

CURRICULUM VITAE – JULY 2020

Brent Alan Blumenstein, Ph.D.

Date of Birth: February 22, 1944

Education: Emory University, B.S., Chemistry, 1966
Emory University, Ph.D., Biometry, 1974

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Current Position:

Trial Architecture (TriArc) Consulting (dba): Principal Consultant, 2002-present.

Academic Positions:

Emory University: Assistant Professor, joint in Departments of Biometry and Medicine, 1975-1980.

Emory University: Associate Professor, joint in Departments of Biometry and Medicine, 1980-1983.

University of Washington: Department of Biostatistics, Research Associate Professor. Director of the Public Health Computer Facility, School of Public Health and Community Medicine. 1983-1986.

Fred Hutchinson Cancer Research Center: Associate Member, 1983-1993. Biostatistician, Community Cancer Care Evaluation Project, 1984-1986.

Deputy Director, Southwest Oncology Group Statistical Center, 1984-1998.

Fred Hutchinson Cancer Research Center: Full Member, 1993-1998.

University of Washington: Affiliate Professor, Department of Biostatistics, 1993-1998.

University of Washington: Affiliate Professor, Department of Urology, 1993-1998.

Group Statistician, American College of Surgeons Oncology Group, 1998-2002.

Northwestern University: Clinical Professor, Department of Preventive Medicine, 1999-2000.

Duke University: Research Professor, Department of Biostatistics and Bioinformatics, 2001-2002.

Other Positions:

Emory University Department of Biometry, part-time Associate, 1970-1974.

Emory University Computing Center, Acting Director during the Director's sabbatical, 1973-1974.

Emory University Computing Center, Assistant Director, 1974-1975.

Honors, Fellowships and Awards:

NSF traineeship, Emory University Department of Biometry, 1966-1968.

National Research Service Award Senior Postdoctoral Fellow, National Cancer Institute at University of Washington, Department of Biostatistics, 1981-1983.
Fellow, American Statistical Association, 2000.
Emory University 2017 Kutner Distinguished Alumni Award

Societies:

American Statistical Association; President of Atlanta Chapter 1978-1979, Secretary of Atlanta Chapter, 1977-1978.
Society for Clinical Trials, Member, Board of Directors, 1997-2001.
Drug Information Association.

Professional Activities:

Consultant, Georgia State Department of Children and Family Services, 1967-1972.
Consultant, Mead Johnson Pharmaceuticals, Evansville, Indiana, 1967-1972.
Consultant, Southeastern Education Evaluators, Atlanta, Georgia, 1976-1978.
Consultant, Oak Ridge Associated Universities, Medical Division, 1977-1981.
Consultant, Atlanta Cancer Surveillance Center, 1981-1985.
Consultant, Iowa State Health Registry, 1978-1986.
Consultant, Statistical and Epidemiological Research Corporation, 1983-present.
Consultant, Virginia Mason Research Center, 1983-1985.
Member, External Advisory Committee, Multi-Center Clinical Trial of Dichloroacetate in the Treatment of Lactic Acidosis, 1985-1990.
Consultant, St. Jude Children's Research Hospital, 1988.
Consultant, Cancer Research Center of Hawaii, 1988-1989, 1994.
Consultant, City of Hope, 1992.
Consultant, Pittsburgh Cancer Institute, 1993.
Consultant, Massachusetts General Hospital, 1994.
Consultant, Cancer and Leukemia Group B, 1994, 1996, 1997, 2002.
Consultant, American Urological Association Prostate Cancer Panel, 1994-1999.
Member, Executive Committee, PIVOT (Prostate Cancer Intervention versus Observation Trial), 1995-present.
Member, Board of Directors, Statistics and Epidemiology Research Corporation, 1995-1998.
Consultant, Cleveland Clinic, 1996.
Member, American Society for Clinical Oncology Bisphosphonate Panel, 1997-present.
Member, Board of Directors, Society for Clinical Trials, 1998-2001.
Consultant, General and Plastic Surgery Devices Panel CDRH, FDA, 1999-2002.
Member, General and Plastic Surgery Devices Panel. CDRH, FDA, 2002-2007.
Consultant, various CDRH Advisory Committees. FDA, 2002-present.
Member of multiple Data Monitoring Committees, chair of several.

Peer Review Activities:

Current:

Journal of Clinical Oncology (Editorial Board Member)
JAMA Oncology
Journal of Urology

Past:

NCI CCIRC, Subcommittee H, 1998-2002.
NICHD
NIAID
NIH Epidemiology and Disease Control Study Section 1, ad hoc committees.
NHLBI
Journal of the American Statistical Association

Journal of the National Cancer Institute
Urology
American Statistician
Cancer Research
Biometrics
Controlled Clinical Trial
Journal of Registry Management
Urologic Oncology
Member of Integration Panel, DOD Prostate Cancer Initiative, 1997-2001.

Committees:

Emory University:

Affirmative Action Committee, 1974-1976 (data analyst).
Senate Computer Policy Committee. Secretary, 1977-1979. Chairman, 1979-1981.

University of Washington:

School of Public Health and Community Medicine representative on the Health Sciences Computer Advisory Committee, 1983-1986.
Subcommittee on Academic Computing Needs for Computing in the Health Sciences, 1984-1985.

Fred Hutchinson Cancer Research Center:

Library Policy Committee, 1984-1998.
Public Health Sciences Computer Committee, 1986-1988.
Chair, Vendor Independence Subcommittee, 1990-1992.
Chair, Public Health Science Faculty Computer Committee, Chair, 1992-1998.
Computer Advisory Committee, 1990-1998.

Duke University:

Member, Ad hoc Due Diligence Review Committee, Department of Medicine
Member, Electronic Data Capture Committee, Duke Clinical Research Institute

Teaching:

Clinical trials methodology and management, biostatistical concepts for clinicians, nonlinear estimation; multivariate methods; discrete multivariate analysis; introductory graduate biostatistics; biostatistics for allied health graduate students; data base management; FORTRAN and BASIC programming; statistical computation methods; basic statistics; digital computer systems; numerical analysis for in-service high school teachers.

Under Review:

1. Taplin M, Antonarakis ES, Ferrante KJ, Horgan K, Blumenstein B, Saad F, Luo J, de Bono JS. ARMOR3-SV: A Phase 3, Randomized Trial of Galeterone Versus Enzalutamide in AR-V7-expressing Metastatic Castration-Resistant Prostate Cancer. *European Urology*.
2. Melief CJM, Welters M, Vergote I, Kroep JR, Kenter GG, Ottevanger N, Tjalma WAA, Denys H, van Poelgeest MIE, Nijman HW, Reyners AKL, Velu T, Goffin F, Lalisang RI, Krebber WJ, Hooftman L, Visscher S, Blumenstein BA, Stead RB, Gerritsen W, van der Burg SH. Chemo-immunotherapy for advanced cervical cancer is associated with prolonged survival. *Nature*.

Works in Progress:

1. Blumenstein BA. Adventures in the simulation of randomized clinical trials with time-to-event endpoints.
2. Blumenstein BA. Statistical model for delayed realization of a constant hazard ratio.
3. Blumenstein BA. A Kaplan-Meier method for descriptively assessing the impact of post-outcome interventions.

