### Laura M. Yee

National Cancer Institute Biometric Research Program, DCTD 240-276-5654 (Office) laura.yee@nih.gov

### **EDUCATION**

University of WashingtonSeattle, WAPhD, Biostatistics2014MS, Biostatistics2011

The George Washington University

BS, Statistics

Washington, DC

2008

#### **EXPERIENCE**

National Cancer Institute, National Institutes of HealthRockville, MDMathematical Statistician2016 – Present

Engage in statistical research and conduct protocol review relating to biomarkers in clinical trials at the Biometric Research Program within the Division of Cancer Treatment and Diagnosis.

### U.S. Food and Drug Administration

Silver Spring, MD

**Mathematical Statistician** 

2014 –2016

Statistical review for in vitro diagnostic device submissions at the Center for Devices and Radiological Health, including evaluation of clinical trials and analytical performance trials such as inter-laboratory reproducibility studies.

## **Collaborative Health Studies Coordinating Center**, University of Washington Seattle, WA **Graduate Research Assistant** 2011 –2014

Statistical analysis and consulting for the Cardiovascular Health Study in the areas of cardiovascular disease and aging.

### **Department of Veterans Affairs**

Seattle, WA

Graduate Research Assistant

Statistical research, analysis, and data preparation pertaining to the health of US veterans.

### **Department of Biostatistics**, University of Washington Seattle, WA

Graduate Teaching Assistant

2011

2011

Teaching assistant for the graduate-level course Applied Biostatistics II (62 students).

## **Department of Radiology**, University of Washington Seattle, WA **Graduate Research Assistant** 2009 –2010

Statistical researcher for the neuroimaging and biotechnology laboratory.

Department of Biostatistics, University of WashingtonSeattle, WAGraduate Research Assistant2008

Statistical research in the field of risk prediction.

# U.S. Department of Energy Washington, DC Statistical Assistant 2007 – 2008

Statistical analysis, modeling, and data management for the Office of Integration Analysis and Forecasting.

### REFEREED PUBLICATIONS (\* denotes novel statistical method/application)

- 1. Harris LN, Blanke CD, Erba HP, Ford JM, Gray RJ, LeBlanc ML, Hu-Leiskovan S, Litzow MR, Luger SM, Meric-Bernstam F, O'Dwyer PJ, Othus MKD, Politi KA, Shephard LE, Allegra CJ, Chen HX, Ivy SP, Korde LA, Little RF, McShane LM, Moscow JA, Patton DR, Thurin M, Yee LM, Doroshow JH (2023). The new NCI precision medicine trials. Clinical Cancer Research. 29 (23): 4728-4732.
- 2. Vega DM, **Yee LM**, McShane LM, Williams PM, Chen L, Vilimas T, Fabrizio D, Funari V, Newberg J, Bruce LK, Chen SJ. Aligning Tumor Mutational Burden (TMB) quantification across diagnostic platforms: Phase 2 of the Friends of Cancer Research TMB Harmonization Project (2021). Annals of Oncology. 32(12): 1626-1636.
- 3. Vural S, Chang LC, **Yee LM**, Sonkin D (2021). TP53 isoform junction reads based analysis in malignant and normal contexts. Scientific reports. 11(1): 1-7.
- 4. Williams PM, Forbes T, P. Lund S, Cole KD, He HJ, Karlovich C, Paweletz CP, Stetson D, **Yee LM**, Connors DE, Keating SM (2021). Validation of ctDNA Quality Control Materials Through a Precompetitive Collaboration of the Foundation for the National Institutes of Health. JCO Precision Oncology. 5: 910-20.
- 5. Krushkal J, Negi S, **Yee LM**, Evans JR, Grkovic T, Palmisano A, Fang J, Sankaran H, McShane LM, Zhao Y, O'Keefe BR (2021). Molecular Genomic Features Associated with in Vitro Response of the NCI-60 Cancer Cell Line Panel to Natural Products. Molecular Oncology. 15(2): 381-406.
- 6. Godsey JH, Silvestro A, Barrett JC, Bramlett K, Chudova D, Deras I, Dickey J, Hicks J, Johann DJ, Leary R, Lee JSH, McMullen J, McShane L, Nakamura K, Richardson AO, Ryder M, Simmons J, Tanzella K, **Yee** L, Leiman LC, on behalf of the BloodPAC Consortium (2020). Generic Protocols for the Analytical Validation of Next-Generation Sequencing-Based ctDNA Assays: A Joint Consensus Recommendation of the BloodPAC's Analytical Variables Working Group. Clinical Chemistry. 66 (9): 1156–1166.
- 7. **Yee LM**, McShane LM, Freidlin B, Mooney MM, Korn EL (2019). Biostatistical and logistical considerations in the development of basket and umbrella clinical trials. The Cancer Journal. 25 (4): 254-263.
- 8. **Yee LM**, Lively TG, McShane LM (2018). Biomarkers in early phase trials: Fundamental issues. Bioanalysis. 10 (12): 933-44.
- 9. **\*Yee LM** and Chan KCG (2017). Nonparametric inference for the joint distribution of recurrent marked variables and recurrent survival time. Lifetime Data Analysis. 23 (2): 207-222.

