CURRICULUM VITAE   *January 2019*

Richard Macey Simon

11920 Glen Mill Rd
Potomac MD 20854
202.422-3462

rmaceysimon@gmail.com

Website: http://rsimon.us

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

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

Brief Chronology of Employment

1978 - 2015	Chief, Biometric Research Branch, Division of Cancer Treatment and Diagnosis, National Cancer Institute, Bethesda Maryland
2015 - 2017	Associate Director, Division of Cancer Treatment & Diagnosis, Director, Biometric Research Program Chief, Computational & Systems Biology Branch National Cancer Institute
2017 -	R Simon Consulting Potomac Maryland

I have retired as Director of the Biometric Research Program and Chief of the Computational/Systems Biology for the Division of Treatment and Diagnosis of the National Cancer Institute (NCI) as of July 1, 2017. In addition to overseeing the NCI genomics and drug development program, I provided leadership for an active research program in computational and systems biology applied to translational research. I hired and provided leadership for development of bioinformatic systems which empower biologists to creatively utilize genomic data in development of improved treatments for cancer. I led a team of computational biologists who develop methods for characterizing tumors to understand resistance mechanisms and develop effective combination regimens. My experience and training in biostatistics, computer science, cancer biology, systems pharmacology, computational biology and bioinformatics will now be available to a small group of companies who I will closely work with to develop breakthrough products.

Membership
American Association of Cancer Research
American Association of Immunologists
American Statistical Association (Elected Fellow)
International Society for Computational Biology

Selected Honors
2017 Marvin Zelen Leadership Award for Statistical Science. Awarded by TH Chan School of Public Health, Harvard University
2013 Karl Peace Award of The American Statistical Association "for outstanding statistical contributions for the betterment of society"
2012 National Federal Government Award for Excellence in Technology Transfer for BRB-ArrayTools
Senior Biomedical Research Service, National Institutes of Health.
NIH Director's Award.
NIH Technology Transfer Award
Elected fellow of The American Statistical Association
Snedecor Prize for Best Publication in Field of Biometry

Selected Professional Activities

Editorial Board: Clinical Cancer Research, Biotarget
NIH Tenure Review Committee for Biostatistics & Epidemiology
Member, National Research Council Advisory Committee on Applied and Theoretical Statistics
Architect of BRB-ArrayTools, an integrated software package for microarray data analysis; http://brb.nci.nih.gov
Member of NCI Intramural Center of Excelence for Integrative Cancer Biology and Genomics
Scientific Advisory Committee, French National Research Agency, 2016

Selected Short Courses & Workshops Planned and Conducted:

Short course of biomarker driven adaptive clinical trials. Center of Excellence in Oncology, FDA, February 2017.
Short course on "Bayesian Statistics without the BS"; October 25, 2017. Savanah Georgia, BASS Annual Meeting
Development and validation of prognostic and predictive biomarkers using high dimensional data; Summer Institute;
   Department of Biostatistics, University of Washington; June 2014, 2015, 2016, 2017; with Noah Simon
Design and analysis of genomic clinical trials; American Statistical Association; August 2014; Boston Mass.
Development and validation of prognostic and predictive biomarkers using high dimensional data; Deming Conference
  for Applied Statistics; December 2014; Atlantic City; with Noah Simon
AMS/IMS/SIAM Workshop on Statistics in Functional Genomics, Mt. Holyoke Mass, June 2001.
Short Course in Microarray Data Analysis, Biometric Society (ENAR), March 2002.
Short Course in Microarray Data Analysis, Rockefeller University, April 2002, January 2003. .
Short Course in Microarray Data Analysis, University of Florida, December 2003.
Short Course on Statistical Methods in Genomics and Computational Biology, Heidelberg Germany (1999)

Major Bioinformatics Systems Designed
BRB-ArrayTools (15,000+ registered users in 65+ countries)
BRB-SeqTools
Transcriptional Pharmacology Workbench
GeneMed portable communications hub for molecularly target driven oncology clinical trials

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, 2013.

Matsui S, Simon R, Buyse M. *Design and Analysis of Clinical Trials for Predictive Medicine*, Taylor and Francis Publisher, 2015

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.

109.   Lan, G, Simon, R, and Halperin, M.: Stochastically curtailed tests in Long-term clinical trials. Communications in Statistics - Sequential Analysis 1: 207-219, 1982.

110.   Makuch, RW, and Simon, RM.: Sample size requirements for comparing time to failure among k treatment groups. J. Chron. Dis. 35: 861-867, 1982.

111.   Yarchoan, R, Tosato, G, Blaese, RM, Simon, RM, and Nelson DL.: Limiting dilution analysis of Epstein-Barr virus-induced immunoglobulin production by human B. cells. J. of Exper. Med. 157: 1-14, 1983.

112.   Simon, R.: A long-term prevention study with oxprenolol in coronary heart disease (letter). N. Engl. J. Med. 308: 1161-1162, 1983.

113.   Ostrow, S, Van Echo, DA, Whitacre, M, Aisner, J, Simon, R, and Wiernick, P.: Physiologic alterations in patients undergoing whole body hyperthermia for the treatment of cancer. Cancer Treatment Rep. 65:323-325, 1981.

114.   Simon, R.: The importance of prognostic factors in cancer clinical trials. Cancer Treatment Rep. 68: 185-192, 1984.

115.   Simon, R, and Makuch, RW.: A nonparametric graphical representation of the relationship between survival and the occurrence of an event. Stat. in Med. 3: 35-44, 1984.

116.   Sugarbaker, PH, Vermess, M, Doppman, JL, and Simon, R. Improved detection of vocal lesions with computerized tomographic examination of the liver using ethiodized oil emulsion (EOE-13) liver contrast. Cancer 54: 1489-1495, 1984.

117.   Makuch, R, and Simon, R. Comment on sample size requirements. J. Chron. Dis. 36: 664, 1983.

118.   Garvin, AJ, Simon, RM, Osborne, CE, Merrill, J, Young, RC, and Berard, CW. An autopsy study of histologic progression in non- Hodgkin's lymphomas: 192 cases from the National Cancer Institute. Cancer 52: 393-398, 1983.

119.   Miller, DL, Vermess, M, Doppman, JL, Simon, RM, Sugarbaker, PH, O'Leary, TJ, Grimes, G, Chatterji, DG, and Willis, M.: CT of the liver and spleen with EOE-13: Review of 225 examinations. Am. J. Roent, 143: 235-243, 1984.

120.   Shoemaker, RH, Wolpert-DeFilippes, MK, Kern, DH, Lieber, MM, Kamuch, RW, Melnick, NR, Miller, WT, Salmon, SE, Simon, RM, Venditti, JM, and Von Hoff, JD.: Application of a human tumor colony forming assay to new drug screening. Cancer Res. 45: 2145-2153, 1985.

121.   Eberlein, T, Simon, RM, Fisher, S, and Lippman, ME.: Height, weight and risk of breast cancer relapse. Breast Cancer Res. and Treat.: Vol. 5, No. 1: 81-86, 1985.

122.   Shackney, SE, Levine, AM, Fisher, RJ, Nichols, P, Jaffe, E, Schuette, WH, Simon, RM, Smith, CA, Occhipinti, SJ, Parker, JW, Cossman, J, Young, RC, and Lukes, RJ.: The biology of tumor growth in the non-Hodgkin's lymphomas. A dual parameter flow cytometry study of 220 cases. J. Clin. Investig. 73: 1201-1214, 1984.

123.   Patronas, NJ, DiChiro, G, Kufta, C, Bairamian, D, Kornblith, PL, Simon, RM, and Larson, SM.: Prediction of Survival in Glioma Patients by Means of Positron Emission Tomography (PET). J. of Neurosurgery 62: 816-822, 1985.

124.   Gail, M, and Simon, R.: Testing for qualitative interactions between treatment effects and patient subsets. Biometrics 41: 361-372, 1985.

125.   Eisenberger, MA, Simon, R, O'Dwyer, PJ, Wittes, RE, and Friedman, MA.: A reevaluation of nonhormonal cytotoxic chemotherapy in the treatment of prostatic carcinoma. J. Clin. Oncol. 3: 827-841, 1985.

126.   Simon, R, Wittes, RE, and Ellenberg, SS.: Randomized phase II clinical trials. Cancer Treatment Rep. 69: 1375-1381, 1985.

127.   Norton, L, and Simon, R.: The Norton-Simon Hypothesis Revisited. Cancer Treatment Rep. 70: 163-169, 1986.

128.   Simon, R.: The size of phase III cancer clinical trials. Cancer Treatment Rep. 69: 1087-1092, 1985.

129.   Shackney, SE, Levine, AM, Fisher, RJ, Nichols, P, Jaffe, E, Schuette, WH, Simon, R, Smith, CA, Occhipinti, SJ, Parker, JW, Cossman, J, Young, RC, and Lukes, RJ.: The biology of tumor growth in the non-hodgkin's lymphomas. In 1985 Year Book of Cancer.

130.   Simon, R.: An evaluation of clinical trial designs that randomize composite units rather than individual patients. Experientia (Suppl.) 41: 318-326, 1982.

131.   Berard, C, Bloomfield, C, Bonadonna, G, Brown, B, Glatstein, E, Hoppe, R, Rosenberg, SA, Rudders, R, and Simon, R.: Classification of Non-Hodgkin's lymphomas. Reproducibility of major classification systems. Cancer 55: 91-95, 1985.

132.   Friedman, L, Simon, R, Verter, J, Wittes, J, and Wittes, R, (ed).: Proceedings of the workshop on evaluation of therapy. Stat. in Med. 3: 305-478, 1983.

133.   Ellenberg, SS, Simon, R, and Wittes, RE, (Eds).: Symposium on methodology and quality assurance in cancer clinical trials. Cancer Treatment Rep. 9: 1039-1229, 1985.

134.   Kant, JA, Hubbard, SM, Longo, DL, Simon, RM, DeVita, VT, and Jaffe, ES.: The pathologic and clinical heterogeneity of lymphocyte depleted Hodgkin's disease. J. Clin. Oncol. 4: 284-294, 1986.

135.   Paull, K, Hodes, L, and Simon, RM.: Efficiency of large-scale antitumor screening relative to activity criteria. J. Natl. Cancer Inst. 76: 1137-1142, 1986.

136.   Wittes, RE, Marsoni, S, Simon, R, and Leyland-Jones, B.: The Phase II Trial. Cancer Treatment Rep. 69: 1235-1239, 1985.

137.   Marsoni, S, Ungerleider, RS, Hurson, SB, Simon, RM, and Hammershaimb, LD.: Tolerance to antineoplastic agents in children and adults. Cancer Treatment Rep. 69 1263-1269, 1985.

138.   Wittes, RE, Friedman, MA, and Simon, R, Editorial: Some thoughts on the future of clinical trials in cancer. Cancer Treatment Rep. 70: 241-250, 1986.

139.   Foster, BJ, Clagett-Carr, K, Marsoni, S, Simon, R, and Leyland-Jones, B. The role of hexamethylmelamine in the treatment of ovarian cancer: Where is the needle in the haystack? Cancer Treatment Rep. 70: 1003-1014, 1986.

140.   Hughes, KS, Simon, R, Songhorabodi, S, et al.: Resection of the liver for colorectal carcinoma metastases: A multi-institutional study of patterns of recurrence. Surgery 100: 278-284, 1986.

141.   Olver, IN, Simon, RM, and Aisner, J.: Antiemetic studies: A methodological discussion. Cancer Treatment Rep. 70: 555-564, 1986.

142.   Simon, R.: Confidence intervals for reporting clinical trial results. Ann. of Int. Med. 105: 4429-435, 1986.

143.   Estey, E, Hoth, D, Simon, R, Marsoni, S, Leyland-Jones, B, and Wittes, R.: Therapeutic response in phase I trials of anti-neoplastic agents. Cancer Treatment Rep. 70: 1105-1115, 1986.

144.   Cheson, BD, Jasperse, DM, Simon, R, and Friedman, MA.: A critical appraisal of low-dose cytosine arabinoside in patients with acute nonlymphocytic leukemia and myelodysplastic syndromes. J. Clin. Oncol. 4: 1857-1864, 1986.

145.   Marsoni, S, Hoth, D, Simon, R, Leyland-Jones, B, and Wittes, RE. Clinical Drug development: An analysis of phase II trials--1970-1985. Cancer Treatment Rep. 71: 71-80, 1987.

146.   Simon, R. The role of quantitative overviews of randomized clinical trials in cancer therapeutics. Stat. in Med. 6: 389-396, 1987.

147.   Yusuf, S, Simon, R, and Ellenberg SS, (Eds.): Symposium on methodology for overviews of randomized clinical trials. Stat. in Med. 6: 217-410, 1987.

148.   Guo, S, Talmadge, JE, Simon, R, and Klabansky, RL. A computer program for the analysis of tumor growth curves. Computers in Biomedical Research 20: 37-48, 1987.

149.   Simon, R, and Shaker R. Interactive statistical analysis of survival data. Computers and Biomedical Res. 20: 49-54, 1987.

150.   Cheson, BD, and Simon, R. Low-dose ara-c in acute non-lymphocytic leukemia and myelodysplastic syndromes; A review of 20 years' experience. Seminars in Oncol. 14: 126-133, 1987.

151.   Kant, JA, Hubbard, SM, Longo, DL, Simon, RM, Devita, VT, and Jaffe, ES. The pathologic and clinical heterogeneity of lymphocyte-depleted Hodgkin's disease. 1987 Yearbook of Cancer. Year Book Medical Publishers.

152.   Mather, FJ, Simon, RM, Clark, GM, and Von Hoff, DD. Cardiotoxicity in patients treated with mitoxantrone on Southwest Oncology Group phase II studies. Cancer Treatment Rep. 71: 609-613, 1987.