Articles in Refereed Journals:

1. Carpenter FA, Steinhaus JE, Turner ME, Parrott TS, Blumenstein BA, Savino MJ: Computer analysis of changes in electrodermal response due to sedative drugs. **Acta Anaesthesiologica Scandinavica Suppl** 1966; XXIV:157-165.
2. Turner ME, Blumenstein BA, Sebaugh JL: A generalization of the logistic law of growth. **Biometrics** 1969; 25:557-580.
3. Kent BB, Drane JW, Blumenstein BA, Manning JW: A mathematical model to assess changes in baroreceptor reflex. **Cardiology** 1972; 57:295-3102.
4. Schlant RC, Felner JM, Heymsfield SB, Gilbert CA, Shulman NB, Tuttle EP, Blumenstein BA: Echocardiographic studies of left ventricular function and anatomy in uncomplicated essential hypertension. **Cardio-vascular Medicine** 1977; 2:477-491.
5. Dykes FD, Lazzara A, Ahmann P, Blumenstein BA, Schwartz J, Brann AW: Intraventricular hemorrhage: A prospective evaluation of etiopathogenesis. **Pediatrics** 1980; 66:42-49.
6. Felner JM, Blumenstein BA, Schlant RC, Carter AD, Alimurung BN, Johnson MJ, Sherman SW, Klicpera MW, Kutner MH, Drucker LW: Sources of variability in echocardiogram measurements. **Am J Cardiol** 1980; 45:995-1004.
7. Kann HE Jr, Blumenstein BA, Petkas A, Schott MA: Radiation synergism by repair-inhibiting nitrosoureas in L1210 cells. **Cancer Research** 1980; 40:771-775.
8. Hall WD, Douglas MB, Blumenstein BA, Hatcher RA: Blood pressure and oral progestational agents: A prospective study of 119 black women. **Am J Obstet and Gynecol** 1980; 136:344-348.
9. Blumenstein BA, Douglas MB, Hall WD: Blood pressure changes and oral contraceptive use: A study of 2676 black women in the southeastern United States. **Am J Epidemiol** 1980; 112:539-552.
10. Child MA, Lynn MJ, Blumenstein BA, Hedrick MM, O'Day RK, Young JL, Devesa SS: Trends in the incidence of cancer in Atlanta: 1937-1978. **J Med Assoc of Georgia** 1981; 70:731-736.
11. Schlant RC, Felner JM, Blumenstein BA, Wollam GL, Hall WD, Schulman NB, Heymsfield SB, Gilbert CA, Tuttle EP: Echocardiographic documentation of left ventricular hypertrophy in patients treated for essential hypertension. **Eur Heart J** 1982; 3(Suppl. A):171-175.
12. Pinner RW, Haley RW, Blumenstein BA, Schaberg DR, Von Allmen SD, McGowan JE: High cost nosocomial infections. **Infection Control** 1982; 3:143-149.
13. Collins DC, Bain R, Coan P, MacPherson RFC, Blumenstein BA, Hall WD: Presence of the "Beaumont protein" in the serum of oral contraceptive users. **Fertility and Sterility** 1983; 40:490-496.
14. Mecklenburg RS, Benson EA, Benson JW, Blumenstein BA, Fredlund PN, Guinn TS, Metz RJ, Nielsen RL: Long-term metabolic control with insulin pump therapy: Report of experience with 127 patients. **NEJM** 1985; 313:465-468.

15. Mecklenburg RS, Guinn TS, Sannar CA, Blumenstein BA: Malfunction of continuous subcutaneous insulin infusion systems: A one-year prospective study of 127 patients. **Diabetes Care** 1986; 9:351-355.
16. Balducci L, Blumenstein BA, Von Hoff DD, Davis M, Hynes HE, Bukowski RM, Crawford ED: Evaluation of fludarabine phosphate in renal cell carcinoma: A Southwest Oncology Group study. **Ca Treat Rpts** 1987; 71:543-544.
17. Oishi N, Berenberg J, Blumenstein BA, Johnson K, Rivkin SE, Bukowski RM, O'Bryan RM, Stephens RL, Quagliana J, Saiers JH: Teniposide in metastatic renal and bladder cancer: A Southwest Oncology Group study. **Ca Treat Rpts** 1987; 71:1307-1308.
18. Saiers JH, Blumenstein BA, Slavik M, Costanzi JJ, Crawford ED: Phase II study of Spirogermanium in advanced adenocarcinoma of the prostate: A Southwest Oncology Group study. **Ca Treat Rpts** 1987; 71:1305-1306.
19. Mullarkey MF, Blumenstein BA, et al: Methotrexate in the treatment of corticosteroid-dependent asthma: A double-blind crossover study. **NEJM** 1988; 318:603-607.
20. Gagliano RG, Blumenstein BA, Crawford ED, Stephens RL, Coltman CA, Costanzi JJ: Cis-diamminedichloroplatin in the treatment of advanced epidermoid carcinoma of the penis: A Southwest Oncology Group study. **J Urol** 1989; 141:66-67.
21. Crawford ED, Eisenberger MA, McLeod DG, Spaulding JT, Benson R, Dorr FA, Blumenstein BA, Davis MA, Goodman P: A controlled trial of leuprolide with and without flutamide in prostatic carcinoma. **NEJM** 1989; 321:419-424.
22. Blumenstein BA: The relational data base model and multiple multicenter clinical trials. **Cont Clin Trials** 1989; 10:386-406.
23. Mullarkey MF, Lammert JK, Blumenstein BA: Long-term methotrexate treatment of corticosteroid-dependent asthma. **Ann Intern Med** 1990; 112:577-581.
24. Von Hoff DD, Blumenstein BA, Pollock TW, Crawford ED, Weick JK, Guy JT, Eisenberger M, Fletcher WS, Natale RB: Methylglyoxal bis-guanylhydrazone in advanced bladder cancer. **Eur J Cancer** 1990; 26:848-849.
25. Osborne CK, Blumenstein BA, Crawford ED, Coltman CA, Smith AY, Lambuth BW, Chapman RA: Combined versus sequential chemo-endocrine therapy in advanced prostate cancer: Final results of a randomized Southwest Oncology Group Study. **J Clin Oncology** 1990; 8:1675-1682.
26. Crawford ED, Blumenstein BA, Goodman PJ, Davis MA, Eisenberger MA, McLeod DG, Spaulding JY, Benson R, Dorr FA: Leuprolide with and without flutamide in advanced prostate cancer. **Cancer** 1990; 66(Supplement):1039-1044.
27. Wozniak AJ, Samson MK, Shah NT, Crawford ED, Ford CD, Altman SJ, Stephens RL, Natale RB, Bouroncle B, Blumenstein BA, Cummings GD: A randomized trial of cisplatin, vinblastine, and bleomycin vs. vinblastine, cisplatin, and etoposide in the treatment of advanced germ cell tumors of the testis: A Southwest Oncology Group study. **J Clin Oncology** 1991; 9:70-76.
28. Morgan WM, Blumenstein BA: Exact conditional tests hierarchical models in multidimensional contingency tables. **Applied Statistics** 40:435-442, 1991.
29. Lamm DL, Blumenstein BA, Crawford ED, Montre JE, Scardino P, Grossman HB, Stanisic TH, Smith JA, Sullivan J, Sarosdy MF, Crissman JD, Coltman CA: A randomized trial of intravesical doxorubicin and immunotherapy with bacille calmette-guerin for transitional-cell carcinoma of the bladder. **NEJM** 1991; 325:1205-1209.