- 10. Jacob ME, **Yee LM**, Diehr PH, Arnold AM, Thielke SM, Chaves PHM, Del Gobbo L, Hirsch C, Siscovick D, Newman AB (2016). Can a healthy lifestyle compress the disabled period in older adults? Journal of the American Geriatrics Society. 64 (10): 1952-1961.
- 11. Karas MG, **Yee LM**, Biggs MLB, Djousse L, Mukamal KJ, Ix JH, Zieman SJ, Siscovick DS, Gottdiener JS, Rosenberg MA, Kronmal RA, Heckbert SR, Kizer JR (2016). Measures of body size and composition and risk of incident atrial fibrillation in older adults: The Cardiovascular Health Study. American Journal of Epidemiology. 183 (11): 998-1007.
- 12. Diehr P, Diehr M, Arnold A, **Yee L**, Odden MC, Hirsch CH, Thielke S, Psaty BM, Johnson WC, Kizer J, Newman AB (2015). Predicting Future Years of Life, Health, and Functional Ability: A Healthy Life Calculator for Older Adults. Gerontology and Geriatric Medicine. January-December 2015 Vol 1. Published online: (ggm.sagepub.com/content/1/2333721415605989.full.pdf+html).
- 13. \*Yee LM and Chan KCG (2015). Nonparametric inference for time-dependent incremental cost-effectiveness ratios. Statistics in Medicine. 34 (30): 4057-4069.
- 14. Thielke SM, Diehr PH, **Yee LM**, Arnold AM, Quinones AR, Whitson HE, Jacob M, Newman A (2015). Sex, race, and age differences in observed years of life, healthy life, and able life among older adults in the Cardiovascular Health Study. Journal of Personalized Medicine. 5 (4): 440-451.
- 15. Alshawabkeh LI, **Yee LM**, Gardin JM, Gottdiener JS, Odden M, Bartz TM, Arnold AM, Mukamal KJ, Wallace RB (2015). Years of Able Life in Older Persons—The Role of Cardiovascular Imaging and Biomarkers: The Cardiovascular Health Study. Journal of the American Heart Association. 4 (4): e001745.
- 16. Longstreth W, Yee L, Newman A, Beauchamp N, Diehr P (2014). Findings on MRI and subsequent years of life, healthy life, and able life in the elderly. Journal of the American Geriatrics Society. 62 (10): 1838-1843.
- 17. Odden MC, **Yee LM**, Arnold AM, Sanders JL, Hirsch C, DeFilippi C, Kizer JR, Inzitari M, Newman AB (2014). Subclinical Vascular Disease Burden and Longevity. Journal of the American Geriatrics Society. 62 (9): 1692-1698.
- 18. Whitson HE, Arnold AM, **Yee L**, Mukamal KJ, Kizer JR, Djousse L, Ix JH, Siscovick D, Tracy RP, Thielke S, Hirsch C, Newman AB, Zieman S (2014). Serum carboxymethyl-lysine (CML), disability, and frailty in older persons: the Cardiovascular Health Study. Journals of Gerontology: Medical Sciences. 69 (6): 710-716.
- 19. Chen LY, Sotoodehnia N, Buzkova P, Lopez FL, **Yee LM**, Heckbert SR, Prineas R, Soliman EZ, Adabag S, Konety S, Folsom AR, Siscovick D, Alonso A (2013). Atrial fibrillation and the risk of sudden cardiac death: the Atherosclerosis Risk in Communities (ARIC) Study and Cardiovascular Health Study (CHS). JAMA Internal Medicine. 173 (1): 29-35.

