

Joseph Costantino

Professor, Biostatistics

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Experience

Academic Appointments

Director, NRG Oncology Statistics and Data Management Center, NRG Oncology Cooperative Group	2014-present
Director, NSABP Biostatistical Center, NSABP Biostatistical Center	2004-2014
Professor of Biostatistics with Tenure, Department of Biostatistics, University of Pittsburgh, Graduate School of Public Health	2002-present
Associate Professor of Biostatistics with Tenure, Department of Biostatistics, University of Pittsburgh, Graduate School of Public Health	1998-2002
Associate Director, NSABP Biostatistical Center, NSABP Biostatistical Center	1995-2003
Associate Professor of Biostatistics, Department of Biostatistics, University of Pittsburgh, Graduate School of Public Health	1995-1998
Coordinating Statistician, Breast Cancer Prevention Research, NSABP Biostatistical Center	1991-1995
Assistant Professor of Biostatistics, Department of Biostatistics, University of Pittsburgh, Graduate School of Public Health	1985-1995
Director, Beta Carotene Biostatistical Center, Clinical Trial of Beta Carotene and Lung Cancer University of Pittsburgh, Graduate School of Public	1984-1989
Project Statistician, NSABP Biostatistical Center	1984-1991
Adjunct Assistant Professor of Biostatistics and Epidemiology, Department of Biostatistics, University of Pittsburgh, Graduate School of Public Health	1983-1985
Adjunct Instructor of Epidemiology, Department of Epidemiology, University of Pittsburgh, Graduate School of Public Health	1977-1983
Instructor of Epidemiology, Department of Epidemiology, University of Pittsburgh, Graduate School of Public Health	1976-1977

Non-Academic Employment

Manager, Environmental and Occupational Health Research, BCR National Laboratory	1982-1984
Supervisor, Health Effects Research, Bituminous Coal Research, Inc	1980-1981
Executive Assistant Director, Allegheny County Health Department	1979-1980
Deputy Director of Medical Services, Allegheny County Health Department	1977-1979
Chief of Epidemiology, Allegheny County Health Department	1977

Education

Degrees

DrPH Epidemiology, University of Pittsburgh, Graduate School of Public Health	1974-1976
MPH Epidemiology, University of Pittsburgh, Graduate School of Public Health	1972-1974
BS Biology, Bethany College	1968-1972

Committee Memberships

University of Pittsburgh Senate Computer Usage Committee	2000-2019
University of Pittsburgh Faculty Assembly	2003-2017
University of Pittsburgh Faculty Senate Council	2003-2017
Search Committee for New Faculty Members in the Department of Biostatistics	2014-2015
Search Committee for Research Assistant Professor Position in the Department of Biostatistics	2012-2013
Search Committee for Two New Tenure-Track Faculty Positions in the Department of Biostatistics	2012-2013
University of Pittsburgh Board of Trustee's Audit Committee	2008-2012
Search Committee for Director of the UPCI Biostatistical Facility	2009
GSPH Junior Faculty Oversight Committee for the Department of Human Genetics, Environmental and Occupational Health, and Infectious Disease and Microbiology	2007-2008
GSPH Search Committee for Director of the Epidemiology Data Center	2006-2007
GSPH Accreditation Committee	2004-2007
GSPH Search Committee for Dean of the Graduate School of Public Health	2005-2006
GSPH Steering Committee for the Center for Public Health Practice	1995-2006
GSPH Faculty Advancement, Promotion, Tenure Committee (Chair)	2001-2005
GSPH Budget Policy and Planning Committee	1999-2005
GSPH Council	1999-2005
GSPH Faculty Senate Executive Committee (President 2001 and 2002)	1999-2005
Department of Biostatistics Budget and Planning Committee	1993-2005
GSPH Search Committee for the Chair of the Department of Epidemiology (Chair)	2002-2003
GSPH Ad Hoc Committee for Retreat Planning	2001-2002
GSPH Search Committee for Director of MMPH Program	2001-2002
GSPH Search Committee for Dean of the Graduate School of Public Health, (Co-chair)	2000-2001
University of Pittsburgh Faculty Senate Council	1996-2001
University of Pittsburgh Faculty Assembly	1995-2001
GSPH Advisory Committee for the Joint MD MPH Program	1996-2000
GSPH Committee for the Integrated Core Course in Public Health	1995-1997
University of Pittsburgh Council for Graduate Study	1991-1997
University of Pittsburgh Subcommittee on Evaluation of Academic Programs	1991-1997
Doctoral Student Organization	1991-1994
GSPH Alumni Executive Committee	1986-1994
GSPH Accreditation Committee	1993