30. Higano CS, Goodman P, Craig JB, Kish JA, Rivkin SE, Blumenstein B, Crawford ED: Phase II evaluation of amonafide in renal cell carcinoma: A Southwest Oncology Group study. **Invest New Drugs** 1991; 9:361-363.
31. Meyers FJ, Blumenstein BA, Crawford ED, Hynes HE, Montie JE, Taylor SA, Grossman HB, Natale RB: Combination cisplatin and dichloromethotrexate in patients with advanced bladder cancer. Phase II Southwest Oncology Group study. **J Urol** 1992; 148:52-54.
32. Osborne CK, Blumenstein BA, Crawford ED, Weiss GR, Bukowski RM, Larrimer NR: Phase II study of platinum and mitoxantrone in metastatic prostate cancer: A Southwest Oncology Group study. **Eur J Cancer** 1992; 28:477-478.
33. Loehrer PJ Sr, Einhorn LH, Elson PJ, Crawford ED, Kuebler P, Tannock I, Raghavan D, Stuart-Harris R, Sarosdy MF, Lowe BA, Blumenstein BA, Trump D: A randomized comparison of cisplatin alone or in combination with methotrexate, vinblastine, and doxorubicin in patients with metastatic urothelial carcinoma: A cooperative group study. **J Clin Oncology** 1992; 10:1066-1073.
34. Bukowski RM, Wolf M, Kulander BG, Montie J, Crawford ED, Blumenstein B: Alternating combination chemotherapy in patients with extragonadal germ cell tumors. **Cancer** 1993; 71:2631-2638.
35. Blumenstein BA, Saiers JH, Stephens RL, Rivkin SE, Sarosdy MF, Tranum B, Costanzi JH, Crawford ED: Doxorubicin, mitomycin-C and 5-fluorouracil in the treatment of metastatic adenocarcinoma of the prostate: A Southwest Oncology Group study. **J Urol** 1993; 150:411-413.
36. Blumenstein BA: Verifying keyed medical research data. **Statistics in Medicine** 1993; 12:1535-1542.
37. McLeod DG, Benson R, Blumenstein BA, Eisenberger M, Crawford ED, Spicer D, Spaulding J: The use of flutamide in hormone refractory metastatic prostate cancer. **Cancer Supplement** 1993; 72:3870-3879.
38. Blumenstein BA: Some statistical considerations for the interpretation of trials of combined androgen therapy. **Cancer Supplement** 1993; 72:3834-3840.
39. Wozniak AJ, Blumenstein BA, Crawford ED, et al: Cyclophosphamide, methotrexate and 5-fluorouracil in the treatment of metastatic prostate cancer: A Southwest Oncology Group study. **Cancer** 1993; 71:3975-3978.
40. Marshall ME, Wolf MK, Crawford ED, Taylor S, Blumenstein B, Flanigan R, et al: Phase II trial of echinomycin for the treatment of advanced renal cell carcinoma. A Southwest Oncology Group study. **Invest New Drugs** 1993; 11:207-209.
41. Taylor SA, Blumenstein BA, Stephens RL, Crawford ED, Pistone B, Hill JB: Phase II trial of menogaril in metastatic adenocarcinoma of the prostate: A Southwest Oncology Group study. **Invest New Drugs** 1994; 12:67-70.
42. Flanigan RC, Saiers JH, Wolf M, Kraut EH, Smith AY, Blumenstein B, Crawford ED: Phase II evaluation of merbarone in renal cell carcinoma. **Invest New Drugs** 12:147-149, 1994.
43. Thompson IM, Paradelo JC, Crawford ED, Coltman CA, Blumenstein BA: An opportunity to determine optimal treatment of pT3 prostate cancer: the window may be closing. **Urology** 1994; 44:804-811.
44. Thompson IM, Blumenstein BA, Crawford ED, Marshall ME, Craig JB, Eisenberger M, Ahmann F: Phase II trial of amonafide for the treatment of advanced, hormonally refractory

- carcinoma of the prostate: A Southwest Oncology Group study. **Am J Clin Oncology** 1994; 17:514-515.
45. Blumenstein BA, James KE, Hermanson BK, Mitchell HE: Functions and organization of coordinating centers for multicenter studies. **Controlled Clin Trials** 1995; 16:4S-29S.
 46. Feigl PF, Blumenstein BA, Thompson I, Crowley J, Wolf M, Kramer B, Coltman CA, Brawley OW, Ford LG: Design of the Prostate Cancer Prevention Trial (PCPT). **Controlled Clin Trials** 1995; 16:150-163.
 47. Sarosdy MF, deVere White RW, Soloway MS, Sheinfeld J, Hudson MA, Schellhammer PF, Jarowenko MV, Adams G, Blumenstein BA: Results of a multicenter trial using the bladder tumor antigen test to monitor for and diagnose recurrent bladder cancer. **J Urol** 1995; 154:379-384.
 48. Blumenstein BA: Overview analysis issues using combined androgen deprivation overview analysis as an example. **Urologic Oncology** 1995; 1:95-100.
 49. Lamm DL, Blumenstein BA, Crawford ED, Crissman JD, Lowe BA, Smith JA, Sarosdy MF, Schellhammer PF, Sagalowsky AI, Messing EM, Loehrer P, Grossman HB: Randomized intergroup comparison of bacillus calmette-guerin immunotherapy and mitomycin C chemotherapy prophylaxis in superficial transitional cell carcinoma of the bladder: A Southwest Oncology Group study. **Urol Oncology** 1995; 1:119-126.
 50. Marshall ME, Wolf M, Crawford ED, Weiss GR, Ahmann F, Meyers F, Blumenstein BA, Eisenberger M, Einstein A: Phase II trial of CHIP for the treatment of advanced, hormonally refractory carcinoma of the prostate: A Southwest Oncology Group study. **Am J Clin Oncology** 1995; 18:400-402.
 51. Berry DL, Blumenstein BA, Magyary DL, Lamm DL, Crawford ED. Local toxicity patterns associated with intravesical bacillus calmette-guerin. A Southwest Oncology Group Study. **Int J Urol** 1996; 3:98-100.
 52. DeVere White RW, Deitch AA, Tesluk H, Blumenstein, BA, Lowe BA, Sagalowsky AI, Smith JA, Schellhamer PF, Stanisic TH, Grossman HB, Messing E, Crissman JD, Crawford ED. Prognostic significance of DNA ploidy in Ta/T1 bladder cancer. A Southwest Oncology Group study. **Urologic Oncology** 1996; 2:27-34.
 53. Elias L, Blumenstein BA, Kish J, Wade JL, Fletcher WS, Goodwin JW, Crawford ED. A phase II trial of interferon-alpha and 5-fluorouracil in advanced renal cell carcinoma. A Southwest Oncology Group study. **Cancer** 1996; 78:1085-1088.
 54. Bostwick D, Wheeler T, Blute M, Barrett D, MacLennan G, Sebo T, Scardino P, Humphrey P, Hudson M, Fradet Y, Miller G, Crawford ED, Blumenstein B, Mahran H, Miles B. Optimized microvessel density analysis improves prediction of cancer stage from prostate needle biopsies. **Urol** 1996; 48:47-57.
 55. Smith Jr. JA, Crawford ED, Paradelo JC, Blumenstein BA, et al. Treatment of advanced bladder cancer with combined preoperative irradiation and radical cystectomy versus radical cystectomy alone. A Phase III intergroup study. **J Urol** 1997; 157:805-808.
 56. Schröder FH, Norming U, Blumenstein B, Busch C, van Glabbeke M, Høisæter PA, Johansson JE, Tribukait B. Phase II studies on prostate cancer. **Urol** 1997; 49:3-14.
 57. Leyh H, Hall R, Mazeman E, Blumenstein BA. Comparison of the Bard BTA test with voided urine and bladder wash cytology in the diagnosis and management of cancer in the bladder. **Urol** 1997; 50:49-53.

