LISA MEIER MCSHANE

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Office Address:
National Cancer Institute
Biometric Research Branch, DCTD
Executive Plaza North, Room 8126
6130 Executive Boulevard MSC 7434
Bethesda, Maryland 20892-7434
(301) 402 - 0636 (office)
(301) 402 - 0560 (fax)
lm5h@nih.gov

Education:

Cornell University, Ithaca, New York
Ph.D. Statistics, August 1989 (Thesis advisor: Bruce W. Turnbull)
M.S. Statistics, August 1986

University of Kentucky, Lexington, Kentucky
M.S. Statistics, May 1984

Millersville State College, Millersville, Pennsylvania
B.A. Mathematics, May 1982

Professional Experience:

Mathematical Statistician. NCI/NIH, Biometric Research Branch, Division of Cancer Treatment and Diagnosis. Development of statistical methods for the evaluation of cancer biomarkers, analysis of marker assay validity, statistical reviewer for biomarker study protocols, statistical advisor to Cancer Diagnosis Program, chief statistician for the Cooperative Breast Cancer Tissue Resource. June 1996 – September 2009.

Senior Staff Fellow. NCI/NIH, Clinical and Diagnostic Trials Section, Biometry Branch, Division of Cancer Prevention and Control. Development of statistical methods and collaborative research for cancer prevention trials and epidemiologic studies. March 1995 - June 1996.

Staff Fellow. NINDS/NIH, Mathematical Statistics Section, Biometry and Field Studies Branch. Development of statistical methods and collaborative research for neurological disorders. October 1989 - October 1992 (staff fellow), October 1992 - March 1995 (senior staff fellow).

Teaching Support Specialist. Cornell University, Biometrics Unit, Ithaca, New York. Teaching support for graduate courses in statistical methods, research, and consulting. July 1988 - June 1989.

Member of Technical Staff. Bell Communications Research, Red Bank, New Jersey. Reliability and Maintainability Methods District. Investigated statistical properties of new reliability tests. Techniques used included computer simulation. Summer 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. January 1986 - May 1987.

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. August 1984 - May 1986.

Teaching Assistant. University of Kentucky, Department of Statistics, Lexington, Kentucky. Had full responsibility for teaching precalculus, elementary and engineering statistics courses. August 1982 - August 1984.

Tutor. Millersville State College, Millersville, Pennsylvania. Math Tutor in Act 101 Program for educationally disadvantaged. Summers 1980, 1981.

Honors and Awards:

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

National Institutes of Health Award of Merit, 1995.

Cornell University, Mathematical Sciences Institute Fellowship, 1987 - 1988 and 1986 - 1987 academic years.

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

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

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.

Professional Societies and Committee Memberships:

American Statistical Association.
- ASA Biometrics Section Program Chair, 1994 Annual Meetings.
- ASA Committee on Professional Ethics, 1998 -2003.
- ASA Committee on Award of Outstanding Statistical Application, 2005-2010.

Biometric Society.
- Biometric Society (ENAR) Representative to the American Statistical Association Committee on Meetings, 1995-1999.

American Society for Clinical Oncology Program Committee.
- Biostatistics Track Reviewer for Annual ASCO Meeting, 2004-2005.

NCI PACCT Strategy Group, 2000-present.
FDA Oncologic Drugs Advisory Committee Special Consultant on Prostate Cancer Endpoints, March 2005.
ASCO-NCI-EORTC Diagnostic Development Tutorial Planning Committee and Faculty, 2009-2011.
Ontario Institute for Cancer Research, Study Section, 2010-2011.

Editorial and Advisory Board Memberships:

Science Translational Medicine, Advisory Board Member, Nov. 2011-present.
Statistics in Biopharmaceutical Research, Associate Editor, 2006-present.

Computing Skills:

Experience with IBM mainframe computers, PCs running Windows, and workstations running UNIX.

Programming languages: proficient with R, Gauss, and FORTRAN.

Statistical packages: proficient with Splus and R, basic knowledge of SAS.

Office applications: proficient with Microsoft Word, Excel, and PowerPoint.

Languages:

German: Reading and some speaking.

American Sign Language: Basic knowledge.

