CURRICULUM VITAE December 2006

Name: Richard Macey Simon

Date and Place of Birth: July 27, 1943, St. Louis, Missouri

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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 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 represent NCI in data monitoring and reporting issues. Provide leadership for an active research program in computational biology, bioinformatics, and biomathematics applied to understanding the mechanisms of cancer development and for the discovery and development of molecular diagnostics and treatments. Conduct a training program in computational biology and bioinformatics for mathematical, computational and physical scientists.

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 Journal of Clinical Oncology, 2007-
Editorial Board Clinical Cancer Research, 2004-
Editorial Board Journal of Clinical Oncology 2007-
Editorial Board BMC Bioinformatics, 2005-
Editorial Board Nature Clinical Practice-Oncology, 2005-
Associate Editor Cancer Informatics, 2006-
Academic Editor, PLOS Medicine 2006-
Visiting Professor of Medicine, University of Virginia, 1989.

Visiting Professor Pro Tempore, Cleveland Clinic Foundation, 1988.
Board of Directors, Society for Clinical Trials, 1986 - 1990.
Member, Committee on Controlled Therapeutic Trials, International Union for the Control of Cancer (UICC), 1987 -90
Advisor to Executive Committee of VA Cooperative Studies Program.
Faculty, Cancer Control Science Associates Program.
Program Committee, American Society for Clinical Oncology (1980,1994).
Program Committee, Society for Clinical Trials (1982).
Advisor to American Diabetes Association.
Member of Time Allocation Group for NCI Supercomputer Center.
Member of International Early Breast Cancer Trialists' Collaborative Group.
Member of NIH Committee for Pertussis Vaccine Trials.
Member of Statistical Working Group for AIDS Clinical Trials.
Organizer, International Symposium on Methodologic Issues in Overviews of Randomized Clinical Trials (1986).
Organizer, International Symposium on Interim Monitoring of Randomized Clinical Trials (1992).
Statistical Advisor, National Bone Marrow Donor Registry (1992).
Organizer, Workshop on Statistical Aspects in the Planning and Analysis of Survival Studies. Society for Clinical Trials International Meeting (1992).
Co-organizer, National Workshop on Prognostic Markers for Cancer (1992).
Co-organizer and Editor, NIH Conference on Current Topics in Biostatistics (1993).
Program Committee, American Society of Clinical Oncology (1993).
Member, NIH Epidemiology and Biostatistics Promotion and Tenure Review Panel (1994-Present)
Member, Data Monitoring Board - VA Cooperative Studies Program Study of Systemic Corticosteriods in Chronic Obstructive Pulmonary Disease Exacerbation (1995).
Advisor to Secretary of Department of HHS, Health Resources and Services Administration on modeling the national liver allocation system (1995-1996).
Member, Combined Organization of Statistical Societies Fisher Lectureship Selection committee (1995-1996).
Member, Student Paper Award Committee of the Biometric Society, ENAR (1996,1997).
Member, Blood Products Advisory Committee, Food and Drug Administration, 1994-1996
Program Committee, International Society of Clinical Biostatistics (1996,1998)
Member, Oncologic Drugs Advisory Committee, Food and Drug Administration (1997-2001)
Organizer, Short Course on Statistical Methods in Genomics and Computational Biology, Heidelberg Germany (1999)
Organizer, Oberwolfach Conference on Molecular Biostatistics (1999)
Member, National Research Council Advisory Committee on Applied and Theoretical Statistics, 1999-2003
Organizer, Institute of Pure & Applied Mathematics Conference on Expression Arrays, Genetic Networks and Diseases, UCLA, Nov. 2000
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.
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.
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.
Member, Translational Research in Clinical Trials Committee, Cancer Research UK, 2004-.
Program Committee, Workshop on Pharmacogenomics in Drug Development & Regulatory Decision-Making of DIA, PhRMA & FDA, 2005.
Advisor to Provost, Harvard University for computational biology appointments
Program Committee, American Association of Cancer Research 2006; Subcommittee chair for computational biology and bioinformatics.
Member of NCI Translational Research Working Group, 2005-.
Member of NCI Clinical Trials Operations Committee, 2005-.

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.: Lake 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, Rozencweig, 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 dimethyl-hydrazine. 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.

