CURRICULUM VITAE

Name: Lisa Meier McShane January 19, 2024

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Education:

8/28/89	Ph.D. Cornell University, Ithaca, New York Major: Statistics Thesis advisor: Bruce W. Turnbull
8/24/86	M.S. Cornell University, Ithaca, NY Major: Statistics
5/6/84	M.S. University of Kentucky, Lexington, Kentucky Major: Statistics
5/15/82	B.A. Millersville State College, Millersville, Pennsylvania Major: Mathematics

Brief Chronology of Employment:

1980 – 1981	*Tutor*. Millersville State College, Millersville, Pennsylvania. Math Tutor in Act 101 Program for educationally disadvantaged
1982 – 1984	*Teaching Assistant*. University of Kentucky, Department of Statistics, Lexington, Kentucky. Had full responsibility for teaching precalculus, elementary and engineering statistics courses
1984 – 1986	*Research Assistant*. Cornell University, School of Operations Research and Industrial Engineering, Ithaca, New York. Studied statistical properties of quality control inspection plan and developed improved measures of effectiveness of the plan
1986 – 1987	*Teaching Assistant*. Cornell University, School of Operations Research and Industrial Engineering, Ithaca, New York. Teaching assistant for graduate courses in statistical quality control and reliability, intermediate statistics and linear models, experimental design, and analysis of discrete data

1987	*Member of Technical Staff*. Bell Communications Research, Red Bank, New Jersey. Reliability and Maintainability Methods District. Investigated statistical properties of new reliability tests (summer)
1988 – 1989	*Teaching Support Specialist*. Cornell University, Biometrics Unit, Ithaca, New York. Teaching support for graduate courses in statistical methods, research, and consulting
10/10/89 – 10/9/92	*Staff Fellow*. NINDS/NIH, Mathematical Statistics Section, Biometry and Field Studies Branch. Development of statistical methods and engage in collaborative research for neurological disorders
10/10/92 – 3/4/95	*Senior Staff Fellow*. NINDS/NIH, Mathematical Statistics Section, Biometry and Field Studies Branch. Development of statistical methods and engage in collaborative research for neurological disorders
3/5/95 – 6/8/96	*Senior Staff Fellow*. NCI/NIH, Clinical and Diagnostic Trials Section, Biometry Branch, Division of Cancer Prevention and Control. Development of statistical methods and engage in collaborative research for cancer prevention trials and epidemiologic studies
6/9/96 – 7/22/16	*Mathematical Statistician*. NCI/NIH, Biometric Research Branch, Division of Cancer Treatment and Diagnosis. Development of statistical methods for the evaluation of cancer biomarkers, assess analytical validity and reproducibility of biomarker assays, review protocols for laboratory correlative science studies and clinical trials utilizing biomarkers.
7/23/16 – 7/1/17	*Chief, Biostatistics Branch.* NCI/NIH Biometric Research Program, Division of Cancer Treatment and Diagnosis. Supervise group of seven PhD statisticians to advise the Division on matters relating to cancer clinical trials, cancer diagnostic and imaging studies. Engage in research and consulting for development and application of statistical methods for the evaluation of cancer biomarkers, assessment of analytical validity of biomarker assays, review protocols for laboratory correlative science studies and clinical trials utilizing biomarkers.
7/2/17 – 8/31/19	*Acting Associate Director, Division of Cancer Treatment and Diagnosis.* *Acting Chief, Biometric Research Program* (Carried out all duties as described below for the permanent position to which I was appointed on 9/1/19)
9/1/19 – present	*Associate Director, Division of Cancer Treatment and Diagnosis* *Chief, Biometric Research Program* Lead the NCI Biometric Research Program, comprised of a Biostatistics Branch and a Computational and Systems Biology Branch.

- Oversee program activities and staff, including 9 statisticians, computational or systems biologists in each branch, postdoctoral fellows, and contract and administrative support personnel.
- Responsible for strategic planning, budget, staffing, and performance evaluations to ensure that statistical and computational needs of the Division are met.
- Provide scientific expertise for development and review of clinical trials and research proposals for matters relating to cancer clinical trials, cancer diagnostic and imaging studies, and developmental therapeutics research.
- Engage in individual and collaborative research and consulting for development and application of statistical methods for the evaluation of cancer therapeutics and biomarkers, and assessment of analytical validity of biomarker assays.
- Represent NCI DCTD on statistical matters and collaborate with other government agencies and biomedical and statistical professional organizations
- NCI Exceptional Responders Initiative, lead statistician
- NCI MATCH trial, co-principal NCI statistician
- ComboMATCH, clinical trial development team
- iMATCH, clinical trial development team

Honors and Awards:

Millersville State College, Class of 1895 Award, to an outstanding senior; Class of 1866 Senior Math Award; Harry E. Canter Statistics Award; Cora Catherine Bitner Music Award; Isaac F. Seiverling Junior Math Award; Thomas R. Baker Memorial Scholarship, to an outstanding junior; Wentzel-Wright Memorial Junior Award; American Association of University Professors Award, to one of top ten sophomores; Phi Kappa Phi Honor Society.

University of Kentucky, Department of Statistics Fellowship, Fall 1982; University of Kentucky Fellowship, Spring 1983; and Graduate School Summer Fellowship, Summer 1983.

Biometric Society (ENAR) Student Award, prize competition for student papers presented at Biometric Society (ENAR) Spring Meetings, Dallas, Texas, March 1987.

Cornell University, Mathematical Sciences Institute Fellowship, 1987-1988

National Institutes of Health Award of Merit, 1995. For development and innovative application of statistical methods in neurology.

National Institutes of Health Director's Award, 2008. In recognition of work in the development and application of innovative trial designs for predictive biomarkers to make personalized medicine a reality.

U.S. Government 20 Year Service Award, 2009. In recognition of twenty years of service in the Government of the United States of America.

National Cancer Institute Special Recognition Award, August 2010.

National Cancer Institute Special Recognition Award, September 2012.

Fellow of the American Statistical Association, April 2013. For outstanding statistical contributions to development of clinical tests for personalized medicine, international efforts to improve the quality and reproducibility of tumor marker research, exceptional ability to communicate statistical principles to cancer researchers, and distinguished service to the statistics profession.

National Institutes of Health Award of Merit, 2014. NCI Exceptional Responders Initiative Development Team: Development and implementation of a plan to molecularly profile 100 exceptional responders to systemic cancer treatment in order to assess the ability to hypothesize molecular conditions conducive to exceptional response.

National Institutes of Health Award of Merit, 2014. Precision Medicine Clinical Treatment Trials in Lung Cancer Development Team: Designed trials to use precise diagnostics allowing selection of patients for therapies in lung cancer that target particular molecular abnormalities on a broad, national scale.

National Institutes of Health, National Cancer Institute Award of Merit, 2015. Molecular Analysis for Cancer Therapy Choice (NCI-MATCH) Clinical Trial Development Team: Statistician involved in the design and conduct of a national trial using molecular profiling of tumors to match patients with cancer to new drugs that target specific molecular alterations.

National Institutes of Health, National Cancer Institute Award of Merit, 2016. Immunotherapy Clinical Trials and Biomarkers Initiative Group: Statistician involved in initiating programs to develop biomarker assays and databases that foster integration across clinical and biomarker datasets to facilitate progress in clinical cancer immunotherapy.

National Institutes of Health, NCI Director's Award for Clinical Science, 2018. NCTN Navigator Clinical Trials Specimen Resource: For outstanding achievement in making a valuable new resource available to the scientific community by developing and launching the NCTN Navigator Clinical Trials Specimen Resource.

National Institutes of Health, NCI Director's Award for Administrative Performance, 2019. NCTN/NCORP Data Archive Development Group: For the development of the NCTN/NCORP Data Archive, a centralized database that allows investigators to utilize de-identified patient-level data from NCI phase 3 trials.

U.S. Government 30 Year Service Award, 2019. In recognition of thirty years of service in the Government of the United States of America.

NCI Group Special Accomplishment Award, 2020. In recognition of significant biostatistical contributions to the rapid development and launch of the NCI COVID-19 in Cancer Patients Study (NCCAPS).

NCI Group Special Accomplishment Award, 2021. In recognition of outstanding contributions of statistical and computational leadership, and analysis and software development expertise, for the Tumor Mutation Burden (TMB) Harmonization Project.

National Institutes of Health, NCI Director's Award for Scientific Accomplishment, 2021. NCI Exceptional Responders Initiative Project: For significant advances in understanding exceptional responses to cancer therapy.

