December 1985.
46. An Assessment of Data Pooling for Breast Cancer Adjuvant Trials. Workshop on Future U.S. Adjuvant Trials in Breast Cancer. Bethesda, MD, November 1985.
47. Organizer of Symposium on Overviews of Clinical Trials. Sponsored by the National Cancer Institute and National Heart, Lung and Blood Institute. Bethesda, MD, May 1986.
48. The Role of Pooling Studies in Cancer Therapeutics. Symposium on Overviews in Clinical Trials. Controversies in Prostate Cancer. Prouts Neck, MA, October 1986.
49. Statistical Aspects of the Design of Cancer Clinical Trials. American Statistical Association Conference on Design of Experiments: Developments and Applications. University of Delaware, April 1986.
50. How Large Should a Phase II Trial Be? National Cancer Institute Research Conference, Bethesda, MD April 1986.

51. Overviews of Randomized Clinical Trials: A Critical Review. International Biometric Society, Seattle, WA, July 1986.
52. Measures of Predictiveness for Survival Models. Biostatistics and Statistics Departments Research Seminar. University of Wisconsin, Madison, WI, September 1986.
53. Design and Analysis of Clinical Trials of Prostate Cancer. Symposium on Clinical Controversies in Prostate Cancer. Prouts Neck, MA, October 1986.
54. Statistical Topics in the Design of Clinical Trials. Johns Hopkins Oncology Center Research Symposium. Baltimore, MD, October 1986.
55. Stochastic Curtailing for Comparison of Slopes in Longitudinal Studies (discussant), Washington Statistical Society Research Symposium, Bethesda, MD, October 1986.
56. Subset Analysis, Friend or Foe. Symposium on Critical Issues in Cancer Clinical Trials, Freiberg, Germany, February 1987.
57. A Critical Review of Approaches to Improving the Efficiency of Clinical Trials. Symposium on Critical Issues in Cancer Clinical Trials, Freiberg, Germany, February 1987.
58. Combining The Results of Research Studies (Session Organizer and Chairman), Biometric Society, Dallas, TX, March 1987.
59. Reporting and Interpreting Clinical Trials. Education Session. American Society of Clinical Oncology. Atlanta, GA, May 1987.
60. Meta-analysis of research studies. Health Protection Branch, Department of Health and Welfare of the Federal Government of Canada, Ottawa, November 1987.
61. The Ethics of Experimentation with Cancer Patients. (Discussant). NIH/FDA Conference on Protecting Human Subjects in Cancer Research. San Antonio, TX, October 1987.
62. Statistical Tools for Subset Analysis. Department of Biostatistics and Epidemiology. Cleveland Clinic, Cleveland, OH, February 1988.
63. Methodologic Guidelines for Reporting the Results of Clinical Trials. Cancer Center Grand Rounds, Cleveland Clinic, Cleveland, OH, February 1988.
64. Bayesian Methods for Subset Analysis. Department of Biostatistics, Medical College of Virginia, March 1988.
65. Statistical Methods in the Design of Phase I Clinical Trials. Biometric Society (ENAR). Boston, MA, March 1988.
66. Optimization in the Design of Sequential Clinical Trials. Symposium on the Interface of Computer Science and Statistics, Washington, DC, April 1988.
67. The Design of Clinical Trials for Cutaneous T-Cell Lymphomas. Amer. Soc. Dermatology, Washington, DC, November 1988.

68. The Role of p-values and Confidence Intervals in Interpreting Clinical Trials. Society for Clinical Trials, Minneapolis, MN 1989.
69. The Design of Phase II Clinical Trials. Society for Clinical Trials, Minneapolis, MN, 1989.
70. Adaptive Treatment Allocation in Clinical Trials. American Statistical Association, Washington, DC, August 1989.
71. New Designs for Clinical Trials. Grand Rounds, University of Maryland Cancer Center, Baltimore, MD, October 1989.
72. A Mathematical Model for Planning Dose Intensive Combination Chemotherapeutic Regimens. Symposium on Clinical Trials with Hematopoietic Growth Factors. National Cancer Institute, Bethesda, MD, November 1989.
73. Biopharmaceutical Statistics for Drug Development. Short course for American Society of Quality control. Atlantic City, NJ, December 1989.
74. A Mathematical Model for Planning Dose Intensive Combination Chemotherapeutic Regimens. Workshop on Use of Cytokines for the Dose Intensification of Chemotherapy. National Cancer Institute Biological Response Modifier Program, Frederick, MD, February 1990.
75. Intergroup Clinical Trials and Tribulations. Keynote address at National Cancer Institute Workshop on National Intergroup Clinical Trials. Denver, CO, April 1990.
76. Efficient Clinical Trial Designs for Selecting among experimental Treatments. National Meeting of the AIDS Clinical Trials Group. Bethesda, MD, February 1990.
77. Problems of Interpretation Involving Multiple Endpoints and Subgroups. Society for Clinical Trials Pre-Conference Workshop on the Design and Analysis of Clinical Trials. Toronto, Canada, May 1990.
78. Advances in Statistical Methodology for Clinical Trials in the 1980's. American Statistical Assn., Anaheim, CA., August 1990.
79. Optimization in the Design of Combination Chemotherapy Clinical Trials. Drug Information Association Workshop on Optimization Methods in Drug Research and Development, Bethesda, MD, October 1990.
80. A Strategy for Evaluating Dose Intensity. Curing Leukemia. Sponsored by Keystone Symposium on Molecular and Cellular Biology. Cape Cod, MA, November 1990.
81. A Design for Screening New Agents for Activity against HIV. AIDS Clinical Trials Group Meeting, Washington, DC, November 1990.
82. Disseminating the Results of Clinical Trials. NIH Office of Medical Applications of Research Conference on Exploring the Information Dissemination Process, Bethesda, MD, Jan. 1991.
83. Monitoring of Therapeutic Equivalence Studies. Biometric Society Meeting (ENAR), Houston, TX, March 1991.
84. Evaluating Qualitative Interactions in Clinical Trials. Department of Biostatistics, University of Michigan, Ann Arbor, April 1991.