58. Newcomer LM, Stanford JL, Blumenstein BA, Brawer MK. Temporal trends in rates of prostate cancer: declining incidence of advanced stage disease, 1974-1990. **J Urol** 1997; 158:1427-1430.
59. Sarosdy MF, Hudson MA, Ellis WJ, Soloway MS, deVere White RW, Sheinfeld J, Jarowenko MV, Schellhammer PF, Messing EM, Schervish EW, Patel JV, Chodak GW, Lamm DL, Johnson RD, Henderson M, Adams G, Blumenstein BA, Thoenke KR, Brunelle SL, Pfalzgraf RD, Murchison HA. Improved detection of recurrent bladder cancer using the Bard® BTA *stat*TM test. **Urol** 1997; 50:349-353.
60. Ellis WJ, Blumenstein BA, Ishak LM, Enfield DL, and the Multicenter Study Group. Clinical evaluation of the BTA TRAK assay and comparison to voided urine cytology and the Bard BTA Test in patients with recurrent bladder tumors. **Urol** 1997; 50:882-887.
61. Stanford JL, Just JJ, Gibbs M, Wicklund KG, Cassandra L, Blumenstein BA, Ostrander EA. Polymorphic repeats in the androgen receptor gene: molecular markers for prostate cancer risk. **Cancer Research** 1997; 57:1194-1198.
62. Schroder LE, Blumenstein BA, Flanigan RL, Crawford ED. Phase II evaluation of Doxorubicin/Vinblastine combined with inhibitors Trifluoperazine/Verapamil of P-Glycoprotein in patients with advanced renal carcinoma. **Urologic Oncology** 1997; 3:94-98.
63. Lin DW, Noteboom JL, Blumenstein BA, Ellis WJ, Lange PH, Vessella RL. Serum percent free Prostate-specific antigen (f-PSA) in metastatic prostate cancer. **Urology** 1998; 52:366-371.
64. Eisenberger MA, Blumenstein BA, Crawford ED, Miller G, McLeod DG, Loehrer PJ, Wilding G, Sears K, Thompson IMJr, Bueschen AJ, Lowe BA. Bilateral orchiectomy with or without flutamide for metastatic prostate cancer. **NEJM** 1998; 339:1036-1042.
65. Moinpour CM, Savage MJ, Troxel A, Lavato LC, Eisenberger M, Veith RW, Higgins B, Skeel R, Yee M, Meyskens F, Crawford ED, Blumenstein BA. Quality of life outcomes for patients with advanced cancer of the prostate from a randomized, double-blind study comparing flutamide to placebo following orchiectomy. **J Nat Cancer Inst** 1998; 90:1537-1544.
66. Blumenstein BA, Ellis WJ, Ishak LM. The relationship between serial measurements of the level of a urinary bladder tumor associated antigen and the hazard for recurrence. **J Urology** 1998; 161:57-61.
67. Berry DL, Wilkie DJ, Huang H-Y, Blumenstein BA. Cancer pain and common pain: a comparison of patient-reported intensities. **Oncology Nursing Forum** 1999; 26:721-726.
68. Haas GP, Wolf M, Gagliano RG, Russell CA, Rivkin SE, Blumenstein BA, Crawford ED. Cisplatin, methotrexate, and bleomycin for the treatment of carcinoma of the penis: Southwest Oncology Group Study. **J Urology** 1999; 161:1823-1825.
69. deVere White RW, Deitch AD, Daneshmand S, Blumenstein B, Lowe BA, Sagalowsky AI, Smith JA Jr, Schellhammer PF, Stanisc TH, Grossman HB, Messing E, Crissman JD, Crawford ED. The prognostic significance of s-phase analysis in stage Ta/T1 bladder cancer: A Southwest Oncology Group study. **European Urology** 2000;37:595-600.
70. Lamm D, Blumenstein BA, Crissman JD, Montie JE, Gottesman JE, Lowe BA, Sarosdy MF, Bohl RD, Grossman HB, Beck TM, Leimert JE, Crawford ED: Maintenance BCG immunotherapy in recurrent Ta, T1 and carcinoma in situ transitional cell carcinoma: a randomized Southwest Oncology Group study. **J Urology** 2000;163:1124-1129.