NCI Group Special Accomplishment Award, 2023. In recognition of providing outstanding statistical leadership, innovative planning, timely analysis, and essential deliverables to advance the Investigational Device Exemption (IDE) filing to FDA for the MyeloMATCH precision medicine initiative.

Professional Societies:

American Statistical Association
Biometric Society
International Society for Clinical Biostatistics

Selected Professional Activities:

Journal Editorial and Scientific Advisory Board Positions

Statistics in Biopharmaceutical Research, Associate Editor, 2006-2011
Science Translational Medicine, Scientific Advisory Board, 2012-Present
BMC Medicine, Editorial Board, 2013-2020
Journal of Clinical Oncology, Editorial Board, 2020-2022
Statistics in Medicine, Co-Editor-in-Chief, 2022-Present

Professional Society Service

ASA Biometrics Section Program Chair for Joint Statistical Meetings, 1994
Biometric Society (ENAR) Representative to the American Statistical Association Committee on Meetings, 1995-1999
ASA Committee on Professional Ethics, Member, 1998 -2003
ASCO Annual Meeting Program Committee, Biostatistics Track Reviewer, 2004-2005
ASA Committee on Award of Outstanding Statistical Application, Member, 2005-2010
ASCO/CAP Expert Panel on Development of Guidelines for HER2 Testing, Member, 2006
ASCO/CAP Expert Panel on Development of Guidelines for Hormone Receptor Testing in Breast Cancer, Member, 2008
ASCO-NCI-EORTC Diagnostic Development Tutorial Planning Committee, 2009-2011

ASCO Expert Panel on Development of Provisional Clinical Opinion for the Use of EGFR Mutation Testing in Patients with Advanced NSCLC, Member, 2010

ASCO/CAP Expert Panel on Development of Updated Guidelines for HER2 Testing, Member, 2012-2013

ASCO Expert Panel on Development of Clinical Practice Guidelines for Use of Tumor Biomarkers in Early Stage Breast Cancer, Member, 2013-2016

ASCO/CAP Expert Panel on Development of Updated Guidelines for HER2 Testing, Steering Committee and Panel Member, 2016-2018

ASCO/CAP Expert Panel on Development of Updated Guidelines for Immunohistochemical Testing of Estrogen and Progesterone Receptors in Breast Cancer, Steering Committee and Panel Member, 2017-2020

American Society of Clinical Oncology (ASCO) - Society for Immunotherapy of Cancer (SITC) Working Group to Develop Guidelines to Standardize Reporting for Immuno-Oncology Clinical Trials, Member, 2017-2018

ASCO Expert Panel on Use of Biomarkers to Guide Decisions on Systemic Therapy for Women with Metastatic Breast Cancer Guideline Update, Member, 2021-Present

Clinical Trial Design Working Group, Society for Immunotherapy of Cancer (SITC) Global Regulatory Summit, Member, Member, 2022-2023

Collaborations and Service with other NCI Programs, NIH, FDA, and other Government Agencies

NCI Program for the Assessment of Clinical Cancer Tests, Strategy Group Member, 2000-2017

FDA Oncologic Drugs Advisory Committee Special Consultant on Prostate Cancer Endpoints, March 2005

FDA/CDRH Molecular and Clinical Genetics Panel, Member, 2014

NIH-FDA Joint Leadership Council Biomarker Working Group, Member, 2015-Present

FDA/CDRH Clinical Chemistry and Clinical Toxicology Panel, Member, 2016

FDA Biomarker Qualification Statistics Working Group, Member, 2016-2021

NIA Study Section, review UO1s applications submitted in response to RFA AG18-018: *Development of Valid Reliable Markers of Aging-Related Biologic Mechanisms for Human Studies*, Member, 2018

NIEHS Board of Scientific Counselors Review Committee for the Biostatistics and Computational Biology Branch, Division of Intramural Research, NIEHS, *ad hoc* Statistical Reviewer, March 2021

NIH-FDA Joint Leadership Council Clinical Research Taxonomy Working Group, NIH lead, 2023-Present

Academic and Public-Private Collaborations

Ontario Institute for Cancer Research, Grant Study Section, Member, 2010-2011

International Ki67 in Breast Cancer Working Group, Member, 2010-2021

Institute of Medicine Advisory Committee on Management of the Air Force Health Study Data and Specimens, Member, 2012-2015

Institute of Medicine Consensus Committee on Management of the Air Force Health Study Data and Specimens-Report to Congress, Member, 2014-2015

Institute of Medicine Committee on the State of the Science in Ovarian Cancer Research, Member, 2015-2016

Fifth Seattle Symposium in Biostatistics: Biomarkers for Diagnosis, Prognosis, and Therapy Guidance, Organizing Committee, Member, 2015

Sustainable Predictive Oncology Therapeutics and Diagnostics (SPOT/Dx) Working Group (facilitated by Tapestry Networks), Member, 2016-2021

Scientific and Regulatory Considerations for the Analytical Validation of Assays Used in the Qualification of Biomarkers in Biological Matrices Working Group (facilitated by Duke-Margolis Center for Health Policy), Member, 2017-2020

Evidentiary Criteria for Surrogate Endpoints Working Group (facilitated by Foundation for the National Institutes of Health), Member, 2017-2019

Scientific Advisory Board for the Medical Informatics in Research and Care in University Medicine (MIRACUM) Consortium (Germany), Member, 2018-Present

Tumor Mutational Burden (TMB) Harmonization Project (facilitated by Friends of Cancer Research), Member, 2017- 2021

STRengthening Analytical Thinking for Observational Studies (STRATOS) Initiative, Co-chair of High-dimensional Data Topic Group, 2015-Present

International ESR1 Expression in Breast Cancer Working Group, Member, 2020-Present

Ontario Institute for Cancer Research, Clinical Translation Pathway Grant Study Section, Member, 2021

Accelerating Anticancer Agent Development and Validation (AAADV) Workshop, Program Committee, Member, 2021

Homologous Recombination Deficiency (HRD) Harmonization Project (facilitated by Friends of Cancer Research), Member, 2021-Present

Standardizing Laboratory Practices in Pharmacogenomics (STRIPE) Study Design Task Force, Member, 2021-Present

International Review Panel for the German Cancer Research Center in Heidelberg (DKFZ, www.dkfz.de), Member, 2023

Scientific Advisory Board for the Small Data Initiative of the German Collaborative Research Center, Member, 2023-Present

Service on Clinical Study Oversight and Data and Safety Monitoring Committees

NIDCR/NIH Clinical Study Oversight Committee for Salivary Diagnostics Program, Member, 2010-2013

NIDCR/NIH Clinical Study Oversight Committee for "Salivary Biomarkers for Primary Sjorgren's Syndrome Detection" and "Salivary Biomarker Panel for Measuring and Predicting Traumatic Stress," Chair, 2012-2019

Books and Book Chapters:

1. Brown P, Cervenakova L, **McShane L**, Kleihues P, Foncin J-F, Collins G, Bastian F, Goldfarb LG, Gajdusek DC. Polymorphic genotype matching in acquired Creutzfeldt-Jakob disease: An analysis of donor/recipient case pairs. pp. 19-24 in *Prions and Brain Diseases in Animals and Humans*, Morrison DRO (ed.), NATO ASI Series A: Life Sciences, Plenum Press, New York, v. 295, 1998.
2. **McShane LM,** 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, Wittekind (eds.), Wiley-Liss, New York, 2001.
3. Simon R, Korn EL, **McShane LM**, Radmacher MD, Wright GW, Zhao Y. *Design and Analysis of DNA Microarray Investigations,* Springer-Verlag, New York, 2004.
4. **McShane LM,** Korn EL, Freidlin B. Statistical considerations in the development and evaluation of therapeutic biomarkers in cancer. pp. 31-58 in *Handbook of Therapeutic Biomarkers in Cancer*, Yang, Dancey (eds.), Pan Stanford, Singapore, 2013.
5. Altman DG, **McShane LM**, Sauerbrei W, Taube SE, Cavenagh MM. REMARK: REporting recommendations for tumour MARKer prognostic studies. In *Guidelines for Reporting Health Research:* A *User's Manual*, Altman, Schulz, Simera, Wager (eds), Wiley, 2014.
6. Abrams J, Conley B, Mooney M, Zwiebel J, Chen A, Welch JJ, Takebe N, Malik S, **McShane L**, Korn E, Williams PM, Staudt L, Doroshow J. National Cancer Institute's precision medicine initiatives for the new National Clinical Trials Network. pp. 71-76 in *American Society of Clinical Oncology Educational Book*, American Society of Clinical Oncology (ASCO) Meeting, 2014.
7. **McShane LM**, Hunsberger S. An overview of phase II clinical trial designs with biomarkers. pp. 71-87 in *Design and Analysis of Clinical Trials for Predictive Medicine*, Matsui, Buyse, Simon (eds.), Chapman and Hall/CRC, 2015.
8. IOM (Institute of Medicine). *The Air Force Health Study Assets Research Program*, The National Academies Press, Washington, DC, 2015. [Committee member]
9. IOM (Institute of Medicine). *Ovarian Cancers: Evolving Paradigms in Research and Care*, The National Academies Press, Washington, DC, 2015. [Committee member]
10. Sachs MC, **McShane LM**. Development and validation of predictive signatures. pp. 133-165 in *Cancer Clinical Trials: Current and Controversial Issues in Design and Analysis,* George, Wang, Pang (eds.), CRC Press, Boca Raton, FL, 2016.
11. **McShane LM**, Lively TG, Makhlouf HR. Translation of biomarkers into clinical practice. pp. 1-18 in *Molecular Pathology of Breast Cancer*, Badve, Gökmen-Polar (eds.), Springer International Publishing, Switzerland, 2016.
12. Palmisano A, Krushkal J, Li M-C, Fang J, Sonkin D, Wright G, Yee L, Zhao Y, **McShane L**. Bioinformatics Tools and Resources for Cancer Immunotherapy Study. In *Biomarkers for the Immunotherapy of Cancer*, Thurin, Cesano, Marincola (eds.), Springer Protocol, Methods and Protocol Series, Humana Press, New York, NY, 2020.

