

**Curriculum Vitae**  
**MEI-YIN CHEN POLLEY**  
**December 2013**

**CONTACT INFORMATION**

Biometric Research Branch  
Division of Cancer Treatment and Diagnosis  
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**EDUCATION**

B. A. Statistics, 1995  
National Taipei University, Taipei, Taiwan

A. M. Statistics, 1999  
Harvard University, Cambridge, Massachusetts

M.S. Biostatistics, 2001  
Ph.D. Biostatistics, 2006  
Columbia University, New York, New York

**DOCTORAL DISSERTATION**

Title: Two-Stage Stepwise Procedures for Dose-Finding in Clinical Trials with a Biological Endpoint  
Sponsor: Ken Cheung, Professor of Biostatistics, Columbia University

**HONORS AND AWARDS**

2012 Distinguished Achievement Award, Kelly Government Solutions (National Cancer Institute)

2009 REAC Pilot Research Awards in Basic and Clinical/Translational Sciences, University of California San Francisco

2009 Award for Excellence in Clinical Research, The Joint Meeting of the Society for Neuro-Oncology and the AANS/CNS Sections on Tumors (supported by American Brain Tumor Association)

- 2008 Award to attend AACR Cancer Biostatistics Workshop
- 2006 The Joseph L. Fleiss Memorial Prize in Biostatistics for an Outstanding Dissertation, Columbia Mailman School of Public Health
- 2001 - 2004 Merck & Co., Inc. Fellowship, Department of Biostatistics, Columbia University
- 1994 - 1995 Academic Honor, Department of Statistics, National Taipei University, Taiwan

## **PROFESSIONAL EXPERIENCE**

- 2000 Research Assistant, Department of Epidemiology, Columbia University
- 2001 - 2002 Graduate Research Assistant, Department of Biostatistics, Columbia University
- 2003 Summer Intern, Amgen Inc.
- 2006 - 2007 Biostatistics Manager, Amgen Inc.
- 2007 - 2010 Assistant Professor, Department of Neurological Surgery, University of California San Francisco
- 2010 - 2012 Statistician, Biometric Research Branch (BRB), Division of Cancer Treatment and Diagnosis, National Cancer Institute
- 2012 - Mathematical Statistician, Biometric Research Branch (BRB), Division of Cancer Treatment and Diagnosis, National Cancer Institute

## **TEACHING EXPERIENCE**

### HARVARD UNIVERSITY

Teaching Assistant, *Introduction to Statistics*, Spring 1998 and Summer 1998

### COLUMBIA UNIVERSITY

Teaching Assistant, *Introduction to Biostatistical Methods*, Fall 2000

Teaching Assistant, *Design of Medical Experiments*, Spring 2001

Teaching Assistant, *Categorical Data Analysis*, Fall 2001 and Spring 2002

Course Instructor, *Applied Regression Analysis*, Summer 2004, 2005 (\* *Developed course*)

Course Instructor, *Statistical Computing with SAS*, Summer 2004 (\* *Developed course*)

### UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

Course Instructor, *Lecture Series on Evidence-Based Medicine*, 2007 - 2010

(\* *Co-developed and co-taught with K. Lamborn and S. Chang as part of a training program for residents in the Department of Neurosurgery*)

### NATIONAL CANCER INSTITUTE

Faculty, *Diagnostic Development Tutorial*, Markers in Cancer Meeting - A Joint Meeting by ASCO, EORTC and NCI, Brussels, 2013

(\* An intensive workshop designed to introduce clinical fellows, junior faculty and early career clinical scientists to issues critical to understanding the advances, development, limitations, and validation of molecular markers)

## **PROFESSIONAL ACTIVITIES AND SERVICE**

- 2007 - 2010 Member, Biostatistics and Computational Biology Core, UCSF Comprehensive Cancer Center
- 2007 - 2010 Member, Protocol Review Committee, UCSF Comprehensive Cancer Center
- 2009 - 2010 Session organizer, Western North American Region (WNAR) of the International Biometric Society
- 2011 - Member, Protocol Review Committee, National Cancer Institute
- 2012 Scientific Committee, Markers in Cancer Meeting - A Joint Meeting by ASCO, EORTC and NCI
- 2013 Tutorial Planning Committee, Markers in Cancer Meeting - A Joint Meeting by ASCO, EORTC and NCI
- 2013 - NCI Breast Cancer Steering Committee (BCSC)
- 2013 - NCI Pediatric and Adolescent Solid Tumor Steering Committee (PASTSC)
- 2013 - NCI Pediatric Leukemia and Lymphoma Steering Committee (PLLSC)
- 2013 - Children's Oncology Group (COG) Data Safety Monitoring Committee (DSMC)
- 2013 - Pediatric Brain Tumor Consortium (PBTC) Data Safety Monitoring Board (DSMB)
- 2013 - New Approaches to Neuroblastoma Therapy (NANT) Consortium Data Safety Monitoring Board (DSMB)
- 2013 - National Surgical Adjuvant Breast and Bowel Project (NSABP) Data Monitoring Committee (DMC)