153.   Hughes, KS, Simon, R, Songhorabodi, S, et al.: Resection of the liver for colorectal carcinoma metastases: A multi-institutional study of indications for resection. Surgery 103:278-288.

154.   Charleson, ME, Ales, KL, Simon, R, and Mackenzie, CR. Why predictive indices perform less well in validation studies. Is it magic or methods? Archives of Int. Med. 147-2155-2161, 1987.

155.   Thall, PF, Simon, R, Ellenberg, SS, and Shrager, R. Optimal two-stage designs for clinical trials with binary response. Stat. in Med. 7: 571-579, 1988.

156.   Thall, PF, Simon, R, and Ellenberg, SS. Two-stage selection and testing designs for comparative clinical trials. Biometrika 75: 303-310, 1988.

157.   Simon, R. How large should a phase II trial of a new drug be? Cancer Treatment Rep. 71: 1079-1085, 1987.

158.   Simon, R, Publication Bias: A problem in interpreting medical data (discussion). J. Royal Statistical Society, Series A, 151,419-463.

159.   Dixon, DO, and Simon, R. Sample size considerations for studies comparing survival curves using historical controls. J. Clin. Epidemiology 41: 1209-1214, 1988.

160.   Simon, R. Optimal two-stage designs for phase II clinical trials. Controlled Clinical Trials 10:1-10, 1989.

161.   Simon, R, Durrleman S, Hoppe, RT, Bonadonna, G, Bloomfield, CD, Rudders, RA, Cheson, BD, and Berard, CW. The non-Hodgkin lymphoma pathologic classification project: Long-term follow-up of 1153 patients with non-Hodgkin lymphomas. Ann. of Int. Med. 109:939-945, 1988.

162.   Durrleman, S, and Simon, R. Flexible regression models with cubic splines. Stat. in Med. 8:551-562, 1989.

163.   Early breast cancer trialists collaborative group. The effects of adjuvant tamoxifen and of cytotoxic therapy on mortality in early breast cancer: An overview of 61 randomized trials among 28,896 women. N. Engl. J. of Med. 319:1681-1691, 1988.

164.   Thall, PF, Simon, R, and Ellenberg, SS. A two-stage design for choosing among several experimental treatments and a control in clinical trials. Biometrics 45:537-548, 1989.

165.   Thall, PF, and Simon, R. Incorporating historical control data in planning phase II clinical trials. Stat. in Med. 9:215-228, 1990.

166.   Mather, FJ, Simon, R, Clark, GM, and VonHoff, DD. A method for the evaluation of dose-toxicity relationships in clinical trials. Stat. in Med. 8:813-824, 1989.

167.   Korn, EL, and Simon, R. Measures of explained variation for survival data. Stat. in Med. 9: 487-504, 1990.

168.   Durrleman, S, and Simon, R. Planning and monitoring of equivalence studies. Biometrics 46:329-336, 1990.

169.   Simon, R, Durrleman, S, Hoppe, RT, Bonadonna, G, Bloomfield, CD, Rudders, RA, Cheson, BD, and Berard, CW. Prognostic factors for patients with diffuse large cell or immunoblastic non-Hodgkin's Lymphomas: Experience of the non-Hodgkin's lymphoma pathologic classification project. Med. and Pediat. Oncol. 18:89-96, 1990.

170.   Rubinstein, LV, Paull, KD, Shoemaker, RH, Simon, RM, Tosini, S, Skehan, P, Scudiero, DA, Monk, A, Boyd, MR. Comparison of in vitro anticancer drug screening data generated with tetrazolium assay (MTT) versus a protein assay (SRB) against a diverse panel of human tumor cell lines. J. Natl. Cancer Inst., 82:1113-1118, 1990.

171.   Korn, EL, Simon, R. Explained residual variation, explained risk and goodness-of-fit. The American Statistician 45:201-206, 1991.

172.   Simon, R. Commentary on the use of prognostic factors in clinical trials. Oncology 4:122-126,1990.

173.   Dixon, DO, and Simon, R. Bayesian subset analysis. Biometrics 47:871-882, 1991.

174.   Simon, R, and Korn, EL. Selecting drug combinations based on dose intensity. J. Natl. Cancer Inst. 82:1469-1476, 1990.

175.   Durrleman, S, and Simon, R. When to randomize? J. Clin. Oncol. 9:116-122, 1991.

176.   Dixon, DD, and Simon, R. Bayesian subset analysis in a Colorectal Cancer Clinical Trial. Stat. in Med. 11:13-22, 1992.

177.   Simon, R. A decade of progress in statistical methodology for clinical trials. Stat. in Med. 10:1789-1818, 1991.

178.   Byar, DP, Schoenfeld, DA, Green, SB, Amato, DA, Davis, R, De Gruttola, V, Finkelstein, DM, Gatsonis, C, Gelber, RD, Lagakos, S, Lefkopoulou, M, Tsiatis, AA, Zelen, M, Peto, J, Freedman, LS, Gail, M, Simon, R, Ellenberg, SS, Anderson, JR, Collins, R, Peto, R, and Peto, T. Design considerations for AIDS trials, N. Engl. J. of Med., vol. 323, no. 19, pp. 1343-1348, 1990.

179.   Russek-Cohen, E, Simon, RM. Qualitative interactions in multifactor studies. Biometrics 49:467-477, 1993.

180.   Smith, MA, Ungerleider, RS, Horowitz, ME, and Simon, R. Doxorubicin dose intensity influences response and outcome for patients with osteogenic sarcoma and Ewing's sarcoma. J. Natl. Cancer Inst., 83:1460-1469, 1991.

181.   Smith, M, Simon, R, Cain, D, and Ungerleider, RS. Children and cancer: A perspective from the Cancer Therapy Evaluation Program of the National Cancer Institute. Cancer 71:3422-3428, 1993.

182.   Torri, V, Simon R, Russek-Cohen, E, Midthune, D, Friedman, M. Relationship of response and survival in advanced ovarian cancer patients treated with chemotherapy, J. Natl. Cancer Inst. 84:407-414, 1992.

183.   Simon, R, Korn, EL. Selecting combinations of chemotherapeutic drugs to maximize dose intensity. J. Biopharmaceutical Statistics 1:247-259, 1991.

184.   Russek-Cohen, E, and Simon, RM. Selecting the best dose when a monotonic dose-response relation exists. Stat. in Med. 13:87-96, 1994.

185.   Chen, TT, and Simon, R. A multiple step selection procedure with sequential protection of preferred treatments. Biometrics 49:753-761, 1993.

186.   Korn, EL, and Simon, R. Selecting dose-intense drug combinations: Metastatic breast cancer. Breast Cancer Res. and Treat. 20:155-166, 1991.

187.   Early Breast Trialists' Collaborative Group. Systemic treatment of early breast cancer by hormonal, cytotoxic or immune therapy (Part 1). Lancet 339:1-15, 1992.

188.   Early Breast Trialists' Collaborative Group. Systemic treatment of early breast cancer by hormonal, cytotoxic or immune therapy (Part 2). Lancet 339:71-85, 1992.

189.   Thall, PF, Simon, R, and Grier, DA. Test based variable selection via cross-validation. Journal of Computational and Graphical Statistics 1:41-62, 1992.

190.   Simon, R. Problems of multiplicity in clinical trials. J. Statistical Planning and Inference 42:209-221, 1994.

191.   Simon, R. Why confidence intervals are useful tools in clinical therapeutics. J. Biopharmaceutical Statistics 3(2): 243-248, 1993.

192.   Simon, R, and Altman, DG. Statistical aspects of prognostic factor studies in oncology. Brit. J. of Cancer 69:979-985, 1994.

193.   Torri, V, Korn, EL, Simon, R. Dose intensity analysis in advanced ovarian cancer patients. Brit. J. of Cancer 67:190-197, 1993.

194.   Korn, EL, Simon, R. Using the tolerable-dose diagram in the design of phase I combination chemotherapy trials. J. Clin. Oncol. 11:794-801, 1993.

195. Simon, R, Thall, P, Ellenberg, SS. New designs for the selection of treatments to be tested in randomized clinical trials. Stat. in Med. 13:417-429, 1994.

196. Thall, PF and Simon, R. Practical Bayesian guidelines for phase IIB clinical trials. Biometrics 50:337-349, 1994.

197. Chen, TT, and Simon, R. A multiple decision procedure in clinical trials. Stat. in Med. 13:431-446, 1994.

198. Koutsoukos, AD, Rubinstein, LV, Faraggi, D, Kalyandrug, S, Weinstein, JN, Paul, KD, and Simon, RM. Discrimination techniques applied to the NCI in-vitro anti-tumor drug screen: Predicting biochemical mechanism of action. Stat. in Med. 13:719-730, 1994.

199. Levin, L, Simon, R, Hryniuk, W. The importance of multi-agent chemotherapy regimens in ovarian carcinoma in a dose intensity analysis. J. Natl. Cancer Inst. 85:1732-1742, 1993.

200. Simon, R. Some practical aspects of the interim monitoring of clinical trials. Stat. in Med. 13:1401-1409, 1994.

201. Chen, TT, Simon, R. Two multi-step selection procedures with possible selection of two treatments of equal prior preference. Communications in Statistics, Theory and Methods 23(3), 781-801, 1994.

202. Chen, TT, Simon, R. Extension of one-sided test to multiple treatment trials. Controlled Clinical Trials 15:124-134, 1994.

203. Korn, EL, Midthune, D, Chen, TT, Rubinstein, LV, Christian, MC, Simon, RM. A comparison of two phase I trial designs. Statistics in Medicine 13:1799-1806, 1994.

204. Faraggi, D., Simon, R. A neural network model for survival data. Statistics in Medicine 14:73-82, 1995.

205. Thall, P F and Simon R. A Bayesian approach to establishing sample size and monitoring criteria for phase II clinical trials. Controlled Clinical Trials 15:463-481, 1994.

206. Thall, PF, Simon R. and Estey E. Bayesian designs for Clinical trials with multiple outcomes. Statistics in Medicine 14:357-379, 1995.

207. Faraggi, D. and Simon R. Maximum likelihood neutral network prediction models. Biometrical Journal 37:713-725,1995.

208. Faraggi D. and Simon R. The maximum likelihood neural network as a statistical classification model. Journal of Statistical Planning and Inference 46:93-104, 1995.

209. Strauss N and Simon R. Investigating a sequence of randomized phase II trials to discover promising treatments. Statistics in Medicine 14:1479-1489,1995.

210. Simon R. Clinical Trials. Encyclopedia of Statistical Sciences 1995 Update. S Kotz, CB Read, DL Banks (eds.) Wiley.

211. Freedman LS, Simon R, Foulkes MA, et al. Inclusion of women and minorities in clinical trials and the NIH Revitalization Act of 1993 - The perspective of NIH Clinical trialists. Controlled Clinical Trials 16:277-285, 1995.

212.	Thall PF, Simon R, Estey E: A new statistical strategy for monitoring safety and efficacy in single-arm clinical trials. Journal of Clinical Oncology 14:296-303, 1996.

213.	Faraggi D and Simon R: A simulation study of cross-validation for selecting an optimal cut- point in univariate survival analysis. Statistics in Medicine 15:2203-2213, 1996.

214.	Russek-Cohen E and Simon R: Evaluating treatments when a gender by treatment interaction may exist. Statistics in Medicine 16:455-464, 1997.

215.	Pompetti F, Simon RM, Freidlin B, et al. Oncogene alterations in primary, recurrent and metastatic human bone tumors. Journal of Cellular Biochemistry 63:37-50,1996.

216.	 Smith M, Arthur D, Camitta B, et al. Uniform approach to risk classification and treatment assignment for children with acute lymphoblastic leukemia. Journal of Clinical Oncology 14:18-24, 1996.

217.	 Korn EL and Simon R. Data monitoring committees and problems of lower than expected accrual or event rates. Controlled Clinical Trials 17:509-525,1996.

218.	Simon R and Freedman LS. Bayesian design and analysis of 2 by 2 factorial clinical trials. Biometrics 53:456-464, 1997.

219.	Parmar MKB, Ungerleider RS and Simon R. Assessing whether to perform a confirmatory randomised clinical trial. Journal of the National Cancer Institute 88:1645-1651, 1996.

220.	Faraggi D and Simon R. Large sample Bayesian inference on the parameters of the proportional hazards model. Statistics in Medicine 16:2573-2586,1997.

221.	Thall PF, Russell KE and Simon R. Variable selection in regression via repeated data splitting. Journal of Computational and Graphical Statistics 6:416-434,1997.

222.	Smith MA, Ungerleider RS, Korn EL, Rubinstein L, Simon R. The role of independent data monitoring committees in randomized clinical trials sponsored by the National Cancer Institute. Journal of Clinical Oncology 15:2736-2743.

223.	Simon R, Freidlin B, Rubinstein L, Arbuck SG, Collins J, Christian MC. Accelerated titration designs for phase I clinical trials in oncology. Journal of the National Cancer Institute 89:1138-1147,1997.

224.	Faraggi D, Simon R, Yaskil E, Kramar A. Bayesian neural network model for censored survival data. Biometrical Journal 39:519-532, 1997.

225.	Smith MA, Chen T, Simon R. Age-specific incidence of acute lymphoblastic leukemia in U.S. children: In utero initiation model. Journal of the National Cancer Institute 89:1542- 1544,1997.

226.	Faraggi D, Simon R. Bayesian variable selection method for censored survival data. Biometrics 54:1475-85, 1998.

227.	Smith MA, Simon R, Strickler HD, McQuillan G, Gloeckler LA, Linet MS. Evidence that childhood acute lymphoblastic leukemia is associated with an infectious agent linked to hygiene conditions. Cancer Causes and Control 9(3):285-98, 1998.