Peer-reviewed Publications:

1. **McShane LM**, Clark LC, Combs GF, Jr, Turnbull BW. Reporting the accuracy of biochemical measurements for epidemiologic and nutrition studies. *American Journal of Clinical Nutrition* 53: 1354-60, 1991.

2. **McShane LM**, Turnbull BW. Probability limits on outgoing quality for continuous sampling plans. *Technometrics* 33(4): 393-404, 1991.
3. Wassermann EM, **McShane LM**, Hallett M, Cohen LG. Noninvasive mapping of muscle representations in human motor cortex. *Electroencephalography and Clinical Neurophysiology* 85: 1-8, 1992.
4. Brasil-Neto JP, **McShane LM**, Fuhr P, Hallett M, Cohen LG. Topographic mapping of the human motor cortex with magnetic stimulation: factors affecting accuracy and reproducibility. *Electroencephalography and Clinical Neurophysiology* 85: 9-16, 1992.
5. **McShane LM,** Turnbull BW. New performance measures for continuous sampling plans applied to finite production runs. *Journal of Quality Technology* 24(3): 153-161, 1992.
6. **McShane LM,** Turnbull BW. Optimal checking procedures for monitoring laboratory analyses. *Statistics in Medicine* 11(10): 1343-1357, 1992.
7. Sheng, JG, **McShane LM**, Plunkett RJ, Cummins AC, Oldfield EH, Kopin IJ, Palmatier MA. Dopaminergic neuronal sprouting and behavioral recovery in hemi-Parkinsonian rats after implantation of amnion cells. *Experimental Neurology* 123(2): 192-203, 1993.
8. **McShane LM**, Palmatier MA. Spatial distribution of neurons in tissue culture wells: implications for sampling methods to estimate population size. *Statistics in Medicine* 13: 523-540, 1994.
9. Valls-Sole J, Pascual-Leone A, Brasil-Neto JP, Cammarota A, **McShane LM**, Hallett M. Abnormal facilitation of the response to transcranial magnetic stimulation in patients with Parkinson's disease. *Neurology* 44(4): 735-741, 1994.
10. Grill SE, Hallett M, Marcus C, **McShane L**. Disturbances of kinaesthesia in patients with cerebellar disorders. *Brain* 117: 1433-1447, 1994.
11. Albert PS, **McShane LM**. A generalized estimating equations approach for spatially correlated binary data: applications to the analysis of neuroimaging data. *Biometrics* 51(2): 627-638, 1995.
12. Brainin M, **McShane LM**, Steiner M, Dachenhausen A, Seiser A. Silent brain infarcts and transient ischemic attacks: a three-year study of first-ever, ischemic stroke patients. The Klosterneuburg Stroke Data Bank. *Stroke* 26(8): 1348-1352, 1995.
13. Lou JS, Goldfarb L, **McShane L**, Gatev P, Hallett M. Use of buspirone for treatment of cerebellar ataxia: an open-label study. *Archives of Neurology* 52(10): 982-8, 1995.
14. **McShane LM**, Dorgan JF, Greenhut S, Damato JJ. Reliability and validity of serum sex hormone measurements. *Cancer Epidemiology, Biomarkers & Prevention* 5(11): 923-8, 1996.
15. Schatzkin A., Freedman LS, Dorgan J, **McShane LM**, Schiffman MH, Dawsey SM. Using and interpreting surrogate end points in cancer research: a critique. [Review] *IARC Scientific Publications* 142: 265-271, 1997.
16. Grill SE, Hallett M, **McShane LM**. Timing and onset of afferent responses and of use of kinesthetic information for control of movement in normal and cerebellar-impaired subjects. *Experimental Brain Research* 113(1): 33-47, 1997.
17. **McShane LM**, Albert PS, Palmatier MA. A latent process regression model for spatially correlated count data. *Biometrics* 53(2): 698-706, 1997.
18. **McShane LM**, Meier KL, Wassermann EM. A comparison of spatial prediction techniques for an exploratory analysis of human cortical motor representations. *Statistics in Medicine* 16: 1337-1355, 1997.
19. Demirci M, Grill S, **McShane L**, Hallett M. A mismatch between kinaesthetic and visual perception in Parkinson's disease. *Annals of Neurology* 41(6): 781-8, 1997.

20. Brown P, Cervenakova L, **McShane L**, Goldfarb LG, Bishop K, Bastian F, Kirkpatrick J, Piccardo P, Ghetti B, Gajdusek DC. Creutzfeldt-Jakob disease in a husband and wife. *Neurology* 50(3): 684-688, 1998.
21. Ferris DG, Cox JT, Burke L, Litaker MS, Harper DM, Campion MJ, Greenberg MD, **McShane L**, Wun LM. Colposcopy quality control: establishing colposcopy criterion ctandards for the National Cancer Institute ALTS Trial using cervigrams. *Journal of Lower Genital Tract Disease* 2: 195-203, 1998.
22. **McShane LM**, Kulldorff M, Wargovich MJ, Woods C, Purewal M, Freedman LS, Corle DK, Burt RW, Mateski DJ, Lawson M, Lanza E, O'Brien B, Lake W, Jr, Moler J, Schatzkin A. An evaluation of rectal mucosal proliferation measure variability sources in the polyp prevention trial: can we detect informative differences among individuals' proliferation measures amid the noise? *Cancer Epidemiology, Biomarkers & Prevention* 7(7): 605-612, 1998.
23. Dorgan JF, Albanes D, Virtamo J, Heinonen OP, Chandler DW, Galmarini M, **McShane LM**, Barrett MJ, Tangrea J, Taylor PR. Relationships of serum androgens and estrogens to prostate cancer risk: results from a prospective study in Finland. *Cancer Epidemiology, Biomarkers & Prevention* 7: 1069-1074, 1998.
24. Hildesheim A., **McShane LM**, Schiffman M, Bratti MC, Rodriguez AC, Herrero R, Morera LA, Cardenas F, Saxon L, Bowman FP, Crowley-Nowick PA. Cytokine and immunoglobulin levels in cervical secretions: reproducibility of a collection instrument and correlates of immune measures. *Journal of Immunological Methods* 225(1-2): 131-143, 1999.
25. Brown P, Cervenakova L, **McShane LM**, Barber P, Rubenstein R, Drohan WN. Further studies of blood infectivity in an experimental model of transmissible spongiform encephalopathy, with an explanation of why blood components do not transmit Creutzfeldt-Jakob disease in humans. *Transfusion* 39: 1169-1178, 1999.
26. **McShane LM**, Aamodt R, Cordon-Cardo C, Cote R, Faraggi D, Fradet Y, Grossman HB, Peng A, Taube SE, Waldman FM, and the National Cancer Institute Bladder Tumor Marker Network. Reproducibility of p53 immunohistochemistry in bladder tumors. *Clinical Cancer Research* 6(5): 1854-1864, 2000.
27. Kulldorff M, **McShane LM**, Schatzkin A, Freedman LS, Wargovich MJ, Woods C, Purewal M, Burt RW, Lawson M, Mateski DJ, Lanza E, Corle DK, O'Brien B, Moler J. Measuring cell proliferation in the rectal mucosa: comparing bromodeoxyuridine (BrdU) and proliferating cell nuclear antigen (PCNA) assays. *Journal of Clinical Epidemiology* 53(8): 875-883, 2000.
28. Pajak TF, Clark GM, Sargent DJ, **McShane L**, Hammond E. Statistical issues in tumor marker studies. *Archives of Pathology and Laboratory Medicine* 124(7): 1011-1015, 2000.
29. Brown P, Preece M, Brandel J-P, Sato T, **McShane L**, Cervenakova L, Zerr I, Will RG, Fletcher A, Pocchiari M, Cashman N, d'Aignaux JH, Fradkin J, Schonberger L, Collins SJ. Iatrogenic Creutzfeldt-Jakob disease at the millennium. *Neurology* 55(8): 1075-1081, 2000.
30. Blegen H, Einhorn N, Sjovall K, Roschke A, Ghadimi BM, **McShane LM**, Nilsson B, Shah K, Ried T, Auer G. Prognostic significance of cell cycle proteins and genomic instability in borderline, early- and advanced stage ovarian carcinomas. *International Journal of Gynecologic Cancer* 10(6): 477-487, 2000.
31. **McShane LM**, Midthune DN, Dorgan JF, Freedman LS, Carroll RJ. Covariate measurement error adjustment for matched case-control studies. *Biometrics* 57(1): 62-73, 2001.
32. Albert PS, **McShane LM**, Shih JH. Latent modeling approaches for assessing diagnostic error without a gold standard: with applications to p53 immunohistochemical assays in bladder tumors. *Biometrics* 57(2): 610-619, 2001.