85. Problems of Multiplicity Involving Patient Subsets and Endpoints in Clinical Trials. Statistical Society of Canada, Toronto, Canada, June 1991.
86. Recent Developments in the Design of Phase II Clinical Trials. Grand Rounds, University of Maryland Cancer Center, Baltimore, MD, November 1991.
87. Cross-validation in Variable Selection. Workshop on Methodological Issues in the Evaluation of Prognostic Factors. University of Freiberg, Freiberg, Germany, February 1992.
88. Survival Analysis: A Non-technical Workshop on Statistical Aspects in the Planning and Analysis of Survival Studies. Society for Clinical Trials, Philadelphia, PA, May 1992.
89. Interpretation of Clinical Trials and Meta-analyses. Lombardi Cancer Center, Georgetown University, Washington, D.C., June 1992.
90. Statistical Issues in the Development and Evaluation of Prognostic Markers. Workshop on Predictive Markers in Clinical Cancer: Assessment and Application, Bethesda, MD, September 1992.
91. New Approaches to the Design of Phase II Clinical Trials. Johns-Hopkins University, Baltimore, MD October 1992.
92. New Approaches for Evaluating Specificity of Treatment Effect in Clinical Trials. Medical College of Virginia, Richmond, VA, October 1992.
93. New Designs for the Selection of Treatments to be Tested in Randomized Clinical Trials. National Institutes of Health Conference on Current Topics in Biostatistics, Bethesda, MD, January 1993.
94. The Role of Large Simple Clinical Trials in Oncology. Keystone Symposium on Discovery and Development of Therapeutic Compounds. Snowmass, CO, March 1993.
95. Practical Aspects of Interim Monitoring of Clinical Trials. Medical Research Council Symposium on Early Stopping Rules in Cancer Clinical Trials. Cambridge, England, April, 1993.
96. Clinical Trials of Innovative New Treatments. National Institutes of Health Lectures of The Art and Science of Experimental Design, Bethesda, MD, April, 1993.
97. Methodologic Issues in the Development of a New Risk Classification System for Acute Lymphoblastic leukemia. National Institutes of Health Workshop on Risk Classification in childhood Acute Lymphoblastic Leukemia, Bethesda, MD September 1993.
98. An Overview of Statistical Methods in Survival Analysis. Food and Drug Administration, Rockville, MD October 1993.
99. The Size of National Clinical Trials Needed for Pediatric Oncology. Pediatric Oncology Group Meeting, Chicago, IL, October 1993.
100. Randomized Clinical Trials: Principles and Obstacles. American Cancer Society National Conference on Clinical Trials, Atlanta, GA, 1993.
101. Bayesian Analysis of Subsets in Medical Studies. John Hopkins University Department of Biostatistics, Baltimore, MD, December 1993.

102. New Methods for the Analysis of Survival Data. John Hopkins University Department of Biostatistics, Baltimore, Md. October 1994
103. The Need for Publication Guidelines for Prognostic Factor Studies. National Coordinating Workshop on Prognostic factors in Cancer sponsored by the National Cancer Institute and the American Joint Committee on Cancer. Bethesda, Md. January 1995.
104. Improving the Science of Prediction in Medical Therapeutics. St. Jude Childrens Cancer Center, Memphis Tenn, January 1995.
105. Bayesian Methods for the Analysis of Survival Data with Covariates. Washington Statistical Society. Washington DC, January 1995.
106. Some Recent Methods for the Analysis of Survival Data. Cancer Prevention and Control Colloquium. Bethesda Md, February 1995.
107. Statistical Bases for Evaluating Comparative Effects in Therapeutic Equivalence Trials. FDA Conference on Comparing Treatments: Safety, Effectiveness and Cost-Effectiveness. Bethesda, Md., March 23-24 1995; Conference repeated for FDA staff October 2, 1995.
108. Subgroup analysis in Clinical trials. National Kidney Foundation Conference on Clinical Trials. Washington, DC, March 1995.
109. Bayesian Methods for Planning and Continuous Monitoring Early Clinical Trials for Efficacy and Safety. Medical College of Virginia, Department of Biostatistics, Richmond, Va. May 1995.
110. Statistical Aspects of Assessing Gender Related Treatment Specificity in Clinical Trials. FDA Workshop on Gender Studies in Product Development: Scientific Issues and Approaches. Rockville Md, November 6-7, 1995.
111. Statistical Models for Evaluating Prognostic and Treatment Selection Factors. National Institute Workshop on Prognostic Factors in Primary Breast Cancer. Bethesda Md, November 12, 1995.
112. Bayesian Design of 2 x 2 Factorial Clinical Trials. Department of Mathematics, University Of Maryland, College Park Md, February 1996.
113. Designs for Combining Phase II/III Clinical Trials. Symposium on Flexible Strategies for Clinical Trials. Harvard University School of Public Health, Boston Mass., May 1996.
114. Accelerated Titration Designs for Phase I Clinical Trials. Workshop on Phase I Clinical Trials. National Cancer Institute, Bethesda MD, April 1996.
115. Accelerated Titration Designs for Phase I Clinical Trials. Department of Biomathematics. Georgetown University, Washington DC, April 26, 1996.
116. Innovative Statistical Approaches for Conducting Therapeutic Research with Limited Patient Populations. Israel Cancer Institute. Tel Aviv, July 2, 1996.
117. Bayesian Design and Analysis of 2 x 2 Factorial Clinical Trials. American Statistical Association. Chicago Illinois, August 8, 1996.
118. Distinctions Among Explained Residual Variation, Explained Risk and Goodness of Fit. International Society for Clinical Biostatistics. Budapest Hungary. August 27, 1996.