## **MEMBERSHIPS IN PROFESSIONAL SOCIETIES**

American Statistical Association, 2004 - present  
Society for Neuro-Oncology, 2007 - 2010

## **EDITORIAL ACTIVITIES**

### EDITORIAL BOARDS

2009 - Associate Editor, *Neurosurgery*

### INVITED REFEREE (STATISTICAL JOURNALS)

Clinical Trials  
Contemporary Clinical Trials  
Statistics in Biopharmaceutical Research

INVITED REFEREE (MEDICAL JOURNALS)

Neuro-Oncology  
Journal of Neuro-Oncology  
Journal of Clinical Oncology  
Neurosurgery  
Annals of Oncology  
Journal of Molecular Diagnosis

**BIBLIOGRAPHY**

ORIGINAL, PEER-REVIEWED ARTICLES

1. **Polley MY**, Freidlin B, Korn EL, Conley BA, Abrams JS, McShane LM. “Statistical and practical considerations for clinical evaluation of predictive biomarkers”. J Natl Cancer Inst. 2013 Nov 20;105(22):1677-83.
2. **Polley MY**, Leung SC, McShane LM, Gao D, Hugh JC, Mastropasqua MG, Viale G, Zabaglo LA, Penault-Llorca F, Bartlett JM, Gown AM, Symmans WF, Piper T, Mehl E, Enos RA, Hayes DF, Dowsett M, Nielsen TO; on behalf of the International Ki67 in Breast Cancer Working Group of the Breast International Group and North American Breast Cancer Group. “An International Ki67 Reproducibility Study”. J Natl Cancer Inst. 2013 Nov 7.
3. McShane LM, Cavenagh MM, Lively TG, Eberhard DA, Bigbee WL, Williams PM, Mesirov JP, **Polley MY**, Kim KY, Tricoli JV, Taylor JM, Shuman DJ, Simon RM, Doroshow JH, Conley BA. “Criteria for the use of omics-based predictors in clinical trials: explanation and elaboration”. BMC Med. 2013 Oct 17;11:220.
4. McShane LM, Cavenagh MM, Lively TG, Eberhard DA, Bigbee WL, Williams PM, Mesirov JP, **Polley MY**, Kim KY, Tricoli JV, Taylor JM, Shuman DJ, Simon RM, Doroshow JH, Conley BA. “Criteria for the use of omics-based predictors in clinical trials”. Nature. 2013 Oct 17;502(7471):317-20.
5. McShane LM, **Polley MY**. “Development of omics-based clinical tests for prognosis and therapy selection: the challenge of achieving statistical robustness and clinical utility”. Clin Trials. 2013 Oct;10(5):653-65.
6. Bodelon C, **Polley MY**, Kemp TJ, Pesatori AC, McShane LM, Caporaso NE, Hildesheim A, Pinto LA, Landi MT. “Circulating levels of immune and inflammatory markers and long versus short survival in early-stage lung cancer”. Ann Oncol. 2013 Aug;24(8):2073-9.
7. Freidlin B, McShane LM, **Polley MY**, Korn EL. “Randomized phase II trial designs with biomarkers”. J Clin Oncol. 2012 Sep 10;30(26):3304-9.
8. Phillips JJ, Huillard E, Robinson AE, Ward A, Lum DH, **Polley MY**, Rosen SD, Rowitch DH, Werb Z. “Heparan sulfate sulfatase SULF2 regulates PDGFR $\alpha$  signaling and growth in human and mouse malignant glioma”. J Clin Invest. 2012 Mar 1;122(3):911-22.