228.	Smith MA, Freidlin B, Gloeckler LA, Simon R. Trends in the reported incidence of primary malignant brain tumors in children in the United States. Journal of the National Cancer Institute 90:1269-1277, 1998.

229. Chen TT, Simon RM, Korn EL, Anderson SJ, Linblad AS, Wieand HS, Douglas HO, Fisher B, Hamilton JM and Friedman MA. Investigation of disease-free survival as a surrogate endpoint for survival in cancer clinical trials. Communications in Statistics- Theory & Methods 27(6):1363-1378, 1998.

230. Ermolaeva O, Rastogi M, Pruitt KD, Schuler GD, Bittner ML, Chen Y, Simon R, Meltzer P, Trent JM and Boguski MS. Data management and analysis for gene expression arrays. Nature Genetics 20:19-23, 1998.

231. Becker KG, Simon RM, Bailey-Wilson JE, Freidlin B, Biddison WE, McFarland HF and Trent JM. Clustering of non-MHC suceptibility candidate loci in human autoimmune diseases. Proc National Academy of Sciences, USA 95(17):9979-84, 1998..

232. Khan J, Simon R, Bittner M, Chen Y, Leignton SB, Pohida T, Smith PD, Jiang Y, Gooden GC, Trent JM and Meltzer PS. Gene expression profiling alveolar rhabdomyosarcoma with cDNA microarrays. Cancer Research 58:5009-13, 1998.

233. Simon R. Bayesian design and analysis of active control clinical trials. Biometrics 55:484-487,1999.

234. Thall PF, Simon RM and Shen Y. Approximate Bayesian evaluation of multiple treatment effects. Biometrics 56:213-219,2000.

235. Simon R. The role of statisticians in intervention trials. Statistical Methods in Medical Research 8:281-286,1999.

236. Simon R. Commentary on "Clinical and sample size considerations: Another perspective" by Lee and Zelen, Statistical Science 15:103-105, 2000.

237. Simon R, Desper R, Papadimitriou C, Peng A, Alberts DS, Taetle R, Trent JM, Schaffer AA. Chromosome abnormalities in ovarian adenocarcinoma III: Using breakpoint data to infer and test mathematical models of oncogenesis. Genes, Chromosomes and Cancer 28:106-120, 2000.

238. Korn EL, Midthune D, Chen TT, Rubinstein LV, Christial MC and Simon RM. Commentary on "Another look at two phase I clinical trial designs", Statistics in Medicine 18:2691-2692, 1999.

239. Radmacher MD and Simon R. A measure of the efficacy of tamoxifen for preventing the initiation and growth of breast tumors. Journal of the National Cancer Institute 92:48-53, 2000. .

240. Hunter L, Taylor RC, Leach SM, Simon R. GEST: A gene expression search tool based on a novel Bayesian similarity metric. Bioinformatics 17 Suppl 1:S115-S122, 2001.

241. Hemmer B, Gran B, Zhao Y, Marques A, Pascal J, Tzou A, Kondo T, Cortese I, Bielekova B, Straus S, McFarland HF, Houghten R, Simon R, Pinilla C, Martin R. Identifiction of candidate T cell epitopes and molecular mimics in chronic Lyme disease, Nature Medicine 5:1375-82,1999.

242. Chen TT, Chute JP, Feigal E, Johnson BE and Simon R. A model to select regimens for phase III clinical trials for extensive stage small cell lung cancer. Journal of the National Cancer Institute 92:1601-1606, 2000..

243. Chute JP, Chen TT Feigal E, Simon R and Johnson BE. Twenty years of phase III trials for patients with extensive stage small cell lung cancer: Perceptible progress. Journal of Clinical Oncology 17: 1794-1801, 1999.

244.   Bittner M, Meltzer P, Chen Y, Jiang Y, Seftor E, Hendrix M, Radmacher M, Simon R, Yakhini Z, Ben-Dor A, Dougherty E, Wang E, Marincola F, Gooden C, Lueders J, Glatfelter A, Pollock P, Gillanders E, Leja D, Dietrich K, Beaudry C, Berens M, Alberts D, Sondak V, Hayward N, and Trent J. Molecular Classification of Cutaneous Malignant Melanoma by Gene Expression Profiling. Nature 406:536-540, 2000.

244.   Nelson MA, Radmacher MD, Simon R, Aickin M, Yang JM, Panda L, Emerson J, Roe D, Adair L, Thompson F, Bangert J, Leong SPL, Taetle R, Salmon S and Trent J. Chromosome abnormalities in malignant melanoma. Clinical significance of non-random chromosome abnormalities in 206 cases. Genes, Chromosomes and Cancer 122:101-109, 2000.

245.   Radmacher MD and Simon R. Estimation of tamoxifen's efficacy for preventing the formation and growth of breast tumors (letter). Journal of the National Cancer Institute 92:943-4, 2000.

246.   Simon R. Are Placebo-controlled clinical trials ethical or needed when alternative treatment exists? Editorial, Annals of Internal Medicine 133:474-5,2000.

247.   Korn EL, Arbuck SG, Pluda JM, Simon R, Kaplan RS and Christian MC. Clinical trial designs for cytostatic agents: Are new approaches needed? Journal of Clinical Oncology 19:265-272, 2001.

248.   Simon RM, Steinberg SM, Hamilton M, Hildesheim A, Khleif S, Kwak LW, Mackall CL, Schlom J, Topalian SL, Berzofsky JA. Clinical Trial Designs for the Early Clinical Development of Therapeutic Cancer Vaccines. Journal of Clinical Oncology 19:1848-54, 2001.

249.   Hedenfalk I, Duggan D, Chen Y, Radmacher M, Bittner M, Simon R, Meltzer P, Gusterson B, Esteller M, Kallioniemi O, Borg A and Trent J. Gene expression profiles of hereditary breast cancer. New England Journal of Medicine 344:549, February 22, 2001.

250.   Simon R. Bayesian subset analysis: Application to studying treatment by gender interactions. Statistics in Medicine 21:2909-2916, 2002.

251.   Radmacher MD, Simon R, Desper R, Taetle R, Schaffer AA and Nelson MA. Graph models of oncogenesis with an application to melanoma. Journal of Theoretical Biology 212:535-548, 2001.

252.   Martin R, Gran B, Zhao Y, Markovic-Plese S, Bielekova B, Marques A, Sung MH, Hemmer B, Simon R, McFarland HF, Pinilla C. Molecular mimicry and antigen-specific T cell responses in multiple sclerosis and chronic cns lyme disease. Autoimmunity 16:187-92, 2001.

253.   Schaffer AA, Simon R, Desper R, Richter J, Sauter G. Tree models for dependent copy number changes in bladder cancer. International Journal of Oncology 18:349-54, 2001.

254.   Smith MA, Freidlin B, Ries LA, Simon R. Increased incidence rates but no space-time clustering of childhood astrocytoma in Sweden, 1973-1992: a population-based study of pediatric brain tumors. Cancer 88:1492-3, 2000.

255.   Zhao Y, Gran B, Pinilla C, Markovic-Plese S, Hemmer B, Tzou A, Whitney L, Biddison WE, Martin R, Simon R. Combinatorial peptide libraries and biometric score matrices permit the quantitative analysis of specific and degenerate interactions between clonotypic T-cell receptors and MHC-peptide ligands. Journal of Immunology 167:2130-41, 2001.

256.   Rosenwald A, Alizadeh AA, Widhopf G, Simon R, Davis RE, Yu X, Yang L, Pickeral O, Powell J, Botstein D, Byrd JC, Grever MR, Chiorazzi N, Wilson WH, Kipps TJ, Brown PO, Staudt LM. Relation of gene expression phenotype to immunoglobulin mutation genotype in chronic lymphocytic leukemia. Journal of

Experimental Medicine 194:1639-47, 2001.

257.   Pinilla C, Rubio-Godoy V, Dutoit V, Guillaume P, Simon R, Zhao Y, Houghten RA,   Cerottini JC, Romero P and Valmori D. Combinatorial peptide libraries as an alternative approach to the identification of ligands for tumor-reactive cytolytic T lymphocytes. Cancer Research 61: 5153-5160, 2001.

258.   Radmacher MD, McShane LM and Simon R. A paradigm for class prediction using gene expression profiles. Journal of Computational Biology 9:505-511, 2002.

259.   Rosenwald A, Wright G, Chan WC, et al. The Use of Molecular Profiling to Predict Survival After Chemotherapy for Diffuse Large B-cell Lymphoma. New Engl JMed 346:1937-47, 2002.

260.   Korn EL, McShane LM, Troendle JF, Rosenwald A and Simon R. Identifying pre-post chemotherapy differences in gene expression in breast tumors: a statistical method appropriate for this aim. British Journal of Cancer 86:1093-1096, 2002.

261.   Sung MH, Zhao Y, Martin R and Simon R. T-cell Epitope Prediction with Combinatorial Peptide Libraries, Journal of Computational Biology 9:527-39, 2002.

262.   Assersohn L, Gangi L, Zhao Y, Dowsett M, Simon R, Powles TJ, Liu ET. The feasibility of using fine needle aspiration from primary breast cancers for cDNA microarray analyses. Clinical Cancer Research 8:794-801, 2002.

263.   Simon R, Radmacher MD, Dobbin K. Design of studies with DNA microarrays. Genetic Epidemiology 23:21-36, 2002.

265.   McShane LM, Radmacher MD, Freidlin B, Yu R, Li MC, Simon R. Methods of assessing reproducibility of clustering patterns observed in analyses of microarray data. Bioinformatics 18:1462-1469, 2002.

266.   Miura K, Bowman ED, Simon R, Peng AC, Robles AI, Jones RT, Katagiri T, He P, Mizukami H, Charboneau L, Kikuchi T, Liotta LA, Nakamura Y, Harris CC. Laser capture microdissection and microarray expression of lung adenocarcinoma reveals tobacco smoking and prognosis-related molecular profiles. Cancer Research 62:3244-50, 2002.

267.   Dobbin K, Simon R. Comparison of microarray designs for class comparison and class discovery. Bioinformatics 18:1462-1469, 2002.

268.   Rubio-Godoy V, Pinilla C, Dutoit V, Borras E, Simon R, Zhao Y, Cerottini JC, Romero P, Houghten R, Valmori D. Toward synthetic combinatorial peptide libraries in positional scanning format (PS-SCL) based identification of CD8+ tumor-reactive T-cell ligands: A comparative analysis of PS-SCL recognition by a single tumor-reactive CD8+ cytolitic T-lymphocyte clone. Cancer Research 62:2058-63, 2002.

269.   Wang E, Miller LD, Ohnmacht GA, Mocellin S, Perez-Diez A, Petersen D, Zhao Y, Simon R, Powell JI, Asaki E, Alexander HR, Durray PH, Herlyn M, Restifo HP, Liu ET, Rosenberg SA, Marincola FM. Prospective molecular profiling of melanoma metastases suggests classifiers of immune responsiveness. Cancer Research 62: 3581-86, 2002.

270.   Edgerton ME, Taylor R, Powell JI, Hunter L, Simon R, Liu E. A bioinformatics tool to mine sequences for microarray studies of mouse models of oncogenesis, Bioinformatics 18(5):774-775, 2002.

271.   Simon R, Radmacher MD, Dobbin K, McShane LM. Pitfalls in the analysis of DNA microarray data for diagnostic and prognostic classification. Journal of the National Cancer Institute 95:14-18, 2003.

272.   Dobbin K, Shih J, Simon R. Statistical design of reverse dye microarrays. Bioinformatics 19:803-810, 2003.

273.   Simon R, Dobbin K. Experimental design of DNA microarray experiments. Biotechniques 34:1-5, 2002.

274.   Sung MH, Simon R. Candidate epitope identification using peptide property models: Application to cancer immunotherapy. Methods 34:460-67, 2004.

275.   Rosenwald A, Wright G, Wiestner A, et al. The proliferation gene expression signature is a quantitative integrator of oncogenic events that predicts survival in mantle cell lymphoma. Cancer Cell 3(2) 185-97, 2003.

276.   Ye QH, Qin LX, Forgues M, He P, Kim JW, Peng A, Simon R, Robles AI, Chen Y, Ma ZC, Wu ZQ, Ye SL, Liu YK, Tang ZY and Wang XW. Predicting metastatic hepatocellular carcinoma using gene expression profiling and supervised machine learning. Nature Medicine 9:416-423, 2003.

277.   Desai KV, Xiao N, Wang W, Gangi L, Green J, Powell JI, Dickson R, Furth P, Hunter K, Kucherlapati R, Simon R, Liu ET and Green JE. Initiating oncogenic event determines gene-expression patterns of human breast cancer models. Proceedings of the National Academy of Science 99:6967-72, 2002.

278.   Borras E, Martin R, Judkowski V, Shukaliak J, Zhao Y, Rubio-Godoy V, Valmori D, Wilson D, Simon R, Houghten R, Pinilla C. J Immunological Methods 267:79-97, 2002.

279.   Sung MH and Simon R. Genome-wide conserved epitope profiles of HIV-1 predicted by biophysical properties of MHC binding peptides. Journal of Computational Biology 11:125-145, 2004..

280.   Vasselli J, Shih JH, Iyengar SR, Maranchie J, Riss J, Worrell R, Torres-Cabala C, Tabios R, MariottiA, Steraman R, Merino M, Walther MM, Simon R, Klausner RD and Linehan WM. Predicting survival in patients with metastatic kidney cancer by gene expression profiling in the primary tumor. Proceedings of the National Academy of Science 100:6958-6963, 2003.

281.   Dobbin K, Shih J and Simon R. Questions and answers on design of dual-label microarrays for identifying differentially expressed genes. Journal of the National Cancer Institute 95:1362-1369, 2003.

282.   Zhao Y, Pinilla C, Valmori D, Martin R, and Simon R. Application of Support Vector Machines for T-cell Epitopes Prediction. Bioinformatics 19:1978-1984, 2003.

