

Lisa Morrissey LaVange

CURRICULUM VITAE

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EDUCATION

1983 University of North Carolina, Chapel Hill, Ph.D. Biostatistics
1976 University of Massachusetts, Amherst, M.A. Mathematics
1974 University of North Carolina, Chapel Hill, B.A. Mathematics

PROFESSIONAL EXPERIENCE

Academic and Government:

2018 to date Professor and Department Associate Chair and Director of the Collaborative Studies Coordinating Center (CSCC), Department of Biostatistics, Gillings School of Global Public Health, University of North Carolina, Chapel Hill, NC. Coordinates school-wide curriculum development in Data Science; teaches statistical leadership and clinical trials courses for doctoral students. Directs approximately 100 research faculty and staff at the CSCC on statistical and data coordinating center projects. Coordinating Center PI (multiple) for the NICHD-funded Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN).

2011 to 2017 Director of the Office of Biostatistics in the Center for Drug Evaluation and Research (CDER), US Food and Drug Administration (FDA). Directed 215 statistical reviewers, analysts, and support staff involved in the development and application of statistical methodology for drug regulation. Responsible for statistical review of all investigational drugs, therapeutic biologics, biosimilar products, and generic drugs. Chaired the Statistical Policy Council and was member of CDER's Medical Policy Council; set statistical policy and oversaw statistical guidance development and publication for the Center. Member of the CDER Task Force on Antibiotic Drug Development since 2012. Member of the Prescription Drug User Fee Act (PDUFA) V Steering Committee and the PDUFA VI negotiation team (2016); responsible for the Complex Innovative Design project under PDUFA VI. Led the Rare Diseases Working Group within CDER. Organized and led FDA public meetings on meta-analysis and interim data disclosure; organized and led statistics think tanks on innovative trial designs and rare diseases. FDA representative to the International Council on Harmonization (ICH); responsible for regulatory oversight of all ICH-E series guidance documents; member of E17 and E9 (R1) working groups and rapporteur for E8 (R1) and the renovation of E6 (Good Clinical Practice). Represented the FDA at numerous national and international scientific and regulatory conferences, industry workshops, and meetings with patient advocacy groups.

2005-2011 Professor of the Practice of Biostatistics and Director, Collaborative Studies Coordinating Center, Department of Biostatistics, Gillings School of Global Public Health, University of North Carolina at Chapel Hill. Directed approximately 90 faculty, staff, and students involved in coordinating center projects for multi-site clinical trials, epidemiology studies, and patient registries. Served as Coordinating Center PI on the NHLBI-funded Hispanic Community Health Study/Study of Latinos (HCHS/SOL) and the Subpopulations and Intermediate Outcomes in COPD Study (SPIROMICS); developed and directed the Bronchiectasis Patient Registry for the COPD Foundation; served as Coordinating Center PI for the NIMH-funded Schizophrenia Trial Network, including the CAMP

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and METS trials; co-directed the Biostatistics and Bioinformatics cores for UNC's CTSA award (NC TraCS Institute); and served on numerous industry-sponsored Data Monitoring Committees.

1989-2005 Adjunct Assistant Professor (1989-1995); Adjunct Associate Professor (1995-1999); Adjunct Professor (1999-2005); Department of Biostatistics, University of North Carolina at Chapel Hill

1979-1980 Graduate Research Assistant, Department of Biostatistics, University of North Carolina at Chapel Hill

1974-1975 Instructor, Department of Mathematics and Statistics, University of Massachusetts at Amherst

Industry and Non-Profit:

2001-2005 Vice President, Biostatistics and Data Management, Inspire Pharmaceuticals, Inc., Durham, NC. Directed the cystic fibrosis drug development program; oversaw the clinical and statistical sections of the company's first NDA submission; and participated in drug development programs in the areas of ophthalmology, lung, and cardiovascular disease. Established a statistics department and directed outsourcing of data management and statistical computing. Participated in strategic planning and portfolio management for the company.