#### RECENTLY SUBMITTED/PREPRINTS

1. Li Y, **Yee LM**, Hunsberger S, Memoli MJ, Sadtler K, Graubard B. Nonprobability follow-up sample analysis: an application to SARS-Cov-2 infection prevalence estimation. ArXiv.org [Preprint]. [2306.08724]. June 14: 2023. doi: 10.48550/arXiv.2306.08724

2. Karkanitsa M, Li Y, Valenti S, Spathies J, Kelly S, Hunsberger S, Yee L, Croker JA, Wang J, Alfonso AL, Faust M, Mehalko J, Drew M, Denson JP, Putman Z, Fathi P, Ngo TB, Siripong N, Baus HA, Petersen B, Ford EW, Sundaresan V, Josyula A, Han A, Giurgea LT, Rosas LA, Bean R, Athota R, Czajkowski L, Klumpp-Thomas C, Cervantes-Medina A, Gouzoulis M, Reed S, Graubard B, Hall MD, Kalish H, Esposito D, Kimberly RP, Reis S, Sadtler K, Memoli MJ. Dynamics of SARS-CoV-2 Seroprevalence in a Large US population Over a Period of 12 Months. medRxiv [Preprint]. Oct 21: 2023. doi: 10.1101/2023.10.20. 23297329. PMID: 37904956; PMCID: PMC10614993.

### **BOOK CHAPTERS**

- 1. **Yee LM**, Korn EL, Freidlin B (2021). "Statistical considerations in the development and evaluation of therapeutic biomarkers in cancer." In Yang S and Dancey J (Eds.). *Handbook of Therapeutic Biomarkers in Cancer, Second Edition*. Singapore: Jenny Stanford Publishing.
- 2. Palmisano A, Kruskal J, Li MC, Fang J, Sonkin D, Wright G, **Yee L**, Zhao Y, McShane L (2020). "Bioinformatics tools and resources for cancer immunotherapy study." *Biomarkers for Immunotherapy of Cancer*. New York: Humana.
- 3. Li M, Pennello G, Wu J, **Yee L**, Zhang Z, Gray G, Jin Y, Xu Y, Xu Z, Ye J (2018). "Personalized medicine." *Encyclopedia of Biopharmaceutical Statistics, Fourth Edition*. Boca Raton: Chapman and Hall/CRC.

### **CONFERENCE POSTERS/CONFERENCE PRESENTATIONS/OTHER PRESENTATIONS (\* denotes presenter)**

- 1. **Yee LM\***. A ctDNA quality control materials project with FNIH. Session: Statistical challenges evaluating circulating cell-free/tumor DNA based in-vitro diagnostic devices. Invited talk at 2023 Joint Statistical Meeting of the American Statistical Association, August 2023.
- 2. Eaton A\* and **Yee LM**. Estimating RMST difference within biomarker groups with misclassification. Contributed talk at 2023 Joint Statistical Meeting of the American Statistical Association, August 2023.
- 3. **Yee LM\***, Liang CJ, Rubenstein K, Fintzi J. "(Still) All this talk about covariate adjustment in RCTs." Talk for Biostatistics Research Branch, NIAID, NIH. January 2023.
- 4. Jiwani S\*, Radich J, Saeed M, Aicher L, Chang TC, Narava S, Holman Z, Beppu L, Sala-Torra O, Majano M, Taylor E, **Yee L**, Li J, McShane L, Sandhuria P, Little RF, Harris L, Williams M, Yeung CS. Rapid clinical mutation screening for the NCI MyeloMATCH trial using the Genexus platform. Poster presented at ASH 2023 Meeting, December 2023. Blood 2023; 142 (Supplement 1): 2288.
- 5. Narava SK\*, Li J, Chen L, Nair N, Das B, Kim B, **Yee L**, Harris L, Doroshow J, Williams PM, McShane LM, Jiwani S, Karlovich CA. A concordance study of NGS laboratories in the NCI ComboMATCH Designated Laboratory Network. Contributed Poster to the AMP 2023 Annual Meeting & Expo, November 2023.
- 6. Paweletz CP, Forbes T, Heavey G, Yee L, He HJ, He Z, Connors D, Stetson D, Keating S, Cole K, Kelloff G, McCormack B, Williams M, Karlovich C. Functional characterization and a real-world clinical laboratory pilot of the Foundation for the National Institutes of Health's (FNIH) circulating tumor DNA (ctDNA) Quality Control Materials (QCMs). Abstract submitted to the AACR Annual meeting 2024.
- 7. Etemadi A, **Yee L**, Shakeri R, Roshandel G, Poustchi H, Abnet CC, Malekzadeh R. Risk factors of gastric cancer in Golestan Cohort Study. Abstract submitted to the Digestive Disease Week 2024 Meeting.