9. Pejavar S, **Polley MY**, Rosenberg-Wohl S, Chennupati S, Prados MD, Berger MS, Banerjee A, Gupta N, Haas-Kogan D. "Pediatric intracranial ependymoma: the roles of surgery, radiation and chemotherapy". J Neurooncol. 2012 Jan;106(2):367-75.
10. Butowski N, Chang SM, Lamborn KR, **Polley MY**, Pieper R, Costello JF, Vandenberg S, Parvataneni R, Nicole A, Sneed PK, Clarke J, Hsieh E, Costa BM, Reis RM, Hristova-Kazmierski M, Nicol SJ, Thornton DE, Prados MD. "Phase II and pharmacogenomics study of enzastaurin plus temozolomide during and following radiation therapy in patients with newly diagnosed glioblastoma multiforme and gliosarcoma". Neuro Oncol. 2011 Dec;13(12):1331-8.
11. **Polley MY**, Lamborn KR, Chang SM, Butowski N, Clarke JL, Prados M. "Conditional probability of survival in patients with newly diagnosed glioblastoma". J Clin Oncol. 2011 Nov 1;29(31):4175-80.
12. Parvataneni R, **Polley MY**, Freeman T, Lamborn K, Prados M, Butowski N, Liu R, Clarke J, Page M, Rabbitt J, Fedoroff A, Clow E, Hsieh E, Kivett V, Deboer R, Chang S. "Identifying the needs of brain tumor patients and their caregivers". J Neurooncol. 2011 Sep;104(3):737-44.
13. **Polley MY**. "Practical modifications to the time-to-event continual reassessment method for phase I cancer trials with fast patient accrual and late-onset toxicities". Stat Med. 2011 Jul 30;30(17):2130-43.
14. Mueller S, Yang X, Sottero TL, Gragg A, Prasad G, **Polley MY**, Weiss WA, Matthay KK, Davidoff AM, DuBois SG, Haas-Kogan DA. "Cooperation of the HDAC inhibitor vorinostat and radiation in metastatic neuroblastoma: efficacy and underlying mechanisms". Cancer Lett. 2011 Jul 28;306(2):223-9.
15. Sanai N, **Polley MY**, McDermott MW, Parsa AT, Berger MS. "An extent of resection threshold for newly diagnosed glioblastomas". J Neurosurg. 2011 Jul;115(1):3-8.
16. Clark AJ, Butowski NA, Chang SM, Prados MD, Clarke J, **Polley MY**, Sughrue ME, McDermott MW, Parsa AT, Berger MS, Aghi MK. "Impact of bevacizumab chemotherapy on craniotomy wound healing". J Neurosurg. 2011 Jun;114(6):1609-16.
17. Li Y, Lupo JM, **Polley MY**, Crane JC, Bian W, Cha S, Chang S, Nelson SJ. "Serial analysis of imaging parameters in patients with newly diagnosed glioblastoma multiforme". Neuro Oncol. 2011 May;13(5):546-57.
18. Prasad G, Sottero T, Yang X, Mueller S, James CD, Weiss WA, **Polley MY**, Ozawa T, Berger MS, Aftab DT, Prados MD, Haas-Kogan DA. "Inhibition of PI3K/mTOR pathways in glioblastoma and implications for combination therapy with temozolomide". Neuro Oncol. 2011 Apr;13(4):384-92.
19. Tate MC, Kim CY, Chang EF, **Polley MY**, Berger MS. "Assessment of morbidity following resection of cingulate gyrus gliomas". J Neurosurg. 2011 Mar;114(3):640-7.