GSPH Educational Policies and Curriculum Committee	1991-1993
GSPH School-wide Master's of Public Health Committee	1991-1993
Computer Advisory Committee of the Pittsburgh Cancer Institute	1986-1988
Executive Committee of the Department of Biostatistics NIH Shared Computer	1986-1987

Distinctions

Distinguish Alumni, Graduate School of Public Health, University of Pittsburgh	2005
President, Delta Omega, Omicron Chapter	1990
RJ Lee, Environmental Health Training Award	1989
President-Elect, Delta Omega, Omicron Chapter	1989
Delta Omega, Public Health Honor Society	1987

Teaching Activity

Courses taught

Infectious Disease Epidemiology, course code: Epidemiology-2160	2003-2004
Design of Clinical Trials II: Contemporary Issues, course code: Epidemiology-2182	2002-2006
Clinical Trials: Methods and Practice, course code: Biostatistics-2062	2000-2005
Design of Clinical Trials, course code: Epidemiology-2181	2000-2002
Principles of Epidemiology, course code: Epidemiology-2100	1999-2006
Clinical Epidemiology and Biostatistics	1998-2000
Integrative Course in Public Health, course code: Public Health-2001	1996-1998
Statistical Methods in Public Health, course code: Biostatistics-2045	1985-2013
Principles of Statistical Reasoning, course code: Biostatistics-2011	1984-1988
Principles of Epidemiology, course code: Epidemiology-201	1973-1976

Mentoring

Doctoral Student Dissertation Committees

Inference on quantile residual life for length-biased survival data, Sima Lopa	2014-2015
Dynamic prediction in competing risks, Qing Liu	2012-2014
Statistical methods for classification based on dose response data: A modified EM algorithm for regression analysis of missing data, Zhang, Yang	2012-2013
Use of bias coin methodology for randomization in clinical trials, Tu, Li-Chaun (Primary Advisor, Committee Chair)	2011-2013
Survival analysis of shared-path adaptive treatment strategies, Kidwell, Kelly	2010-2012
Issues in Breast Cancer Prevention: Body Mass Index, Breast Density, and Fractures, Cecchini, Reena	2010-2012
A meta-analytic framework for combining incomparable Cox proportional hazard models caused by omitting important covariates, Yuan, Xing	2008-2010
Analyzing survival data from sequentially randomized designs, Tang, Xinyu	2008-2010
Prediction of accrual closure date in multi-center clinical trials with Poisson process models, Kong, Yuan	2007-2009
Association of emergency room visits for asthma with air quality in Allegheny County, Glad, Jo Ann	2007-2009
Inference on competing risk in breast cancer data, Haile, Sarah	2006-2008