71. Flanigan RC, Salmon SE, Blumenstein BA, Bearman SI, Roy V, McGrath PC, Caton JR, Munshi N, Crawford ED. Nephrectomy followed by interferon alfa-2b compared with interferon alfa-2b alone for metastatic renal-cell cancer. **NEJM** 2001; 345:1655-1659.
72. Melchior S, Noteboom J, Blumenstein BA, Fichtner JD, Thüroff JW, Gillitzer R, Lange PH, Vessella RL. The percentage of free prostate-specific antigen does not predict extracapsular disease in patients with clinically localized prostate cancer before radical prostatectomy. **Brit J Urol International** 2001; 87:1-6.
73. Guller U, Blumenstein BA. Trends in clinical trials in surgical oncology: implications for outcomes research. **Clin Therapeutics** 2003; 25:684-698.
74. Halabi S, Small EJ, Kantoff PW, Kattan MW, Kaplan EB, Dawson NA, Levine EG, Blumenstein BA, Vogelzang NJ. Prognostic model for predicting survival in men with hormone-refractory metastatic prostate cancer. **J Clin Oncology** 2003; 21:1232-1237.
75. Blumenstein BA. A comment on the utility of recursive partitioning. **J Clin Oncology** 2005;23.
76. Jung SH, Kang SJ, Mackie LS, Blumenstein B: Sample size computation for two-sample noninferiority logrank test. **J Biopharm Stat** 2005; 15:969-979.
77. Berry, DL, Ellis, WJ, Russell, KJ, Blasko, JC, Bush, N. Blumenstein, BA, Lange, PH. Factors that predict treatment choice and satisfaction with the decision in men with localized prostate cancer. **Clin Genitourinary Ca** 2006; 5:219-226.
78. Hoos A, Parmiani G, Hege K, Sznol M, Loibner H, Eggermont A, Urba W, Blumenstein B, Sacks N, Keilholz U, Nichol G. A clinical development paradigm for cancer vaccines and related biologics. **J Immunotherapy** 2007; 30:1-15.
79. Finke LH, Wentworth K, Blumenstein B, Rudolph NS, Levitsky H, Hoos A. Lessons from randomized phase III studies with active cancer immunotherapies – Outcome from the 2006 Meeting of the Cancer Vaccine Consortium (CVC). **Vaccine** 2007; 25S:B97-B109.
80. Kantoff PW, Schuetz TJ, Blumenstein BA, Glode LM, Bilhartz DL, Wyand M, Manson K, Panicali DL, Laus R, Schlom J, Dahut WL, Arlen PM, Gulley JL, Godfrey WR. Overall survival analysis of a Phase II randomized controlled trial of a poxviral-based PSA-targeted immunotherapy in metastatic castration-resistant prostate cancer. **J Clin Oncology** 2010; 28:1099-1105.
81. Zuraw BL, Busse BJ, White M, Jacobs J, Lumry W, Baker J, Craig T, Grant JA, Hurewitz D, Bielory L, Cartwright WE, Koleilat M, Ryan W, Schaefer O, Manning M, Patel P, Bernstein JA, Friedman RA, Wilkinson R, Tanner D, Kohler G, Gunther G, Levy R, McClellan J, Redhead J, Guss D, Heyman E, Blumenstein BA, Kalfus K, and Frank MM. Nanofiltered C1 inhibitor concentrate for treatment of hereditary angioedema. **NEJM** 2010; 363:513-522.
82. Hoos A, Eggermont AMM, Janetzki S, Hodi FS, Ibrahim R, Anderson A, Humphrey R, Blumenstein B, Old L, Wolchok J. Improved Endpoints for Cancer Immunotherapy Trials. **J Nat Ca Inst** 2010; 102:1388-1397.
83. Berry DL, Blumenstein BA, Halpenny B, Wolpin S, Fann JR, Austin-Seymour M, Bush N, Karras BT, Lober WB, McCorkle R. Enhancing Patient-Provider Communication with the Electronic Self-Report Assessment for Cancer: A Randomized Trial. **J Clin Oncology** 2011, 29:1029–1035.
84. Brenson JR, Yellin O, Blumenstein B, Bajanower D, Crooprick J, Aboulafia D, Upachyaya G, Spadaccini C. Using a powered bone marrow biopsy system results in shorter procedures, causes less residual pain to adult patients, and yields larger specimens. **Diagnostic Pathology** 2011, 6:23-28.

85. Church TR, Wandell M, Lofton-Day C, Mongin SJ, Burger M, Payne SR, Castaños-Vélez E, Blumenstein BA, Rösch R, Osborn N, Snover D, Day RW, Ransohoff DF. Prospective evaluation of methylated SEPT9 in plasma for detection of asymptomatic colorectal cancer. *GUT* 2014; 63(2): 317-325.
86. Blumenstein BA, Saad F, Hotte S, Chi KN, Eigl B, Gleave M, Jacobs C. Reduction in serum clusterin is a potential therapeutic biomarker in patients with castration-resistant prostate cancer treated with custirsen. *Cancer Medicine* 2013; 2(4): 468–477.
87. Kim N, Chi, Celestia S, Higano, Brent Blumenstein, Jean-Marc Ferrero, James Reeves, Susan Feyerabend, Gwenaëlle Gravis, Axel Merseburger, Arnulf Stenzl, André Andries M, Bergman, Som D, Mukherjee, Pawel Zalewski, Fred Saad, Cindy Jacobs, Martin Gleave, and Johann de Bono. Randomized Phase 3 Trial of Custirsen (OGX-011) in Combination with Docetaxel and Prednisone in Patients with Metastatic Castration-Resistant Prostate Cancer: SYNERGY Trial. *Lancet Oncology* 2017; 18(4): 473-485.
88. Bellmunt J, Eigl BJ, Senkus E, Loriot Y, Twardowski P, Castellano D, Blais N, Sridhar SS, Sternberg CN, Retz M, Pal S, Blumenstein B, Jacobs C, Stewart PS, Petrylak D: Borealis-1: a randomized, first-line, placebo-controlled, phase II study evaluating apatansin and chemotherapy for patients with advanced urothelial cancer. *Annals of Oncology* 2017; 28(10): 2481-2488.
89. Beer TM, Hotte SJ, Saad F, Alekseev B, Matveev V, Fléchon A, Gravis G, Joly F, Chi KN, Malik Z, Blumenstein B, Stewart PS, Jacobs CA, Fizazi K: Custirsen (OGX-011) combined with cabazitaxel and prednisone versus cabazitaxel and prednisone alone in patients with metastatic castration-resistant prostate cancer previously treated with docetaxel (AFFINITY): a randomised, open-label, international, phase 3 trial. *Lancet Oncology* 2017; 18(11): 1532–1542.

Book Chapters, Conference Proceedings, Letters, etc.:

1. Blumenstein BA. A dictionary-based data storage and extraction system. In: 1976 Proceedings of the Statistical Computing Section of the American Statistical Association. Pages 112-115, 1976.
2. Blumenstein BA, O'Day RK. A system for dictionary-driven data entry using an intelligent terminal. In: Computer Science and Statistics: Tenth Annual Symposium on the Interface. David Hogbin, ed. NBS Special Publication 503, pages 367-372, 1978.
3. Dykes FD, Lazzara A, Ahmann P, Blumenstein BA, Brann AW. Central Nervous System Morbidity. In: Assisted Ventilation of the Nervous System Morbidity. JP Goldsmith and EH Karotkin, eds. Philadelphia: WB Saunders, 1981.
4. Wollam GL, Hall WD, Porter VD, Douglas MB, Unger DB, Blumenstein BA, Kundtson ML, Felner JM, Schlant RC. The time course of regression of left ventricular hypertrophy in treated hypertensive patients. In: Am J Medicine, Proceedings of Symposium: Left Ventricular Hypertrophy in Essential Hypertension, 1983.
5. Rosman HS, Blumenstein BA: IHD Risk Score (letter). *Circulation* 62:1140-1141, 1982.
6. Johnson RE, Blumenstein BA, Rice VL, Fletcher BJ, Watt EW, Fletcher GF. Correlation of hyperventilation electrocardiographic changes, exercise testing and coronary angiography. In: Clinical Essays on the Heart, Volume 5. J. Willis Hurst, ed. New York: McGraw Hill, 1985.
7. Byar DP, Anderson JR, Blumenstein BA, Gibbons RP, Lepor H, Olsson CA, Simon RM. Guidelines for reporting studies of treatment for prostatic cancer. In: A multidisciplinary