Reviewer for Professional Journals:

BMC Bioinformatics
Bioinformatics
Biometrics
BioTechniques
Breast Cancer Research and Treatment
Cancer Research
Communications in Statistics
Genetic Epidemiology
Journal of Clinical Oncology
Journal of Computational Biology
Journal of Quality Technology
Journal of Statistical Planning and Inference
Journal of the National Cancer Institute
Journal of the American Statistical Association
Laboratory Investigation
Medical and Pediatric Oncology
Neurology
Science Translational Medicine
Statistics in Medicine
Technometrics
The American Statistician

Presentations and Short Courses:

A Quality Control Procedure for Monitoring Laboratory Analyses. Invited Presentation at Biometric Society (ENAR) Spring Meetings, Dallas, Texas, March 1987.

Quality Control Procedures for High Performance Liquid Chromatographic Analysis of Plasma Vitamin E. L. M. McShane, L. C. Clark, G. F. Combs, Jr., and B. W. Turnbull. Poster presentation at the Third International Conference on the Prevention of Human Cancer: Chemoprevention, Tucson, Arizona, January 1988.

Probability Limits on Outgoing Quality for Continuous Sampling Plans. Invited Presentation at ASA/ASQC Fall Technical Conference, Lexington, Kentucky, October 1991.

Reporting the Accuracy of Biochemical Measurements for Epidemiologic and Nutrition Studies. Invited Presentation at Biometric Society (ENAR) Spring Meetings, Cincinnati, Ohio, March 1992.

Experiences with a Chemoprevention Trial of Nonmelanoma Skin Cancer with a Nutritional Supplement of Selenium. Invited Presentation at National Cancer Institute, Division of Cancer Prevention and Control, Bethesda, Maryland, October 1992.

Spatial Distribution of Neurons in Tissue Culture Wells: Implications for sampling methods to estimate population size. Presentation at National Institutes of Health Conference on Current Topics in Biostatistics, Bethesda, Maryland, January 1993.

Diagnostic Markers. Presentation at the National Cancer Institute, Rockville, Maryland, June 1997.

Covariate Measurement Error Adjustment for Matched Case-Control Studies. Presentation at the National Cancer Institute, Rockville, Maryland, June 1998.

Issues in the Use of Specimens for Studies of Prognostic Markers in Cancer. Presented to the NCI Glioma Marker Network, Baltimore, Maryland, October 1998.

An Evaluation of Variability in Immunohistochemical Measurements of p53 in Bladder Cancer. Invited Presentation at the Second International Workshop on Diagnostic and Prognostic Markers in Bladder Cancer, Barcelona, Spain, October 1998.

Case Studies in Statistical Ethics. Discussant for Session Presented at the Joint Statistical Meetings, Baltimore, Maryland, August 1999.

Statistical Issues in the Evaluation of HER-2/neu. Invited Presentation at the Detection of HER2/neu (erbB2) Antigen Overexpression Symposium, Bethesda, Maryland, October 1999.

Statistical Analysis of Microarray Data. Short course presented (with R. Simon and M. Radmacher) at the International Biometric Society (ENAR) Meeting, Arlington, VA, March 2002.

Statistical Issues in the Design and Analysis of Tissue Microarrays. Presentation to Pediatric Proteomic Meeting, Rockville, Maryland, April 2002.

Statistical Analysis of Microarray Data. Short course presented (with R. Simon) at the Society for Clinical Trails Meeting, Arlington, VA, May 2002.

Comparison of Sampling Designs for Selecting Cases for Prognostic Marker Studies: Discussion of Appropriate Analysis Methods. Invited presentation at the NCI-EORTC 2nd International Meeting on Cancer Diagnostics, Washington, D.C., June 2002.

Statistical Issues in the Analysis of Microarray Data. Invited presentation at the XXIst International Biometric Conference 2002, Freiburg, Germany, July 2002.

Statistical Issues in the Design and Analysis of Gene Expression Microarray Experiments. Invited presentation at College of William and Mary, Williamsburg, VA, October 2003.

Controlling the number of false discoveries: Application to high-dimensional genomic data. Invited presentation at College of William and Mary, Williamsburg, VA, October 2003.

Statistical Issues in Molecular Profiling Studies: Building and Validating Prognostic Classifiers. Invited presentation at the NCI-EORTC 3rd International Meeting on Cancer Molecular Markers, Brussels, Belgium, April 2004.