Inference on median residual life function for censored survival data, Bandos, Hanna	2005-2007
Estrogen metabolism, breast density and breast cancer, Simpson, Jennifer	2004-2006
Geographic variations in stroke incidence and mortality among older populations in four U.S. communities, El-Saed, Aiman	2004-2006
Study of risk factors for post-operative pulmonary complications, Wojnakowski, Mary	2002-2004
Assessment of the potential ascertainment bias associated with the use of biopsies from non-systematic follow-up of liver transplant patients, Ruppert, Kristine (Primary Advisor, Committee Chair)	2002-2004
Impairment of endothelial function in women with a history of preeclampsia; an indicator of cardiovascular risk, Agatisa, Patricia	2001-2003
A Bayesian group sequential approach for multiple endpoints, Mor, Maria Katrina	2001-2003
Methods for combining covariate data obtained by multiple sampling schemes in occupational cohort, Gaus, Christine	1999-2001
The assessment of environmental and socioeconomic factors with respiratory health in Nigerian families, Gathuru, Irene	1999-2001
Determining the prevalence of early male pattern baldness and risk of coronary heart disease in brothers of women with poly-cystic ovary syndrome, Remsberg, Karen	1999-2001
Violent behavior among youth drinkers: pattern and predictors, Swan, Monica	1999-2001
Evaluation of the Erie County immunization registry of children 12 to 23 months of age, Rea, Nancy	1998-2000
Bone mineral density among women with polycystic ovary syndrome, Zbrowski, Jeanne	1998-2000
Utilization of compliance information in clinical trials. A new methodology, Chen, Wei (Primary Advisor, Committee Chair)	1998-2000
Bone mineral density, breast density and sex steroid hormones in older women, Ngo, Duyen L.	1997-1999
An expert system to assess the effect of molecular modification on drug response, Cunningham, Albert	1996-1998
The relationship of psychopathology, psychosocial, family and neurological course of illness factors to relapse in of schizophrenia, Pandalai, Sudha P.	1996-1998
Meta-analysis with sparse data, dichotomized discrete outcomes, and linear regression applied to ordinal data, Sankey, Scott	1996-1998
Women's perceptions of the value of genetic screening at different life stages, Twal, Marie McConville	1996-1998
Homocysteine and leptin levels in African-American women as related to subclinical atherosclerosis, Zeigler-Johnson, Charnita	1996-1998
Comparison of variances estimates of the standard mortality ratio in the presence of small comparison populations, Lieb, Anita	1995-1997
A simulation study of statistical modeling with neural networks, Landsittel, Douglas	1995-1997
The additive hazards model and its application to the analysis of censored data, Lee, Eunyong Choi	1994-1996
Iterative allocation of partially classified data in epidemiologic studies, Youk, Ada Owens	1994-1996
Multiple endpoint problems in survival analysis, Dignam, James	1992-1994
Comparison and evaluation of smoothing methods and their application to toxicological bioassays, Boylstein, Lee Ann	1992-1994
Socio-economic status and John Henryism: Associations with blood Pressure in a Nigerian civil servant Population, Markovic, Nina	1992-1994

The role of thyroid function in weight and cholesterol changes among menopausal women, Massoudi, Mehran	1991-1993
Electrocardiography left ventricular hypertrophy and related factors in Nigerians, Houston, Sara	1991-1993
Evaluation of the D/ART Training Program, McDonald, Margaret	1991-1993
An analysis of nutrient intake, eating behaviors, and risk for coronary heart disease in premenopausal women, Nowalk, May P	1991-1993
Covariates associated with neonatal and post-neonatal mortality: The case of Peru, Valencia, Ramos G	1989-1991
The relationship between risk factors and the mentally ill homeless: predictors of homelessness in the mentally ill, Kim, Min Shik	1989-1991
Procedure for stopping long-term clinical trials via requiring "r" rejections out of "n" multiple looks to control elevation of type I error, Hussein, Mohamed	1988-1990
An epidemiologic study of lipid levels in adult cystic fibrosis patients, Slesinski, Mary Jane	1988-1990
Nutritional status of vegetarians, Ferris, Denise	1987-1989