- analysis of controversies in the management of prostate cancer, Coffey DS, Resnick MI, Dorr FA, Karr JP, ed. New York: Plenum Press, 1988.
8. Blumenstein BA: Benefits of combination therapy with flutamide in patients relapsing after castration (letter). *Br J Urol* 63:655-656, 1989.
 9. Lamm DL, Crissman J, Blumenstein BA, Crawford ED, et al. Adriamycin versus BCG in superficial bladder cancer. In: EORTC Genitourinary Monograph 6: BCG in Superficial Bladder Cancer. New York: Alan R Liss, Inc., pages 263-270, 1989. FMJ Debruyne, L Denis, Ad P.M. vander Meijden (eds).
 10. Crawford ED, Goodman P, Blumenstein B. Combined androgen blockade: Leuprolide and flutamide versus leuprolide and placebo. *Seminars in Urology* 8:154-158, 1990, ed. William R. Fair.
 11. Blumenstein BA: Finasteride's effect on sexual function (letter). *NEJM* 328:443, 1993.
 12. Eisenberger MA, Crawford ED, Wolf M, Blumenstein B, McLeod DG, Benson R, Dorr FA, Benson M, Spaulding T, Investigators of the NCI INT-0036. Prognostic factors in stage D2 prostate cancer; important implications for future trials: Results of a cooperative intergroup study (INT 0036). *Seminars in Oncology* 21:613-619, 1994.
 13. De Mulder PHM, Williams R, Ohashi Y, Blumenstein BA, De Pauw M, Kumazawa F, Obata K, Sylvester R, Tolley D. The Design of Clinical Trials for New Therapies in Bladder Cancer: Is It Time for New Strategies? *Int J Urol.* 2(suppl 2):1-132, 1995.
 14. Crawford ED, Hussain M, DeAntoni EP, Thompson IM, Eisenberger MA, Blumenstein B, Coltman CA: Southwest Oncology Group strategies in prostatic carcinoma. *Seminars in Surgical Oncology*, 11:60-64, 1995.
 15. Blumenstein BA. Medical Research Data (letter). *Controlled Clinical Trials* 1995; 16:453-454.
 16. Hussain M, Blumenstein B, Eisenberger M, Crawford E. Southwest oncology group studies in hormone-refractory prostate cancer. *Semin. Oncol.* 23:6(suppl 14): 24-27, 1996.
 17. Blumenstein BA. The Principles of Sample Size Computation. In: *Comprehensive Textbook of Genitourinary Oncology*. Vogelzang, NJ, Scardino PT, Shipley WU, Coffey DS, eds. Baltimore: Williams & Wilkins, 1996.
 18. Blumenstein BA. Statistical considerations for the use of literature in health systems research. In: *Principles and Practice of Genitourinary Oncology*. Ragaven D, Scher HJ, Leibel SA, Lange P, eds. Philadelphia: Lippincott-Raven, 1996.
 19. Blumenstein BA. Evaluation of superficial bladder cancer treatments (invited commentary). *J Urol* 156:1940-1941, 1996.
 20. Blumenstein BA. Statistical considerations in the comparison of quantitative assays measured on the same scale. In: *Proceedings of the First International Consultation on Prostate Cancer*. Chairman: G. Murphy. Murphy G, Denis L, Chatelain C, Griffiths K, Khoury S, Cockett AT; eds. Scientific Communication International, Ltd., 1997.
 21. Blumenstein BA. The randomized clinical trial. In: *Urologic Oncology*. Oesterling JE, Richie JP, eds. Philadelphia: W.B. Saunders Company, 1997.
 22. Crawford ED, Blumenstein BA. Proposed substages for metastatic prostate cancer (letter). *Urology* 50:1027-1028, 1997.
 23. Crawford ED, Blumenstein B, Thopson I. Type III statistical error (letter). *Urology* 1998; 51:675.
 24. Green S, Crowley J, Blumenstein B, Benedetti J. An open letter to the American Society of Clinical Oncology (letter). *J Clin Oncology* 1998; 16:3478.

25. Moinpour CM, Troxel A, Lovato LC, Eisenberger M, Blumenstein BA, Crawford ED. Editoriol response to Re: Quality of life in advanced prostate cancer: results of a randomized trial (letter). JNCI 1999; 91:381-382.

Presentations:

1. Experiences in nonlinear regression using the Marquardt algorithm, Hartley algorithm, and an algorithm using the second partials of the function. Presented at the Association for Computing Machinery Mid-Southeast Chapter Meeting, Gatlinburg, Tennessee, November, 1968.
2. Impact of a virtual memory system on program development. Presented in the Virtual Memory Concepts Session of the ACM73 Conference (Association for Computing Machinery), Atlanta, Georgia, August, 1973.
3. The maximum likelihood estimation of linear path regression models (dissertation). Presented at the Summer Research Conference of the Committee on Statistics of the Southern Regional Education Board, Mountain Lake, Virginia, June, 1974.
4. Invited seminar: Path analysis. Part of advanced methodology seminar. Department of Epidemiology, University of North Carolina at Chapel Hill, October, 1975.
5. Invited panelist for Information Science and General Systems workshop at the Society for General Systems Research Southeastern meeting, April, 1976.
6. A dictionary-based data storage and extraction system. Presented at the annual meeting of the American Statistical Association, Boston, Massachusetts, August, 1976.
7. A system for dictionary-driven data entry using an intelligent terminal. Poster presentation at the Computer Science and Statistics 10th Annual Symposium on the Interface, Gaithersburg, Maryland, April, 1977. (Co-author: RK O'Day.)
8. The use of multidimensional scaling in a drug comparison study. Invited seminar for the Statistical Sciences Department of the Oak Ridge Associated Universities, Oak Ridge, Tennessee, October, 1977.
9. The analysis of multiple variable dependencies in chronic disease etiology. Invited paper, Statistics Section, 1977 annual meeting of the American Public Health Association, Washington, DC, October, 1977. (Co-author: MH Kutner.)
10. The use of the dictionary-driven datasystem for the management of cancer data. Invited presentation for the SEER Data Management and Analysis Workshop sponsored by the National Cancer Institute, Annapolis, Maryland, November, 1977.
11. Multivariate methods of controlling confounding. Preventive Medicine Retreat on Advanced Epidemiologic Techniques, Center for Disease Control, Atlanta, Georgia, February, 1979.
12. The planning and administration of research data bases and the use of DDD. Presented at the University of Iowa, sponsored by the Department of Preventive Medicine and Environmental Health, September, 1979.
13. Research data management. Invited paper at the 1980 Southern Regional Education Board's Summer Research Conference in Statistics, Pensacola, Florida, June, 1980.
14. Exact conditional tests for hierarchical models in multidimensional contingency tables. University of Washington Department of Biostatistics Seminar, March, 1982.
15. Data management at the Atlanta Cancer Surveillance Center. Contributed paper, 13th International Cancer Congress, September, 1982.
16. The management of large clinical trials. Department of Preventative Medicine and Environmental Health, University of Iowa, September, 1985.