Validation of Biomarkers: A Statistical Perspective. Invited presentation at Acute Renal Failure Strategic Planning Retreat, Washington, D.C., June 2004.

Statistical Issues in the Analysis of High-Throughput Biologic Data. Invited presentation at Early Detection Research Network Third Scientific Workshop, Bethesda, MD, June 2004.

Statistical Issues in Molecular Profiling Studies: Statistical considerations in the development and validation of prognostic profiles derived from gene expression microarray data. Presentation at the Joint Statistical Meetings, Toronto, Canada, August 2004.

Statistical Issues in Molecular Profiling: Building and validating prognostic classifiers. Invited presentation at 2004 FDA/Industry Statistics Workshop, Washington, D.C., September 2004.

Statistical Issues in Molecular Profiling: Development of clinically useful molecular profiles. Invited presentation at the U.S. Food and Drug Administration, CDRH Staff College, Rockville, MD, October 2004.

PSA and Other Biological Markers in Prostate Cancer: A Statistical Perspective. Presentation to NCI PACCT Strategy Group, Bethesda, MD, May 2005.

A Rational Approach to the Development and Validation of a Molecular Classifier. Invited presentation at Statistical Methods in Biopharmacy: Statistical Innovations in Clinical Trials, Paris, France, September 2005.

Difficulties of Translational Research. Invited presentation to expert panel discussing the research agenda at the newly formed French National Cancer Institute, Paris, France, September 2005.

Controlling the Number of False Discoveries: Application to High-Dimensional Genomic Data. Invited presentation at the Department of Biostatistics, Virginia Commonwealth University School of Medicine, Richmond, VA, November 2005.

A Rational Approach to the Development and Validation of a Molecular Classifier. Invited presentation at the U.S. Food and Drug Administration, CDRH Staff College, Rockville, MD, February 2006.

Statistical Considerations in Developing a Laboratory Proficiency Testing Program. Presentation at ASCO-CAP HER-2 Testing Guideline Meeting, Alexandria, VA, March 2006.

Methodologic Challenges and Problems in Tumor Prognostic Marker Research. Invited presentation at the UICC World Cancer Congress 2006, Washington, D.C., July 2006.

Progress in Developing Clinically Useful Multi-Gene Signatures in Breast Cancer: A Statistician's Perspective. Invited Presentation at NCI-EORTC 4th International Meeting on Cancer Molecular Markers, Stone Mountain, GA, September 2006.

How should we use predictive biomarkers; how do we assess the clinical reliability? Presentation (joint with S. Taube) at AACR–FDA–NCI Think Tank on Clinical Biomarkers, Philadelphia, PA, November 2006.

Statistical Issues in Molecular Profiling: Development of Clinically Useful Molecular Profiles. Invited presentation at the U.S. Food and Drug Administration, CDER, Silver Spring, MD, March 2007.

Roles for Biomarkers in Patient Care and Drug Development. Invited presentation at the Radiological Society of North America (RSNA) Biomarkers Methodology Workshop, Bethesda, MD, May 2007.

Tumor Marker Development: The Problems and Pitfalls of Translating Laboratory Observations to Clinical Utility: It Isn't Easy! Education session (joint with D. Hayes, M. Dowsett, and D. Ransohoff) at 2007 ASCO Annual Meeting, Chicago, IL, June 2007.

Issues in Cancer Biomarker/Signature Development: A Statistician's Perspective. Invited presentation at MRC Clinical Trials Unit, London, England, August 2007.

Study Design and Regulatory Issues for Use of Cancer Stem Cells. Invited discussion at the Cancer Stem Cell Workshop, Rockville, MD, January 2008.

Effective Inclusion of Correlative Studies in Phase 2 Trials. Invited presentation at Clinical Trials Design Task Force Meeting, Rockville, MD, January 2008.

Statistical Issues in the Analysis of High-Throughput Biologic Data. Invited lecturer in the NCI Division of Cancer Epidemiology and Genetics Molecular Epidemiology Course, Rockville, MD, February 2008.

Adaptive Designs: Potential for Use in Cancer Prevention Trials. Invited presentation to NCI Division of Cancer Prevention Chemoprevention Consortium, August 2008.

Development of Statistically Robust and Clinically Meaningful Multiplex Markers. Invited lecturer at ASCO-NCI-EORTC Annual Meeting on Molecular Markers in Cancer Diagnostic Development Tutorial, Hollywood, FL, October 2008.