Master's Student Essay Committees

Functional and Medical Impairments among hospitalized older-drivers, Agimi, Yll	2011-2012
Inference on median failure time for censored survival data, Tang, Shaowu, (Primary Advisor, Committee Chair)	2009-2010
Is there a difference in completeness of radiation treatment when comparing African American and Caucasian Women?, Glover, Khaleelah	2008-2009
Estimating the probability of Lymphedema following breast cancer surgery, Wench, Wu	2007-2008
Syndromic surveillance for the early detection of influenza outbreaks, Rizzo, Sarah (Primary Advisor, Committee Chair)	2004-2005
Psychometric Evaluation of NSABP C-07 Neurotoxicity self-administered Questionnaire, Sundry, Reena (Primary Advisor, Committee Chair)	2003-2004
A method to identify potential longitudinal biomarkers for survival, Ko, Feng-shou (Primary Advisor, Committee Chair)	2003-2004
Prostate cancer, androgen deprivation and the risk of periodontal disease studies, Famili, Pouran	2002-2003
Statistical Properties of Tree-structure models for survival data, Gao, Weimin	2002-2003
Cardiopulmonary manifestations of systemic lupus erythematosus; evaluation and management, Kao, Amy	2002-2003
Factor composition of the Cannon-Spoor Premorbid Adjustment Scale and the Implications of a multidimensional model, Garratt, Lorraine (Primary Advisor, Committee Chair)	1995-1996
Environmental tobacco smoke exposure and illness in young children, Sledak, Suzanne (Primary Advisor, Committee Chair)	1994-1995
The association between pollution and respiratory hospital admissions in Allegheny County, Pennsylvania, Sankey, Scott (Primary Advisor, Committee Chair)	1991-1992
Assessment of factors associated with Rhabdomyosarcoma, Johnson, Elizabeth (Primary Advisor, Committee Chair)	1991-1992
Prediction of mortality from summary electrocardiogram parameters, Cecchetti, Alfred (Primary Advisor, Committee Chair)	1991-1992
An analysis of prognostic indicators of chronic rejection of lung transplants, Similo, Shari (Primary Advisor, Committee Chair)	1991-1992

Giardiasis detection by a commercial elisa, ProSpec T/giardia, Van Praagh, Andrew D.	1991-1992
Assessment of factors associated with rhabdomyosarcoma, DeSensi, Elizabeth	1991-1992
The effect of blood transfusion on disease-free survival and survival of patients with colon cancer, Jones, Judy	1990-1991
Evaluation of microbial resistance through production of beta-lactamose in otitis media pathogens, Kasian, Charlene	1989-1990
Cancer clusters: an approach to study for the occupational physician, Kemp, Margaret	1989-1990
A comparison of survival between black and white female breast cancer patients participating in NSABP randomized clinical trials., Dignam, James	1988-1989
Cause-Specific mortality in non-Allegheny County coke oven workers, Bearden, Audrey (Primary Advisor, Committee Chair)	1988-1989
Methods to control for normal mortality risk in a study with long-term follow-up; comparison of the relative and the adjusted survival rates, Diklah, Ron	1988-1989
A comparative analysis of growth curve modeling in a population of cleft-palate children, Beres, Leslie	1986-1987
Assessing multiple endpoints associated with occupational exposure: a multivariate approach with application to a sample of chemical workers, Lyons, Ella	1985-1986
The Cauchy distribution as an alternative to the normal for certain biomedical measurements, Ubringer, Elizabeth	1984-1985

Graduate Student Researcher Supervision

GSR position in the NSABP SDMC, Zhang, Yang	2012-2014
GSR position in the NSABP SDMC, Liu, Qing	2011-2014
GSR position in the NSABP SDMC, Christian, Nicholas	2010-2012
GSR position in the NSABP SDMC, Kidwell, Kelly	2010-2012
GSR position in the NSABP SDMC, Haile, Sarah	2007-2008
GSR position in the NSABP SDMC, Bandos, Hanna	2004-2007
GSR position in the NSABP SDMC, Dean, Scott	2004-2006
GSR position in the NSABP SDMC, Sundry, Reena	2002-2004

