

Lori E. Dodd, Ph.D.
Curriculum Vitae — June 2010

National Institute of Allergy and Infectious Diseases
Division of Clinical Research
Biostatistics Research Branch
6700B Rockledge Dr, MSC 7630
Bethesda, MD 20892
(301) 451-2485
doddl@mail.nih.gov

Education:

University of Utah, Salt Lake City, Utah; Honors Bachelor of Science, Anthropology, 1994
Harvard University, Cambridge, Massachusetts, Special Student, Biostatistics & Statistics, 1995-96
University of Washington, School of Public Health, Seattle, Washington; M.S., Biostatistics, 1999
University of Washington, School of Public Health, Seattle, Washington; Ph.D., Biostatistics, 2001

Experience:

Biostatistics Intern, Amgen Inc., Summer 1997
Teaching Assistant, Department of Biostatistics, University of Washington, 1997 - 2000
Statistics Tutor, Department of Biostatistics, University of Washington, 1998 - 2000
Research Assistant, Department of Biostatistics, University of Washington, 1999 - 2001
Statistical Consultant, Department of Biostatistics, University of Washington, 1998-2001
Guest Researcher, National Cancer Institute, Division of Cancer Prevention, Biometry Research Group, 1999 - 2001
Mathematical Statistician, National Cancer Institute, Division of Cancer Treatment and Diagnosis, Biometric Research Branch, September 2001 - June, 2009
Mathematical Statistician, National Institute of Allergy and Infectious Diseases, Division of Clinical Research, Biostatistics Research Branch, July 2009 - present

Professional Activities:

Ex officio member, October 2001- June 2009, American College of Radiology Imaging Network DSMB
Temporary Voting Member, March 2008, FDA Radiological Devices Panel on computer aided detection devices for radiological images
Member, RECIST 1.1 committee, January 2009-July 2009
Co-chair, October 2009, DIA/FDA/NCI PhRMA Progression-free survival oncology workshop

Temporary Voting Member, November 2009, FDA Radiological Devices Panel on digital mammography

Temporary Voting Member, November 2009, FDA Radiological Devices Panel on computer aided detection devices for radiological images

Faculty, January 2010, Radiological Society of North America Clinical Trials Methodology Workshop

Faculty, June 2010, Accelerating Anticancer Agent Development and Validation Workshop

Referee for *American Journal of Roentgenology*, *Biometrics*, *Biometrika*, *Bioinformatics*, *Biotechniques*, *Canadian Journal of Statistics*, *Clinical Trials*, *Computational Statistics and Data Analysis*, *Controlled Clinical Trials*, *Journal of Clinical Oncology*, *Journal of the National Cancer Institute*, *Radiology*, *Statistics in Medicine*

Honors:

Young Alumni Scholarship, University of Utah, 1994

Kennecott Corporation Scholarship, University of Utah, 1994

Anderson Scholar Finalist, Department of Anthropology, University of Utah, 1995

Service-Learning Scholar, University Of Utah, 1995

Undergraduate Research Opportunities Program Fellowship, University of Utah, 1994 - 95

NIH Cardiovascular Training Grant, University of Washington 1996 - 2001

Talks:

Invited:

“Regression methodology in diagnostic testing,” Joint Statistical Meetings, August 2002

“Validating measures of tumor response,” Application of High Resolution CT Imaging Data to Lung Cancer Drug Development, April, 2004

“Design of trials to demonstrate usefulness of FDG-PET in lymphoma,” FDG-PET Lymphoma meeting, March 2006

“Study design issues to evaluate the utility of FDG-PET as a biomarker in lymphoma ,” FDA/Industry Statistics Workshop , September 2006

“Monitoring and regulation of studies of imaging modalities” , Radiological Society of North America Clinical Trials Methodology Workshop, January 2007

“Evaluating response markers in oncology” Eastern North American Region/International Biometric Society Conference, Spring, 2007

“Managing and monitoring response to treatment: evaluating biomarkers for both patient-level and trial-level decision making,” RSNA Biomarkers Workshop, Spring, 2007

“Sensitivity and Specificity in the context of treatment effects,” Joint Statistical Meetings, August, 2008