Statistical Considerations in Developing a Laboratory Proficiency Testing Program. Invited presentation to ASCO/CAP Expert Panel on the Development of Guidelines for Hormone Receptor Testing in Breast Cancer, Alexandria, VA, December 2008.

Reporting of Tumor Marker Studies. Invited presentation at the 2nd TBCI Breast Correlative Sciences Workshop, Rockville, MD, February 2009.

Development of Multi-parameter Marker Assays. Invited presentation at the 2nd TBCI Breast Correlative Sciences Workshop, Rockville, MD, February 2009.

Reporting of Tumor Marker Studies. Invited presentation at the 2nd Annual Biospecimen Research Network (BRN) Symposium: Advancing Cancer Research Through Biospecimen Science, Bethesda, MD, March 2009.

Process Followed to Develop REMARK: Potential Applicability to Other Guidelines. Invited presentation at the 2nd Annual Biospecimen Research Network (BRN) Symposium: Publishing in Biospecimen Science Workshop, Bethesda, MD, March 2009.

Challenges of Translating Gene Expression Microarray Data into Clinically Useful Tests. Invited presentation at Joint Meeting of the Pediatric Advisory Committee and the Oncologic Drugs Advisory Committee, Gaithersburg, MD, April 2009.

Development of Clinically Meaningful and Statistically Robust Molecular Markers. Education session (joint with M.C. Liu and A.C. Wolff) at 2009 ASCO Annual Meeting, Orlando, FL, May 2009.

Statistical Challenges in the Study of Adolescent and Young Adult Cancer. Invited presentation at AYAO Biology Workshop, Bethesda, MD, June 2009.

Development of High-dimensional Multiplex Marker Tests. Invited presentation at Ontario Institute for Cancer Research Workshop on Designing a Successful Biomarker Study, Toronto, Ontario, Canada, June 2009.

How to Increase the Chances of a Successful Biomarker Study: Lessons from the REMARK and STARD Guidelines. Invited presentation at Ontario Institute for Cancer Research Workshop on Designing a Successful Biomarker Study, Toronto, Ontario, Canada, June 2009.

Development of Statistically Robust and Clinically Meaningful Multiplex Markers. Invited lecture at EORTC-NCI-ASCO Annual Meeting on Molecular Markers in Cancer Diagnostic Development Tutorial, Brussels, Belgium, October 2009.

Challenges in the Development and Validation of Biomarker Signatures for Personalized Medicine: Principles of Study Design and Analysis, Bioinformatics Needs, and Informative Study Reporting. Invited presentation at Worldwide Innovations Network (WIN) Symposium, Paris, France, July 2010.

Statistical Challenges in the Development of Reliable and Clinically Meaningful Biomarkers. Invited presentation at Personalized Cancer Therapy and Prevention Symposium, MD Anderson Cancer Center, Houston, TX, October 2010.

Statistical design issues: Randomized trials with Biomarkers. Invited lecture at EORTC-NCI-ASCO Annual Meeting on Molecular Markers in Cancer Diagnostic Development Tutorial, Hollywood, FL, October 2010.

Major Statistical Design and Analysis Issues for Correlative Research: Challenges in Translating Biomarkers to Clinically Useful Diagnostics in Oncology. Invited presentation at NCRI Conference, Liverpool, UK, November 2010.

Statistical Challenges in Predictive and Prognostic Biomarker Studies: How to Avoid Wasting Your Time and Specimens. Invited presentation at 33rd Annual San Antonio Breast Cancer Symposium, San Antonio, TX, December 2010.

NCI Address to Institute of Medicine Committee Convened to Review Omics-Based Tests for Predicting Patient Outcomes in Clinical Trials. Invited presentation at Institute of Medicine, Washington, DC, December 2010.

Biomarkers in NCI Clinical Trials. Webinar presentation (with R. Petryshyn and M. Smith) to NCI Patient Advocate Steering Committee, Rockville, MD, May 2011.

Biomarker Challenges for Future Trial Planning. Invited presentation to Breast Cancer Steering Committee Clinical Trials Planning Meeting: HER2+ Breast Cancer, Rockville, MD, May 2011.

Challenges in the Development and Validation of Biomarker-Based Tests for Personalized Therapeutic Decision Making in Oncology. Invited presentation at Accelerating Anticancer Agent Development and Validation Workshop, Bethesda, MD, May 2011.