119. New Approaches for the Design and Analysis of Phase I Clinical Trials. German Society of Medical Statisticians. Bonn Germany, September 17, 1996.
120. Design and Analysis of Factorial Clinical Trials. Henry Stewart Conference on Understanding, Applying and Not Misusing the Mathematical and Statistical Techniques Used in Clinical Trials. Rockville Maryland, October 25, 1996.
121. Accelerated Titration Designs for Phase I Clinical Trials. Memorial Sloan-Kettering Cancer Center. New York, November 1996.
122. Bayesian methods for developing improved prediction and classification systems when there are many potential covariates. Mathematical Models for Diagnosis and Prognosis. Oberwolfach, Germany, February 1997.
123. Bayesian design and analysis of active-control clinical trials. Institute for Mathematics and its Applications. Workshop on Medical Statistics, University of Minnesota, July 1997.
124. Accelerated escalation designs for phase I oncology trials. Workshop on FDA and Industry: Working Together to Expedite the Development of New Pharmaceutical Products. October 1997, Washington D.C.
125. Megavariate analysis of DNA micro-array data. Second Workshop on Methods and Applications of DNA micro-array technology. Tucson Arizona, January 1998.
126. Innovative designs for translational cancer vaccine clinical trials. Cancer Vaccine Development Workshop, National Cancer Institute, Bethesda Maryland, March 1998.
127. Early stopping of clinical trials when there is evidence that the experimental treatment will not prove beneficial. International Biometric Society, Pittsburgh Pa, March 1998.
128. A Bayesian approach to the design and analysis of active control clinical trials. Henry Stewart Conference on Understanding, Applying and Not Misusing the Mathematical and Statistical Techniques used in Clinical Trials. Reston Va, April 1998.
129. A new approach to the design and analysis of factorial trials. Society for Clinical Trials, Atlanta Georgia, May 1998.
130. An overview of the development and use of prognostic classification systems. Society for Clinical Trials, Atlanta Georgia, May 1998.
131. Accelerated titration designs for phase I clinical trials in oncology. Drug Information Association National Meeting. Boston Ma, June 1998.
132. Using surrogate endpoints in cancer clinical trials. NIH Workshop on Surrogate Endpoints in Clinical Trials. Potomac Md, November 1998.
133. Innovative clinical trial designs for the development of tumor vaccines. First Walker's Cay Colloquium on Cancer Vaccines and Immunology. Walker's Cay Bahamas, March 1999.
134. A new Bayesian approach to the design and analysis of therapeutic equivalence trials. Harvard Symposium on Bayesian Statistics. Harvard University, June 1999.

135. Organizer and sole presenter of short course on statistical methods in genomics and computational biology. Heidelberg Germany, September 1999.
136. Statistics in molecular medicine. International Association for Clinical Biostatistics and German Society for Medical Informatics, Biometry and Epidemiology, September 1999.
137. The role of neural networks in developing prognostic classification systems for cancer. Conference on Prognostic Factors and Staging in Cancer Management: Contributions of Artificial Neural Networks and other Statistical Methods. Sponsored by American Joint Committee on Cancer, International Union Against Cancer, and Institute for Clinical Research, Washington D.C., September 1999.
138. Statistical analysis of unexpected events. FDA/Industry Statistical Workshp. Sponsored by the Americal Statistical Association, September 1999.
139. Design of clinical trials in pediatric oncology. Surgical Committee of the Children's Oncology Group, Chicago Ill, October 1999.
140. Principles for the design and interpretation of clinical trials. Oncology Research Nurse Education Program, National Cancer Institute, Bethesda Md, October 1999.
141. Successes and lessons learned from the sequencing world and challenes for the microarray world. Keynote address at the Granlibakken Conference on Microarray Algorithms and Statistical Analysis: Methods and Standards, Lake Tahoe CA, November 1999.
142. Bayesian design and analysis of therapeutic equivalence trials. Oncologic Drug Advisory Committee Meeting, Food and Drug Administration, December 1999.
143. Bayesian subset analysis. 9th International Symposium on long-term clinical trials, London England, June 2000.
144. Bayesian design and analysis of positive control clinical trials. Midwest Biopharmaceutical Statistics Workshop, Muncie Indiana, May 2000.
145. Statistical Challenges in the use of DNA Microarray technology. Oberwolfach Meeting on adaptive clinical trials and molecular medicine. Oberwolfach Germany, February 2000.
146. A Bayesian approach to indirect comparisons using external data in the analysis of a phase III clinical trial. Annual meeting of the Drug Information Association, San Diego Ca, June 2000.
147. Statistical challenges in molecular medicine. University of Michigan Department of Biostatistics. March 2000.
148. Assessing cluster reproducibility in the analysis of DNA microarray expression profiles. National Cancer Institute Meeting on Analytic Tools for a Molecular Classification of Cancer, Bethesda MD, April 2000.
149. Biostatistics, DNA Microarrays and molecular medicine. Fred Hutchinson Cancer Research Center, University of Washington, Seattle, May 2000.
150. Organizer of Institute for Pure and Applied Mathematics Conference on Expression Arrays, Genetic Networks and Diseases, UCLA, November 2000.
151. Organizer of Conference on Expression Arrays, Genetic Networks and Diseases, Institute of Pure and Applied Mathematics, UCLA, October 2000.