“The use of blinded independent central review in Phase III oncology trials.” FDA meeting with Dr. Pazdur August, 2009

“Use of blinded independent review for auditing purposes,” Joint Statistical Meetings, August, 2009

“Use of blinded independent review for auditing purposes,” Biometric Research Branch, NCI seminar, August, 2009

“Use of blinded independent review for auditing purposes,” FDA/Industry workshop, September, 2009

“Use of blinded Independent Central Review in Phase III trials with PFS endpoints,” Brookings conference on clinical cancer research, September 2009

“An audit of locally-determined progression free survival using blinded independent central review,” University of Pennsylvania Department of Biostatistics seminar, December, 2009

“Standardization of imaging endpoints in clinical trials: some statistical considerations,” Joint FDA/SNM/RSNA Two Topic Workshop on Standards for Imaging Endpoints and Manufacturing of PET Radiopharmaceutical Products in Clinical Trials, April, 2010

“On the appropriate use of blinded independent central review in phase III oncology trials,” Brown University Center for Statistical Sciences, May, 2010

Contributed:

“Navajo aging and the aged in the context of change.” National Conference on Undergraduate Research, Union College, April 1995

“Regression analysis of the area under the ROC curve using methods for correlated binary data,” International Biometric Conference, Western North American Region, July 2000

“Semi-parametric regression analysis of areas under the ROC curve for continuous test results,” International Conference on Health Policy Research, December 2001

“A method for partial AUC regression,” International Biometric Conference, Eastern North American Region, March 2002

Publications in Refereed Journals:

1. Dodd LE and Pepe MS (2003). Semi-parametric regression for the area under the receiver operating characteristic curve. *Journal of the American Statistical Association* **98**: 409-417.
2. Dodd LE and Pepe MS (2003). Partial AUC estimation and regression. *Biometrics* **59**: 614-623.
3. Dodd LE, Wagner R.F., Armato S, McNitt-Gray M, and other members of the LIDC (2004). An overview of assessment methodologies and related statistical issues for computer-assist modalities in lung imaging: a status report of the Lung Image Database Consortium (LIDC). *Academic Radiology* **11**: 462-475.
4. Albert PS and Dodd LE (2004). A cautionary note on the robustness of latent class models for estimating diagnostic error without a gold standard. *Biometrics* **60**: 427-435.