33. Albert PS, **McShane LM**, Korn EL. Design of a binary biomarker study from the results of a pilot study. *Biometrics* 58: 576-585, 2002.
34. Korn EL, **McShane LM**, Troendle JF, Rosenwald A, Simon R. Identifying pre-post chemotherapy differences in gene expression in breast tumours: a statistical method appropriate for this aim. *British Journal of Cancer* 86(7): 1093-1096, 2002.
35. Radmacher MD, **McShane LM**, Simon R. A paradigm for class prediction using gene expression profiles. *Journal of Computational Biology* 9(3): 505-511, 2002.
36. **McShane LM**, Radmacher MD, Freidlin B, Yu R, Li M, Simon R. Methods for assessing reproducibility of clustering patterns observed in analyses of microarray data. *Bioinformatics* 18(11): 1462-1469, 2002.
37. Miller LD, Long PM, Wong L, Mukherjee S, **McShane LM**, Liu ET. Optimal gene expression analysis by microarrays. *Cancer Cell* 2(5): 353-361, 2002.
38. 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(1): 14-18, 2003.
39. **McShane LM**, Shih JH, Michalowska AM. Statistical issues in the design and analysis of gene expression microarray studies of animal models. *Journal of Mammary Gland Biology and Neoplasia* 8(3): 359-374, 2003.
40. Sotiriou C, Neo S, **McShane LM**, Korn EL, Long P, Jazaeri A, Martiat P, Harris AL, Liu ET. Breast cancer classification and prognosis based on gene expression profiles from a population based study. *Proceedings of the National Academy of Sciences* 100(18): 10393-10398, 2003.
41. Pfeiffer R, **McShane L**, Wargovich M, Burt R, Kikendall W, Lawson M, Lanza E, Schatzkin A. The effect of a low-fat, high fiber, fruit and vegetable intervention on rectal mucosal proliferation. *Cancer* 98(6): 1161-1168, 2003.
42. Cervenakova L, Yakovleva O, McKenzie C, Kolchinsky S, **McShane L**, Drohan W, Brown P. Similar levels of infectivity in the blood of mice infected with human-derived vCJD and GSS strains of transmissible spongiform encephalopathy. *Transfusion* 43(12): 1687-1694, 2003.
43. Troendle JF, Korn EL, **McShane LM**. An example of slow convergence of the bootstrap in high dimensions. *The American Statistician* 58(1): 25-29, 2004.
44. Korn EL, Habermann JK, Upender MB, Ried T, **McShane LM**. An objective method of comparing DNA microarray image analysis systems with application to comparison of UCSF Spot and GenePix. *BioTechniques* 36: 960-967, 2004.
45. Korn EL, Troendle JF, **McShane LM**, Simon R. Controlling the number of false discoveries: application to high-dimensional genomic data. *Journal of Statistical Planning and Inference* 124: 379-398, 2004.
46. Dodd LC, Korn EL, **McShane LM**, Chandramouli GVR, Chuang EY. Correcting log ratios for signal saturation in cDNA microarrays. *Bioinformatics* 20: 2685-2693, 2004.
47. Upender MB, Habermann JK, **McShane LM**, Korn EL, Barrett JC, Difilippantonio MJ, Ried T. Chromosome transfer induced aneuploidy results in complex dysregulation of the cellular transcriptome in normal immortalized and diploid cancer cells. *Cancer Research* 64: 6941-6949, 2004.
48. Yakovleva O, Janiak A, McKenzie C, **McShane L**, Brown P, Cervenakova L. Effect of protease treatment on plasma infectivity in variant CJD mice. *Transfusion* 44: 1700-1705, 2004.
49. Korn EL, Albert PS, **McShane LM**. Assessing surrogates as trial endpoints using mixed models. *Statistics in Medicine* 24: 163-182, 2005.

50. **McShane LM**, Altman DG, Sauerbrei W, Taube SE, Gion M, Clark GM, for the Statistics Subcommittee of the NCI-EORTC Working Group on Cancer Diagnostics. REporting recommendations for tumor MARKer prognostic studies (REMARK). Simultaneously published in the following journals: *British Journal of Cancer* 93(4): 387-391, 2005; *European Journal of Cancer* 41: 1690-1696, 2005; *Journal of Clinical Oncology* 23(36): 9067-9072, 2005; *Journal of the National Cancer Institute* 97(16): 1180-1184, 2005; *Nature Clinical Practice Oncology* 2(8): 416-422, 2005. Re-published in the following journals: *Breast Cancer Research and Treatment* 100(2): 229-235, 2006; *Experimental Oncology* 28(2): 99-105, 2006.
51. Dodd LE, Sengupta S, Chen I-H, den Boon JA, Cheng Y-J, Westra W, Newton MA, Mittl BF, **McShane L**, Chen C-J, Ahlquist P, Hildesheim A. Genes involved in DNA repair and nitrosamine metabolism and those located on chromosome 14q32 are dysregulated in nasopharyngeal carcinoma. *Cancer Epidemiology, Biomarkers, and Prevention* 15(11): 2216-2225, 2006.
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Journal Correspondence:

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Publications not Peer-reviewed:

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3. **McShane LM**. Reporting of tumor marker studies. *DAKO Connection* 12: 62-66, 2008.

Invited Presentations:

1. A quality control procedure for monitoring laboratory analyses. Biometric Society (ENAR) Spring Meeting, Dallas, TX, March 1987.
2. Probability limits on outgoing quality for continuous sampling plans. ASA/ASQC Fall Technical Conference, Lexington, KY, October 1991.
3. Reporting the accuracy of biochemical measurements for epidemiologic and nutrition studies. Biometric Society (ENAR) Spring Meetings, Cincinnati, OH, March 1992.
4. Experiences with a chemoprevention trial of nonmelanoma skin cancer with a nutritional supplement of selenium. National Cancer Institute, Division of Cancer Prevention and Control, Bethesda, MD, October 1992.
5. Spatial distribution of neurons in tissue culture wells: implications for sampling methods to estimate population size. National Institutes of Health Conference on Current Topics in Biostatistics, Bethesda, MD, January 1993.
6. An evaluation of variability in immunohistochemical measurements of p53 in bladder cancer. Second International Workshop on Diagnostic and Prognostic Markers in Bladder Cancer, Barcelona, Spain, October 1998.
7. Case studies in statistical ethics. [Discussion] Joint Statistical Meetings, Baltimore, MD, August 1999.
8. Statistical issues in the evaluation of HER-2/neu. Detection of HER2/neu (erbB2) Antigen Overexpression Symposium, Bethesda, MD, October 1999.
9. Statistical issues in the design and analysis of tissue microarrays. Pediatric Proteomic Meeting, Rockville, MD, April 2002.
10. Comparison of sampling designs for selecting cases for prognostic marker studies: discussion of appropriate analysis methods. NCI-EORTC 2nd International Meeting on Cancer Diagnostics, Washington, D.C., June 2002.
11. Statistical issues in the analysis of microarray data. XXIst International Biometric Conference, Freiburg, Germany, July 2002.
12. Statistical issues in the design and analysis of gene expression microarray experiments. College of William and Mary, Williamsburg, VA, October 2003.
13. Controlling the number of false discoveries: application to high-dimensional genomic data. College of William and Mary, Williamsburg, VA, October 2003.
14. Statistical issues in molecular profiling studies: building and validating prognostic classifiers. NCI-EORTC 3rd International Meeting on Cancer Molecular Markers, Brussels, Belgium, April 2004.
15. Validation of biomarkers: a statistical perspective. Acute Renal Failure Strategic Planning Retreat, Washington, D.C., June 2004.