20. Chang EF, Clark A, Smith JS, **Polley MY**, Chang SM, Barbaro NM, Parsa AT, McDermott MW, Berger MS. “Functional mapping-guided resection of low-grade gliomas in eloquent areas of the brain: improvement of long-term survival”. J Neurosurg. 2011 Mar;114(3):566-73.
21. Mueller S, **Polley MY**, Lee B, Kunwar S, Pedain C, Wembacher-Schröder E, Mittermeyer S, Westphal M, Sampson JH, Vogelbaum MA, Croteau D, Chang SM. “Effect of imaging and catheter characteristics on clinical outcome for patients in the PRECISE study”. J Neurooncol. 2011 Jan;101(2):267-77.
22. Essock-Burns E, Lupo JM, Cha S, **Polley MY**, Butowski NA, Chang SM, Nelson SJ. “Assessment of perfusion MRI-derived parameters in evaluating and predicting response to antiangiogenic therapy in patients with newly diagnosed glioblastoma”. Neuro Oncol. 2011 Jan;13(1):119-31.
23. Srinivasan R, Phillips JJ, Vandenberg SR, **Polley MY**, Bourne G, Au A, Pirzkall A, Cha S, Chang SM, Nelson SJ. “Ex vivo MR spectroscopic measure differentiates tumor from treatment effects in GBM”. Neuro Oncol. 2010 Nov;12(11):1152-61.
24. Khayal IS, **Polley MY**, Jalbert L, Elkhalel A, Chang SM, Cha S, Butowski NA, Nelson SJ. “Evaluation of diffusion parameters as early biomarkers of disease progression in glioblastoma multiforme”. Neuro Oncol. 2010 Sep;12(9):908-16.
25. Cloyd JM, Acosta FL Jr, **Polley MY**, Ames CP. “En bloc resection for primary and metastatic tumors of the spine: a systematic review of the literature”. Neurosurgery. 2010 Aug;67(2):435-44.
26. Butowski N, Chang SM, Lamborn KR, **Polley MY**, Parvataneni R, Hristova-Kazmierski M, Musib L, Nicol SJ, Thornton DE, Prados MD. “Enzastaurin plus temozolomide with radiation therapy in glioblastoma multiforme: a phase I study”. Neuro Oncol. 2010 Jun;12(6):608-13.
27. McBride SM, Perez DA, **Polley MY**, Vandenberg SR, Smith JS, Zheng S, Lamborn KR, Wiencke JK, Chang SM, Prados MD, Berger MS, Stokoe D, Haas-Kogan DA. “Activation of PI3K/mTOR pathway occurs in most adult low-grade gliomas and predicts patient survival”. J Neurooncol. 2010 Mar;97(1):33-40.
28. **Polley MY**, Lamborn KR, Chang SM, Butowski N, Clarke JL, Prados M. “Six-month progression-free survival as an alternative primary efficacy endpoint to overall survival in newly diagnosed glioblastoma patients receiving temozolomide”. Neuro Oncol. 2010 Mar;12(3):274-82.
29. Schiffman JD, Hodgson JG, Vandenberg SR, Flaherty P, **Polley MY**, Yu M, Fisher PG, Rowitch DH, Ford JM, Berger MS, Ji H, Gutmann DH, James CD. “Oncogenic BRAF mutation with CDKN2A inactivation is characteristic of a subset of pediatric malignant astrocytomas”. Cancer Res. 2010 Jan 15;70(2):512-9.
30. Sanai N, **Polley MY**, Berger MS. “Insular glioma resection: assessment of patient morbidity, survival, and tumor progression”. J Neurosurg. 2010 Jan;112(1):1-9.

31. Liu R, Solheim K, **Polley MY**, Lamborn KR, Page M, Fedoroff A, Rabbitt J, Butowski N, Prados M, Chang SM. “Quality of life in low-grade glioma patients receiving temozolomide”. Neuro Oncol. 2009 Feb;11(1):59-68.
32. **Polley MY**, Cheung YK. “Two-stage designs for dose-finding trials with a biologic endpoint using stepwise tests”. Biometrics. 2008 Mar;64(1):232-41.

#### MANUSCRIPT SUBMITTED

1. **Polley MY**, Polley EC, Huang EP, Freidlin B, Simon R. “Two-stage adaptive cutoff (TACO) design for building and validating a prognostic biomarker signature”. (submitted to *Statistics in Medicine*)
2. Ionan AC, **Polley MY**, McShane LM, Dobbin KK. “Frequentist properties of confidence intervals for the intra-class correlation coefficient (ICC)”.

#### MANUSCRIPT IN PREPARATION

1. **Polley MY**, Leung SC, Gao D, Mastropasqua MG, Zabaglo LA, Bartlett JM, McShane LM, Enos RA, Badve S, Bane A, Borgquist S, Fineberg S, Lin M-G, Gown AM, Grabau D, Gutierrez C, Hugh JC, Larsimont D, Moriya T, Ohi Y, Osborne CK, Penault-Llorca F, Piper T, Porter P, Sakatani T, Salgado R, Starczynski J, Lænkholm A-V, Viale G, Dowsett M, Hayes DF, Nielsen TO; on behalf of the International Ki67 in Breast Cancer Working Group of the Breast International Group and North American Breast Cancer Group. “An international study to increase concordance in Ki67 scoring”.

#### **INVITED OR CONTRIBUTED LECTURES**

1. “Two-Stage Designs for Dose-Finding with a Biologic Endpoint Using Stepwise Tests.” New York State Psychiatric Institute, New York, NY; February 2002.
2. “Two-Stage Designs for Dose-Finding with a Biologic Endpoint Using Stepwise Tests.” The Merck Symposium, Merck Inc., NJ; June 2002.
3. “Missing Data Imputation with an Application to a KGF Phase III trial.” Summer internship presentation, Amgen Inc., Thousand Oaks, CA; August 2003.
4. “Two-Stage Designs for Dose-Finding with a Biologic Endpoint Using Stepwise Tests.” Biostatistics Seminar, Amgen Inc., Thousand Oaks, CA; 2005.
5. “Two-Stage Designs for Dose-Finding with a Biologic Endpoint Using Stepwise Tests.” Genentech Inc., South San Francisco, CA; July 6, 2007.
6. “Two-Stage Designs for Dose-Finding with a Biologic Endpoint Using Stepwise Tests.” Department of Epidemiology and Biostatistics, UCSF, San Francisco, CA; December 4, 2007.