1996-2001 Quintiles, Inc., Research Triangle Park, NC
 Vice President (1999 – 2001) of Biostatistics. Directed over 200 statisticians and programmers, located in five offices across North America, supporting clinical trial operations, regulatory submissions, and post-marketing evaluations for a variety of both large and small pharmaceutical and biotechnology companies. Served as statistical consultant for drug development programs in CNS and cardiovascular research. Senior Director (1998), Director (1997), and Associate Director (1996).

1995 Director, Rho Federal Systems, Rho, Inc. Chapel Hill, NC. Directed small business grants.

1976 -1994 Research Triangle Institute, Research Triangle Park, North Carolina.
 Principal Scientist (1991-1994): Served as principal investigator, co-investigator, project director, and senior statistician for large-scale sample surveys, clinical trials, and survey data analysis software projects (SUDAAN). Department Manager (1987-1989); Senior Research Statistician (1986-1987); Research Statistician (1981-1986); Programmer/Analyst (1976-1978).

1989-1990 Director of Design and Statistical Computing Unit, Frank Porter Graham Child Development Center, University of North Carolina at Chapel Hill. Responsible for statistics and data management operations in support of early childhood behavioral and health research studies.

PROFESSIONAL MEMBERSHIPS and POSITIONS HELD

American Statistical Association
 President 2018; President-elect 2017; *Past-President 2019*
 Education Workgroup on Undergraduate Curriculum Guidelines 2013-2014
 Education Workgroup on Master's Curriculum Guidelines 2011-2012
 Committee on Publications 2008-2014
 Overall Program Chair, Joint Statistical Meetings 2006
 Committee on Meetings 2004 - 2007
 General Methodology Program Chair, Joint Statistical Meetings 2003
 Section on Statistical Consulting Program Chair, Joint Statistical Meetings 1998

International Biometric Society (IBS)
 Executive Board Member 2013-2014

Eastern North American Region (ENAR) of IBS:
 President-elect 2006; President 2007; Past-President 2008
 Chair, Corporate Sponsorship Committee, 2001-2004
 Program Committee, ENAR Spring Meeting 2003
 Correspondent to the IBS Bulletin, 2001-2002
 Secretary, 1999-2000
 Chair, Case Studies Competition, 1994-1997
 Regional Advisory Board, 1992-1994

Drug Information Association
 Program Committee, DIA/FDA Statistics Forum, 2012-2017
 Adaptive and Bayesian Statistics Working Groups, 2013 to date

Program Committee co-Chair, Adaptive and Bayesian Clinical Trials Workshop, 2013
Program Committee, Workshop on Statistical Methodology in the Biopharmaceutical Sciences, 2004-2005

SELECTED TEACHING EXPERIENCE

Semester courses (3 credit hours) taught at University of North Carolina at Chapel Hill:

Biostatistics 844 – Statistical Leadership; Developed course; co-Instructor for inaugural year, 2011

Biostatistics 752 – Design and Analysis of Clinical Trials; co-Instructor, 2007-2010

Biostatistics 841 – Principle of Statistical Consulting; co-Instructor, 2008-2011

Semester courses (3 credit hours) taught at other institutions:

Statistics 610 – Statistical Issues in Pharmaceutical Research, North Carolina State University, 2004 and 2008

International teaching experience:

Instructor for 2-week course, Diseño y Análisis de Ensayos Clínicos, IX (and X) Escuela Internacional de Verano, University of Chile School of Public Health, Santiago, Chile, 2007-2008

Instructor for 1-week course, NUS-Quintiles Good Clinical Practice Programme, Department of Biostatistics, National University of Singapore, 1996

Instructor for 1-week course, Analysis of Complex Survey Data, Department of Statistics, University of Bologna, Bologna, Italy, 1995

Instructor for 1-week course, Analysis of Complex Survey Data, Centre for Survey Data Analysis, University of Southampton, Southampton, England, 1994

Recent tutorials:

Multi-regional clinical trials (MRCTs). Workshop (with Aloka Chakravarty and William Wang) for the Joint Statistical Meetings, Baltimore, MD: July 30-August 3, 2017.

