

### BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.  
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NAME Lu, Ying	POSITION TITLE Professor of Biostatistics, Stanford University Director of Palo Alto Cooperative Studies Program Center, Palo Alto VA Healthcare System		
eRA COMMONS USER NAME (credential, e.g., agency login) YINGLU			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
Fudan University, Shanghai, China	B.S.	07/82	Mathematics
Shanghai Jiao Tong University, Shanghai, China	M.S.	07/84	Applied Mathematics
University of California, Berkeley, CA	Ph.D.	06/90	Biostatistics

#### A. Personal Statement

I have been a professor in major medical schools in the past 20 years. I have taught graduate students in biostatistics, bioengineering, public health, and medical fellows and students in all these years. My research focuses on statistical methods development and applications in medical diagnosis, medical decision making, classification, prognostic prediction, and clinical trials. As the director and principal investigator of the Veterans Affairs Palo Alto Cooperative Studies Program Coordinating Center, I will also be able to provide hands-on practice opportunities to graduate students, including clinical trials and personalized medicine. Thus, I think that I can make unique contributions to this Biostatistics Training Grant and be a qualified mentor for students.

#### B. Positions and Honors

##### Positions and Employment

- 2009-present Director, Palo Alto Cooperative Studies Program Center, Palo Alto VA Health Care System
- 2009-present Professor of Biostatistics, Department of Health Research and Policy, Stanford University
- 1994-2009 Assistant (94-98), Associate Adjunct Professor (98-03), and Associate Professor in Residence (2003-06), Professor in Residence (2006-2009), Dept of Radiology and Biomedical Imaging; Associate Professor in Residence (2003-06), Professor in Residence (2006-09), Dept of Epidemiology and Biostatistics, University of California, San Francisco, CA
- 2000-2009 Faculty Member: Bioengineering Graduate Program, University of California San Francisco & Berkeley.
- 1999-2009 Director (2002-2009): Biostatistics Core Facility, Cutaneous Oncology Program, and GI Oncology Program of the HDF UCSF Comprehensive Cancer Center, University of California, San Francisco, CA
- 1990-1994 Assistant Professor, Department of Epidemiology and Public Health, School of Medicine, University of Miami, Miami, Florida
- 1986-1989 Biostatistician/Analyst. Triton Biosciences, Inc., Alameda, CA 94501
- 1984-1985 Instructor, Dept. of Applied Mathematics, Shanghai Jiao Tong University, Shanghai, China

##### Other Experience and Professional Memberships

- 1995-2009 Vice President (1995-97), President Elected (1997-98, 2004-05), President (1998-99, 2005-06), Chapter Representative (2006-present), American Statistical Association San Francisco Bay Area Chapter
- 1995-1999 Member, International Committee on Standardization of Bone Measurement
- 2001-2002 Ad hoc reviewer of project program grant, NIH
- 2004-2006 Temporary Member, Epidemiology of Clinical Disorders and Aging Study Section, NIH;
- 2006-2011 Member, NIH Neurological, Aging, & Musculoskeletal Epidemiology (NAME) Study Section

- 2006-2009 Member, American Joint Committee on Cancer (AJCC) Statistical Task Force  
2009-present Member, American Joint Committee on Cancer (AJCC) Molecular Modeler Group  
2007-2009 Member, WNAR Regional Committee  
2007-2011 Member, Peripheral and Central Nervous System Drugs Advisory Committee, Center for Drug Evaluation and Research, U.S. Food and Drug Administration  
2008-present Member, the External Advisory Board of the Tufts Medical Center Cancer Center  
2008-2012 Chair, Program Committee, International Chinese Statistical Association  
2011-2014 Member, the Advisory Committee, School of Biomedical Engineering, Shanghai Jiao Tong University

### **Honors**

- 1985-1988 University Fellowship, UC Berkeley, CA  
1989 School of Public Health Alumnus Scholarship, UC Berkeley, CA  
1990 The Evelyn Fix Memorial Medal and Citation, Dept of Statistics, UC Berkeley, CA  
2003 Healthstar Osteoporosis Medical Research Award, the Chinese Development Foundation For Science and Technology, Beijing, China  
2009 Exemplary Service Award, UCSF Helen Diller and Family Comprehensive Cancer Center, San Francisco, CA  
2010 Advisory Committee Service Award, US Food and Drug Administration, Washington DC  
2011 Elected Fellow, American Statistical Association

### **C. Selected Peer-reviewed Publications** (out of 206 peer-reviewed papers)

#### **Most relevant to the current application**

1. Lu Y, Malani HM. Analysis of Animal Carcinogenicity Experiments with Multiple Tumor Types. *Biometrics* 1995;51:73-86. PMID: 7766797
2. Lu Y, Ye K, Ashwini MK, Hui S, Fuerst TP, Genant HK. Comparative calibration without a gold standard. *Statistics in Medicine* 1997;16:1889-1905. PMID:9280040
3. Lu Y, Heller D., Zhao, S. ROC analysis for diagnostic examinations with uninterpretable cases, *Statistics in Medicine* 2002; 21:1849-1865. PMID:12111893
4. Lu Y, Jin H, Genant HK. On the equivalence of two diagnostic tests based on paired observations. *Statistics in Medicine* 2003 Oct; 22(10):3029-44. PMID:12973785
5. Lu Y, Jin H, Lamborn K. Design of phase II cancer trials with both total and complete responses. *Statistics in Medicine* 2005 Oct 30;24(20):3155-70. PMID:16189806