283.   Simon R. Using DNA microarrays for diagnostic and prognostic prediction. Expert Review of Molecular Diagnostics, 3(5) 587-595, 2003.

284.   Simon R. Diagnostic and prognostic prediction using gene expression profiles in high dimensional microarray data. British Journal of Cancer 89:1599-1604, 2003.

285.   Korn EL, Troendle JF, McShane LM, and Simon R. Controlling the number of false discoveries: Application to high-dimensional genomic data. Journal of Statistical Planning and Inference 124:379-398, 2004.

286.   Wright G.W. and Simon R. A random variance model for detection of differential gene expression in small microarray experiments. Bioinformatics 19:2448-2455,2003.

287. Wang E, Adams S, Zhao Y, Panelli MC, Simon R, Klein H, Marincola FM. A strategy for detection of known and unknown SNPs using a minimum number of oligonucleotides applicable in the clinical setting. Translational Medicine 1(1):4, 2003.

288. Best CJM, Leiva IM, Chuaqui RF, Gillespie JW, Duray PH, Murgai M, Zhao Y, Simon R, Kang JJ, Green JE, Bostwick DG, Linehan WM, Emmert-Buck MR. Molecular differentiation of high- and moderate-grade human prostate cancer by cDNA microarray analysis. Diagnostic Molecular Pathology 12:63-70, 2003.

289. Park T, Yi S-G, Lee SY, Lee Y-S, Simon R. Evaluation of normalization methods for microarray data. BMC Bioinformatics 4:33, 2003.

290. Glebov OK, Rodriguez LM, Nakahara K, Jenkins J, Cliatt J, Humbyrd C, DeNobile J, Soballe P, Simon R, Wright G, Lynch H, Gallinger S, Buchbinder A, Gordon G, Hawk E, Kirsch IR. Distinguishing right from left colon by the pattern of gene expression. Cancer Epidemiology, Biomarkers & Prevention 12:755-762, 2003.

291. Rosenwald A, Wright G, Leroy K et al. Molecular diagnosis of primary mediastinal B cell lymphoma identifies a clinically favorable subgroup of diffuse large B cell lymphoma related to Hodgkin lymphoma. Journal of Experimental Medicine 198:851-862, 2003.

292. QH Ye, LX Qin, M FOrgues, P He, JW Kim, AC Peng, R Simon, Y Li. et.al. Predicting hepatitis B virus-positive metastatic hepatocellular carcinomas using gene expression profiling and supervised machine learning. Nature Medicine 9:416-23, 2003.

293. Simon R, Supervised analysis when the number of candidate features (p) greatly exceeds the number of cases (n). Association for Computing Machinery SIGKDD Explorations 5:2:31-36, 2003.

294. Sung MH and Simon R. *In silico* simulation of inhibitor drug effects on NF-κB pathway dynamics. Molecular Pharmacology 66:70-75, 2004.

295. Bielekova B, Sung MH, Kadom N, Simon R, McFarland H and Martin R. Expansion and functional relevance of high-avidity myelin-specific $CD4^+$ T cells in multiple sclerosis, The Journal of Immunology 22:3893-3904, 2004.

296. Dobbin K and Simon R. Sample size determination in microarray experiments for class comparison and prognostic classification. Biostatistics 6:27-38, 2005.

297. Dobbin K and Simon R. Experimental Design in Expression Profiling. Section on Computational Methods for High Throughput Genetic Analysis, Encyclopedia of Genetics, Proteomics and Bioinformatics, (eds L Jorde, P Little, M Dunn, S Subramaniam), Wiley 2005.

298. Simon R and Maitournam A. Evaluating the efficiency of targeted designs for randomized clinical trials. Clinical Cancer Research 10:6759-63, 2005.

299. Maitournam A and Simon R. On the efficiency of targeted clinical trials. Statistics in Medicine 24:329-339, 2005.

300. Freidlin B and Simon R. An evaluation of the randomized discontinuation design. Journal of Clinical Oncology 23:5094-98,2005.

301. Varma S and Simon R. Iterative class discovery and feature selection using minimal spanning trees. BMC Bioinformatics 5:126, 2004.

302. Simon R. When is a genomic classifier ready for prime time? Nature Clinical Practice – Oncology 1:4-5, 2004.

303. Dave SS, Wright G, Tan B, et al. Length of survival following the diagnosis of follicular lymphoma is predicted by molecular features of non-malignant tumor-infiltrating immune cells. New England Journal of Medicine 351:2159-69, 2004.

304. Dobbin K, Beer DG, Meyerson M, et al. Inter-laboratory comparability study of cancer gene expression analysis using oligonucleotide microarrays. Clinical Cancer Research 11:565-572, 2005.

305. Simon R. Statistical aspects of class prediction for DNA microarray studies. International Chinese Statistical Association Bulletin, July 2004, 39-44.

306. Simon R. An agenda for Clinical Trials: clinical trials in the genomic era. Clinical Trials 1:468-470, 2004.

307. Zhang X and Simon R. Estimating the number of rate-limiting genomic changes for human breast cancer. Breast Cancer Research and Treatment 91:121-124, 2005.

308. Zhao Y, Li MC and Simon R. An adaptive method for cDNA microarray normalization, BMC Bioinformatics 6:28, 2005.

309. Dobbin KK, Kawasaki ES, Petersen DW, and Simon RM. Characterizing dye bias in microarray experiments. Bioinformatics 21:2430-37, 2005.

310. Ghadimi BM, Grade M, Difillippantonio MJ, Varma S, Simon R, Montagna C, Fuzesi L, Langer C, Becker H, Liersch T, Ried T. Effectiveness of gene expression profiling for response prediction of rectal adenocarcinomas in preoperative chemoradiotherapy, Journal of Clinical Oncology 23:1826-38, 2005.

311. Dobbin K and Simon R. Comment of 'Evaluation of the gene-specific dye bias in CDNA microarray experiments. Bioinformatics 21:2803-4, 2005.

312. Simon R. Development and Validation of Therapeutically Relevant Multi-gene Biomarker Classifiers. Journal of the National Cancer Institute 97:866-7, 2005.

313. Molinaro A, Simon R, Pfeiffer R. Prediction error estimation: A comparison of resampling methods. Bioinformatics 21:3301-3307, 2005.

314. Simon R. DNA microarrays for diagnostic and prognostic prediction. Encyclopedia of Medical Genomics & Proteomics. (J. Fuchs, M. Podda, eds.), Marcel Dekker, New York, 2005.

315. Simon R. Bioinformatics in cancer therapeutics – hype or hope? Nature Clinical Practice Oncology 2:223, 2005.

316. Simon R. Roadmap for developing and validating therapeutically relevant genomic classifiers. Journal of Clinical Oncology 23:7332-41, 2005.

317. Dobbin K and Simon R. Experimental design of DNA microarray studies. Encyclopedia of Genetics, Genomics, Proteomics and Bioinformatics. (L Jorde, P Little, M Dunn & S Subramaniam, eds). Wiley, 2005.

318.   Bea S, Zettl A, Wright G, et al. Diffuse large B-cell lymphoma subgroups have distinct genetic profiles that influence tumor biology and improve gene expression-based survival prediction. Blood 10:1182, 2005.

319.   Yang SX, Simon RM, Tan AR, Nguyen D and Swain SM. Gene Expression Patterns and Profile Changes Pre- and Post-Erlotinib Treatment in Patients with Metastatic Breast Cancer, Clinical Cancer Research 11:6226-32, 2005.

320.   Freidlin B and Simon R. Adaptive signature design: An adaptive clinical trial design for generating and prospectively testing a gene expression signature for sensitive patients. Clinical Cancer Research 11:7872-8, 2005.

321.   Simon R. Validation of pharmacogenomic biomarker classifiers for treatment selection. Cancer Biomarkers 2:89-96, 2006.

322.   Trepicchio WL, Essayan D, Hall ST, Schechter G, Tezak Z, Wang SJ, Weinreich D, Simon R. Designing prospective clinical pharmacogenomic trials- Effective use of genomic biomarkers for use in clinical decision-making. The Pharmacogenomics Journal 6:89-94, 2006.

323.   Simon R, Wang SJ. Use of genomic signatures in therapeutics development. The Pharmacogenomics Journal 6:166-173, 2006.

324.   Zhao Y, Sung MH, Simon R. Artificial intelligence methods for predicting T-cell epitopes, In Immunoinformatics: Predicting Immunogenicity in silico, Methods in Molecular Biology (DR Flower, ed), Humana Press, pp 217-226, 2007.

325.   Simon R. A checklist for evaluating reports of expression profiling for treatment selection. Clinical Advances in Hematology and Oncology 4:219-224, 2006.

326.   Sospedra M, Muraro P, Stefanova I, Zhao Y, Chung K, Li Y, Giulianotti M, Simon R, Mariuzza R, Pinilla C, Martin R. Redundancy in antigen presenting function of the HLA-DR and –DQ molecules in the multiple sclerosis associated HLA-DR2 haplotype1, Journal of Immunology 176:1951-1961, 2006.

327.   Venturini S, Allicotti G, Zhao Y, Simon R, Burton DR, Pinilla C, Poignard P. Identification of peptides from human pathogens able to cross-active an HIV-1-gag-specific CD4+ T cell clone. European Journal of Immunology 36:27-36, 2006.

328.   Simon R, Norton L. The Norton-Simon hypothesis for designing more effective and less toxic chemotherapeutic regimens. Nature Clinical Practice-Oncology 3:406, 2006.

329.   Grade M, Ghadimi M, Varma S, Simon R, Wangsa D, Stapleton L, Liersch T, Becker H, Ried T, Difilippantonio MJ. Selective utilization of the Wnt/β-catenin signaling pathway and aneuploidy-dependent massive deregulation of the cellular transcriptome in human rectal carcinomas. Cancer Research 66:267-282, 2006.

330.   Grade M, Hormann P, Becker S, Hummon AB, Wangsa D, Varma S, Simon R, Liersch T, Becker H, Difilippantonio MJ, Ghadimi BM, Ried T. Gene expression profiling reveals a massive aneuploidy-dependent transcritonal deregulation and distinct differences between lymph node-negative and lymph node-positive colon carcinomas. Cancer Research 67:41-56, 2007.

331.   Grade M, Hormann P, Becker S, Hummon AB, Wangsa D, Varma S, Simon R, Liersch T, Becker H, Difilippantonio MJ, Ghadimi BM, Ried T. Gene expression profiling reveals a massive, aneuploidy-dependent transcriptional deregulation and distinct differences between lymph node-negative and lymph node-positive colon carcinomas, Cancer Research 67:41-56, 2007.

332.   Danforth DN, Zujewshi J, Abati A, Filie A, Prindiville SA, Palmieri D, simon R, Ried T, Steeg PS. Breast ductial lavage and ductal endoscopy for the high risk breast: A comprehensive approach. Journal of Surgical Oncology 94:555-564, 2006..

333.   Simon R. Development and validation of biomarker classifiers for treatment selection. Journal of Statistical Planning and Inference 138(2):308-320, 2008.

334.   Dave SS, Kai F, Wright GW, et al. Molecular diagnosis of Burkitt Lymphoma. New England Journal of Medicine 354:2431-42, 2006.

335.   Simon R. Development and validation of therapeutically relevant predictive classifiers using gene expression profiling. Journal of the National Cancer Institute 98:1169-71, 2006.

336.   Varma S, Simon R. Bias in error estimation when using cross-validation for model selection. BMC Bioinformatics 7:91, 2006.

337.   Dobbin K and Simon R. Sample size planning for developing classifiers using high dimensional DNA microarray data. Biostatistics 8:101-117, 2007.

338.   Simon R. New challenges for 21st century clinical trials, Clinical Trials 4:167-169, 2007.

339.   Dupuy A and Simon RM, Critical review of published Microarray studies for cancer outcome and guidelines on statistical analysis and reporting, Journal of the National Cancer Institute 99:147-157, 2007.

340.   Simon RM Subgroup analysis, Wiley Encyclopedia of Clinical Trials, R D'Agostino, L Sullivan, J Massaro editors, John Wiley & Sons, 2008, Online DOI: 10.1002/9780471462422.eoct1356.

341.   Korn EL, Li MC, McShane LM and Simon R. An investigation of SAM and the multivariate permutation test for controlling the false discovery proportion. Statistics in Medicine 26;4428-4440, 2007.

342.   Lusa L, McShane LM, Radmacher MD, Shih JH, Wright GW, Simon R. Appropriateness of inference procedures based on within-sample validation for assessing gene expression Microarray-based prognostic classifier performance. Statistics in Medicine 26:1102-1113, 2007.

343.   Simon R, Lam A, Li MC, Ngan M, Menenzes S, Zhao Y. Analysis of gene expression data using BRB-Array Tools, Cancer Informatics 2:11-17, 2007.

344.   Jiang W and Simon R. A comparison of bootstrap methods and an adjusted bootstrap approach for estimating prediction error in microarray classification. Statistics in Medicine 26:5320-5334.

345.   Jiang W, Freidlin B, and Simon R. Biomarker adaptive threshold design: "A procedure for evaluating treatment with possible biomarker-defined subset effect. Journal of the National Cancer Institute 99:1036-43, 2007.

346.   Dobbin K, Zhao Y and Simon R. How large a training set is needed to develop a classifier for Microarray data? Clinical Cancer Research 14:108-114, 2008.

347.   Simon R, Zhang X. On the dynamics of breast tumor development in women carrying germline BRCA1 and BRCA2 mutations. International Journal of Cancer 122:1916-17, 2008.