Issues in the Validation of 'Omics Predictors for Use in Clinical Trials. Invited presentation at NCI Translational Science Meeting: From Molecular Information to Cancer Medicine, Washington, DC, July 2011.

Towards Stratified Medicine – Modeling Interactions Between Treatment and Continuous Markers: Discussion of Issues in Translating Statistical Models into Clinical Tools for Therapy Decisions. Invited discussion at International Society for Clinical Biostatistics Meeting, Ottawa, Canada, August 2011.

Development of Reliable and Clinically Useful Molecular Signatures: A Statistical Perspective. Invited presentation at Johns Hopkins Kimmel Cancer Center, Baltimore, MD, September 2011.

Novel Targets and Intermediate Endpoints for Antitumor Activity: Statistical Methodology for Biomarker Analysis. Invited presentation at NCI Workshop on Neoadjuvant Therapy for Bladder Cancer, Gaithersburg, MD, September 2011.

Aspects of Novel and Traditional Clinical Trial Design. Invited presentation at NCI Director's Consumer Liaison Group Meeting, Washington, DC, September 2011.

Statistical Issues in the Development of Reliable and Clinically Relevant Prognostic and Predictive Proteomic Signatures. Invited presentation at The Human Proteome: A Scientific Opportunity for Transforming Diagnostics, Therapeutics, and Healthcare Meeting, Bethesda, MD, September 2011.

Adaptive Design Clinical Trials. Invited presentation at NCI Patient Advocate Steering Committee Meeting, Rockville, MD, October 2011.

Statistical design issues: Randomized trials with Biomarkers. Invited lecture at EORTC-NCI-ASCO Annual Meeting on Molecular Markers in Cancer Diagnostic Development Tutorial, Brussels, Belgium, October 2011.

Requirements for Prospective Use of Omics-Based Tests in NCI-Sponsored Trials. Invited presentation at EORTC-NCI-ASCO Annual Meeting on Molecular Markers in Cancer, Brussels, Belgium, October 2011.
Development of Clinical Trials Incorporating (Gen)omic Signatures: Lessons Learned. Invited presentation at AACR-NCI-EORTC Molecular Targets and Cancer Therapeutics Meeting, San Francisco, CA, November 2011.

Development of Clinical Trials Incorporating (Gen)omic Signatures: Lessons Learned. Invited presentation at Prostate Cancer Clinical Trials Consortium (PCCTC) Annual Meeting, Fairfax, VA, December 2011.

Statistical Analysis of Gene Expression Microarray Data. Class taught several times a year as part of the NIH CIT training course series.

Bibliography:

1. **McShane, L.M.**, L.C. Clark, G.F. Combs, Jr., and B.W. Turnbull. Reporting the Accuracy of Biochemical Measurements for Epidemiologic and Nutrition Studies. American Journal of Clinical Nutrition 53: 1354-60, 1991.

2. **McShane, L.M.** and B.W. Turnbull. Probability Limits on Outgoing Quality for Continuous Sampling Plans. Technometrics 33(4): 393-404, 1991.

3. Wassermann, E.M., **L.M. McShane**, M. Hallett, and L.G. Cohen. Noninvasive Mapping of Muscle Representations in Human Motor Cortex. Electroencephalography and Clinical Neurophysiology 85: 1-8, 1992.

4. Brasil-Neto, J.P., **L.M. McShane**, P. Fuhr, M. Hallett, and L.G. Cohen. 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, L.M.** and B.W. Turnbull. New Performance Measures for Continuous Sampling Plans Applied to Finite Production Runs. Journal of Quality Technology 24(3): 153-161, 1992.

6. **McShane, L.M.** and B.W. Turnbull. Optimal Checking Procedures for Monitoring Laboratory Analyses. Statistics in Medicine 11(10): 1343-1357, 1992.

7. **McShane, L.M.**, L.C. Clark, G.F. Combs, Jr., and B.W. Turnbull. Application of Variance Components Methods to Laboratory Quality Control for Biochemical Measurements. 1992 Proceedings of the American Statistical Association Biopharmaceutical Section, pp. 250-256, 1993.