152. Short Course in analysis of microarray expression data. M.D. Anderson Cancer Center, November 2000.
153. Short course in analysis of microarray expression data. National Institutes of Health, Bethesda MD, September 2000, October 2000.
154. Statistical analysis of microarray expression data. Seminars in Clinical and Molecular Medicine, National Institutes of Health, Bethesda MD, December 2000.
155. Advanced statistics and informatics for DNA microarray expression data. First Annual Meeting of Microarray Researchers. National Institute of Drug Abuse and National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda MD, January 2001
156. Analytic methods for the analysis of DNA microarray data., Siteman Cancer Center, Washington University School of Medicine, St. Louis Missouri, February 2001.
157. Bioinformatics in whole genome expression profiling using DNA microarrays. American Association for the Advancement of Science, San Francisco, February 2001.
158. Analytic methods for the analysis of gene expression profiles from DNA microarrays, Samuel Lunenfeld Research Institute, Toronto Ontario Canada, April 2001.
159. Development of molecular classification systems using whole genome expression profiles. The Henry Kunkel Society, Rockefeller University, May 2001.
160. Bayesian methods in the design and analysis of clinical trials: Today and tomorrow.. The Life Scientists Guide to Statistical Issues in Drug Development. Washington D.C., June 2001.
161. BRB-ArrayTools, integrated bioinformatics for the analysis of DNA-Microarray data. Am Mathematical Society, Institute of Mathematical Statistics, Society of Industrial and Applied Mathematics Conference on Statistics in Functional Genomics; Mt. Holyoke College, June 10-14 2001.
162. Statistical methods for discovery using DNA-microarrays. Starr Seminar on Human Genetics, Rockefeller University, June 19, 2001.
163. Design and analysis of experiments using DNA-microarrays. National Cancer Institute Early Detection Research Network, Washington D.C. June 21-22, 2001.
164. Biostatistics and the book of life. Keynote address at Eighth Annual Biopharmaceutical Applied Statistics Symposium, December 3-7, Savannah Georgia.
165. Bioinformatic issues in gene expression profiling using DNA microarrays. University of Maryland Lecture Series on Computational Biology, College Park MD, January 30, 2002.
166. Bioinformatics in cancer research. Cancer Prevention and Control Colloquia Lecture Series, Bethesda MD, February 6, 2002.
167. Bioinformatics in 21st century cancer therapeutics. Conference on Cancer Trials in Asia, March 5-6, Hong Kong.
168. Biometric issues in the study of cancer pathogenesis using DNA microarray expression profiles, Grand Rounds, Department of Biostatistics, Johns Hopkins University, March 13, 2002, Baltimore MD.

169. Short Course on the Statistical analysis of DNA microarray studies. Biometric Society (ENAR), March 17, 2002, Arlington VA.
170. Intensive short course in the design and analysis of DNA microarray studies. Rockefeller University, Statistical Genetics Laboratory, April 18-20, 2002.
171. State of the art in DNA microarray bioinformatics. Conference on Macro-results thru Microarrays, April 29-May 1, 2002, Boston MA.
172. Short Course on applications of DNA microarrays in clinical trials. Society for Clinical Trials, May 12 2002, Washington D.C.
173. Molecular biometry in the genomic era: Applications to use of DNA microarrays for the discovery and development of molecularly targeted pharmaceuticals. 38th Annual Meeting of the Drug Information Association, Chicago Illinois, June 17, 2002.
174. Accelerated titration designs for phase I oncology trials. Henry Stewart International Conference on New Statistical Methods for Dose Finding. Washington D.C. September 18-19, 2002.
175. Design and analysis of studies using DNA microarrays. FDA Center for Veterinary Medicine. Rockville Maryland, September 17, 2002.
176. Design of DNA microarray studies. Fox Chase Cancer Center, Philadelphia PA, October 18, 2002.
177. Short Course on design and analysis of DNA microarray studies. Biopharmaceutical Applied Statistics Symposium, December 2002, Savannah Georgia.
178. Use of DNA microarrays for diagnostic and prognostic classification. Inserm Workshop on Statistical Analysis of Microarrays, May 2003, Toulon, France.
179. The design of DNA microarray studies. Royal Statistical Society Conference on the design and analysis of gene expression studies, July 2003, Imperial College, Wye, England.
180. Myths and Truths about gene expression profiling. Transplantation Genomics Workshop, National Institute of Allergy and Infectious Diseases, April 30-May 1 2003, Bethesda MD.
181. Strategies for the Development of Molecularly Targeted Therapeutics: Bioinformatics and Clinical Trial Design, Tromso Symposium on Targeted Cancer Therapies, Tromso Norway, June 2003.
182. Where Bayesian methods are essential in clinical trials. Keynote address at German Society for Medical Informatics, Biometry and Epidemiology, September 2003, Munster Germany.
183. Design of DNA microarray studies. Microarray Data Analysis Conference, Cambridge Healthtech Institute, September 2003, Baltimore MD.
184. Development of cancer diagnostics using DNA microarrays. National Cancer Policy Board, Institute of Medicine, October 2003, Washington D.C.
185. Design & analysis of DNA microarray expression profiling studies: Myths, hype and scientific discovery. Keynote Address: U.S. AMRMC Bioinformatics Workshop, Fredrick MD Nov 4-6, 2003.