348.   Xu X, Zhao Y, Simon R. Gene sets expression comparison kit for BRB-ArrayTools. Bioinformatics 24:137-139, 2008.

349.   Simon R. Microarray based expression profiling and informatics. Current Opinion in Biotechnology 19:26-29, 2008.

350.   Simon R. Interpretation of genomic data: Questions and answers. Seminars in Hematology 45(3), 196-204. 2008..

351.   Zhao Y, Simon R. BRB-ArrayTools data archive for human cancer gene expression. Cancer Informatics 6:9-15, 2008.

352.   Simon R. Using genomics in clinical trial design. Clinical Cancer Research 14:5984-93, 2008.

353.   Simon, R. Designs and adaptive analysis plans for pivotal clinical trials of therapeutics and companion diagnostics. Expert Opinion on Medical Diagnostics 2:721-29, 2008.

354.   Simon R. Lost in translation: Problems and pitfalls in translating laboratory observations to clinical utility. European Journal of Cancer 44:2707-13, 2008.

355.   Jiang W, Varma S, Simon R. Calculating Confidence Intervals for Prediction Error in Microarray Classification Using Resampling, Statistical Applications in Genetics and Molecular Biology :7(1)article 8, 2008.

356.   Simon R. Simple defensible sample sizes based on cost efficiency: A commentary. Biometrics 64:589-591, 2008.

357.   Qi Q, Zhao Y, Li MC, Simon R. Nonnegative matrix factorization of gene expression profiles: a plug-in for BRB-ArrayTools. Bioinformatics 25: 545-547, 2009.

358.   Hunsberger S, Zhao Y, Simon R. A comparison of phase II study strategies. Clinical Cancer Research 15:5950-5, 2009.

359.   Simon R. Analysis of DNA microarray expression data. Best Practice & Research in Clinical Hematology 22:271-282, 2009.

360.   Simon R. Clinical trial designs for evaluating the medical utility of prognostic and predictive biomarkers in oncology. Personalized Medicine 7:33-47, 2010.

361.   Simon R, Paik S, Hayes DH. Use of archived specimens in evaluation of prognostic and predictive biomarkers. Journal of the National Cancer Institute 101(21):1-7, 2009.

362.   Simon R. Advances in clinical trial design for predictive biomarker discovery and validation, Current Breast Cancer Reports 1(4):216-221, 2009.

363.   Vidaurre T, Wilkerson J, Simon R, Bates SE, Fojo T. Stable disease is not preferentially observed with targeted therapies and as currently defined has limited value in drug development. The Cancer Journal 15:366-373, 2009.

364. Freidlin B, Jiang W, Simon R. The cross-validated adaptive signature design. Clinical Cancer Research 16:691-8, 2010.

365. Zhao Y, Simon R. Development and validation of predictive indices for a continuous outcome using gene expression profiles. Cancer Informatics 9:105-14, 2010.

366. Subramanian J, Simon R. Gene expression-based prognostic signatures in lung cancer: Ready for clinical use? Journal of the National Cancer Institute 102:464-74, 2010.

367. Simon R. Clinical trials for predictive medicine: New challenges and paradigms. Clinical Trials 2010;0:1-9

368. Subramanian J, Simon R. What physicians should look for in evaluating reports of gene expression signatures. Nature Reviews Clinical Oncology 7:466-75, 2010.

369. Simon R. Moving from correlative science to predictive oncology. The EPMA Journal 1(3):377-87, 2010.

370. Subramanian J, Simon R. An evaluation of resampling methods for assessment of survival risk prediction in high dimensional settings. Statistics in Medicine 30(6):642-53, 2011.

371. Simon R. Translational clinical trials in oncology: Key bottlenecks and new paradigms. Expert Reviews in Molecular Medicine 12, e32, 2010.

372. Kim K, Simon R. Probabilistic classifiers with high dimensional data. Biostatistics 12(3): 399-412, 2010.

373. Zhao Y, Simon R. Gene expression deconvolution in clinical samples. Genome Medicine 2:93, 2010

374. Youn A, Simon R. Identifying cancer driver genes in tumor genome sequencing studies. Bioinformatics 27(2):175-81, 2011.

375. Simon, RM, Subramanian J, Li MC, Menezes S. Using cross validation to evaluate prediction accuracy of survival risk classifiers based on high dimensional data. Briefings in Bioinformatics 12(3):203-214, 2011.

376. Simon R, Simon NR. Using randomization tests to preserve type I error with response-adaptive and covariate-adaptive randomization. Statistics and Probability Letters, 81(7):767-772, 2011.

377. Simon RM, Freidlin B. Re: Designing a randomized clinical trial to evaluate personalized medicine: A new approach based on risk prediction. Journal of the National Cancer Institute, 103(5):445, 2011..

378. Iwamoto T, Bianchini G, Booser D, Qi Y, Coutant C, Shiang Y, Santarpia L, Matsuoka J, Hortobagyi GN, Symmans WF, Holmes FA, O'Shaughnessy J, Hellerstedt B, Pippen J, Andre F, Simon R, Pusztai L. Gene pathways associated with prognosis and chemotherapy sensitivity in molecular subtypes of breast cancer. Journal of the National Cancer Institute 103(3):264-272, 2011.

379. Dobbin K, Simon R. Optimally splitting cases for training and testing high dimensional classifiers. BMC Medical Genomics 4:31, 2011.

380. Simon R. Genomic biomarkers in predictive medicine: An interim analysis. EMBO Molecular Medicine 3(8): 429-35, 2011.

381. Simon RM. Does topoisomerase II-alpha gene amplification provide useful information for treatment selection for patients with breast carcinoma? (letter). Journal of Clinical Oncology 29(21):2941, 2011.

382.   Skinner J, Kotliarov Y, Varma S, Mine KL, Yambartsev A, Simon R, Huyen Y and Morgun A. Construct and compare gene coexpression networks with DAPfinder and DAPview. BMC Bioinformatics 12:286, 2011.

383.   Sher HI, Nasso SF, Rubin E and Simon R. Adaptive clinical trial designs for simultaneous testing of matched diagnostics and therapeutics. Clinical Cancer Research 17:6634-40, 2011.

384.   Wang X, Simon R. Microarray-based cancer prediction using single genes. BMC Bioinformatics 12:391, 2011.

385.   Karuri SW, Simon R. A two-stage Bayesian design for co-development of new drugs and companion diagnostics. Statistics in Medicine 31:901-14, 2012.

386.   Simon R. Clinical trials for predictive medicine. Statistics in Medicine 31:3031-40, 2012.

387.   Uccellini L, De Giorgi V, Zhao Y, Tumaini B, Erdenebileg N, Dudley ME, Tomei S, Bedognetti D, Ascierto ML, Liu Q, Simon R, Kottyan L, Kaufman KM, Harley JB, Wang E, Rosenberg SA, Marincola FM. IRF5 gene polymorphisms in melanoma. Journal of Translational Medicine, 2012.

388.   Simon R, Subramanian J. Oncology clinical trials in the genomic era. Proceedings of the Fourth Seattle Symposium on Biostatistics: Clinical Trials, Chapter 5, Weir B and Fleming T eds. Springer, 2013.

389.   Simon R. How to develop treatments for biologically heterogeneous "diseases", Clinical Cancer Research 18:4001-3, 2012.

390.   Matsui S, Simon R, Qu P, Shaughnessy JD, Barlogie B & Crowley J. Developing and validating continuous genomic signatures in randomized clinical trials for predictive medicine, Clinical Cancer Research 18:6065-6073.

391.   Youn A, Simon R. Estimating the order of mutations during tumorigenesis from genome sequencing data. Bioinformatics 28 (12): 1555-61, 2012.

392.   Bekelman JE, Deye JA, Vikram B, Bentzen SM, Bruner D, Curran WJ, Dignam J, Efstathiou JA, FitzGerald TJ, Hurkmans C, Lee JJ, Merchant TE, Michalski J, Palta JR, Simon R, Ten RK, Timmerman R, Tunis S, Coleman CN, Purdy J. Redisigning radiotherapy quality assurance: opportunities to develop an efficient, evidence-based system to support clinical trials- report of the National Cancer Institute Work Group on radiotherapy quality assurance. International Journal of Radiation Oncology, Biology, Physics, 2012.

393.   Hong F, Simon R. The run-in phase III trial design with post-treatment predictive biomarkers. Journal of the National Cancer Institute 106:1628-33, 2013.

394.   Moore CM, Kasivisvanathan V, on behalf of the START consortium: Eggener S, Emberton M, Fütterer J, Gill IS, Grubb R, Hadaschik B, Klotz L , Margolis D, Marks LS, Melamed J, Oto A, Palmer SL, Pinto P, Puech P, Punwani S, Rosenkrantz AB, Schoots IG, Simon R, Taneja S, Turkbey B, Ukimura O, van der Meulen J, Villers A, Watanabe Y. Standards in reporting of MRI targeted biopsies (START): Recommendations from an international working group. European Urology, 2013.

395.   Simon N, Simon R. Adaptive enrichment designs for clinical trials. Biostatistics, doi:10.1093/biostatistics/kxt010, published online March 21, 2013.

396.   Simon R, Polley E. Clinical trials for precision oncology using next generation sequencing. Personalized Medicine 10:485-95, 2013.

397.   Subramanian J, Simon R. Overfitting in prediction models: Is it a problem only in high dimensions. Contemprorary Clinical Trials 36:636-41, 2013.

398.   Youn A, Simon R. Using passenger mutations to estimate the timing of driver mutations and identify mutator alterations. BMC Bioinformatics 2013, 14:363

399.   Wang X, Simon R. Identification of genes potentially synthetic lethal with p53 mutations using a computational biology approach. BMC Medical Genomics doi:10.1186/1755-8794-6-30, 2013.

400.   Simon R, Roychowdhury S. Implementing personalized cancer genomics in clinical trials. Nature Reviews Drug Discovery 12:358-69, 2013.

401.   Abaan OD, Polley EC, Davis SR, Zhu YJ, Bilke S, Walker RL, Pineda M, Gindin Y, Jiang Y, Reinhold WC, Holbeck SL, Simon RM, Doroshow JA, Pommier Y, Meltzer P. The exomes of the NCI-60 Panel: A genomic resource for cancer biology and systems pharmacology. Cancer Research 73:4372-82, 2013..

402.   McShane LM, Cavenagh MM, Lively TG, Eberhard DA, Bigbee WL, Williams PM, Mesirov JP, Polley MC, Kim KY, Tricoli JV, Taylor JMG, Shuman DJ, Simon RM, Doroshow JH, Conley BA. Criteria for the use of omics based predictors in clinical trials. Nature 502:317-20, 2013.

403.   McShane LM, Cavenagh MM, Lively TG, Eberhard DA, Bigbee WL, Williams PM, Mesirov JP, Polley MC, Kim KY, Tricoli JV, Taylor JMG, Shuman DJ, Simon RM, Doroshow JH, Conley BA. Criteria for the use of omics based predictors in clinical trials: Explanation and elaboration. BMC Medicine 11:220, 2013.

404.   Fridlyand J, Simon RM, Walrath JC, Roach N, Buller R, Schenkein DP, Flaherty KT, Allen JD, Sigal EV, Scher HI. Considerations for the effective co-development of targeted cancer therapies and companion diagnostics. Nature Reviews Drug Discovery, Published online Sept 6 2013.

405.   Stamatakis L, Siddiqui MM, Nix JW, Logan J, Rais-Bahrami S, Walton-Diaz A, Hoang AN, Vourganti S, Truong H, Shuch B, Parnes HL, Turkbey B, Choyke PL, Wood BJ, Simon RM, Pinto PA. Accuracy of multiparametric magnetic resonance imaging in confirming eligibility for active surveillance for men with prostate cancer. Cancer 119:3359-63, 2013.

406.   Kummar S, Allen D, Monks A, Polley EC, Hose CD, Ivy SP, Turkbey B, Lawrence S, Kinders RJ, Choyke P, Simon R, Steinberg SM, Doroshow JH, Helman L. Cediranib for metastatic alveolar soft tissue sarcoma. Journal of Clinical Oncology 31:2296-2302, 2013.

407.   Simon R. Drug-diagnostics co-development in oncology. Frontiers of Oncology 2013; 3:315.

408.   Kim KI, Simon R. Using single cell sequencing data to model the evolutionary history of a tumor. BMC Bioinformatics 15:27, January 2014.

409.   Kim KI, Simon R. Over-fitting, generalization and reducing MSE in probabilistic prediction with high-dimensional data. The Biometrical Journal 56:256-69, 2014.

410.   Simon R. Stratification and partial ascertainment of biomarker value in biomarker driven clinical trials. Journal of Pharmaceutical Statistics 24 (5):1011-1021, 2014.

411. Lih CJ, Sims D, Harington R, Polley E, Zhao Y, Mehaffey M, Forbes T, Das B, Walsh W, Datta V, Simon R, Conley B, Chen A, Kummar S, Doroshow J, Williams PM. Analytical validation of a targeted next generation sequencing assay for the MPACT (Molecular Profiling based Assignment for Cancer Therapy) Clinical Trial. Journal of Molecular Diagnostics 18:51-67, 2015.

412. Simon, RM. Class probability estimation for medical studies, The Biometrical Journal, (first appeared online 25February2014).

413. Simon, R. Biomarker based clinical trial design. Chinese Clinical Oncology 2014; 3(3):39

414. Walton-Diaz A, Shakir N, Rais-Bahrami S, Turkbey B, George AK, Rothwax J, Stamatakis L, Hong CW, Siddiqui MM, Okoro C, Raskolnikov D, Su D, Shih J, Han H, Merino MJ, Simon R, Wood BJ, Choyke PL, Pinto PA. Utility of serial multi-parametric MRI in the management of prostate cancer patients on active surveillance. Urologic Oncology 33:202.e1-7, 2015.

415. Polley MYC, Polley EC, Huang EP, Freidlin B, Simon R. Two-stage adaptive cutoff (TACO) design for building and validating a prognostic biomarker signature. Statistics in Medicine 33:5097-5110, 2014.