Professional Activity

Consulting / Advisories

NRG Oncology Board of Directors	2014-2019
Olympia Study Scientific Steering Committee, Olympia Study Scientific Steering Committee	2014-2019
National Clinical Trial Network Leadership Committee, National Cancer Institute	2014-2019
National Cancer Institute National Clinical Trials Network Working Group, National Cancer Institute	2012-2014
Federal Drug Administration Panel on Innovations in Breast Cancer Drug Development	2012-2013
American Society of Clinical Oncology Expert Panel on 5-Alpha-Reductase Inhibitors	2010-2012
National Cancer Institute Program for Assessment of Clinical Cancer Tests Clinical Assay Development Program Eligibility Criteria Working Group	2010-2011
National Cancer Institute Clinical Trials Planning Committee: Next generation trials for HER2-positive breast cancer	2010-2011
National Cancer Institute, Breast Cancer Steering Committee, National Cancer Institute	2009-2019

Statistical Task Force of the American Joint Committee on Cancer	2006-2009
Foregut Task Force of the American Joint Committee on Cancer	2006-2009
American Society of Clinical Oncology Expert Panel on 5-Alpha-Reductase Inhibitors	2006-2008
National Cancer Institute's Working Group on the Feasibility of a Physical Activity, Weight Control Trial to Prevent Breast Cancer	2006
Early Breast Cancer Trialist Cooperative Group Scientific Steering Committee	2005-2019
NSABP Foundation Board of Scientific Directors, NSABP Foundation INC	2005-2019
Institute of Medicine's Committee on Assessing the Need for Clinical Trials of Testosterone Replacement Therapy	2002-2003
Review Panel-National Cancer Institute, Small Grants Program for Cancer Epidemiology	2002
Advisory Committee-NIEHS Program Project: Molecular Toxicology of Environmental Carcinogens	1991-1997
Special Review Committee-National Institute of Heart, Lung and Blood, Clinical Coordinating Center for	1990

Grants

National Cancer Institute through subcontract with SWOG (PI), A randomize Phase III trial to evaluate the efficacy and safety of MK-3475 as adjuvant therapy for triple-negative breast cancer with > 1 cm residual invasive cancer or positive lymph nodes, \$969,740	2019-2026
National Cancer Institute through subcontract with University of Chicago (PI-multiple), U10CA180822 NRG Oncology Statistics and Data Management Center, \$60,799,128	2019-2025
NSABP Foundation, Inc (Co-investigator), Colorectal cancer metastatic dMMR immunotherapy (COMMIT) study: A randomized Phase III study of mFOLFOX/Bevacizumab combination chemotherapy with or without atezolizumab in the first-line treatment of patients with deficient DNA mismatch repair (dMMR) metastatic colorectal cancer, \$1,141,993	2019-2023
NSABP Foundation, Inc. (PI), A randomized double-blind, Phase II clinical trial of neoadjuvant chemotherapy with azetolizumab or placebo in patients with triple-negative breast cancer followed by adjuvant continuation of azetolizumab, \$373,461	2018-2025
GOG Foundation, Inc (PI), PHAR1-NRG-GY008, \$77,965	2018-2023
National Cancer Institute through subcontract with Cedars-Sinai Medical Center (PI), Advance analysis and interpretation of adverse events and PROs in cancer clinical trials, \$172,735	2018-2019
National Cancer Institute through subcontract with Washington University (PI), SU10CA180860, Intergrated Translational Genoproteomics Center at Washington University, \$58,722	2017-2019
NSABP Foundation Inc. (Co-investigator), Data Management center for ARGO, A phase III randomized placebo-controlled study evaluating regorafenib following completion of standard chemotherapy for patients with stage III colon cancer, \$5,882,891	2016-2024
NSABP Foundation Inc. (PI), Supplement to support the implementation of B-55, a randomized Phase III study to assess the efficacy and safety of olaparib versus placebo as adjuvant treatment in patients with high risk germline BRCA mutated HER2 negative primary breast cancer, \$1,607,837	2014-2027
National Cancer Institute (PI-multiple), 5 U10 CA180822 NRG Oncology Statistical and Data Management Center, \$45,725,137	2014-2019
National Cancer Institute via subcontract with the NRG Oncology Foundation (PI-multiple), 5 UG1 CA189867 NRG Oncology Statistics and Data Management Center- NCORP Research Base, \$13,363,077	2014-2019
NSABP Foundation Inc. (PI), NSABP Foundation Core Support, \$909,091	2014-2019