186. Design strategies for the development of molecularly targeted therapeutics in oncology. University of Chicago, January 23, 2004.
187. Key features in the design and analysis of DNA microarray studies. PhRMA/FDA Genomics Biostatistics Workshop. University of Maryland Shady Grove, Gaithersburg MD, April 15-16, 2004.
188. Challenges in the application of DNA microarrays to biomedical research. Auburn University Symposium on Biomathematics & Statistical Genetics. Auburn University, May 4, 2004.
189. Methods and myths in prognostic prediction with microarray and proteomic data. International Conference on Analysis of Genomic Data, Harvard Medical School, May 10-11, 2004.
190. Use of Bayesian methods in FDA decision making (discussant). FDA-Johns Hopkins University Workshop on Can Bayesian Approaches to Studying New Treatments Improve Regulatory Decision-Making. Bethesda Maryland, May 20-21, 2004.
191. Design and analysis of DNA microarray studies. Special Invited Address, Statistical Society of Canada, Montreal, June 1, 2004.
192. Supervised analysis when the number of candidate features greatly exceeds the number of cases. 36th Symposium on the Interface: Computing Science and Statistics. Baltimore, May 26-29, 2004.
193. Integrating DNA microarrays into clinical trials. Organizer and speaker for education session. American Society of Clinical Oncology National Meeting, New Orleans, June 5-6 2004.
194. Breast Cancer Genomics: Ready for the Prime Time? American Society of Clinical Oncology National Meeting, New Orleans, June 5, 2004.
195. Validation of Profile Biomarkers, Joint NCI-FDA Workshop on Research Strategies, Study Designs and Statistical Approaches to Biomarkers Validation for Cancer Diagnosis and Detection, Bethesda MD, July 28-29, 2004.
196. Effectively developing and evaluating medical diagnostics based on whole genome technologies. American Statistical Association Joint Statistical Meetings, Toronto Canada, August 8-12, 2004.
197. Inference and prediction with genomic and proteomic data. International Society of Clinical Biostatistics, Leiden Netherlands, August 15-19, 2004.
198. Design considerations for DNA microarray experiments. Microarray Gene Expression Data (MGED) Society, Toronto Canada, September 8-10, 2004.
199. Key features in the design and analysis of DNA microarray studies, Fourth Virtual Conference on Genomics and Bioinformatics, September 23, 2004.
200. What is adequate validation of a diagnostic classifier developed from high dimensional genomic data, FDA-Industry Statistics Workshop, Washington D.C., September 21-23, 2004.
201. Key features in the design and analysis of DNA microarray studies. CAMDA (Critical Assessment of Microarray Data Analysis) 2004, Duke University, November 10-12, 2004.
202. Effective validation of pharmacogenomic biomarkers, Gordon Conference on Cancer Detection and Diagnosis, Santa Barbara California, January 2005.

203. Pharmacogenomics in phase II clinical trials. NCI Early Drug Development Meeting, Bethesda Maryland, March 2005.
204. Expression profiling of tumors: Transforming clinical oncology or stuck on the research bench? American Association of Cancer Research, Anaheim California, April 2005.
205. Statistical designs for validating high dimensional pharmacogenomic signatures in drug development, Drug Information Association, Washington D.C., June 2005.
206. On the efficiency of targeted clinical trials, Drug Information Association Workshop on Statistical Methodology in the Biopharmaceutical Sciences, Washington D.C., March 2005.
207. The development and validation of pharmacogenomic biomarkers, American Association for the Advancement of Science, Washington D.C., February 2005.
208. Conducting definitive phase 3 pharmacogenomic based clinical trials. Workshop on Pharmacogenomics in Drug Development and Regulatory Decision Making Sponsored by the Drug Information Association, Pharmaceutical Research and Manufactures of America and Food & Drug Administration, Washington D.C., April 2005.
209. Development and validation of therapeutically relevant genomic classifiers. Center for Devices and Radiological Health, U.S. Food and Drug Administration, June 20, 2005.
210. Prospective use of pharmacogenomics in pivotal studies of new drugs. Biomarker Strategies in Cancer Therapeutics Development, Johnson & Johnson, Bridgewater NJ, June 27, 2005.
211. Genomic targeting of patients likely to benefit from a new therapeutic for improving the efficiency of clinical trials. FDA/Industry Statistics Workshop, Safety & The Critical Path: Keys to the Successful Development of Medical Products, Washington D.C., September 14-16, 2005.
212. Developing and validating genomic classifiers. Application & Validation of Genomic Biomarkers for Use in Drug Development and Regulatory Submissions, Drug Information Association, Bethesda MD, October 7, 2005.
213. A roadmap for developing and validating genomic classifiers for treatment selection, International Workshop on Translational Genomics in Neuroblastoma, Bethesda Maryland, October 16-18, 2005.
214. Development and validation of genomic classifiers for treatment selection. 58th Annual Symposium on Cancer Research, MD Anderson Cancer Center, October 28, 2005.
215. A new paradigm for the co-development of drugs and predictive biomarkers. Visiting Professor Lecture, Food and Drug Administration, February 2, 2006.
216. Roadmap for co-development of therapeutics and diagnostics in the genomic era. International Conference on Drug Development, Austin Texas, February 15, 2006.
217. Clinical trial designs and biomarker-based tumor classification systems, Institute Of Medicine National Cancer Policy Forum on Developing Biomarker-based Tools for Cancer Screening, Diagnosis and Treatment, Washington D.C., March 2006.
218. New clinical trial designs for the clinical development of molecularly targeted drugs, American Society of Clinical Oncology, Atlanta Ga, June 2006.