416. Bedognetti D, Spivey TL, Zhao Y, Uccellini L, Tomei S, Dudley ME, Ascierto ML, De Giorgi V, Liu Q, Delogu LG, Sommariva M, Sertoli MR, Simon R, Wang E, Rosenberg SA, Marincola FM. CXCR3/CCR5 pathways in metastatic melanoma patients treated with adoptive therapy and interleukin-2. British Journal of Cancer doi: 10.1038/bjc.2013.557, 2013.

417. Shakir NA, George AK, Siddiqui MM, Rothwax JT, Rais-Bahrami S, Stamatakis L, Su D, Okoro C, Raskolnikov D, Walton-Diaz A, Simon R, Turkbey B, Choyke PL, Merino MJ, Wood BJ, PintoPA. Identification of threshold prostate-specific antigen levels to optimize the detection of clinically-significant prostate cancer by MRI/US fusion guided biopsy. The Journal of Urology192:1642-9, 2014.

418. Rahma OE, Gammoh E, Simon R, Khleif SN. Is the "3+3" dose escalation phase 1 clinical trial design suitable for therapeutic cancer vaccine development? A recommendation for an alternative design. Cancer Research 20:4758-67, 2014.

419. Rais-Bahrami S, Siddiqui MM, Vourganti S, Turkbey B, Rastinehad AR, Stamatakis L, Truong H, Walton-Diaz A, Hoang AN, Nix JW, Merino MJ, Wood BJ, Simon RM, Choyke PL, Pinto PA. Diagnostic value of biparametric MRI as an adjunct to PSA-based detection of prostate cancer in men without prior biopsies. British Journal of Urology International, doi:10.1111/bju.12639, 2014.

420. Simon R, Blumenthal G, Rothenberg ML, Sommer J, Roberts SA, Armstrong DK, LaVange LM, Pazdur R. The role of non-randomized trials in the evaluation of oncology drugs. Clinical Pharmacology & Therapeutics 97(5): 502-7, 2015.

421. Zhao Y, Polley E, Li MC, Lih CJ, Palmisano A, Sims D, Rubinstein L, Conley B, Chen A, Williams PM, Kummar S, Doroshow J, Simon R. GeneMed: An informatics hub for coordinating next-generation sequencingstudies that support precision oncology studies. Cancer Informatics 14(Suppl 2):45-55, 2015.

422. Simon R. Sensitivity, specificity, ppv and npv for predictive biomarkers. Journal of the National Cancer Institute 107(8)L 153-6, 2015.

423. Kummar S, Fleming GF, Oza AM, et al. Randomized trial of oral cyclophosphamide and veliparib in high-grade serous ovarian, primary peritoneal, or fallopian tube cancers, or BRCA-mutant ovarian cancer. Clinical Cancer Research, 21:1575, 2014.

424.   Kummar S, Williams M, Lih CJ, Polley EC, et al. Application of molecular profiling in clinical trials for advanced metastatic cancers. Journal of the National Cancer Institute 104(4):djv003,2015.

425.   Simon R. Personalized/precision medicine. Wiley StatsRef: Statistics Reference Online (2015).

426.   Simon R. Genomic clinical trials. Wiley StatsRef: Statistics Reference Online (2015).

427.   ICECaP Working Group. The development of intermediate clinical endpoints in cancer of the prostate. Journal of the National Cancer Institute 107(12): djv261, 2015.

428.   Siddiqui MM, Truong H, Rais-Bahrami S, Stamatakis L, Logan J, Walton-Diaz A, Turkbey B, Choyke PL, Wood BJ, Simon RM, Pinto PA. Clinical Implications of a multiparametric magnetic resonance imaging based nomogram applied to prostate cancer active surveillance. The Journal of Urology 193: 1943-9, 2015.

429.   Simon R, Geyer S, Subramanian J, Roychowdhury S. The Bayesian basket design for genomic variant driven phase II trials. Seminars in Oncology 43:13-18, 2016.

430.   Simon R. Genomic driven clinical trials in oncology. Annals of Internal Medicine 165:270-8, 2016.

431.   Simon R. Precision medicine in cancer diagnosis and treatment. Harvard Review of Health Policy http://hhpronline.org/precision-medicine-in-cancer-diagnosis-and-treatment/.

432.   Simon R, Picart-Gebhart MJ. Biomarker based clinical trial design in the era of genomic medicine. Holland-Frei Cancer Medicine, 2016 (In Press).

433.   Siddiqui MM< George AK, Rubin R, Rais-Bahrami S, Parnes HL, Merino MJ, Simon RM, Turkbey B, Choyke PL, Wood BJ, Pinto PA. Efficiency of prostate cancer diagnosis by MR/Ultrasound fusion-guided biopsy vs standard extended-sextant biopsy for MR-visible lesions. Journal of the National Cancer Institute 108(9), 2016.

434.   Palmisano A, Zhao Y Li MC, Polley E, Simon RM. OpenGeneMed: A portable, flexible and customizable informatics hub for the coordination of next-generation sequencing studies in support of precision medicine trials. Briefings in Bioinformatics, doi 10.1093, 1-12, 2016.

435.   Krushkal J, Zhao Y, Hose C, Monks A, Doroshow JH, Simon R. Concerted changes in transcriptional regulation of genes involved in DNA methylation, demethylation and folate-mediated one-carbon metabolism pathways in the NCI-60 cancer cell line panel in response to cancer drug treatment. Clinical Epigenetics (In press).

436.   Muthigi A, George AK, Sidana A, Kongnyuy M, Simon R, Moreno V, Merino MJ, Choyke PL, Turkbey B, Wood BJ and Pinto PA. Missing the mark: Prostate cancer upgrading by systemic biopsy over MRI/TRUS fusion biopsy. Journal of Urology, dx.doi.org/10.1016/j.juro2016, 2016.

437.   Simon R. New designs for basket clinical trials in oncology. Journal of Biopharmaceutical Statistics, published online October 30, 2017; doi.org/10.1080/10543406.2017.1372779

438.   Simon R. Immunotherapy is different: Implications for immunotherapy clinical trial design. Human Vaccines & Immunotherapeutics 2017, 13(9) published online May 24 2017; doi.org/10.1080/21645515.2017.1316910

439.   Simon NR and Simon R. Using Bayesian modeling in frequentist adaptive enrichment designs.

Biostatistics 2018, 19(1):27-41.

440.   R Simon & NR Simon. Inference for multi-marker adaptive enrichment designs. Statistics in Medicine 2017, 36(26):4083-93.

441.   Bender J, Fang J and Simon R. A computational study of the inhibition mechanisms of P-glycoprotein mediated efflux by kinase inhibitors. BMC Systems Biology 2017, 11:108; doi.org/10.1186/s12918-017-0498-xdoi.org/10.1186/s12918-017-0498-x

442.   Simon R. Critical Review of Umbrella, Basket and Platform Designs for Oncology Clinical Trials. Clinical Pharmacology & Therapeutics 2017, published online October 20, 2017; **DOI:** 10.1002/cpt.814

443.   Doroshow JH and Simon RM. On the design of combination chemotherapy. Cell 2017, 171:1476.

444.   Simon R. Personalized Cancer Genomics, In: Annual Review of Statistics and Its Application (2018) 5:1, 169-182.

445.   Simon R. (2017) Clinical trials in precision medicine. In: Verma M & Barh D (eds) Progress and Challenges in Precision Medicine, Chapter 11: 209-217, Academic Press.

446.   Simon R. (2017) Challenges for Biometry in 21st Century Oncology. In: Matsui S., Crowley J. (eds) Frontiers of Biostatistical Methods and Applications in Clinical Oncology. Springer, Singapore

447.   Monks A, Zhao Y, Hose C, Hossein H, Krushkal J, Fang J, Sonkin D, Polley EC, Li MC, Harris E, Wu X, Connelly J, Rapisarda A, Teicher BA, Simon R and Doroshow JW. (2018) The NCI Transcriptional Pharmacodynamic Workbench: A tool to examine dynamic expression profiling of therapeutic response in the NCI60 cell line panel that identifies favorable and adverse combinations. Cancer Research(In Press)

448.   Simon R & Simon N. (2019) Finding the intended use population for a new treatment. J. of Biopharmaceutical Statistics (Submitted).

449.   Simon R & Simon N. Sample size planning for binary classification. BMC Journal of Diagnostic & Prognostic Research (Invited, Submitted).

450.   Simon R. (2019) A review of statistical methods for biomarker driven clinical trials. JCO Precision Oncology (In Press).

451.   Simon R. (2019) Biomarker driven adaptive pivotal clinical trials. In Principles and Practice of Clinical Trials, Piantadosi & Geller eds.

452.   Simon R. & Simon N.R (2019) A new paradigm for subset analysis in randomized clinical trials. In Design and Analysis of Subgroups with Pharmaceutical Applications. N Ting, JC Cappelleri, S Ho & DG Chen eds.

Other Publications

1.   Simon, RM.: The uniform distribution of inventory position for continuous review (s,Q) policies. The Rand Corporation, P3938, 1968.

2.   Simon, RM.: Waiting time till service for a simple inventory model. The Rand Corporation, RM5927-PR, 1968.

3.   Simon, RM, and Boll, CH.: Combining analytic and simultaneous models to relate logistic operations to weapon system performance. In Bureau, R.(ed): *The Organization of Logistic Support Systems*. London University of London Press Ltd., 1971, pp. 71-88.

4.   Woo, KB, and Simon, RM.: Use of polyamine concentrations as a diagnostic tool in cancer detection. In Proceedings of 1972 International Conference of Cybernetics. Institute of Elec. & Electronics Engs., Publishers, 1972, pp. 88-93.

5.   Woo, KB, and Simon, RM.: A quantitative model for relating tumor cell number of polyamine concentrations. In: *Polyamines in Normal and Neoplastic Growth*. Russell, DH, (ed) New York, Raven Press, 1973, pp. 381-393.

6.   Leventhal, BL, Simon, R, Henderson, ES, and Ziegler, JL.: The relation of duration of first remission to survival. In Fliedner, T. (ed): *Prognostic Factors in Human Acute Leukemia*. Germany, Pergamon Press, 1973, Vol. 14, pp. 83-89.

7.   Kenady, DE, Potvin, C, Simon, R, and Chretien, PB.: *In vitro* of thymosin on T cell levels in cancer patients receiving radiation therapy. In *Control of Neoplasia by Modulation of the Immune System*, M. A. Chirigos (Ed.), New York, Raven Press, 1977, pp. 305-313.

8.   Leventhal, BG, Poplack, DG, Johnson, GE, Simon, R, Bowles, C, and Steinberg, S.: The effect of chemotherapy and immunotherapy on the response to mitogens in acute lymphocytic leukemia. In: *Mitogens in Immunobiology*, Oppenheim, J. (ed), New York, Academic Press, 1976.

9.   Norton, L, and Simon, R.: New thoughts on the relationship between tumor growth characteristics and sensitivity to treatment. In Development, Vol. 17, Part B, DeVita, V. T. Jr.(ed), Academic Press.

10. Poplack, DG, Leventhal, BG, Simon, R, Pomeroy, T, Graw, RG, and Henderson, ES.: Treatment of acute lymphatic leukemia with chemotherapy alone or chemotherapy plus immunotherapy. In *Immunotherapy of Cancer: Present Status of Trials in Man*, Windhorst, D, and Terry, WT, (Eds.), New York, Raven Press, 1978, pp 497-501.

11. Simon, R.: The design of prospective clinical trials. Javadpour, N. (Ed.): In *Principles and Management of Urologic Cancer*. Williams and Wilkins Publishing Co., Baltimore, 1979, 291-319.

12. Simon, R.: Heterogeneity and standardization in clinical trials. Tagnon, H. J. and Staquet, MJ, (Eds.): In *Controversies in Cancer Design of Trials and Treatment*. Masson Publishing, New York, 1979, 37-50 .

13. Allegra, JC, Lippman, ME, Thompson, EB, and Simon, R.: The influence of steroid hormone receptors on response to chemotherapy in patients with metastatic breast cancer. In: *Steroid Receptors and the management of Cancer*, E. B. Thompson and M. E. Lippman (Eds.) CRC Press, New York, 1979.

14. Simon, R.: The design and analysis of clinical trials. In *Cancer in the Young*, Levine, A. S.(ed), Masson Publishing Co, 1982, 391-402.

15.   DeVita, VT Jr, Glatstein, EJ, Young, RC, Hubbard, SP, Simon, RM, Ziegler, JL, and Wiernik, PH.: Changing concepts: The lymphomas. Proceedings Second International Conference on Adjuvant Therapy in Oncology. S. Salmon and S. Jones (Eds.). New York, Grune and Stratton Publishing Co., 173-190, 1979.

16.   Simon, R.: Clinical prognostic factors in osteosarcoma. Orthopedics Digest, February 1979: 8.

17.   Allegra, JC, Simon, R, and Lippman, M.: The association between steroid hormone receptor status and the disease-free interval in breast cancer. Proc. Second International Conference on Adjuvant Therapy in Oncology. S. Salmon and S. Jones (Eds.). New York, Grune and Stratton Publishing Co., 1979.

18.   Simon, R.: The design and conduct of clinical trials in oncology. In *Principles and Practice of Oncology*. DeVita, V. T., Hellman, S. and Rosenberg, S. A. (Eds.). Philadelphia, Lippincott Publishing, 1982. pp.198-225.

19.   Young, RC, Chabner, BA, Hubbard, SP, Fisher, RI, Bender, RA, Anderson, T, Simon, RM, Canellos, GP, and DeVita, VT, Jr.: Who is guilty of pseudoscience? Forum 3: 289-291, 1980.