5. Dodd LE, Korn EL, McShane LM, Chandramouli GV and Chuang EY (2004). Correcting log ratios for signal saturation in cDNA microarrays. *Bioinformatics* **20**: 2685-2693.
6. Dodd LE, Sengupta S, Chen IH, den Boon JA, Cheng YJ, Westra W, Newton MA, Mitti BF, McShane L, Chen CJ, Ahlquist P, and Hildesheim, A (2006). Evaluation of DNA expression levels in tissue obtained from normal and cancerous nasopharyngeal tissue suggests a role of host factors involved in nitrosamine activation and DNA repair in the etiology of nasopharyngeal carcinoma (NPC). *Cancer Epid Biomarker Prev* **15** : 2216-2225.
7. Garcia-Pineros AP, Hildesheim A, Dodd LE, Kemp TJ, Williams M, Harro C, Lowy DR, Schiller JT and Pinto LA (2007) Cytokine and Chemokine profiles following vaccination with human papillomavirus type 16 L1 virus-like particles, *Clinical Vaccine Immunology* **14** 984-9.
8. Kelloff GJ, Sullivan DM, Wilson W, Cheson B, Juweid M, Mills GQ, Zelenetz AD, Horning SJ, Weber W, Sargent DJ, Dodd L, Korn E, Armitage J, Schilsky R, Christian M, O'connor OA, Wang SJ, Farrell AT, Pazdur R, Graham M, Wahl RL, Larson SM, Kostakoglu L, Daube-Witherspoon M, Gastonis C, Siegel BA, Shankar LK, Lee DB, Higley HR, Sigman CC, Carucci D, Timko D, deGennaro LJ, Sigal E, Barker A, Woodcock J. (2007). FDG-PET lymphoma demonstration project invitational workshop. *Acad Radiol.* **14**:330-9.
9. Dodd LE and Korn EL (2007) The Bootstrap Variance of the Square of a Sample Mean, *The American Statistician* **61** 127-131.
10. Cai T and Dodd, L. (2008) Regression Analysis for the Partial Area Under the ROC Curve. *Statistica Sinica*, **18**: 817-836.
11. Albert PS and Dodd LE (2008). On Estimating Diagnostic Accuracy From Studies With Multiple Raters and Partial Gold Standard Evaluation. *Journal of the American Statistical Association*, **103**: 61-73.
12. Dodd LE and Korn EL (2008) Lack of generalizability of sensitivity and specificity with treatment effects. *Statistics in Medicine*, **27**: 1734-44.
13. Dodd LE, Korn EL, Freidlin B, Jaffe CC, Rubinstein LV, Dancey J, and Mooney MM. (2008) Blinded independent central review of progression-free survival in phase III clinical trials: important design element or unnecessary expense? *Journal of Clinical Oncology*, Aug 1;26(22):3791-6.
14. Ford R, Schwartz L, Dancey J, Dodd LE, Eisenhauer EA, Gwyther S, Rubinstein L, Sargent D, Shankar L, Therasse P, Verweij J. Lessons learned from independent central review. (2009). *Eur J Cancer*, **45**: 268-74.
15. Dancey JE, Dodd LE, Ford R, Kaplan R, Mooney M, Rubinstein L, Schwartz LH, Shankar L, Therasse P. (2009). Recommendations for the assessment of progression in randomised cancer treatment trials. *Eur J Cancer*, **45**: 281-9.
16. Eisenhauer EA, Therasse P, Bogaerts J, Schwartz LH, Sargent D, Ford R, Dancey J, Arbuck S, Gwyther S, Mooney M, Rubinstein L, Shankar L, Dodd L, Kaplan R, Lacombe D, Verweij J. (2009) New response evaluation criteria in solid tumours: revised RECIST guideline (version 1.1). *Eur J Cancer*, **45**:228-47.
17. Sargent DJ, Rubinstein L, Schwartz L, Dancey JE, Gatsonis C, Dodd LE, Shankar LK. (2009) Validation of novel imaging methodologies for use as cancer clinical trial end-points. *Eur J Cancer*, **45** :290-9.

18. Garcia-Pineros AJ, Hildesheim A, Dodd L, Kemp TJ, Yang J, Fullmer B, Harro C, Lowy DR, Lempicki RA, Pinto LA. (2009). Gene expression patterns induced by HPV-16 L1 virus-like particles in leukocytes from vaccine recipients. *J Immunol.* **182**: 1706-29.
19. Oyelaran O, McShane LM, Dodd LE, Gildersleeve JC. Profiling human serum antibodies with a carbohydrate antigen microarray. (2009). *J Proteome Res* **8**: 4301-10.
20. Dodd LE. ROC Curves for Continuous Data by KRZANOWSKI, W. J. and HAND, D. J. (2010). *Biometrics* **66**: 657-658.
21. Amit O, Bushnell W, Dodd L, Roach N, and Sargent D. Blinded independent central review of the progression-free survival endpoint. (2010). *The Oncologist* **15**: 492-495.

Publications under review:

22. Dodd LE, Korn EL, Freidlin B, Gray R, Bhattacharya S, An audit strategy for progression-free survival.
23. Korn EL, Dodd LE, Freidlin B, Measurement error in the timing of events: effect on survival analyses in randomized clinical trials.

Letters to the Editor

24. Dodd LE, Simon R (2004). PSA velocity and prostate cancer. *New England Journal of Medicine* **351**: 1800.
25. Dodd LE, Korn EL, and Freidlin B, Response to Raunig DL: "Are onsite image evaluations the solution or are we trading one problem for another?" (2009). *J Clin Oncol*
26. Dodd LE, Korn EL, and Freidlin B, Response to Drs. Samsi and Patt: "Onsite image evaluations and independent image blinded reads: close cousins or distant relatives?" (2009). *J Clin Oncol*