219. Transforming correlative science to predictive science: New approaches to the interface of laboratory and clinic in cancer therapeutics development. American Society of Clinical Oncology Education Session, Atlanta Ga, 2006.
220. Pre-conference workshop on the design and analysis of DNA microarray experiments. Conference on Critical Assessment of Microarray Data Analysis (CAMDA) 2006. Duke University, June 2006.
221. Sample size planning for clinical studies based on microarray expression profiling. Annual Meeting of the Biometric Society WNAR, Flagstaff Arizona, June 2006.
222. New clinical trial designs for molecularly targeted drugs. Symposium on Developmental Strategies and Clinical Trial Methods for Oncological Products, Arlington Va., July 2006.
223. Moving from correlative studies to predictive medicine: How to include biomarkers in clinical trials. First American Association of Cancer Research International Conference on Molecular Diagnostics in Cancer Therapeutics Development, Chicago Illinois, September 2006.
224. Development and validation of genomic classifiers for treatment selection. German Society for Medical Informatics, Leipzig Germany, September 2006.
225. A roadmap for the development and validation of therapeutically relevant predictive biomarkers. 9th Annual West Hawaii Cancer Symposium, Hawaii, September 2006.
226. New designs for biomarker utilization in new drug development. FDA-Industry Workshop, American Statistical Association, Washington D.C., September 2006.
227. The design of targeted clinical trials. Experimental Medicine Symposium on Optimizing Drug Development with Genomics, Abbott Laboratories, Chicago Ill., September 2006.
228. New frontiers for clinical trial design. Day 1- Molecular targeted agents; Day 2- Analysis of DNA Microarray gene expression data. National Cancer Center, Taipei Taiwan, November 2006.
229. On validating predictive biomarkers: Multi-platform comparison of DNA Microarray based classifiers. The MicroArray Quality Control Project Planning Committee, National Center for Toxicological Research, US Food and Drug Administration, Jefferson Arkansas, September 2006.
230. Moving from correlative science to predictive medicine, Danny Thomas invited lecture, St. Jude Children's Research Hospital, October 2006.
231. Cancer clinical trials in the genomic era, Division of Biostatistics, Yale University Medical School, New Haven Conn., October 2006.
232. Half Day Workshop on Clinical Trial Design for Molecularly Targeted Agents, Sponsored by National Institute of Cancer Research, Taipei Taiwan, November 9, 2006.
233. One Day Workshop on Analysis of Microarray Gene Expression Data Using BRB-ArrayTools, Sponsored by National Institute for Cancer Research, Taipei Taiwan, November 10, 2006.
234. Development and evaluation of predictive gene expression classifiers, Microarray Quality Control II Project, Food and Drug Administration, Silver Spring Maryland, November 29, 2006.
235. Statistical considerations in analysis of whole genome data, oncogenomics 2007: Dissecting Cancer Thru Genome Research, American Association of Cancer Research, Phoenix Arizona, February 1 2007.

236. Development and use of pharmacogenomic biomarkers in cancer drug development, Novartis, Florham Park NJ, February 5 2007.
237. Challenges in early development of therapeutic cancer vaccines, NCI/FDA Conference on Bringing therapeutic cancer vaccines and immunotherapies through development to licensure, National Institutes of Health, Bethesda MD, February 8-9, 2007.
238. Development and use of pharmacogenomic biomarkers in cancer drug development, Pfizer Conference on Cancer Drug Development, La Jolla CA, February 28-March 2, 2007.
239. New designs for translational studies of molecularly targeted agents. American Association of Cancer Research, Los Angeles, April 2007.
240. New approaches to using biomarkers in the design of cancer clinical trials. American Association of Cancer Research, Education Session on Clinical Trial Design, Los Angeles, April 2007.
241. Using gene expression profiling for developing predictive classifiers. Genentech, San Francisco, May 2007.
242. Using predictive biomarkers in the design of phase III clinical trials. Genentech, San Francisco, May 2007.
243. Guidelines on statistical analysis and reporting of DNA Microarray studies of cancer outcome, Laboratory of Carcinogenesis, Center for Cancer Research, National Cancer Institute, Bethesda MD, May 2007.
244. Using predictive biomarkers in the design of adaptive phase III clinical trials. Keynote address, International Conference on Adaptive Designs for Clinical Trials, Cambridge MA, May 2007.
245. Statistical aspects of using gene expression profiling for the development and validation of predictive classifiers, Department of Biostatistics, Vanderbilt University, Nashville TN, May 2007.
246. Developing predictive classifiers and their use in the design of pivotal clinical trials, Midwest Biopharmaceutical Workshop, Muncie Indiana, May 2007.
247. Statistical genomics in cancer therapeutics. Keynote address at the Statistical Genomics Workshop, Pacific Institute for the Mathematical Sciences, Calgary Canada, June 20, 2007.
248. Adaptive designs for using predictive biomarkers in phase III clinical trials; Center for Biologics Evaluation and Research, Food and Drug Administration, Rockville MD, September 10, 2007.
249. Predictive classifiers based on high dimensional data: Development & Use in clinical trial design. Glaxo SmithKline, King of Prussia PA, September 27, 2007.
250. Planned subset analyses in phase III clinical trials; Cancer Vaccine Consortium annual Meeting, Bethesda MD, September 28, 2007.
251. Moving from correlative clinical science to predictive cancer medicine. SPECS Investigators Meeting, National Cancer Institute, St. Louis Mo, October 11-12, 2007.
252. [Use of predictive classifiers in the design of pivotal clinical trials, Amgen, Thousand Oaks CA, October 24, 2007.](#)