101. Simon, R, and Lee, YJ.: Nonparametric confidence limits for survival probabilities and median survival time. Cancer Treatment Rep. 66: 37-42, 1982.

102. Anderson, T, Chabner, BA, Young, RC, Berard, CW, Garvin, AJ, Simon, RM, and DeVita, VT.: Malignant lymphoma I: The histology and staging of 473 patients at the National Cancer Institute. Cancer 50: 2699-2707, 1982.

103. Anderson, T, DeVita, VT, Simon, RM, Berard, CW, Canellos, GW, Garvin, AJ, and Young, RC.: Malignant lymphoma II: Prognostic factors and response to treatment of 473 patients at the National Cancer Institute. Cancer 50: 2708-2721, 1982.

104. Abrams, RA, Glaubiger, D, Simon, R, Lichter, A, and Deisseroth, AB.: Hemopoietic recovery in Ewing's sarcoma after intensive combination therapy and autologous marrow infusion. The Lancet II: 385-389, 1980.

105. Simon, R.: Imbalance functions. In Encyclopedia of Statistical Sciences, Vol. IV, S. Kotz and N. L. Johnson, (ed), Wiley, 1983, 19-21.

106. Simon, R.: Randomized clinical trials and research strategy. Cancer Treatment Rep. 66: 1083-1087, 1982.

107. Hubbard, SM, Chabner, BA, DeVita, VT, Jr, Simon, R, Berard, CW, Jones, RB, Garvin, JG, Canellos, GP, Osborne, K, and Young, RC.: Histologic progression in non-Hodgkin's lymphoma. Blood 59: 258-264, 1982.

108. The Non-Hodgkin's Lymphoma Pathologic Classification Project; National Cancer Institute sponsored study of classifications of non-Hodgkin's lymphomas: Summary and description of a working formulation for clinical usage. Cancer 49: 2112-2135, 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.

84. Rubinstein L. and Simon R. Phase I clinical trial design. In *Handbook of Anticancer Drug Development*, Budman DR, Calvert H and Rowinsky E (eds), pp 297-308, Lippincott Williams & Wilkins, Baltimore MD, 2003.

85. Simon R. Clinical trial designs for therapeutic vaccine studies. In *Handbook of CancerVaccines*, Morse MA, Lyerly HK and Clay TM (eds), pp 519-526, Humana Press, Totawa NJ, 2004.

86. Simon R. Clinical trial designs for therapeutic cancer vaccines. In *Tumor Immunology and Cancer Vaccines*, pp 339-350, Khleif S (ed), Kluwer Academic Publishers, Norwell MA, 2005.

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. 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.

90. Simon R. Targets for treatment success (Editorial), Nature Clinical Practice-Oncology 3:1, 2006.

91. Simon R. New approaches to phase II development for molecularly targeted agents. American Society of Clinical Oncology Education Book, 2006.

92. 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.

93. Dobbin KK and Simon RM. Statistical issues in the design and interpretation of Microarray experiments, In Bioinformatics in Cancer and Cancer Therapy, Gordon GG editor, In Press.

94. 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, In Press.

95. Simon R. Identification of pharmacogenomic biomarker classifiers in cancer drug development, In Pharmacogenomics, Anticancer Drug Discovery and Response, F Innocenti editor, Humana Press, In Press.

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.

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., Annaheim, 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 Dug 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 Biostatics, 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, Appllying 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 Vacines 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 Worksop. 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 profileing using DNA microarrays. American Association for the Advancement of Science, San Francisco, February 2001.

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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, Savanah 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, 200.

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 Symposius 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 Me.eting, 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 Virtural 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, Americal 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, Pfeizer 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 Reserarch, 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. Validation of predictive classifiers. Conference on Using the OMIC Technologies to Phenotype Disease, Banff Conference on Allograft Pathology, Banff Canada, June 18-19, 2007.

242. Study designs for evaluation of molecular classifiers for diagnosis and treatment selection. Aggressive Lymphoma 2007- Workshops & Symposium, Gottingen Germany, September 14, 2007.

243. How do you discover new cancer genes? Special Session, European Cancer Congress, Barcelona Spain, September 23-27, 2007.