- 8. Little RF\*, Othus M, Assouline S, Ansher S, Atallah EL, Lindsley RC, Freidlin B, Gore SD, Harris L, Hourigan CS, Ivy SP, Jiwani S, Lanagan E, Luger S, Michaelis LC, Odenike O, Patton D, Perales M, Radich JP, Ramineni B, Salk JJ, Stiff P, Stock W, Stone RM, Uy GL, Williams PM, Wood BL, Worthington KH, Yee LM, Zeidan AM, Zhang J, Litzow M, Erba HP. Umbrella Trial in Myeloid Malignancies: The MyeloMATCH National Clinical Trials Network Precision Medicine Initiative. ASH Annual Meeting and Exposition, December 2022.
- 9. **Yee LM\***. Blood-based biomarkers, complex biomarkers, and beyond. Invited short course for FDA CDRH Division of Clinical Evidence and Analysis 2 (Biostatistics), September 2022.
- 10. **Yee LM\***. Experience with complex biomarkers and beyond at NCI. Session: Evaluation of complex biomarkers. FDA/AdvaMed Medical Device Statistical Issues Conference, May 2022.
- 11. Bowen CM\*, Koepke A\*, Maxwell L\*, Palacios J\*, **Yee LM\***. Which path should I choose? A discussion of employment in academia, industry, government, and nonprofits. Member of panel at the American Statistical Association Women in Statistics and Data Science Conference, October 2021.
- 12. Merino DM\*, Yee LM, McShane LM, Williams PM, Vilimas T, Patidar R, Barrett JC, Chen SJ, Cheng JH, Conroy JM, Cyanam D, Eyring KR, Fabrizio DA, Funari V, Garcia EP, Glenn ST, Gocke CD, Gupta V, Haley LM, Hellmann MD, Keefer L, Keeler LR, Kennedy B, Lazar AJ, MacConaill LE, Meier KL, Papin A, Rizvi NA, Sokol E, Stafford P, Thompson JF, Tom W, Weigman VJ, Xie M, Zhao C, Stewart MD, Allen J (2020). Alignment of TMB measured on clinical samples: Phase IIB of the Friends of Cancer Research TMB Harmonization Project. American Association for Cancer Research 2020 Annual Meeting, April 2020. Abstract: Cancer Research. 80 (16: Suppl): 5671.
- 13. Yee LM\*. Statistical considerations in the design and analysis of basket and umbrella trials. Contributed talk at the American Statistical Association Women in Statistics and Data Science Conference, October 2019.
- 14. Tricoli JV, Zane L, Harrington R, Yee L, Harper KN, Chang TC, Harris L, Chen AP, Flaherty K, O'Dwyer PJ, Conley BA, Winter C, Lee J, Williams PM, Sklar J, Patton D, Tsongalis GJ, Hamilton SR, Iafrate AJ, Karlovich CA\*. Design and development of the molecular analysis for therapy choice (NCI-MATCH) designated laboratory network. Poster presentation & discussion at American Society of Clinical Oncology 2019 Annual Meeting, May 2019. Abstract: Journal of Clinical Oncology. 37 (Suppl 15): 3016.
- 15. Merino DM\*, Yee LM, McShane LM, Butler MG, Funari V, Hellmann MD, Chaudhary R, Chen SJ, Chen W, Conroy JM, Fabrizio D, MacConaill, Pallavajjala A, Papin A, Sausen M, Weigman VJ, Xie M, Zehir A, Zhao C, Williams PM. TMB standardization by alignment to reference standards: Phase 2 of the Friends of Cancer Research TMB standardization project. Poster presentation at American Society of Clinical Oncology 2019 Annual Meeting, May 2019. Abstract: Journal of Clinical Oncology. 37 (Suppl 15): 2624.
- 16. **Yee LM\*.** Generating the scientific evidence: the challenges in implementing to daily practice. Panelist at the Innovation and Biomarkers in Cancer Drug Development Meeting, November 2018.
- 17. **Yee LM\*.** Study design with therapeutic biomarkers. Invited talk at the American Statistical Association Biopharmaceutical Section Regulatory-Industry Statistics Meeting, September 2018.