16. Statistical issues in the analysis of high-throughput biologic data. Early Detection Research Network Third Scientific Workshop, Bethesda, MD, June 2004.
17. Statistical issues in molecular profiling studies: statistical considerations in the development and validation of prognostic profiles derived from gene expression microarray data. Joint Statistical Meetings, Toronto, Canada, August 2004.
18. Statistical issues in molecular profiling: building and validating prognostic classifiers. FDA/Industry Statistics Workshop, Washington, D.C., September 2004.
19. Statistical issues in molecular profiling: development of clinically useful molecular profiles. U.S. Food and Drug Administration, CDRH Staff College, Rockville, MD, October 2004.
20. PSA and other biological markers in prostate cancer: a statistical perspective. NCI PACCT Strategy Group, Bethesda, MD, May 2005.
21. A rational approach to the development and validation of a molecular classifier. Statistical Methods in Biopharmacy: Statistical Innovations in Clinical Trials, Paris, France, September 2005.
22. Difficulties of translational research. French National Cancer Institute, Paris, France, September 2005.
23. Controlling the number of false discoveries: application to high-dimensional genomic data. Department of Biostatistics, Virginia Commonwealth University School of Medicine, Richmond, VA, November 2005.
24. A rational approach to the development and validation of a molecular classifier. U.S. Food and Drug Administration, CDRH Staff College, Rockville, MD, February 2006.
25. Statistical considerations in developing a laboratory proficiency testing program. ASCO-CAP HER-2 Testing Guideline Meeting, Alexandria, VA, March 2006.
26. Methodologic challenges and problems in tumor prognostic marker research. UICC World Cancer Congress 2006, Washington, D.C., July 2006.
27. Progress in developing clinically useful multi-gene signatures in breast cancer: a statistician's perspective. NCI-EORTC 4th International Meeting on Cancer Molecular Markers, Stone Mountain, GA, September 2006.
28. How should we use predictive biomarkers; how do we assess the clinical reliability? (joint with S Taube) AACR–FDA–NCI Think Tank on Clinical Biomarkers, Philadelphia, PA, November 2006.
29. Statistical issues in molecular profiling: development of clinically useful molecular profiles. U.S. Food and Drug Administration, CDER, Silver Spring, MD, March 2007.
30. Roles for biomarkers in patient care and drug development. Radiological Society of North America (RSNA) Biomarkers Methodology Workshop, Bethesda, MD, May 2007.
31. Tumor marker development: the problems and pitfalls of translating laboratory observations to clinical utility: it isn't easy! (joint with D. Hayes, M. Dowsett, and D. Ransohoff) at 2007 ASCO Annual Meeting, Chicago, IL, June 2007.
32. Issues in cancer biomarker/signature development: a statistician's perspective. MRC Clinical Trials Unit, London, England, August 2007.
33. Study design and regulatory issues for use of cancer stem cells. Cancer Stem Cell Workshop, Rockville, MD, January 2008.
34. Effective inclusion of correlative studies in phase 2 trials. Clinical Trials Design Task Force Meeting, Rockville, MD, January 2008.
35. Adaptive designs: potential for use in cancer prevention trials. NCI Division of Cancer Prevention Chemoprevention Consortium, Rockville, MD, August 2008.

36. Development of statistically robust and clinically meaningful multiplex markers. ASCO-NCI-EORTC Annual Meeting on Molecular Markers in Cancer Diagnostic Development Tutorial, Hollywood, FL, October 2008.
37. Statistical considerations in developing a laboratory proficiency testing program. ASCO/CAP Expert Panel on the Development of Guidelines for Hormone Receptor Testing in Breast Cancer, Alexandria, VA, December 2008.
38. Reporting of tumor marker studies. 2nd TBCI Breast Correlative Sciences Workshop, Rockville, MD, February 2009.
39. Development of multi-parameter marker assays. 2nd TBCI Breast Correlative Sciences Workshop, Rockville, MD, February 2009.
40. Reporting of tumor marker studies. 2nd Annual Biospecimen Research Network (BRN) Symposium: Advancing Cancer Research Through Biospecimen Science, Bethesda, MD, March 2009.
41. Process followed to develop remark: potential applicability to other guidelines. 2nd Annual Biospecimen Research Network (BRN) Symposium: Publishing in Biospecimen Science Workshop, Bethesda, MD, March 2009.
42. Challenges of translating gene expression microarray data into clinically useful tests. Joint Meeting of the Pediatric Advisory Committee and the Oncologic Drugs Advisory Committee, Gaithersburg, MD, April 2009.
43. Development of clinically meaningful and statistically robust molecular markers (joint with M.C. Liu and A.C. Wolff). ASCO Annual Meeting, Orlando, FL, May 2009.
44. Statistical challenges in the study of adolescent and young adult cancer. AYAO Biology Workshop, Bethesda, MD, June 2009.
45. Development of high-dimensional multiplex marker tests. Ontario Institute for Cancer Research Workshop on Designing a Successful Biomarker Study, Toronto, Ontario, Canada, June 2009.
46. How to increase the chances of a successful biomarker study: lessons from the REMARK and STARD guidelines. Ontario Institute for Cancer Research Workshop on Designing a Successful Biomarker Study, Toronto, Ontario, Canada, June 2009.
47. Development of statistically robust and clinically meaningful multiplex markers. EORTC-NCI-ASCO Annual Meeting on Molecular Markers in Cancer Diagnostic Development Tutorial, Brussels, Belgium, October 2009.
48. Challenges in the development and validation of biomarker signatures for personalized medicine: principles of study design and analysis, bioinformatics needs, and informative study reporting. Worldwide Innovations Network (WIN) Symposium, Paris, France, July 2010.
49. Statistical challenges in the development of reliable and clinically meaningful biomarkers. Personalized Cancer Therapy and Prevention Symposium, MD Anderson Cancer Center, Houston, TX, October 2010.
50. Statistical design issues: randomized trials with biomarkers. EORTC-NCI-ASCO Annual Meeting on Molecular Markers in Cancer Diagnostic Development Tutorial, Hollywood, FL, October 2010.
51. Major statistical design and analysis issues for correlative research: challenges in translating biomarkers to clinically useful diagnostics in oncology. NCRI Conference, Liverpool, England, November 2010.

52. Statistical challenges in predictive and prognostic biomarker studies: how to avoid wasting your time and specimens. 33rd Annual San Antonio Breast Cancer Symposium, San Antonio, TX, December 2010.
53. NCI address to Institute of Medicine Committee Convened to Review Omics-Based Tests for Predicting Patient Outcomes in Clinical Trials. Institute of Medicine, Washington, DC, December 2010.
54. Biomarkers in NCI clinical trials (with R. Petryshyn and M. Smith). NCI Patient Advocate Steering Committee, Rockville, MD, May 2011.
55. Biomarker challenges for future trial planning. Breast Cancer Steering Committee Clinical Trials Planning Meeting: HER2+ Breast Cancer, Rockville, MD, May 2011.
56. Challenges in the development and validation of biomarker-based tests for personalized therapeutic decision making in oncology. Accelerating Anticancer Agent Development and Validation Workshop, Bethesda, MD, May 2011.
57. Issues in the validation of 'omics predictors for use in clinical trials. NCI Translational Science Meeting: From Molecular Information to Cancer Medicine, Washington, DC, July 2011.
58. Towards stratified medicine – modeling interactions between treatment and continuous markers: discussion of issues in translating statistical models into clinical tools for therapy decisions. 32nd Annual Conference of the International Society for Clinical Biostatistics (ISCB), Ottawa, Canada, August 2011.
59. Development of reliable and clinically useful molecular signatures: a statistical perspective. Johns Hopkins Kimmel Cancer Center, Baltimore, MD, September 2011.
60. Novel targets and intermediate endpoints for antitumor activity: statistical methodology for biomarker analysis. NCI Workshop on Neoadjuvant Therapy for Bladder Cancer, Gaithersburg, MD, September 2011.
61. Biomarker studies reported in the biomedical literature: a statistical perspective. *Science Translational Medicine* Editors Meeting, Washington, D.C., September 2011.
62. Aspects of novel and traditional clinical trial design. NCI Director's Consumer Liaison Group Meeting, Washington, DC, September 2011.
63. Statistical issues in the development of reliable and clinically relevant prognostic and predictive proteomic signatures. The Human Proteome: A Scientific Opportunity for Transforming Diagnostics, Therapeutics, and Healthcare Meeting, Bethesda, MD, September 2011.
64. Adaptive design clinical trials. NCI Patient Advocate Steering Committee Meeting, Rockville, MD, October 2011.
65. Statistical design issues: randomized trials with biomarkers. EORTC-NCI-ASCO Annual Meeting on Molecular Markers in Cancer Diagnostic Development Tutorial, Brussels, Belgium, October 2011.
66. Requirements for prospective use of omics-based tests in NCI-sponsored trials. EORTC-NCI-ASCO Annual Meeting on Molecular Markers in Cancer, Brussels, Belgium, October 2011.
67. Development of clinical trials incorporating (gen)omic signatures: lessons learned. AACR-NCI-EORTC Molecular Targets and Cancer Therapeutics Meeting, San Francisco, CA, November 2011.
68. Development of clinical trials incorporating (gen)omic signatures: lessons learned. Prostate Cancer Clinical Trials Consortium (PCCTC) Annual Meeting, Fairfax, VA, December 2011.