#### **Additional publications of importance to the field (in chronological order)**

1. Lu Y, Bean JA. On the sample size for studies of bioequivalence based upon McNemar's test. *Statistics in Medicine* 1995; 14:1831-1839. PMID: 7481214
2. Lu Y, Jin H, Mi J. On comparison of two classification methods with survival endpoints. *Handbook of Statistics*, 2004; Vol. 23, Advances in Survival Analysis:43-59.
3. Jin H, Lu Y. Permutation test for non-inferiority of the linear to the optimal combination of multiple tests. *Statistics and Probability Letters*. 2009 March 79 (5):664-669. PMCID: PMC2699684
4. Jin H, Lu Y. The ROC region of a regression tree. *Statistics and Probability Letters*. 2009 April 79(7):936-942. doi:10.1016/j.physletb.2003.10.071
5. Fan S, Venook AP, Lu Y. Design issues in dose-finding phase I trials for combinations of two agents. *Journal of Biopharmaceutical Statistics* 2009; 19(3):509-23, PMID: 19384692
6. Jin H, Lu Y. Comparison of correlated proportions based on paired binary data from clustered samples. *Journal of Statistical Planning and Inference* 2009 Dec. 139(12):4206-4212. doi:10.1016/j.jspi.2009.06.005
7. Jin H, Lu Y. The optimal linear combination of multiple predictors under the generalized linear models. *Statistics and Probability Letters* 2009 Nov. 79(22):2321-2327. PMCID: PMC2772215
8. Li C, Lu Y. Evaluating the improvement in diagnostic utility from adding new predictors. *Biom J*. 2010 Jun;52(3):417-35.PMID: 20496347

9. Zhao Q, Li W, Li C, Chu PW, Kornak J, Lang TF, Fang J, Lu Y. A statistical method (cross-validation) for bone loss region detection after space flight. *Australia Phys Eng Sci Med*. 2010 Jun;33(2):163-9. Epub 2010 Jul 15. PMID: 20632144.
10. Kornak J, Lu Y. Bayesian Decision Analysis for Choosing Between Diagnostic/Prognostic Prediction Procedures. *Statistics and Its Interface* 2011; 4(1):27-36. NIHMSID #241219

#### **D. Research Support**

##### **Ongoing Research Support**

VA Palo Alto Cooperative Studies Program Coordinating Center (Prog 825)                      09/01/2009-09/30/2012  
Department of Veterans Affairs  
Role: PI

##### **Completed Research Support**

Continuation R01 CA69587 Hylton (PI)                      08/01/06 - 02/28/11  
National Institutes of Health

Anatomic and Biologic Staging of Breast Disease With MRI

The goal of this study is to evaluate the effectiveness of quantitative measurements derived from contrast enhanced MRI for assessing primary breast tumors, to support their use as in-vivo predictive markers for neoadjuvant treatments.

Role: Co-Investigator (\*left position; not working on it)

NIH R01 CA116182 Hylton (PI)                      08/01/06-07/31/11  
National Institutes of Health

MRI for Staging DCIS and Assessing Response to Treatment

The primary study aim is to refine existing contrast-enhanced (CE) MR methods for characterizing ductal carcinoma in situ (DCIS) to better identify DCIS and define its extent, for application to assessing response to neoadjuvant hormonal and statin treatment.

Role: Co-Investigator (\*left position; not working on it)

R01EB004079-02 Lu (PI)                      04/01/2006-2/31/2009  
National Institutes of Health

Statistical Methods for Evaluation and Validation of Diagnostic Tests. Study Aim: This grant is to develop statistical methods for evaluation of non-inferiority test and for accurate estimation of relative risk using cross-sectional and short-term follow-up data.

Role: Principal Investigator

P30 CA82103 McCormick, F.(PI)                      08/05/99-05/31/12  
NIHINCI

Cancer Center Support Grant

The Cancer Center Support Grant provides support for administration and infrastructure for the UCSF Helen Diller Family Comprehensive Cancer Center. Dr. Lu is the Director of the Biostatistics and Computational Biology Core.

Role: Director of Biostatistics Core (\*left position; not working on it)

1 R01 CA102303-01 Fong (PI)                      04/1/04-03/31/09  
National Institutes of Health

Dendritics Cell Immunotherapy for Colorectal Cancer

The Objective of this project is to evaluate novel approaches to generating antigen-pulsed dendritic cells (DC) for the treatment of colorectal cancer.

Role: Co-Investigator