7. "An Adaptive Simon's Two-Stage Design for Phase II Studies of Targeted therapies - by C. Jones and E. Holmgren." Journal Club, Biostatistics and Computational Biology Core, UCSF Helen Diller Family Comprehensive Cancer Center; October 14, 2008.
8. "CRM and TITE-CRM Designs for Phase I Oncology Trials." Journal Club, Biostatistics and Computational Biology Core, UCSF Helen Diller Family Comprehensive Cancer Center; May 12, 2009.
9. "Some Modifications to the TITE-CRM Design for Phase I Cancer Trials with Fast Patient Accrual and Late-Onset Toxicities." Journal Club, Biostatistics and Computational Biology Core, UCSF Helen Diller Family Comprehensive Cancer Center; January 2010.
10. "Adjusting for Cluster Effect with a Random Intercept Model." Department of Radiology and Biomedical Imaging, UCSF; February 1, 2010.
11. "Efficacy Endpoints for Brain Tumor Clinical Trials: A Statistical Perspective." One lecture in Biomedical Science Graduate Program lecture series, Department of Neurological Surgery, UCSF; March 29, 2010.
12. "Practical Modifications to the Time-to-Event Continual Reassessment Method for Phase I Cancer Trials with Fast Patient Accrual and Late-Onset Toxicities." Biometric Research Branch, National Cancer Institute, Bethesda, MD; March 2010.
13. "Prediction Models: Logistic Regression versus Recursive Partitioning Analysis." Science Session, Cancer Diagnosis Program, National Cancer Institute, Bethesda, MD; October 26, 2010.
14. "Planning Studies to Validate Prognostic and Predictive Biomarkers: A Statistical Perspective." NCI SPECS II Grants Investigators Workshop; August 16-17, 2012.
15. "Statistical and Practical Considerations for Clinical Evaluation of Predictive Biomarkers." Science Session, Cancer Diagnosis Program, National Cancer Institute; May 28, 2013.
16. "Statistical Considerations for Multi-Site Assay Reproducibility Studies." A didactic lecture at the Diagnostic Development Tutorial, Markers in Cancer Meeting - A Joint Meeting by ASCO, EORTC and NCI, Brussels, Belgium; November 6, 2013.

#### **PRESENTATIONS AT PROFESSIONAL MEETINGS**

1. "Two-Stage Designs for Dose-Finding with a Biologic Endpoint Using Stepwise Tests." Invited oral presentation at the International Chinese Statistical Association (ICSA) Applied Statistics Symposium, Raleigh, NC; July 2, 2007.
2. "Two-Stage Designs for Dose-Finding with a Biologic Endpoint Using Stepwise Tests." Invited oral presentation at the Joint Statistical Meeting (JSM), Salt Lake City, UT; July 31, 2007.

3. “The Calibration of the TITE-CRM Design for Phase I Cancer Trials with Late Onset Toxicities and Fast Patient Accrual.” Oral presentation at the annual meeting of the Joint Statistical Meeting (JSM), Washington DC; August 1-6, 2009.
4. “Six-month Progression-Free Survival as an Alternative Primary Efficacy Endpoint to Overall Survival in Newly-Diagnosed Glioblastoma Patients Receiving Temozolomide.” Invited oral presentation at the Joint Meeting of the Society for Neuro-Oncology and the AANS/CNS Sections on Tumors, New Orleans, LA; October 18, 2009. (*\* won the Award for Excellence in Clinical Research*)
5. “Practical Modifications to the Time-to-Event Continual Reassessment Method for Phase I Cancer Trials with Fast Patient Accrual and Late-Onset Toxicities.” Oral presentation at the annual meeting of the International Biometric Society, Western North American Region (WNAR), Seattle, WA; June 20-23, 2010.
6. “Two-Stage Adaptive Cutoff (TACO) Design for Building and Validating a Prognostic Biomarker Signature.” Invited oral presentation at the annual Markers in Cancer Meeting - A Joint Meeting by ASCO, EORTC and NCI, Brussels, Belgium; November 7, 2013. (*\* selected as one of the six top abstracts for oral presentation at the main meeting*)