- 18. McShane LM and **Yee LM\***. Reproducibility in 'omics studies. Invited talk at the NCI Summer Curriculum in Cancer Prevention Program, August 2017, 2018, & 2019.
- 19. **Yee LM\***, Jin Y, and Li M. Prescreening bias in companion diagnostic devices. Invited talk at the Society for Clinical Trials 37<sup>th</sup> Annual Meeting, May 2016.
- 20. **Yee LM\***, Li M. One-armed oncology biomarker trials in the accelerated approval program: a biomarker perspective. Poster presented at the FDA Biomarker Working Group Meet & Greet, May 2016.
- 21. **Yee LM\***. Immunohistochemistry Devices: Analytical and Clinical Validation. Invited talk at the 9th Annual FDA/AdvaMed Medical Devices and Diagnostics Statistical Issues Conference, May 2016.
- 22. **Yee LM\***. Bias in Diagnostic Studies. Center for Devices and Radiological Health, Office of Biometrics and Surveillance Course Series: Statistics for Diagnostic Devices, September 2015.
- 23. **Yee LM** and Chan KCG\*. Nonparametric inference for the joint distribution of recurrent marked variables and recurrent survival time. Invited talk at the International Chinese Statistical Association /Graybill Joint Conference, June 2015.
- 24. Jacob M\*, Yee L, Arnold A, Chaves P, Diehr P, Hirsch C, Newman A. Lifestyle factors and active life expectancy in the Cardiovascular Health Study. Poster presented at the Gerontological Society of America Annual Scientific Meeting, November 2013.
- 25. **Yee L\*.** Methods in Medical Cost Data. Collaborative Health Studies Coordinating Center Seminar Series, University of Washington Department of Biostatistics, April 2013.
- 26. Zeliadt SB\*, Yee L, Batten AJ, Chapko MK, Wagner TH, Zhao XH. Assessing bias in current methods for estimating disease-attributable costs across 31 common conditions in VA users. Poster presented at the US Department of Veterans Affairs HSR&D/QUERI National Conference, July 2012.
- 27. Carlbom DJ\*, **Yee L**, Ehler J, Copass MK. Paramedic Central Venous Catheter Training: Simulation vs. Lecture. Poster presented at American Thoracic Society International Conference, May 2012.
- 28. Karas M\*, Yee L, Biggs ML, Djousse L, Mukamal K, Ix JH, Zieman SJ, Siscovick DS, Gottdiener JS, Rosenberg MA, Kronmal RA, Kizer JR. Measures of central and general adiposity and risk of incident atrial fibrillation in older persons: the Cardiovascular Health Study. Poster presented at American College of Cardiology Scientific Sessions, March 2012.
- 29. Thiele F\*, Yee L, Wenzel F, Zhou XH, Minoshima S. 2010. Combination of predictors to classify cognitive decline in individual subjects with mild cognitive impairment. Alzheimer's and Dementia. 6 (4): S298-S298. Poster presented at Alzheimer's Association International Conference on Alzheimer's Disease, July 2010.

#### **PROFESSIONAL SERVICE**

Medical Devices and Diagnostics Section of the American Statistical Association.

- Chair: 2024.
- Chair Elect: 2023.

- Program Chair: 2021.
- Program Chair Elect: 2020.
- Member of JSM Student Paper Committee: 2017, 2018, 2019, 2020, 2021.
- Correspondence Secretary: 2017-2018.

NCI Core Correlative Sciences Committee NCI Protocol Review Committee 2016 - Present

2016 – Present

Journal Referee for Statistics in Medicine, Nature Medicine, Science Translational Medicine, British Journal of Cancer, JAMA Oncology, JNCI Cancer Spectrum, BMC Cancer, Statistics in Biopharmaceutical Research, Biostatistics & Epidemiology, and others.