NSABP Foundation Inc. (PI), Supplemental to support the alliance of the NSABP , RTOG, and GOG into NRG Oncology Group, \$518,744	2011-2013
NSABP Foundation Inc. (PI), GHI Study 5-038, \$22,828	2011-2012
NSABP Foundation Inc. (Co-investigator), Pre-implementation Development for a Phase III Trial to test the value of Bevacizumab Given for Two Years in Combination with 5-FU, Leucovorin, and Oxaliplatin Given for 6 Months in Patients with Stage III Colon Cancer, \$280,000	2010
NSABP Foundation Inc. (Co-investigator), Long-term follow-up of patients in a phase III trial comparing the combination of TC plus bevacizumab to TC alone and to TAC for women with node-positive or high-risk node-negative, HER2-negative breast cancer, \$4,572,935	2009-2021
NSABP Foundation Inc. (PI), A randomized phase III study to evaluate trastuzumab emtansine versus trastuzumab as adjuvant therapy for patients with Her-2+ breast cancer who have residual tumor present after preoperative therapy, \$4,810,701	2009-2021
NSABP Foundation Inc. (PI), Phase III trial to compare the safety and efficacy of Adrianycin and Cyclophosphamide Followed by Taxol to that of Adrianycin and Cyclophosohamide Followed by Taxol Plus Herceptin in Node-Positive, HER2+ Breast Cancer Patients, \$124,800	2009-2012
NSABP Foundation Inc. (PI), Phase III trial assessing bevacizumab with trastuzumab adjuvant therapy in HER2+ breast cancer patients (BETH Trial): NSABP B-44-I - Protocol Development, \$1,422,106	2008-2014
NSABP Foundation Inc. (PI), Phase III trial of neoadjuvant therapy for patients with palpable and operable HER2-positive breast cancer comparing the combination of trastuzumab plus lapatinib to trastuzumab and to lapatinib administered with weekly paclitaxel following AC, \$354,000	2007-2014
NSABP Foundation Inc. (PI), NSABP Biostatistical Center Core Support, \$845,454	2006-2009
NSABP Foundation Inc. (PI), NSABP Biostatistical Center Core Support, \$259,091	2005-2006
NSABP Foundation Inc. (PI), NSABP Biostatistical Center Core Support, \$733,000	2003-2006
Discovery International (Co-investigator), Breast cancer risk assessment education for health professionals, \$12,000	1999
National Cancer Institute (PI), 5 U10 CA 069974 CCOP Biostatistical Center, \$32,491,346	1995-2015
National Cancer Institute (PI), 5 U10 CA069651 Biostatistical Center for the NSABP, \$25,562,870	1995-2014
R.J. Lee Group (PI-sole), Environmental Health Training Grant, \$63,390	1989-1992
U.S. Environmental Protection Agency (Co-investigator), Surveillance of Giardia Infections through Analysis of Fecal Samples and Raw Sewage, \$50,000	1989-1991
Allegheny County Health Department (Co-investigator), Feasibility Study of Community Health Effects Associated with Coke Oven Emissions-Part D, \$25,000	1989-1990
Pennsylvania State Department of Environmental Resources (Co-investigator), Feasibility Studyof Community Health Effects Associated with Coke Oven Emissions-Part A, \$30,000	1989-1990
USX Corporation (Co-investigator), Feasibility Study of Community Health Effects Associated with Coke Oven Emissions-Part B, \$50,000	1989-1990
Pennsylvania Department of Health (Co-investigator), Statistical Analysis of the Drake Superfund Site Drake Occupational Health Survey, \$16,000	1985
Environmental Protection Agency (Co-investigator), Morbidity Survey of Coke Oven Workers, \$24,200	1984-1985
Environmental Protection Agency (Co-investigator), Cancer Risk Assessment Based on Coke Oven Workers Mortality, \$303,800	1983-1986
Consolidation and Peabody Coal Companies (PI-sole), Assessment of Coal Related Environmental and Occupational Health Risk, \$34,200	1983-1984