253. Critical review of published Microarray studies for cancer outcome: Do's and Don'ts in design, analysis and reporting. NIH Symposium on the Functional Genomics of Critical Illness and Injury, Bethesda MD, November 14-15, 2007.
254. Novel clinical trial designs for predictive cancer medicine. Hematology/Oncology Grand Rounds at the Beth Israel Deaconess Medical Center-Harvard Medical School, Boston MA, November 28, 2007
255. Moving from correlative clinical science to predictive medicine. Cleveland Clinic Department of Quantitative Health, December 14, 2007.
256. Prospective subset analysis. International Conference on Bayesian Biostatistics, M.D. Anderson Cancer Research Center, Houston Texas, Jan 30-31, 2008.
257. Moving from correlative science to predictive medicing. AvaMed Conference on Molecular Diagnostics and the Changing Landscape, Washington D.C., February 6-7, 2008.
258. Using genomics in clinical trial design. Genomics Interest Group, Food and Drug Administration, Silver Spring MD, March 12, 2008.
259. 21st century clinical trials in transforming oncology into a predictive science. Conference on FDA Oversight of Oncology Drug Development and Commercialization, American Enterprise Institute, Washington D.C., March 13-14, 2008.
260. Moving from correlative clinical science to predictive medicine. International Biometric Society (ENAR), Arlington Va, March 16-19, 2008.
261. Using predictive biomarkers in clinical trial design. American Society of Clinical Oncology Education Session on Advanced Topics in Clinical Trial Design, Chicago Illinois, May 30, 2008.
262. Development and use of predictive biomarkers in new drug development. Novartis, Florham Park NJ, June 16, 2008.
263. Moving from correlative clinical science to predictive medicine, American Association of Cancer Research Conference on Cancer Clinical Trials and Personalized Medicine, Monterey Ca, July 20-23, 2008.
264. Pathways and roadblocks in translating genomic advances to predictive medicine. FDA/DIA Conference on FDA Critical Path Initiative on the Move: Complexities and Challenges, Bethesda MD, September 15-16, 2008.
265. Co-development of diagnostics and therapeutics. Brookings Institution Conference on Clinical Cancer Research, Washington D.C., September 26, 2008.
266. Applications of genomics to breast cancer. Istituto Nazionale Tumori, Milan Italy, October 2, 2008.
267. Development of gene expression based predictive classifiers and their use in clinical trial design. Novartis Diagnostics, Emeryville Ca, October 14, 2008.
268. Development and validation of prognostic and predictive biomarkers, FDA Center for Drug Evaluation and Research Educational Conference on Development of Biomarkers: From Exploration to Qualification of Clinical Utility for Therapeutics, White Oak MD, November 3, 2008.
269. Steps on the path to predictive oncology, Department of Biostatistics & Medical Informatics, University of Wisconsin, Madison WI, November 4, 2008.

270. Predictive oncology today and tomorrow. Keynote speaker at the 24th Nagoya International Cancer Treatment Symposium, Nagoya Japan, February 14-15 2009.
271. Statistical aspects of the development and validation of prognostic and predictive biomarkers. Department of Biostatistics and Epidemiology, University of Tokyo, February 18, 2009.
272. Development and validation of prognostic and predictive biomarkers. Future of Genomic Medicine II, Sponsored by The Scripps Research Institute and J. Craig Venter Institute, La Jolla CA, February 27-28, 2009.
273. Prospective and prospective-retrospective study designs for the validation of prognostic and predictive biomarkers. U.S. Cooperative Oncology Group Breast Cancer Correlative Sciences Workshop, February 23, 2009, Bethesda MD.
274. Development and use of predictive biomarkers. First Quebec Conference on Therapeutic Resistance in Cancer. Montreal, March 27-28, 2009.
275. Levels of evidence for studies using archived tissue in evaluating the medical utility of prognostic and predictive biomarkers. American Association of Cancer Research, April 19, Denver Colorado.
276. Validation of predictive biomarkers in prospective and prospective-retrospective clinical trials. Third Annual Statistical Forum co-sponsored by the Drug Information Association and the Food and Drug Administration, Washington D.C., April 27, 2009.
277. Clinical trials for predictive medicine, new challenges and paradigms. University of Pennsylvania Annual Conference on Statistical Issues in Clinical Trials. Philadelphia, April 29, 2009.
278. Development of predictive biomarkers based on gene expression signatures for oncology therapeutics development. Wyeth Inc., Pearl River NY, May 8, 2009.
279. Development and use of predictive biomarkers in oncology therapeutics development. Biogen-Idec Inc., Boston Massachusetts, May 15, 2009.
280. Making sense of molecular markers in lung cancer. American Society of Clinical Oncology, May 29, 2009.
281. When is a prognostic and predictive biomarker ready for prime time. 14th Congress of the European Hematology Association, Berlin, June 5, 2009.
282. Use of genomics in clinical trial design. Annual Meeting of the Drug Information Association, San Diego CA, June 24, 2009.
283. Pre-conference workshop on the development of prognostic and predictive biomarkers. Dalla Lana School of Public Health, University of Toronto, Toronto Canada, July 24-26, 2009.
284. Workshop on use of genomic biomarkers in the design of pivotal clinical trials. American Statistical Association, New Jersey Chapter, July 31, 2009.
285. Personalizing cancer therapeutics using predictive biomarkers. Cancer Research UK Cambridge Research Institute Annual Symposium, Cambridge UK, September 11-12, 2009.
286. Interpretation of diagnostic markers in the development of targeted agents, Joint Meeting of the European Cancer Organization and European Society of Medical Oncology, Berlin, September 24, 2009.