17. Randomized design and analysis of randomized clinical trials. Society for Clinical Trials, May, 1986.
18. A study-driven data base management system for multi-center trials. American Public Health Association, September, 1986.
19. A data system for multiple multicenter clinical trials. SinoAmerican Statistical Meeting, Beijing, China, August, 1987.
20. Data management strategies workshop. Society for Clinical Trials, May, 1988 (Chair).
21. The Southwest Oncology Group Data Management System. St. Jude Children's Research Hospital, November, 1988.
22. Statistical Considerations for Leuprolide With and Without Flutamide in Advanced Prostate Cancer. Workshop on combined castration and androgen blockade therapy in prostate cancer: Results and future directions, American Cancer Society, Atlanta, Georgia, September, 1989.
23. Effect of colony forming unit dose of Connaught BCG on outcome to immunotherapy in superficial bladder cancer. American Urological Association, May, 1990.
24. Statistics Subcommittee Co-chair, Workshop on Overview Analysis of Randomized Trials of Combined Therapy in Advanced Disease, Paris, France, June, 1990.
25. Evidence for Excessive BCG Dose. Workshop on Biological Rationale for BCG therapy of bladder cancer, Toronto, Ontario, November, 1990.
26. The Southwest Oncology Group Statistical Center: Assuring statistical validity. Japanese National Cancer Center, Tokyo, Japan, November, 1990.
27. Data quality control at the Southwest Oncology Group Statistical Center. Annual meeting of the Society for Survival Time Studies on Cancer Patients, Tokyo, Japan, December, 1990.
28. Recent Southwest Oncology Group urologic clinical trials. Ad hoc meeting of Japanese urologists, Tokyo, Japan, December, 1990.
29. Statistics in Cancer Research. Sixth Annual Genitourinary Cancer Update, Denver, Colorado, March, 1991.
30. Statistics for Urologists. Second International Prostate Cancer Update, Beaver Creek, January, 1992.
31. Statistical Evaluation of Clinical Trials. Second International Prostate Cancer Update, Beaver Creek, January, 1992.
32. Statistical considerations in designing prostate cancer clinical trials. NCI Conference on Early Stage Prostate Cancer Clinical Trials, Rockville, MD. March, 1992.
33. Statistics and Cancer Research. Sixth Annual GU Cancer Update, Denver, March, 1992.
34. Interpretation of results: What every urologist should know (invited). At the preconference symposium Prostate Cancer: Meeting the Therapeutic Challenges. American Urological Association Meeting. Washington, D.C., May, 1992.
35. Some statistical considerations for the interpretation of trials of combined androgen therapy (invited). 3rd International Workshop on Combined Androgen Blockade Randomized Trials in M1 Prostate Cancer, Paris, France, June, 1992.
36. The design of clinical trials for new therapies in bladder cancer(invited). International consensus meeting on bladder cancer. Antwerp, Belgium, April, 1993.
37. The prostate cancer prevention trial. University of Pittsburg, Department of Biostatistics seminar, April, 1993.
38. New technologies in data capture (workshop session chair). 14th Annual meeting of the Society for Clinical Trials, Orlando, May, 1993.

39. Statistics and interpretation of the literature (invited). Instructional Course, American Urological Association Meeting, San Antonio, May, 1993.
40. Innovative Statistical Computing Environments for the 90's (invited). Drug Information Association Annual Meeting, Chicago, July, 1993.
41. Statistical considerations for a trial of intermittent therapy in stage D2 prostate cancer (invited). International Workshop on Intermittent Androgen Suppression in Prostate Cancer, Seattle, July, 1993.
42. The PCTCG Meta-Analysis: Issues and Considerations. The Sixth International Prostate Cancer Update, Beaver Creek, Colorado, February, 1994.
43. Clinical versus statistical significance: Evaluation of the prediction of extrapsular prostate cancer (invited). Walter Reed Army Hospital Urology Seminar, April, 1994.
44. Introduction. Nuts and Bolts of Data Collection in Multi-Center Clinical Trials Preconference Workshop. Annual Meeting of the Society for Clinical Trials, Houston, May, 1994.
45. Toward more comprehensive data management in multicenter studies: The Women's Health Initiative example (session chair). Annual Meeting of the Society for Clinical Trials, Houston, May, 1994.
46. Treatment of histologically confirmed D2 prostate cancer - a comparison of bilateral orchiectomy with and without flutamide (Intergroup study 0105). American Urological Association Annual Meeting, San Francisco, May, 1994.
47. On the Utility of Case Series and Registration Studies (invited). Southwest Oncology Group Meeting Plenary Session, October, 1994.
48. Enabling the telecommuting statistician (invited). Drug Information Association Annual Meeting, Washington, June, 1994.
49. Current statistical issues in urologic cancer clinical studies. (Invited Professor). Canadian Urologic Oncology Group Meeting, Jasper (Canada), June, 1994.
50. Optimal Trial Design to Demonstrate Modest Therapeutic Gains. Advances in the Biology and Therapy of Renal Cell Carcinoma (session chair). The Third Annual Genitourinary Oncology Conference, Houston, February, 1995.
51. Time to good thing. WNAR Biometric Society Meeting, Los Angeles, June, 1994.
52. Statistics and interpretation of the literature (invited). Postgraduate Course, American Urological Association Annual Meeting, Las Vegas, May, 1995.
53. Statistical Considerations in Clinical Trials (invited). Organization of Regulatory & Clinical Associates Meeting, Washington, August, 1995.
54. PCTCG Meta Analysis Issues and Considerations (invited). Eulexin Speaker Update Meeting Agenda, Puerto Rico, September, 1995.
55. Statistical and Study Design Issues for Trials of Therapies for Sepsis (invited). The European Sepsis Trials Consortium Meeting, near Strasbourg, France, September, 1995.
56. The PCTCG Meta-Analysis (invited). Conference on Total Androgen Blockade, Stockholm, Sweden, April, 1996.
57. Issues in Clinical Trial Design, Implementation and Analysis (invited). Society for Urologic Oncology, Orlando, May 1996.
58. Statistics and interpretation of the literature (invited). Postgraduate Course, American Urological Association Annual Meeting, Orlando, May, 1996.
59. Evaluation of Markers (invited). Society for Basic Urological Research, Orlando, Florida, May 1996.