69. Requirements for prospective use of omics-based tests in NCI-sponsored trials. RTOG Semiannual Meeting Symposium, Atlanta, GA, January 2012.
70. Statistical issues in clinical trial design: adaptive designs. Thoracic Malignancies Clinical Trials Planning Meeting: Strategies for Integrating Biomarkers into Clinical Development of New Therapies for Lung Cancer, Bethesda, MD, February 2012.
71. Development of clinical trials incorporating (gen)omic signatures: lessons learned. AACR Annual Meeting, Chicago, IL, March 2012.
72. Statistical issues in the design of clinical trials to establish the utility of biomarker-based tests for guiding therapy decisions. Biometric Society (ENAR) Annual Meeting, Washington, D.C., April 2012.
73. Development of omics-based clinical tests: the challenge of achieving statistical robustness and clinical utility. University of Pennsylvania 5th Annual Conference on Statistical Issues in Clinical Trials: Emerging Statistical Issues in Biomarker Validation, Philadelphia, PA, April 2012.
74. Statistical issues in the development of (gen)omic signatures. 5th Annual FDA/MTLI Medical Device and IVD Statistical Issues Workshop, Washington, D.C., May 2012.
75. Designing studies to evaluate biomarkers for clinical applications. Institute of Medicine Genomics Roundtable Workshop: Evidence for Clinical Utility of Molecular Diagnostics in Oncology, Washington, D.C., May 2012.
76. Statistical challenges in the development of reliable and clinically meaningful biomarkers. EACR 22 Congress, Barcelona, Spain, July 2012.
77. Statistical issues in the development of clinically useful (gen)omic tests for prognosis and therapy selection. ASA Biopharmaceutical Section FDA-Industry Statistics Workshop, Washington, D.C., September 2012.
78. Evolution of translational omics: lessons learned. ASCO-EORTC-NCI Diagnostics Development Tutorial, Hollywood, FL, October 2012.
79. Critical evaluation of published literature on omics predictors. University of Washington Institute of Translational Health Sciences Fall 2012 Omics Workshop, Seattle, WA, November 2012.
80. Statistical issues in the design of therapy trials incorporating biomarkers. NIH Biostatistics Symposium, Bethesda, MD, November 2012.
81. Statistical review considerations for preclinical and small clinical studies. Nature Publishing Group Editors Meeting, New York, NY, December 2012.
82. Accelerating innovation in statistical design. Implementing a National Cancer Clinical Trials System for the 21st Century Workshop, Institute of Medicine, Washington, DC, February 2013.
83. The role of reporting guidelines in promoting reproducible research. NCI Board of Scientific Advisors Meeting, Bethesda, MD, March 2013.
84. Challenges in the development and validation of biomarker-based tests for personalized therapeutic decision making in oncology. DIA/FDA Statistics Forum, Bethesda, MD, May 2013.
85. Challenges in the development and validation of biomarker-based tests for personalized therapeutic decision making in oncology. Accelerating Anticancer Agent Development and Validation Workshop, Bethesda, MD, May 2013.
86. Statistical approaches to selection of cutoffs for biomarkers. Accelerating Anticancer Agent Development and Validation Workshop, Bethesda, MD, May 2013.

87. Designing prospective trials in the era of molecular profiling. ASCO Annual Meeting, Chicago, IL, June 2013.
88. Translation of biomarker signature discoveries to clinically useful tests (a statistician's perspective). Pediatric Cancer Research at the INTERFACE, Vienna, Austria, June 2013.
89. Statistical and practical considerations for cancer clinical trials designed to evaluate novel biomarker-guided therapies. Worldwide Innovations Network (WIN) Symposium, Paris, France, July 2013.
90. Statistical innovations developed for cancer clinical trials. [Discussion] Joint Statistical Meetings, Montreal, Quebec, August 2013.
91. Best practices in the development of omics-based tests to guide patient care. ASA Biopharmaceutical Section FDA-Industry Statistics Workshop, Washington, D.C., September 2013.
92. Comparing and contrasting clinical trial designs incorporating biomarkers. Markers in Cancer Diagnostic Development Tutorial, Bethesda, MD, May 2014.
93. Challenges in the development and validation of biomarker-based tests for personalized therapeutic decision making in oncology. Accelerating Anticancer Agent Development and Validation Workshop, Bethesda, MD, May 2014.
94. Reproducible research: many dimensions and shared responsibilities. NCI Division of Cancer Prevention and Control Colloquium, Rockville, MD, May 2014.
95. Developing a useable biomarker: necessary validation for a clinical trial. ASCO Annual Meeting, Chicago, IL, June 2014.
96. Development of omics-based tests for clinical use: the challenge of achieving statistical robustness and clinical utility. FDA Proteomics in the Clinic Workshop, Silver Spring, MD, June 2014.
97. Critical issues in biomarker development for clinical trial enrichment. Advancing the Use of Biomarkers and Pharmacogenomics in Drug Development Meeting, Washington, DC, September 2014.
98. Design of oncology clinical trials in the omics era. Meet-the-Oncology-Expert Seminar Series, Jules Bordet Institute, Brussels, Belgium, October 2014.
99. A chat with a statistician. Mallya Aditi International School, Bangalore, India, October 2014.
100. Assessment of omics-based predictor readiness for use in a clinical trial. Biopharmaceutical Applied Statistics Symposium XXI, Rockville, MD, November 2014.
101. Reporting and evaluation of studies of biomarkers and omics-based predictors: the REMARK guidelines and the NCI Omics Checklist. Workshop on Statistical Issues in Biomarker and Drug Co-development, Fields Institute, Toronto, Ontario, Canada, November 2014.
102. Opportunities for embedding biomarkers in prospective trials of non-muscle invasive bladder cancer. NCI Clinical Trials Planning Meeting: Novel Therapeutics for Non-Muscle Invasive Bladder Cancer, Bethesda, MD, March 2015. Reproducible research: many dimensions and shared responsibilities. University of Georgia Statistics & Biostatistics Seminar Series, Athens, GA, April 2015.
103. Identification and validation of treatment-selection biomarkers using specimens archived from completed clinical trials. AACR Annual Meeting, Philadelphia, PA, April 2015.
104. Preparation of the genomic assay and informatics system for a clinical trial. AACR Annual Meeting, Philadelphia, PA, April 2015.