20.   Rosenberg, SA, Rapp, H, Terry, W, Zbar, B, Costa, J, Seipp, C, and Simon, R.: Intralesional BCG therapy of patients with primary stage I melanoma. Proc. Second International Conference Immunotherapy of Cancer: Present Status of Trials in Man. Terry, W. D. and Rosenberg, S. A. (Eds.). New York, Elsevier North-Holland Publishing, 1982, 239-244.

21.   Simon, R.: Use of Regression Models: Statistical Aspects. In *Cancer Clinical Trials: Design, Practice and Analysis*. M.E. Buyse, M. J. Staquet and R. J. Sylvester, Eds. Oxford University Press, 445-466, Oxford, England, 1983.

22.   Simon, R.: Comment on statistical defensibility. The American Statistician 36: 215-216, 1982.

23.   Simon, R.: Biostatistics and data management considerations for multi-center clinical trials. In *Proceedings of the Third Annual Meeting of the Collaborative Cancer Treatment Research Program*. Pan American Health Organization, 1981.

24.   Simon, R.: An evaluation of clinical trial designs that randomize composite units rather than individual patients. In *Proceedings of the Second International Meeting on Clinical Trials in Early Breast Cancer*. Scheurlin, H. (Ed.) Birkhauser Verlag, 1982, 318-326.

25.   Shoemaker, RH, Wolpert-DeFilippes, MK, Melnick, NR, Venditti, JM, Simon, RM, Kern, DH, Lieber, MM, Miller, WT, Salmon, SE, and Von Hoff, DD.: Recent results of new drug screening trials with a human tumor colony forming assay. In Human Tumor Cloning, Salmon, S E, and Trent, J. (Eds.), Orlando, Fl., Grune and Stratton, 1984, 345-356.

26.   Simon, R.: Patient subsets and variation in therapeutic efficacy. In *Current Problems in Clinical Trials*, Chaput de Saintonge, D. M. and Vere, D. W. (Eds.). Oxford, Blackwell Scientific Publications, 444-466, 1984.

27.   Simon, R, and Wittes, RE.: Editorial: Methodologic Guidelines for Clinical Trial Reports. Cancer Treatment Rep. 69: 1-3, 1985.

28.   Simon, R.: Design and Conduct of Clinical Trials. In *Principles and Practice of Oncology*, 2nd Edition. DeVita, VT, Hellman, S, and Rosenberg, SA, (eds.). Philadelphia, Lippincott Publishing, 329-352, 1985.

29.   Simon, R. Methodologic aspects of the design, analysis and reporting of oncology trials. In *Handbook of Biopharmaceutical Statistics for Drug Development* (K. E. Peace, Ed.). Marcel Dekker, New York, 1987.

30.   Simon, R, and Wittes, RE.: Editorial: Methodologic Guidelines for Clinical Trial Reports. Cancer 58: 212-214, 1986.

31.   Guo, S, Simon, R, Talmadge, JE.: A computer program for the comparison of growth curves. American Statistical Association. Proceedings. on Statistical Computation, 236-238, 1986.

32.   Simon, R. Overviews of randomized clinical trials (editorial). Cancer Treatment Rep. 71: 3-5, 1987.

33.   Wittes, RE, Friedman, MA, and Simon, R. Clinical trials. Cancer Treatment Rep. (letter) 70: 1137-1138, 1986.

34.   Simon, R. Statistical tools for subset analysis in clinical trials. In *Recent Results in Cancer Research, Vol. 111*, (Baum M, Kay R, and Scheurlen H, Eds.), Springer Berlin, 55-66, 1988.

35.   Simon, R. A critical assessment of approaches to improving the efficiency of cancer clinical trials. In *Recent Results in Cancer Trials* (Baum M, Kay R, and Scheurlen H. Eds.), Springer Verlag, 1988.

36.   Byar, DP, Anderson, J, Blumenstein, B, Simon, R, Gibbons, RP, Lepor, H, and Olsson, CA. Guidelines for reporting studies of treatment for prostatic cancer. In *A Multidisciplinary Analysis on Controversy in the Management of Prostate Cancer*, Coffey D, Door FA, Karr J(eds.), New York Plenum Corp., 1988, 309-320.

37.   Byar, DP, Anderson, N, Blumenstein, B, Gibbons, RP, Lepor H, and Olsson, CA, and Simon, R. Guidelines for reporting studies of treatment for prostatic cancer. In *Clinical Aspects of Prostate Cancer: Assessment of New Diagnostic and Management Procedures*, Catalora WJ, Coffey DS, Karr SP, (eds) Elsevier, 1989.

38.   Simon, R. Optimization in the design of sequential clinical trials. Computing Science and Statistics: Interface '88, (E.J. Wegman Ed), Am. Statist. Assn., Alexandria, Va., 1988.

39.   Durrleman, S, and Simon, R. The effect of diltiazem on mortality and reinfarction after myocardial infarction (letter). N. Engl. J. of Med. 320: 123, 1989.

40.   Simon, R. Interim analysis: the repeated confidence interval approach (discussion). J. Royal Statistical Society, Series B 51: 531, 1989.

41.   Simon, RM. Design and Conduct of Clinical Trials. In *Principles and Practice of Oncology*, 3rd edition, DeVita, V.T., Hellman, S. and Rosenberg, S.A. (eds.). Philadelphia, Lippincott Publishing, 396-420, 1989.

42.   Freedman, L, Javadpour, N, Sylvester R, Aso Y, Debruyne, FMJ, Fossa, SD, Geller, N, Horwich, A, Levine, L, Mostofi, FK, Murphy, GP, Simon, R, Stenning, SP, and Stoter, G. Basic principles of clinical trials as applied to testicular cancer. In *EORTC Genitourinary Group Monograph 7: Prostate Cancer and Testicular Cancer*. Newling, DWW, Jones WG, (eds), New York: Wiley-Liss, 1990, 255-266.

43.   Dallal, GE, Guo, S, Simon, R, Talmadge, JE.: MUDFIT, multivariate distribution free comparison of growth curves. American Statistician 43:125, 1989.

44.   Simon, R. Designs for efficient clinical trials. Oncology 3:43-48, 1989.

45.   Simon, R, and Friedman, MA. The design and interpretation of clinical trials. In *The Chemotherapy Source Book* (M. Perry, ed.), Williams and Wilkins, Baltimore, Maryland, 1991.

46.   Simon, R. Commentary on the analysis of count data in clinical trials. Oncology 4:106-113, 1990.

47.   Simon, R. Commentary on monitoring of interim data in clinical trials. Oncology 4;134-136, 1990.

48.   Simon, R. Adaptive allocation in clinical trials. 1989 Proceedings of the Biopharmaceutical Section of the American Statistical Association: 23-25, American Statistical Association, Alexandria, VA

49.   Simon, RM. Meta-analysis and cancer clinical trials. In Principles and Practice of Oncology Update Series, DeVita, V.T., Hellman, S. and Rosenberg, S.A. (eds), Philadelphia, Lippincott Publishing, 1991.

50.   Simon, RM. Commentary on interpretation of survival data in clinical trials. Oncology 5:110-114, 1991.

51.   Simon, R. Evaluating differential effect of diet on rat carcinogenesis (letter), J. Natl. Cancer Inst. 83:1261-1262, 1991.

52.   Simon, RM. Design and Conduct of Clinical Trials. In *Principles and Practice of Oncology*, 4th edition, DeVita, V.T., Hellman, S. and Rosenberg, S.A. (eds.). Philadelphia, Lippincott Publishing, 1991.

53.   Simon, R. The NCI program of therapeutic research. Bulletin of Cancer 78:1105-1108, 1991.

54.   Korn, EL, Simon, R, Friedman, MA, and Moore, TD. Phase II trials of small cell lung cancer (letter). J. Clin Oncol 10:1369-1370, 1992.

55.   Torri, V, Simon R, Russek-Cohen, E, Midthune, D, and Friedman, M. Relationship between response and survival in patients with advanced ovarian cancer (letter). J. Natl. Cancer Inst. 84:899, 1992.

56.   Thall, PF, and Simon, R. Bayesian design and monitoring of phase II clinical trials. Proceedings of the 1992 meeting of the International Biometrics Society.

57.   Smith, M, Simon, R. Whole brain irradiation and decline in intelligence : The influence of dose and age on IQ score (Letter). J. Clin. Oncol. 11:195-196, 1993.

58.   Korn, EL, Simon, R. Optimal dose-intense drug combinations subject to toxicity constraints. Proceedings of the Biopharmaceutical Section. American Statistical Association, 1993.

59.   Ellenberg, J, Gail, M, Simon, R, (editors). NIH Conference on Current Topics in Biostatistics, Statistics in Medicine 13:399, 1994.

60.   Ellenberg, S, Geller, N, Simon, R, Yusuf, S, (eds.). Proceedings of "Practical Issues in Data Monitoring of Clinical Trials." Statistics in Medicine 12:415-615, 1993.

61.   Simon, R. Randomized clinical Trials: Principles and Obstacles. Cancer 74:2614-2619, 1994.

62.   Simon, R, Dixon DO and Freidlin B. A Bayesian model for evaluating specificity of   treatment effects in clinical trials. In *Recent Advances in Clinical Trial Design*, Thall PF editor, Kluwer Academic Publishers, Norwell MA, 1995.

63.   Simon, R., Dixon DO and Freidlin B. Bayesian subset analysis of a clinical trial for the   treatment of HIV infections. In *Bayesian Biostatistics*, Berry DA and Stangel D editors,   Marcel-Dekker, New York, 555-576, 1996.

64.   Friedman MA and Simon R. The design and conduct of cancer clinical trials. In *Textbook of Internal Medicine* (Kelley WN editor), Lippincott, Philadelphia 1545-1547, 1996.

65.   Simon R. Adaptive designs in clinical trials: The Lilly experience (Discussion). Biopharmaceutical Report, American Statistical Association, volume 3, no 1 1995.

66.   Simon R and Friedman MA. The design and interpretation of clinical trials. In *The Chemotherapy Sourcebook*, Second Edition, Perry MC (editor), Williams & Wilkins, 127-140, 1996.

67.   Simon, R. Discovering the Truth about Tamoxifen: Problems of Multiplicity in the statistical evaluation of biomedical data. Journal of the National Cancer Institute 87:627-629, 1995.

68.   Thall PF and Simon R: Recent developments in the design of phase II clinical trials. In   *Recent Advances in Clinical Trial Design*. Thall PF editor, Kluwer Academic Publishers,   Boston, 49-72, 1995.

69.   Simon, RM. Design and Analysis of Clinical Trials. In *Principles and Practice of Oncology*, 5th edition, DeVita, V.T., Hellman, S. and Rosenberg, S.A. (eds.). Philadelphia, Lippincott Publishing, 513-527, 1997.

70.   Simon RM and Thall PH Phase II Clinical Trials. In *Encyclopedia of Biostatistics*,   Armitage, P. and Colton T.(Eds.). John Wiley, 1998.

71.   Simon RM. Prognostic Factors for Survival In *Encyclopedia of Biostatistics*, Armitage,   P. and Colton T.(Eds.). John Wiley, 1998.

72.   Simon R. New statistical designs for clinical trials of immunomodulating agents. Kresina,   T.F. (Ed). Marcel Dekker, 539-550, 1998.

73.   Simon R and Freedman LS. Bayesian design and analysis of 2 x 2 factorial clinical trials.   Proceedings of the Bayesian Section of the American Statistical Association, 180-   185,1996 .

74.   Simon R. Clinical Trials. *Encyclopedia of Statistical Sciences*, Update Volume 1, S.Kotz   (editor), 116-124, Wiley 1997.

75.   Simon R. A conversation with Marvin A. Schneiderman. Statistical Science 12:98-102, 1997.

76.   Simon R. Therapeutic Equivalence Trials. In *Handbook of Statistics in Clinical Oncology*, Crowley J. (Ed.). Marcel Dekker, 2001.

77.   Simon R. Meta-analysis of clinical trials: Opportunities and Limitations. pp305-320, In *Meta-Analysis in Medicine and Public Policy*. Stanglel DK and Berry DA editors. Marcel Dekker, 2000

78.   Simon R. New methods for the design and analysis of clinical trials. In Principles and Practice of Oncology Update Series, DeVita, V.T., Hellman, S. and Rosenberg, S.A. (eds), Philadelphia, Lippincott Publishing, (1999).

79.   Simon R. Reading and assessing reports of treatment studies in oncology. Surgical Clinics of North America 80:487-494, 2000.

80.   Simon R. Design and analysis of therapeutic equivalence trials. Chapter 3 in *Advances in Clinical Trial Biostatistics*, Geller N. (ed.), Marcel Dekker 2004.

81.   McShane LM and Simon R. Statistical methods for the analysis of prognostic factor studies, pp 37-48 in *Prognostic Factors in Cancer*, Gospodarowicz, Henson, Hutter, O'Sullivan, Sobin and Wittekind (eds.), Wiley-Liss, New York, 2001.

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.   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 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, Volume 1, pp237-246, (G Ginsburg and H Williard eds), Elsevier, 2nd edition, 2012.

103.   Simon R. Biomarker development as a parallel to drug development. 2012 Genitourinary Cancers Symposium Proceedings. American Society of Clinical Oncology, 2013.

104.   Simon, R.: Design and Conduct of Clinical Trials. In *Principles and Practice of Oncology*, 10th Edition. DeVita, VT, Hellman, S, and Rosenberg, SA, (eds.). Philadelphia, Lippincott Publishing, 329-352, 1985.

105.   Simon R, Piccart Gebhart,M. Biomarker based clinical trial design in the era of genomic medicine. In Holland-Frei Cancer Medicine. DW Kufe, RE Pollock, RR Weichselbaum et al. eds. Wiley publishers, 9th edition, 2015.

107.   Mandrekar SJ, Dahlberg SE, Simon R. Improving clinical trial efficiency: Thinking outside the box. 2015 ASCO Educational Book.