Environmental Protection Agency (Co-investigator), Clinical Evaluation of Health Status Among Coke Oven Workers, \$36,300	1983-1984
National Coal Association (PI-sole), Statistical Evaluation of Data from Precipitation Quality Network, \$31,700	1983-1984
American Mining Congress (PI-sole), Assessment of Respirable Particulate Levels at Surface Mining Operations, \$70,000	1982-1983
Kerr McGee Coal Corporation (PI-sole), Assessments of Health Risk Associated with Use of Diesel Equipment in Underground Coal Mines, \$9,700	1982
North American and Old Ben Coal Companies (PI-sole), Analysis of Federal Coal Mine Safety and Health Legislation, \$14,900	1982
Reitz Coal Company (PI-sole), Evaluation of Respirable Dust Levels at a Coal Preparation Plant, \$6,200	1982
National Coal Association (PI-sole), Environmental Health Risk Associated with Mining Preparation and Utilization of Coal, \$140,000	1980-1981

Publications

Books

Blazer, D. G., Barrent-Conner, E., Brody, B. A., Califf, R. M., Costantino, J. P., Federman, D. D., . . . Vaughan, Jr., E. D. (2004). *Testosterone and Aging: Clinical Research Directions*. C. T. Liverman, & D. G. Blazer (Eds.), Washington D.C.: The National Academies Press.

Chapters

Costantino, J. P. (2008). Benefit/risk assessment in prevention trials. In R. D'Agostino, L. M. Sullivan, & J. Marssaro (Eds.), *Wiley Encyclopedia of Clinical Trials* (pp. 1-8). John Wiley and Sons.

Redmond, C. K., Costantino, J. P., & Colton, T. (2006). Challenges in monitoring the Breast Cancer Prevention Trial. In *Data Monitoring in Clinical Trials: A Case Studies Approach* (pp. 118-135). doi:[10.1007/0-387-30107-0_11](https://doi.org/10.1007/0-387-30107-0_11)

Wickerham, D. L., & Costantino, J. P. (2003). Tamoxifen for chemoprevention. In M. Morrow, & C. V. Jordon (Eds.), *Managing Breast Cancer Risk* (pp. 175-185). Hamilton, Ontario: BC Decker, Inc..

Wickerham, D. L., & Costantino, J. P. (2003). Breast cancer prevention: the U.S.A. point of view. In *Breast Cancer Management: Application of evidence to Patient Care* (2nd ed., pp. 535-547). Philadelphia, PA: Lippincott, Williams and Wilkins.

Costantino, J. P. (2001). Benefit/risk assessment. In C. K. Redmond, & T. Colton (Eds.), *Biostatistics in Clinical Trials* (pp. 18-25). Wiley.

Costantino, J. P. (1999). Evaluating women for breast cancer risk reduction therapy. In *American Society of Clinical Oncology Fall Education Book* (pp. 208-214). American Society of Clinical Oncology.

Journal articles

Gray, R., Bradley, R., Braybrooke, J., Liu, Z., Peto, R., Davies, L., . . . Jackisch, C. (2019). Increasing the dose intensity of chemotherapy by more frequent administration or sequential scheduling: a patient-level meta-analysis of 37 298 women with early breast cancer in 26 randomised trials. *The Lancet*, 393(10179), 1440-1452. doi:[10.1016/S0140-6736\(18\)33137-4](https://doi.org/10.1016/S0140-6736(18)33137-4)

Kim, R. S., Song, N., Gavin, P. G., Salgado, R., Bandos, H., Kos, Z., . . . Pogue-Geile, K. L. (2019). Stomal Tumor-infiltrating Lymphocytes in NRG Oncology/NSABP B-31 Adjuvant Trial for Early-stage HER2-positive Breast Cancer. *J Natl Cancer Inst*. doi:[10.1093/jnci/djz032](https://doi.org/10.1093/jnci/djz032)