8. Sheng, J.G., **L.M. McShane**, R.J. Plunkett, A.C. Cummins, E.H. Oldfield, I.J. Kopin, and M.A. Palmatier. Dopaminergic Neuronal Sprouting and Behavioral Recovery in Hemi-Parkinsonian Rats After Implantation of Amnion Cells. Experimental Neurology 123(2): 192-203, 1993.

9. **McShane, L.M.** and M.A. Palmatier. Spatial Distribution of Neurons in Tissue Culture Wells: Implications for Sampling Methods to Estimate Population Size. Statistics in Medicine 13: 523-540, 1994.

10. Valls-Sole, J., A. Pascual-Leone, J.P. Brasil-Neto, A. Cammarota, **L.M. McShane**, and M. Hallett. Abnormal Facilitation of the Response to Transcranial Magnetic Stimulation in Patients with Parkinson's Disease. Neurology 44(4): 735-741, 1994.

11. Grill, S.E., M. Hallett, C. Marcus, and **L. McShane**. Disturbances of Kinaesthesia in Patients with Cerebellar Disorders. Brain 117: 1433-1447, 1994.

12. Albert, P.S. and **L.M. McShane**. A Generalized Estimating Equations Approach for Spatially Correlated Binary Data: Applications to the Analysis of Neuroimaging Data. Biometrics 51(2): 627-638, 1995.

13. Brainin, M., **L.M. McShane**, M. Steiner, A. Dachenhausen, and A. Seiser. 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.

14. Lou, J.S., L. Goldfarb, **L. McShane**, P. Gatev, and M. Hallett. Use of Buspirone for Treatment of Cerebellar Ataxia: An Open-Label Study. Archives of Neurology 52(10): 982-8, 1995.

15. **McShane, L.M.**, J.F. Dorgan, S. Greenhut, and J.J. Damato. Reliability and Validity of Serum Sex Hormone Measurements. Cancer Epidemiology, Biomarkers & Prevention 5(11): 923-8, 1996.

16. Schatzkin, A., L.S. Freedman, J. Dorgan, **L.M. McShane**, M.H. Schiffman, S.M. Dawsey. Surrogate End Points in Cancer Research: A Critique. [Editorial] Cancer Epidemiology, Biomarkers & Prevention 5(12): 947-53, 1996.

17. Schatzkin, A., L.S. Freedman, J. Dorgan, **L.M. McShane**, M.H. Schiffman, S.M. Dawsey. Using and Interpreting Surrogate End Points in Cancer Research: A Critique. [Review] IARC Scientific Publications 142: 265-271, 1997.

18. Grill, S.E., M. Hallett, and **L.M. McShane**. 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.

19. **McShane, L.M.**, P.S. Albert, and M.A. Palmatier. A Latent Process Regression Model for Spatially Correlated Count Data. Biometrics 53(2): 698-706, 1997.

20. **McShane, L.M.**, K.L. Meier, and E.M. Wassermann. A Comparison of Spatial Prediction Techniques for an Exploratory Analysis of Human Cortical Motor Representations. Statistics in Medicine 16: 1337-1355, 1997.

21. Demirci, M., S. Grill, **L. McShane**, and M. Hallett. A Mismatch Between Kinaesthetic and Visual Perception in Parkinson's Disease. Annals of Neurology 41(6): 781-8, 1997.

22. Brown, P., L. Cervenakova, **L. McShane**, P. Kleihues, J-F. Foncin, G. Collins, F. Bastian, L.G. Goldfarb, and D.C. Gajdusek. Polymorphic Genotype Matching in Acquired Creutzfeldt-Jakob Disease: An Analysis of Donor/Recipient Case Pairs. In: Prions and Brain Diseases in Animals and Humans, Morrison D. R. O., ed. NATO ASI Series A: Life Sciences, v. 295. Plenum Press, New York, 1998, pp. 19-24.

23. Brown, P., L. Cervenakova, **L. McShane**, L.G. Goldfarb, K. Bishop, F. Bastian, J. Kirkpatrick, P. Piccardo, B. Ghetti, and D.C. Gajdusek. Creutzfeldt-Jakob Disease in a Husband and Wife. Neurology 50(3): 684-688, 1998.

24. Ferris, D.G., J.T. Cox, L. Burke, M.S. Litaker, D.M. Harper, M.J. Campion, M.D. Greenberg, **L. McShane**, L.M. Wun. Colposcopy Quality Control: Establishing Colposcopy Criterion Standards for the National Cancer Institute ALTS Trial Using Cervigrams. Journal of Lower Genital Tract Disease 2: 195-203, 1998.