108.   Simon R. Challenges for biometry in 21st century oncology. In Frontiers of Biostatistical Methods and Applications in Clinical Oncology, S Matsui & J Crowley (eds), Springer, 2017.

109.   Simon R. Statistical methods for genomics driven clinical trials. In Oncology Clinical Trials: Successful Design, Conduct and Analysis. S Halabi & WK Kelly (eds). Demos Publishing, (In Press).

110.   Simon R. Adaptive Trial Designs for Biomarker Driven Clinical Trials with Quantitative and Multiple Candidate Biomarkers. Companion and Complementary Diagnostics: From Biomarker Discovery to Clinical Implementation (Editor, Jan Trøst Jørgensen). Elsiever (In Press)

111.   Simon R, Primary site independent clinical trials in oncology. In Platform Trial Designs in Modern Drug

Development (RA Beckman & A Zoran ets.). (In Press).

112.   Zhao Y & Simon R. Developing software for cancer discovery.

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.
.

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.   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 Restance 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 forcasters. 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 wokshop 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 Biopharmacuetical 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 toevaluate survival risk with high dimensional data. Workshop on analysis of survival and event history data. Centre de researches mathematiques, 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 predictive medicine: New paradigms and challenges. Georgetown University, January 2012.

315.   Innovative clinical trial designs for discovering highly effective treatments for molecularly characterized target populations. Multi-institutional prostate cancer program retreat. Fort Lauderdale Fla, March 2012.

316.   Biostatistics for discovery, prediction and decision making in biomedical research. Keynote address, Cerner Symposium, University of Kansas Medical Center. Kansas City Kansas, April 2012.

317.   Predictive analysis of clinical trials. Biometric Society (Eastern North American Region), Washington D.C.,April 2012.

318.   Clinical trials for personalized predictive medicine. Keynote address to the International Chinese Statistical Association, Boston, June 23-26, 2012.

319.   Genomics and personalized medicine: An interim analysis. Keynote address to the Pacific Coast Statisticians and Pharmacometricians Innovation Conference. San Louis Obispo Ca, June 26, 2012.

320.   Predictive analysis of clinical trials. FDA Statistical Association. Silver Spring MD, July 9, 2012.

321.   Predictive analysis of clinical trials. International Biometric Society, Kobe Japan, August 2012.

322.   Cancer clinical trials in the genomic era. Cambridge Health Institute Conference on Clinical Trial Designs for Personalized Therapy, Washington DC, September 20, 2012.

323.   Using genomics to develop effective therapeutics and companion diagnostics. Biomarker Development 2012: Concepts, Assays, Bioinformatics. Austrian Institute of Technology, Vienna Austria, October 3, 2012.

324.   New clinical trial designs for co-development of drugs with companion diagnostics. Millenium, Cambridge MA, October 14, 2012.

325.   Using high dimensional assays in the development of new drugs with companion diagnostics. Novartis Statistics Workshop, Cambridge MA, October 15, 2012.

326.   Development of predictive biomarkers for targeted therapies. IMPACT Smposium on Clinical Trials in the Era of Personalized Medicine, Raleigh NC, Nov 1-2, 2012.

327.   Cancer clinical trials in the genomic era. Deming Conference on Applied Statistics, Atlantic City NJ, Dec 5, 2012.

328. Using prognostic and predictive biomarkers in therapeutics development. 12th annual McGill Workshop on Systems Biology. Barbados, January 25-31 2013.

329. Biomarker development as a parallel to drug development. 2013 Genitourinary Cancers Symposium, American Society of Clinical Oncology, Orlando FL, February 16, 2013.

330. Biomarker validation based on archived tumor tissue from clinical trials to obtain level I evidence for medical utility. Interdisciplinary Workshop on Methodology in Stratified Medicine. Berlin – Brandenburg Academy of Medicine, Berlin, March 18, 2013.

331. Efficient designs for screening combination regimens in cancer immunotherapy development. Cancer Immunotherapy Clinical Trials: Concepts and Challenges. Bethesda MD, April 5, 2013.

332. Finding the right target population for a drug.. FDA-Industry Biostatistics Symposium, Washington D.C.. September 16-18 2013.

333. Big data and biomarkers. FDA-Industry Biostatistics Symposium, Washington D.C. September 16-18 2013.

334. Replacing subset analysis with indication classifier development in clinical trials. FDA-Industry Biostatistics Symposium, Washington D.C. September 16-18 2013.

335. New clinical trial designs for co-development of a drug and diagnostic. Department of Biostatistics and Epidemiology, Memorial Sloan Kettering Cancer Research Center, New York NY, October 2, 2013.

336. New clinical trial designs for co-development of a drug and diagnostic. Drug Information Association, Washington D.C., November 6, 2013.

337. Cancer genomics in drug development and clinical trial design. Medical Grand Rounds, Ohio State University James Cancer Center. January 2014.

338. Cancer genomics and oncology drug development. Department of Biostatistics, University of Pittsburgh, January 2014.

339. Using genomics in oncology clinical trials. Memorial Sloan-Kettering Cancer Center, New York, February 2014.

340. Some new clinical trial designs for prospective use in genomic cancer clinical trials. Department of Biostatistics, Johns Hopkins University, Baltimore MD, March 2014.

341. Using next generation DNA sequencing in cancer clinical trials. Biometrics Society, ENAR, Baltimore MD, March 2014.

342. Workshop on development and validation of prognostic and predictive classifiers with high dimensional data. With Noah Simon. University of Washington Short Course, June 2014.

343. Genomic clinical trials and predictive medicine. One-day short course at the Joint Statistical Meetings, Boston, August 2014.

344. Design of enrichment and adaptive enrichment clinical trials. FDA/Industry Statistical Workshop, September 2014.

345.   An overview of adaptive biomarker-driven clinical trial designs. Biopharmaceutical Applied Statistics Symposium 2014 Meeting, Rockville Maryland, November 2014.

346.   Adaptive biomarker driven clinical trials in oncology. Department of Biostatistics, Johns Hopkins University, Baltimore MD, October 2014.

347.   Adaptive clinical trials. Biopharmaceutical Applied Statistics Symposium. Rockville MD, November 2014.

348.   Software for biological discovery by biologists with genome-wide assays: BRB-ArrayTools. Workshop on Statistical Issues in Biomarker and Drug Co-development, Canadian Statistical Sciences Institute, Toronto, November 2014.

349.   Design and analysis of genome-wide assays to answer medically relevant questions. University of Toronto, Strategic Training for Advanced Genetic Epidemiology Program. Toronto, November 2014.

350.   Evaluating the medical utility of a biomarker test for informing treatment decisions. Evidence-Based Reimbursement Summit, Bethesda MD, November 2014.

351.   Statistical aspects of the design of single arm pivotal clinical trials for breakthrough therapies. Friends-Brookings Conference on Clinical Cancer Research. Engleberg Center for Health Care Reform at Brookings Institution, Friends of Cancer Research. Washington D.C. November 2014.

352.   Workshop on development and validation of prognostic and predictive classifiers with high dimensional data. With Noah Simon. Deming Conference on Applied Statistics, Atlantic City NJ, November 2014.

353.   Adaptive designs for developing and validating predictive biomarkers. ENAR Biometrics Conference, Miami, March 2015.

354.   New paradigms for clinical trials in oncology. Symposium on Innovative Clinical Trial Designs: Personalized Medicine, Statistical and Operational Challenges. Sponsored by Johns Hopkins University, Stanford University and VA Cooperative Studies Program. May 2015.

355.   On the intended use population in clinical trials. FDA-Industry Statistics Workshop, Washington D.C. September 17, 2015.

356.   Cancer biomarkers: Opportunities and obstacles. Plenary Address to meeting of Cancer Steering Committee Annual Meeting of the Biomarkers Consortium of the Foundation of the NIH, Rockville MD, October 15, 2015.

357.   Design of clinical trials for omics data. 5th Seattle Symposium in Biostatistics, November 23, 2015, Seattle Washington

358.   How best to design a personalized medicine trial? What can be learned from oncology trialists. 12th Global Cardiovascular clinical trialists forum. Washington D.C. December 3-4, 2015.

359.   Innovative designs for early clinical trials of immunomodulating agents. Immunotherapy for Cancer, Current Status and Future Prospects. Atlanta Georgia, January 21, 2016.

360.   A New Paradigm for Finding the Subset of Patients who Benefit from a Test Treatment; Tutorial with Noah Simon at Biometrics Society (ENAR) Meeting, Austin Texas, March 7, 2016.

361.   Personalized Oncology in 2015: New paradigms in clinical trial methodology. Session on Statistical Considerations in Personalized Medicine: Concept & Methodology. Biometrics Society (ENAR) Meeting, Austin Texas, March 8, 2016.

362.   Immunotherapy is Different: Clinical Development of Cancer Immunotherapy, National Cancer Policy Forum of the Institute of Medicine. Washington D.C. February 29, 2016.

363.   Innovative designs for genomics driven clinical trials. Workshop on Translational Science in Prostate Cancer, April 4-5, 2016, Rockville MD.

364.   Accuracy measures for predictive biomarkers. Joint Statistical Meetings. Chicago Illinois, July 31, 2016.

365.   A Bayesian design for basket discovery clinical trials. Duke-Industry Symposium on Precision Medicine in Cancer Research ,Duke University, September 24, 2016.

366.   A Bayesian design for basket discovery clinical trials. UMBC-Stanford Workshop on Clinical Trials and Regulatory Science. Baltimore MD, September 24, 2016.

367.   New designs for finding the intended use population in therapeutic clinical trials. Society of Clinical Trials-QSPI Regulatory Fall Innovation Workshop. November 14, 2016.

368.   Efficient clinical trial designs for targeted therapies. 2016 NCRI Cancer Conference. Liverpool UK. Nov 8, 2016.

369.   Statistic Alps, Biomarkers & Classifiers for Diagnostic & Therapeutic Research: Discovery, Study Design and Analysis. 4 day short course, (taught jointly with Lisa McShane), March 19-24, 2017.

370.   Design issues in early cancer prevention trials. Annual Meeting of Division of Cancer Prevention Early Development Contractors. Rockville MD, March 31, 2017.

371.   Novel methods for the development and evaluation of predictive biomarkers. Princeton - Trenton Chapter of Biopharmaceutical Statistics Section of the American Statistical Association. April, 2017.

372.   State of the art in development and validation of models to inform treatment decisions. EMBL-EBI Industry Programme: Predictive modeling of biomarkers workshop. Cambridge MA, May 22-23, 2017.

373.   Enhancements to Adaptive Signature Designs. Invited Discussant on International Webinar on Adaptive Signature Designs by the Royal Statistical Society. July 12, 2017.

374.   Workshop on development and analysis of prognostic and predictive biomarkers using high dimensional assays. Taught jointly with NR Simon. Summer Institutes in Clinical Research. Department of Biostatistics, University of Washington Seattle. July 26, 2017, Seattle Wa.

375.   Determination of the intended use population for adaptive enrichment designs. Duke-FDA Annual Statistics Symposium. Durham NC, September 6-8, 2017.

376.   Analysis of unexpected outcomes. FDA-ASA Biopharmaceutical Workshop, Washington DC, September 26, 2017.

377.   Options for the design of small clinical trials. Department of Transfusion Management, National Institutes of Health, September 26, 2017.

378.   'ayesian 'tatistics: Bayesian statistics without the BS. Workshop presented at the 24th annual Biopharmaceutical Applied Statistics Symposium. November 2017, Savanah Ga.

379.   New designs for Basket clinical trials and comments on exploratory to confirmatory transition. Workshop on Site and Histology – Independent Indications in Oncology. European Medicines Agency, December 14-15 2017, London.

380.   A Workshop on Biomarker Driven Clinical Trials. U.S. Food & Drug Administration, White Oak Maryland, February 27, 2018.

381.   New paradigms for identifying the appropriate intended use population for new therapeutics. FDA/AvaMed Conference on Precision Medicine, Statistical Opportunities and Challenges. Washington D.C. May 9, 2018.

382.   Design of System immunology studies for therapeutics development in immune-oncology. Cancer Immune Responsiveness Workshop, Society for Immunotherapy of Cancer, San Francisco Ca, May 14-15, 2018.

383.   Methods for identification of driver mutations in cancer. Aalborg University, Denmark, May 23, 2018.

384.   New designs for histology agnostic clinical trials. Aalborg University, Denmark, May 24, 2018.

385.   New designs for histology agnostic clinical trials. International Chinese Statistical Association Applied Statistics Symposium, New Brunswick NJ. June 14, 2018.

386.   What is effective translational oncology and where is academic medicine? Jackson Laboratory, Bar Harbor Me, June 27 2018.

387.   BRB-ArrayTools – From Development to 7000 Registered Users in 65 Countries. International Scientific Conference on Biostatistical Advising. University of Oslo, Norway, September 9, 2018.

388.   New developments in the design of basket trials in oncology. FDA-ASA Industry Statistics Workshop. Washington D.C. September 14, 2018.

389.   The impact of genomics on cancer drug development. Washington University Medical School. St. Louis Mo. November 2, 2018.

390.   Role of external data in combination drug development. Panel Discussion; Dr. Rajeshwari Sridhara moderator. Friends of Cancer Research Workshop, Washington D.C. March 2019.

391.   Developmental strategies for diseases where nothing works and there are no predictive biomarkers. Duke – Industry Statistics Symposium, Durham NC, April 2019.

392.   External Controls in clinical trials of rare diseases. Panel Discussion; Dr. Rajeshwari Sridhara moderator. 2019 Accelerating Anticancer Agent Development and Validation (AAADV) Workshop, May 2019, Bethesda MD.

393.   Short Course on Resampling in the evaluation of predictive classifiers. International Chinese Statistical Association. June 2019, Durham NC.