Jayasekera, J., Schechter, C. B., Sparano, J. A., Jaggi, R., White, J., Chapman, J. A. W., . . . Mandelblatt, J. (2018). Effects of radiotherapy in early-stage, low-recurrence risk, hormone-sensitive breast cancer. *Journal of the National Cancer Institute*, 110(12). doi:[10.1093/jnci/djy128](https://doi.org/10.1093/jnci/djy128)

Ingle, J. N., Kalari, K. R., Wickerham, D. L., Von Minckwitz, G., Fasching, P. A., Furukawa, Y., . . . Weinshilboum, R. M. (2018). Germline genome-wide association studies in women receiving neoadjuvant chemotherapy with or without bevacizumab. *Pharmacogenetics and Genomics*, 28(6), 147-152. doi:[10.1097/FPC.0000000000000337](https://doi.org/10.1097/FPC.0000000000000337)

Asselain, B., Barlow, W., Bartlett, J., Bergh, J., Bergsten-Nordström, E., Bliss, J., . . . von Minckwitz, G. (2018).

Long-term outcomes for neoadjuvant versus adjuvant chemotherapy in early breast cancer: meta-analysis of individual patient data from ten randomised trials. *The Lancet Oncology*, 19(1), 27-39. doi:[10.1016/S1470-2045\(17\)30777-5](https://doi.org/10.1016/S1470-2045(17)30777-5)

Geyer, C. E., Tang, G., Mamounas, E. P., Rastogi, P., Paik, S., Shak, S., ... Wolmark, N. (2018). 21-Gene assay as predictor of chemotherapy benefit in HER2-negative breast cancer.. *NPJ Breast Cancer*, 4, 37. doi:[10.1038/s41523-018-0090-6](https://doi.org/10.1038/s41523-018-0090-6)

Mamounas, E. P., Tang, G., Paik, S., Baehner, F. L., Liu, Q., Jeong, J. H., ... Wolmark, N. (2018). 21-Gene Recurrence Score for prognosis and prediction of taxane benefit after adjuvant chemotherapy plus endocrine therapy: results from NSABP B-28/NRG Oncology. *Breast Cancer Research and Treatment*, 168(1), 69-77. doi:[10.1007/s10549-017-4550-8](https://doi.org/10.1007/s10549-017-4550-8)

Mamounas, E. P., Liu, Q., Paik, S., Baehner, F. L., Tang, G., Jeong, J. H., ... Wolmark, N. (2017). 21-gene recurrence score and locoregional recurrence in node-positive/ER-positive breast cancer treated with chemo-endocrine therapy. *Journal of the National Cancer Institute*, 109(4). doi:[10.1093/jnci/djw259](https://doi.org/10.1093/jnci/djw259)

Bear, H. D., Tang, G., Rastogi, P., Geyer, C. E., Zoon, C. K., Kidwell, K. M., ... Wolmark, N. (2017). The Effect on Surgical Complications of Bevacizumab Added to Neoadjuvant Chemotherapy for Breast Cancer: NRG Oncology/NSABP Protocol B-40. *Annals of Surgical Oncology*, 24(7), 1853-1860. doi:[10.1245/s10434-016-5662-9](https://doi.org/10.1245/s10434-016-5662-9)

Gavin, P. G., Song, N., Rim Kim, S., Lipchik, C., Johnson, N. L., Bandos, H., ... Pogue-Geile, K. L. (2017). Association of polymorphisms in FCGR2A and FCGR3A with degree of trastuzumab benefit in the adjuvant treatment of ERBB2/HER2-positive breast cancer analysis of the NSABP B-31 trial. *JAMA Oncology*, 3(3), 335-341. doi:[10.1001/jamaoncol.2016.4884](https://doi.org/10.1001/jamaoncol.2016.4884)

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