25. **McShane, L.M.**, M. Kulldorff, M.J. Wargovich, C. Woods, M. Purewal, L.S. Freedman, D.K. Corle, R.W. Burt, D.J. Mateski, M. Lawson, E. Lanza, B. O'Brien, W. Lake, Jr., J. Moler, A. Schatzkin. 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.

26. Dorgan, J.F., D. Albanes, J. Virtamo, O.P. Heinonen, D.W. Chandler, M. Galmarini, **L.M. McShane**, M.J. Barrett, J. Tangrea, P.R. Taylor. 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.

27. Hildesheim, A., **L.M. McShane**, M. Schiffman, M.C. Bratti, A.C. Rodriguez, R. Herrero, L.A. Morera, F. Cardenas, L. Saxon, F.P. Bowman, P.A. Crowley-Nowick. 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.

28. Brown, P., L. Cervenakova, **L.M. McShane**, P. Barber, R. Rubenstein, W.N. Drohan. 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.

29. **McShane, L.M.**, R. Aamodt, C. Cordon-Cardo, R. Cote, D. Faraggi, Y. Fradet, H.B. Grossman, A. Peng, S.E. Taube, F.M. Waldman, and the National Cancer Institute Bladder Tumor Marker Network. Reproducibility of p53 Immunohistochemistry in Bladder Tumors. Clinical Cancer Research 6(5): 1854-1864, 2000.

30. Kulldorff, M., **L.M. McShane**, A. Schatzkin, L.S. Freedman, M.J. Wargovich, C. Woods, M. Purewal, R.W. Burt, M. Lawson, D.J. Mateski, E. Lanza, D.K. Corle, B. O'Brien, J. Moler. 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.

31. Pajak, T.F., G.M. Clark, D.J. Sargent, **L. McShane**, E. Hammond. Statistical Issues in Tumor Marker Studies. Archives of Pathology and Laboratory Medicine 124(7): 1011-1015, 2000.

32. Brown, P., M. Preece, J-P Brandel, T. Sato, **L. McShane**, L. Cervenakova, I. Zerr, R.G. Will, A. Fletcher, M. Pocchiari, N. Cashman, J.H. d'Aignaux, J. Fradkin, L. Schonberger, S.J. Collins. Iatrogenic Creutzfeldt-Jakob Disease at the Millennium. Neurology 55(8): 1075-1081, 2000.

33. Blegen, H., N. Einhorn, K. Sjovall, A. Roschke, B.M. Ghadimi, **L.M. McShane**, B. Nilsson, K. Shah, T. Ried, G. Auer. 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.

34. **McShane, L.M.**, D.N. Midthune, J.F. Dorgan, L.S. Freedman, R.J. Carroll. Covariate Measurement Error Adjustment for Matched Case-Control Studies. Biometrics 57(1): 62-73, 2001.

35. Albert, P.S., **L.M. McShane**, J.H. Shih. 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.

36. **McShane, L.M.** and R. Simon. Statistical methods for the analysis of prognostic factor studies, In Prognostic Factors in Cancer, Gospodarowicz, Henson, Hutter, O'Sullivan, Sobin and Wittekind (eds.), 2001.

37. Albert, P.S., **L.M. McShane**, E.L. Korn. Design of a binary biomarker study from the results of a pilot study. Biometrics, 58: 576-585, 2002.

38. Korn, E.L., **L.M. McShane**, J.F. Troendle, A. Rosenwald, R. Simon. 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.

39. Radmacher, M.D., **L.M. McShane**, R. Simon. A paradigm for class prediction using gene expression profiles. Journal of Computational Biology 9(3): 505-511, 2002.

40. **McShane, L.M.**, M.D. Radmacher, B. Freidlin, R. Yu, M. Li, R. Simon. Methods for assessing reproducibility of clustering patterns observed in analyses of microarray data. Bioinformatics 18(11): 1462-1469, 2002.

41. Miller, L.D., P.M. Long, L. Wong, S. Mukherjee, **L.M. McShane**, E.T. Liu. Optimal gene expression analysis by microarrays. Cancer Cell, 2(5): 353-361, 2002.

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