287. Use of genomic biomarkers in the design of pivotal clinical trials. Webinar for American Statistical Association Biopharmaceutical Section, September 28, 2009.
288. Development and evaluation of probabilistic forecasters. University of Michigan, Dept of Biostatistics, Ann Arbor MI, October 1, 2009.
289. Predictive classification with high dimensional data: the $p > n$ problem, and use of classifiers in clinical trial design. American Statistical Association, Delaware Chapter, October 22, 2009.
290. Use of prognostic and predictive biomarkers in the design of clinical trials for therapeutic cancer vaccines. FDA-NCI Workshop on Therapeutic Cancer Vaccines, National Cancer Institute, Bethesda MD October 27, 2009.
291. On the road to predictive oncology with genomics: New challenges for statistics and for clinical investigation. Distinguished Scholars Lecture, University of Buffalo, Buffalo NY, February 18, 2010.
292. Lost in translation. Key barriers to bridging the “valley of death”. NCI Symposium on Integrative Cancer Biology and Genomics. Bethesda MD, March 5, 2010.
293. New paradigms for the design of clinical trials for predictive oncology. Am Society of Clinical Oncology, Chicago Ill, June 4, 2010.
294. A key hallmark of cancer is heterogeneity; Lessons for therapeutics development. Am Association of Cancer Research Meeting on Translational Cancer Medicine, San Francisco Ca, July 12, 2010.
295. New approaches to clinical trial design for predictive medicine. National Cancer Institute workshop on methods for adaptive quality assurance and trial designs in radiation therapy. Rockville Md, September 7-8, 2010.
296. Novel clinical trial designs for oncology. American Congress of Clinical Pharmacology, Baltimore MD, Sept 13, 2010.
297. Personalized predictive medicine and genomic clinical trials. Workshop on clinical trials: Past, present and future. Sponsored by the National Heart, Lung and Blood Institute, Bethesda MD, September 14, 2010.
298. Predictive analysis of phase III clinical trials. FDA-Industry Statistics Workshop, Washington D.C., September 20, 2010.
299. Adaptive clinical trial designs for simultaneous testing of matched diagnostics and therapeutics. Conference on Clinical Cancer Research sponsored by Engelberg Center for Health Care Reform at Brookings and Friends of Cancer Research, Washington D.C., October 20, 2010.
300. Use of genomics in the design of clinical trials. Short course at the Seventeenth Annual Biopharmaceutical Applied Statistics Symposium, Hilton Head South Carolina, October 10-12, 2010.
301. Prospective-retrospective designs for assessing the medical utility of prognostic and predictive biomarkers. Institute of Medicine Workshop on Evidence Development for Genomic Diagnostic Test Development. Washington D.C. November 17, 2010.
302. Clinical trials for predictive personalized oncology. 4th Seattle Symposium on Biostatistics. Seattle Washington. November 20-23, 2010.

303. Use of genomics for design of phase III clinical trials. Workshop on Androgen receptor signaling in prostate cancer: Translating biology into clinical practice. Arlington VA, December 6-7, 2010.
304. Novel clinical trial designs for use when all cancers are orphan diseases. American Society of Clinical Oncology Workshop on Clinical trial designs in small populations. Alexandria Va. December 9, 2010.
305. The use of archived tissues in evaluating the medical utility of prognostic and predictive biomarkers. Institute of Medicine Workshop on Omics-based Tests for Predicting Patient Outcomes in Clinical Trials. Washington D.C., March 30, 2010.
306. Use of cross-validation to evaluate survival risk with high dimensional data. Workshop on analysis of survival and event history data. Centre de recherches mathématiques, Montreal, May 16-19, 2011.
307. Bottlenecks in Translational Research: New paradigms to enhance progress. Cancer Prediction, Prevention, Prognosis Workshop, Sponsored by The Defense Advanced Research Projects Agency and the National Cancer Institute, Rockville MD, April 25-26, 2011.
308. Adaptive designs for development and validation of predictive biomarkers in randomized clinical trials. International Conference on Sequential Analysis, Stanford University, June 14-16, 2011.
309. Clinical trial designs for development of new drugs and companion diagnostics. FDA Industry Statistics Workshop, Washington D.C., September 19-21, 2011.
310. Probabilistic classification for high dimensional data. Conference on Risk Assessment and Evaluation of Predictions. University of Maryland, October 13-14, 2011.
311. Impact of companion diagnostics on the design of early phase clinical trials. Drug Information Association, Mumbai India, October 15-18, 2011.
312. New paradigms for the development and validation of biomarkers with medical utility. Non-clinical Biostatistics Conference. Harvard School of Public Health. Boston MA, October 18-20, 2011.
313. Clinical trials for predictive medicine. Drug Industry Association/FDA meeting. Rockville MD, October 25-26, 2011.
314. Clinical trials for personalized predictive medicine. Keynote address to the International Chinese Statistical Association, Boston, June 23-26, 2012.