105. Key issues in the design, conduct and analysis of oncology trials: the role of biomarkers for enrichment. Accelerating Anticancer Agent Development and Validation Workshop, Bethesda, MD, May 2015.
106. Development and validation of biomarker-based tests for personalized therapeutic decision-making. Accelerating Anticancer Agent Development and Validation Workshop, Bethesda, MD, May 2015.
107. Evidentiary standards for prognostic and predictive biomarkers in oncology. FDA CDER OB/OHOP Biostatistics Mini-symposium on Evidentiary Standards for Prospective Biomarker Evaluation in Oncology Trials, Silver Spring, MD, July 2015.
108. Assay validation and reproducibility considerations for biomarkers used in drug development. FDA and M-CERSI Workshop on Evidentiary Considerations for Integration of Biomarkers in Drug Development, Baltimore, MD, August 2015.
109. Reproducibility of omics research: responsibilities and consequences. 36th Annual Conference of the International Society for Clinical Biostatistics (ISCB), Utrecht, The Netherlands, August 2015.
110. Development and validation of biomarkers and omics predictors for use in guiding therapy decisions for pediatric patients. NIGMS-NICHD and NICHD T32 Programs in Pediatric Clinical Pharmacology Workshop, Rockville, MD, September 2015.
111. Assessment of omics-based predictor readiness for use in a clinical trial. 2015 Symposium on Methodological Challenges in Biomedical Research, Freiburg, Germany, October 2015.
112. Developing a standard glossary of terms in biomarker development. Workshop on Facilitating Biomarker Development: Strategies for Scientific Communication, Pathway Prioritization, Data-Sharing, and Stakeholder Collaboration, Center for Health Policy at Brookings, Washington, DC, October 2015.
113. Best practices to promote reproducibility and ensure integrity of omics research. Fifth Seattle Symposium in Biostatistics: Biomarkers for Diagnosis, Prognosis, and Therapy Guidance, Seattle, WA, November 2015.
114. Assessment of omics-based predictor readiness for use in a clinical trial. Seminar Series for the Research Program in Quantitative Sciences, Division of Biostatistics & Bioinformatics, Johns Hopkins University, Baltimore, MD, December 2015.
115. Opportunities for embedding biomarkers in prospective trials of endometrial cancer. NCI Clinical Trials Planning Meeting on Moving Forward in Endometrial Cancer: Designing Targeted Trials for Targeted Endometrial Cancer Populations Using Targeted Agents, Rockville, MD, January 2016.
116. Harmonization of terminology for biomarkers and endpoints to strengthen quality and improve efficiency of translational science. Trans-NIH Biomarkers in Pediatric Therapeutic Special Interest Group, Bethesda, MD, February 2016.
117. Establishing clinical usefulness of a biomarker-based test intended to guide therapeutic decisions. Biometric Society ENAR 2016 Spring Meeting, Austin, TX, March 2016.
118. Reproducible research: many dimensions and shared responsibilities. NIH π Day Data Science Workshop, Bethesda, MD, March 2016.
119. Precision medicine: promise, innovation, trials and tribulations. Dana-Farber Cancer Institute and Frontier Science Technology and Research Foundation Marvin Zelen Memorial Symposium, Boston, MA, April 2016.
120. Early phase trials incorporating omics data. Workshop on Translational Research in Prostate Cancer, Rockville, MD, April 2016.

121. Statistical considerations for the biomarker qualification process: summary from the statistics working group. Evidentiary Standards Biomarker Qualification Workshop, Bethesda, MD, April 2016.
122. Innovative trial designs and their potential impact on accrual. NCI Patient Advocate Steering Committee Meeting, Bethesda, MD, April 2016.
123. Evidentiary considerations for surrogate endpoints: discussion of pCR as an endpoint in neoadjuvant breast cancer studies and MRD as an endpoint in acute lymphoblastic leukemia (ALL) studies. FDA-NCI Monthly Meeting, Rockville, MD, April 2016.
124. Harmonization of terminology for biomarkers and endpoints to strengthen quality and improve efficiency of translational science. DIA Statistics Forum 2016, Bethesda, MD, April 2016.
125. Clinical trial designs. ASCO-EORTC-NCI Markers in Cancer Diagnostic Development Tutorial, Bethesda, MD, May 2016.
126. Assessment of trial-level surrogacy of an early endpoint using a non-linear mixed effects model with measurement error. Applied Statistics 2016 International Conference, Ribno (Bled), Slovenia, September 2016.
127. Assessment of trial-level surrogacy of an early endpoint using a non-linear mixed effects model with measurement error. Department of Biostatistics, University of Michigan, Ann Arbor, MI, September 2016.
128. Statistical considerations for trials (or studies) designed to determine clinical utility of cfDNA assays. Workshop on Circulating Tumor DNA in Clinical Cancer Research, Rockville, MD, September 2016.
129. Assay validation and reproducibility considerations for biomarkers used in drug development. 2016 ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop, Washington, DC, September 2016.
130. Considerations in the design of clinical trials to validate predictive biomarkers. Gynecologic Cancer InterGroup Translational Research Brainstorming Meeting, Lisbon, Portugal, October 2016.
131. Supporting an environment of reproducible research: factors for success and consequences of failure (an NIH perspective). University of Utah, Salt Lake City, UT, November 2016.
132. Appropriate terminology for biomarkers and related issues. Workshop on Development of Human Aging Mechanistic Predictive Markers, Bethesda, MD, December 2016.
133. Design considerations for biomarker correlative studies in oncology. NCI-SGO Early Career Investigators Workshop, Rockville, MD, March 2017.
134. Reflections on challenges and ingredients for success in development of clinically useful molecular ("omics") signatures. SPECS II Investigators Meeting, delivered to Duke University, Durham, NC, delivered via webinar, April 2017.
135. Use of biomarkers for enrichment in clinical trials. Accelerating Anticancer Agent Development and Validation Workshop, Bethesda, MD, May 2017.
136. Statistical issues in overcoming drug resistance. Refining Precision Therapeutics Using Exceptional Response and Resistance Workshop, Rockville, MD, May 2017.
137. FDA-NIH collaboration to harmonize terminology for biomarkers and endpoints: striving to strengthen quality and improve efficiency of translational science. FDA Science Forum, Silver Spring, MD, May 2017.
138. Statistical considerations for design of clinical studies to evaluate medical utility of cfDNA tests. Clinical Application of Cell-Free DNA - Next Generation Diagnostics Summit 2017, Washington, DC, August 2017.

139. Exceptional responders clinical trial design issues: a proposed phase III RCT schema and sample size considerations (with W. Barlow and S. Hwang). NCI Breast Cancer Steering Committee (BCSC) Clinical Trial Planning Meeting (CTPM) (Omitting Surgery in Patients with Complete Clinical/Radiologic Response to Neoadjuvant Chemotherapy: A Paradigm Shift), Rockville, MD, October 2017.
140. The role of big data analytics in the evolution of clinical trials. MIRACUM Symposium, Erlangen, Germany, February 2018.
141. Incorporating biomarkers into early and late phase trials. Collaboration for Research methods Development in Oncology (CReDO) Workshop, Lonavla, Maharashtra, India, March 2018.
142. Prognostic and predictive factors. Collaboration for Research methods Development in Oncology (CReDO) Workshop, Lonavla, Maharashtra, India, March 2018.
143. Analysis of high-dimensional data: opportunities and challenges. TU Dortmund University, Dortmund, Germany, March 2018.
144. An NIH perspective on research rigor & reproducibility: many dimensions and shared responsibilities. Mid-Atlantic Directors and Staff of Scientific Cores (MADSSCi) Annual Meeting, Baltimore, MD, June 2018.
145. Biomedical research reproducibility: many dimensions and shared responsibilities. Southeastern Association of Shared Resources Chapter of the Association of Biomolecular Resource Facilities (SEASR) Annual Meeting, Atlanta, GA, June 2018.
146. Concepts and case study template for surrogate endpoints. Framework for Defining Evidentiary Criteria: Surrogate Endpoint Qualification Workshop, Silver Spring, MD, July 2018.
147. Issues in the evaluation of biomarkers to serve as surrogate endpoints. U.S. Food and Drug Administration Statistical Association seminar series, Silver Spring, MD, October 2018.
148. Assessing readiness of an omics signature for use in a clinical trial. Improving Cancer Diagnosis and Care: The Clinical Application of Computational Methods in Precision Oncology Workshop, National Academies of Sciences, Engineering, and Medicine, Washington, DC, October 2018. Reproducibility of omics research: Shared responsibility and consequences of ignorance. Ludwig-Maximilians University, Munich, Germany, December 2018.
149. Considerations in the development of biologically informed treatment selection scores from high-dimensional omics data. University of Pennsylvania, Philadelphia, PA, April 2019.
150. Are liquid biopsies ready for prime time? NCI Breast Cancer Steering Committee (BCSC) Clinical Trial Planning Meeting (CTPM) (Identification and Treatment of Patients at Risk for Late Recurrence of ER+ Breast Cancer), Rockville, MD, May 2019.
151. Issues in the planning and reporting of studies that assess performance of statistical & computational methods, with emphasis on high-dimensional data. 2nd STRATOS General Meeting, Banff International Research Station, Banff, Alberta, Canada, June 2019.
152. Use of biomarkers in clinical investigations for new animal drugs. FDA Workshop on Incorporating Alternative Approaches in Clinical Investigations for New Animal Drugs, Rockville, MD, July 2019.
153. Role of statistics & statisticians in promoting clinically relevant, reproducible omics research. [Discussion] Joint Statistical Meetings, Denver, CO, July 2019.
154. Ki67 as a prognostic or predictive biomarker. International Ki67 Working Group: Updated Consensus Meeting, New York, NY, October 2019.