60. The PCTCG Meta Analysis (invited): Issues and Considerations. Gothenburg, Sweden, September, 1996.
61. The PCTCG Meta Analysis (invited): Issues and Considerations: Laval University, October, 1996.
62. Regression, Logistic Regression and ROC Curves (invited). Uniformed Services Medical School, November, 1996.
63. Orchiectomy +/- Flutamide: Preliminary Results of the Southwest Oncology Group Study (invited). Kennilworth, NJ, November, 1996.
64. Phase II prostate cancer trials: issues and future directions (visiting professor). University of Toronto, Department of Urology, March, 1997.
65. The randomized clinical trial in urologic oncologic (visiting professor). University of Toronto, Department of Urology, March, 1997.
66. Combined androgen blockade in prostate cancer (visiting professor). University of Toronto, Department of Urology, March, 1997.
67. Some biostatistical issues in urology (visiting professor). University of Toronto, Department of Urology, March, 1997.
68. Statistics and interpretation of the literature (invited). Postgraduate Course, American Urological Association Annual Meeting, New Orleans, May, 1997.
69. Statistical issues in the evaluation of bladder tumor markers (session chair). International conference on bladder tumor markers. Barcelona, Spain, May, 1997.
70. A montage of statistical issues. Organization of Regulatory and Clinical Associates, Seattle, November, 1997.
71. Statistical issues in tumor marker evaluation (invited). NCI Conference on Bladder Tumor Markers, Sarasota, February, 1998.
72. Statistical issues in tumor marker evaluation (invited). Emory University Department of Biostatistics, Atlanta, April, 1998.
73. Some statistical thoughts about tumor markers and related things (invited). Southwest Oncology Group Meeting Plenary Session, April, 1998.
74. A survey of contemporary software tools for clinical data systems (session chair and presenter). Preconference Workshop, Annual Meeting of the Society for Clinical Trials, Atlanta, May, 1998.
75. Assessing marker performance. Emory University, May, 1998.
76. Phase II clinical trials in the age of tumor markers. Emory University, May, 1998.
77. Statistics and interpretation of the literature (invited). Postgraduate Course, American Urological Association Annual Meeting, San Diego, June, 1998.
78. Maintenance BCG immunotherapy in recurrent Ta, T1 and carcinoma in situ transitional cell carcinoma: Results and some statistical considerations. Department of Urology, University of Iowa, March, 1999.
79. Maintenance BCG immunotherapy in recurrent Ta, T1 and carcinoma in situ transitional cell carcinoma: Results and some statistical considerations. Rush Presbyterian, March, 1999.
80. Maintenance BCG immunotherapy in recurrent Ta, T1 and carcinoma in situ transitional cell carcinoma: Results and some statistical considerations. Department of Urology, Washington University, August, 1999.
81. Building a Whole New Group: Design and Statistical Considerations of the ACOSOG. Department of Biostatistics and Medical Informatics, University of Wisconsin Madison, March, 2000.

82. Essentials of Clinical Trials, Pre-Conference Workshop with Jennifer Gassman, Bob Byington, and Sylvan Green, Society for Clinical 21st Annual Meeting, May, 2000.
83. Coordinating Center in Multicenter Clinical Trials. Epidemiology and Biostatistics Division of the School of Public Health, University of Illinois Chicago, October, 2000.
84. Adventures in the Simulation of Clinical Trials with Time-to-Event Endpoints. Midwest Biopharmaceutical Statistics Workshop, Muncie, IN, May, 2006
85. Statistical Models for Safety Issues. FDA and Industry Conference: Integrating Quality in Clinical Trials, Update on Clinical Trial and IRB Management. ORCA, Seattle, WA, July, 2006.
86. Planning Cancer Vaccine Trials with Time-to-Event Endpoint and a Delayed Effect (invited). Sabin Vaccine Institute Cancer Vaccine Consortium 6th Meeting, Washington, DC, November, 2006.
87. Simulations Assessing Deviations from Trial Design Assumptions (invited). Bringing Therapeutic Cancer Vaccines and Immunotherapies Through Development To Licensure, An FDA-NCI Sponsored Workshop, February, 2007.
88. A Form of Nonproportional Hazards Important in Cancer Immunotherapy Evaluations (invited). Seminar, Fred Hutchinson Cancer Research Center, September, 2007.
89. Dendreon Effect Size Estimates: Impact of Delayed Effect (invited). In Hot Topics Session: The Dendreon Debate, International Society for Biologic Therapy of Cancer 22nd Annual Meeting, November, 2007.
90. Multivariate Methods and Characterization of Clinical Effect Using Multiple Sclerosis as an Example. Rare Disease Workshop Series (Kakkis EveryLife Foundation), Workshop 1: Optimizing the Choice of Statistical Analysis and Study Design for Ultra Rare Diseases, November 8, 2010.
91. Clinical Trial and Analysis Issues for Cancer Vaccine Trials. FDA/Industry Statistics Workshop, September 2011.
92. Survival Analysis without Proportional Hazards: Delayed Effect. Emory University Department of Biostatistics 50th Anniversary, October 2014.
93. Statistics in the Regulatory Setting. Emory University Department of Biostatistics and Bioinformatics, Distinguished Alumni Award Event October 2017, honoring me.

Grants and Contracts:

1. Received partial support from NICHD contract "Effect of contraceptive steroids on hypertension in young women", 1975-1978.
2. Co-Investigator on NICHD contract "A case-control study of the relative risk of diabetes in users of steroid contraceptives", 1979-1981.
3. Co-Investigator on NICHD contract "Research on the presence of abnormal proteins in the serum of users of oral contraceptives", 1980-1981.
4. Co-Investigator on NCI contract under the Surveillance, Epidemiology and End-Results (SEER) Program, 1976-1981.
5. Co-Investigator on the NIA grant "Chronic Antihypertensive Drug Effects on Aged Cognition", 1983-.
6. Statistician for the Statistical Analysis and Quality Control Center on the contract "Community Cancer Care Evaluation", 1983-1986.
7. Deputy Director and Co-Principal Investigator on the Southwest Oncology Group Statistical Center, 1984-1998.

8. Statistician for Statistical Methods for Therapeutic Trials, 1986-1991. (10% effort, \$101,820 annual direct cost).
9. Principal Investigator for Statistical Methods, Central Computing Support, 1986-1991. (10% effort, \$23,331 annual direct cost).
10. Principal Investigator and Biostatistician for Connaught Labs support for SWOG-8507, Bladder Cancer Study, 1991-1993. (0% effort, \$69,892 annual direct cost).
11. Principal Investigator and Biostatistician. for Upjohn support for SWOG-9140 Genitourinary study, 1992-1994. (0% effort, \$10,856 annual direct cost).
12. Principal Investigator and Group Statistician for the American College of Surgeons Oncology Group, 1998-2002 (100% effort, approximately \$2,000,000 direct costs).

Continued Education:

1. 1975: ASA short course on Exploratory Data Analysis given by John W. Tukey and David Hoaglin.
2. 1976: ASA short course on Discrete Multivariate Analysis given by Yvonne Bishop, Stephen Fienberg and Paul Holland.
3. 1977: ASA short course on Data Analysis of Multivariate Observations given by R. Gnanadesikan, Jon R. Kettenring and Paul A. Tukey.

Other Work Experience:

1963-1964 Argonne National Laboratories. Spent two trimesters working in the Physics division as a co-op student. Work included laboratory technician duties, data reduction, and computer programming.

Computing Experience:

Current experience with Windows, Mac OSX, Unix. Past experience with prior version of Windows, OS/2, PC DOS, AIX, IBM 4381 CMS, DEC VAX-11, Univac 90/80, Decsystem 10/20's; Wang 2200; IBM 370/303x; Datapoint Diskette 1100; DEC GT-40, IBM 1620, 704, 7094, 1410, 360; CDC 3600; Philbrick Analog Computer.

Proficiency in SAS, R, Java, FORTRAN, Rexx, C, Assembly, BASIC. Experience in COBOL, PL/1, SNOBOL, ALGOL.