155. Statistical challenges in the development and interpretation of evidence for tumor-agnostic therapy indications. Workshop on Tumor-Agnostic Cancer Therapies: Regulatory and Ethical Issues, Harvard University, Boston, MA, November 2019.
156. Ethical and regulatory issues for new paradigms in oncology: tumor-agnostic therapy indications. Health Policy & Research Consortium, Harvard Medical School, Boston, MA, November 2019.
157. Statistical considerations for evaluating biomarkers for irAEs. NIH-AACR-CAI Cancer, Autoimmunity, and Immunology Conference, delivered via webinar, March 2020.
158. Clinical trial disruptions due to COVID-19: an NCI perspective. National Institute of Statistical Sciences: Ingram Olkin Statistics Serving Society Forum, delivered via webinar, July 2020.
159. Friends of Cancer Research TMB Harmonization Project: application and operationalization of a calibration tool. Friends of Cancer Research Virtual Meeting on TMB Results: The Future Use of Complex Biomarkers, delivered via webinar, July 2020.
160. Friends of Cancer Research TMB Harmonization Project. NCI Immune-Oncology Biomarkers Scientific Series, delivered via webinar, July 2020.
161. Public-private collaborations aiming to improve the reliability and consistency of clinical tests to guide cancer care. Joint Statistical Meetings, delivered via webinar, August 2020.
162. Biologically-informed development of treatment selection scores from high-dimensional omics data. Sixth Seattle Symposium in Biostatistics, University of Washington, delivered via webinar, November 2020.
163. Statistical analysis of high-dimensional biomedical data: issues and challenges in translation to medically useful results. 67th Biometric Colloquium, German Region, International Biometric Society, Muenster, Germany, delivered via webinar, March 2021.
164. Biologically-informed development of treatment selection scores from high-dimensional omics data. 42nd Annual Conference of the International Society for Clinical Biostatistics (ISCB), Lyon, France, delivered via webinar, July 2021.
165. Biologically-informed development of treatment selection scores from high-dimensional omics data. Joint Statistical Meetings, delivered via webinar, August 2021.
166. Biologically-informed development of treatment selection scores from high-dimensional omics data. 32nd Conference of the Austro-Swiss Region (ROeS) of the International Biometric Society, Salzburg, Austria, delivered via webinar, September 2021.
167. Statistical issues in the development & validation of predictive biomarkers for ICI therapy. ASCO/CAP Immune Checkpoint Inhibitor/Inhibition (ICI) Predictive Factor Summit, delivered via webinar, September 2021.
168. Statistical and practical considerations in the translation of biomarker research findings into medically useful tests. 2021 ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop, Washington, DC, delivered via webinar, September 2021.
169. Prospective planning for (biomarker-defined) subgroup analyses in clinical trials. Accelerating Anticancer Agent Development and Validation Workshop, Bethesda, MD, delivered via webinar, September 2021.
170. Statistical considerations for the use of pCR in clinical trials. Accelerating Anticancer Agent Development and Validation Workshop, Bethesda, MD, delivered via webinar, September 2021.

171. Statistical and practical considerations in the translation of biomarker research findings into medically useful tests. Pediatric Oncology Branch, NCI Center for Cancer Research, Bethesda, MD, delivered via webinar, February 2022.
172. BEST: a resource for effective communication. FDA Public Meeting on Identification of Concepts and Terminology for Multi-Component Biomarkers, Rockville, MD, delivered via webinar, March 2022.
173. Translation of omics predictors to clinically useful tests: avoiding the pitfalls and paving the way to success. AACR Annual Meeting Education Session, New Orleans, LA, April 2022.
174. Finding the (biomarker-defined) subgroup of patients who benefit from a novel therapy: no time for a game of hide and seek. 14th Annual University of Pennsylvania Conference on Statistical Issues in Clinical Trials, Philadelphia, PA, delivered via webinar, April 2022.
175. Steps to validation of early endpoints to support drug development in neuroblastoma: key concepts. FDA Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee (pedsODAC) Meeting, Silver Spring, MD, delivered via webinar, May 2022.
176. Statistical learning in cancer medicine: from early-phase trials to preclinical systems. [Discussion] Joint Statistical Meetings, Washington, DC, August 2022.
177. Statistical and practical considerations in evaluation of clinical utility of tests to assess germline indicators of toxicity risk (GITR). STRIPE Study Design Task Force Meeting, delivered via webinar, April 2023.
178. Genomic screening for actionable genomic alterations - experience from NCI precision medicine platform trials. 20th Annual Meeting of the Association for Cancer Immunotherapy CIMT, Mainz, Germany, delivered via webinar, May 2023.
179. Statistical adventures in pursuit of precision medicine: secret signatures, sliding subgroups & more. 44th Annual Conference of the International Society for Clinical Biostatistics (ISCB), Milan, Italy, August 2023.
180. ctDNA clinical trial designs. ctDNA in Cancer Treatment and Clinical Care Workshop, Rockville, MD, September 2023.
181. Clinical trial designs to evaluate liquid biopsy-guided therapy. Accelerating Anticancer Agent Development and Validation Workshop, Bethesda, MD, delivered via webinar, September 2023.

Short Courses:

1. Statistical analysis of microarray data. Short course taught (with R. Simon and M. Radmacher) at the International Biometric Society (ENAR) Meeting, Arlington, VA, March 2002.
2. Statistical analysis of microarray data. Short course taught (with R. Simon) at the Society for Clinical Trials Meeting, Arlington, VA, May 2002.
3. Statistical issues in the analysis of high-throughput biologic data. Invited lecture in the NCI Division of Cancer Epidemiology and Genetics Molecular Epidemiology Course, Rockville, MD, February 2008.
4. Statistical analysis of gene expression microarray data. Class taught several times per year as part of the NIH CIT training course series, Bethesda, MD, 2004-2011.
5. Statistical issues in the development of biomarker- and omics-based tests. Invited lecture in Pharmaceutical Education and Research Institute Course "Cancer: Pathophysiology, Current Therapies, Clinical Trials and Drug Development," Washington, D.C., April 2012.
6. EORTC-NCI-ASCO Annual Meeting on Molecular Markers in Cancer Diagnostic Development Tutorial, Faculty Member, 2008-2012.

7. ASCO Markers in Cancer Diagnostic Development Tutorial, Faculty Member, Bethesda, MD, May 2014.
8. Roles of biomarkers in clinical trial design (Biomarkers as enrichment factors in drug development and as prognostic & predictive clinical tests; Assessment of omics-based predictor readiness for use in a clinical trial). Short course taught at the Fifth Seattle Symposium in Biostatistics: Biomarkers for Diagnosis, Prognosis, and Therapy Guidance, Seattle, WA, November 2015.
9. ASCO-EORTC-NCI Markers in Cancer Diagnostic Development Tutorial, Faculty Member, Bethesda, MD, May 2016.
10. Reproducibility in omics studies. Invited lecture in the NCI Molecular Prevention Course, Rockville, MD, August 2016.
11. Biomarkers & classifiers for diagnostic and therapeutic research: discovery, study design and analysis. Short course taught (with R. Simon) as part of *StatisticAlps* series, Ponte di Legno – Brescia, Italy, March 2017.
12. Collaboration for Research methods Development in Oncology (CReDO) Workshop, Faculty Member, Lonavla, Maharashtra, India, March 2018.
13. Statistical aspects of correlative studies. Invited lecture in the NCI Early Career Investigator Letter of Intent Writing Workshop, Rockville, MD, September 2019.
14. Statistical aspects of correlative studies. Invited lecture in the NCI Early Career Investigator Letter of Intent Writing Workshop, delivered via webinar, September 2020.
15. Statistical aspects of correlative studies. Invited lecture in the NCI Early Career Investigator Letter of Intent Writing Workshop, delivered via webinar, September 2021.
16. LOI statistical plans. Invited lecture in the NCI Early Career Investigator Letter of Intent Writing Workshop, delivered via webinar, September 2022.
17. LOI statistical plans. Invited lecture in the NCI Early Career Investigator Letter of Intent Writing Workshop, delivered via webinar, September 2023.