Statisticians as leaders. Tutorial (with J. Schindler) for the DIA/FDA Statistics Forum, Bethesda, MD: April 19-22, 2015.

Statistical leadership and the important role of influence. Tutorial (with W. Sollecito) for the ENAR Spring Meeting, Miami, FL: March 15-18, 2015.

Dropouts from randomized trials in the regulatory environment. Tutorial (with T. Permutt) presented at the DIA/FDA Statistics Forum, Bethesda, MD: April 6-9, 2014.

FDA courses:

Regulatory review of efficacy in clinical trials. Instructor for new reviewer training. Yearly, 2012 to 2017.

Missing data, estimands, and sensitivity analysis. Co-Instructor for new reviewer training. Yearly, 2015 -2017.

Statistical considerations in small populations. Instructor for the Rare Diseases Training Workshop – reviewers of all disciplines, 2012 and 2014.

HONORS AND AWARDS

FDA Group Recognition Award for the Biosimilar Product Review Training Team, 2016

FDA Group Recognition Award for the Benefit-Risk Research Team in the Office of Biostatistics, 2015

FDA Group Recognition Award for the Antibacterial Drug Development Task Force, 2014

COPD Foundation Award for Outstanding Contribution in COPD Research, 2011

2010 Distinguished Alumna, Harpeth Hall School, Nashville, Tennessee

Mary Jane Kugel Award, Juvenile Diabetes Research Foundation, 2008

Triangle Business Journal's Top 25 Women in Business Award, 2005

Fellow of the American Statistical Association, elected 2004

Delta Omega Public Health Honor Society – inducted 1998

Phi Beta Kappa – inducted 1973

SELECTED BOARDS, STUDY SECTIONS, AND ADVISORY PANELS

2013 National Cancer Institute Special Emphasis Panel NCTN Statistics Centers Review

2009-2011 Cystic Fibrosis Foundation Therapeutics, Inc., Clinical Research Committee

2008-2013 Board Member, North Carolina Health and Wellness Trust Fund Commission

2006-2011 NIAMS, NIH Study Section and Special Emphasis Panels (R01, R34, and P50 reviews)

2004-2008 Juvenile Diabetes Research Foundation, Medical Science Review Committee

2002-2008 Board of Directors, UNC School of Public Health Foundation

1999-2010 National Advisory Council, Harpeth Hall School, Nashville, Tennessee

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1998-2000 Alumnae Advisory Panel to the Dean, UNC School of Public Health
1997-1998 Alumnae Board of Directors, UNC School of Public Health

RESEARCH INTERESTS

Clinical trials design and analysis
Regulatory science
Analysis of complex sample survey data

EDITORIAL ACTIVITIES

Statistics in Biopharmaceutical Research, a journal of the American Statistical Association
Guest Editor, Special Issue: Challenges, Trends, and Innovation in Clinical Trial Statistics, 2015
Chair, Search Committee for Editor, 2010-2011
Associate Editor, 2007-2010
Pharmaceutical Statistics, John Wiley & Sons
Editor, 2012-2014
Special Issue Co-Editor: Bayesian Methods in Drug Development and Regulatory Review (2014)
ASA-SIAM Book Series on Statistics and Applied Probability
Editor-in-Chief, 2008-2013
Editorial Board member, 2002-2008
Encyclopedia of Clinical Trials, John Wiley & Sons, Inc.
Associate Editor, 2005-2008
Reviewer of individual manuscripts for numerous statistical and subject matter journals throughout my career

PEER REVIEWED PUBLICATIONS

LaVange LM, Davis SM, Hankinson J, Enright P, Wilson R, Barr RG, Aldrich TK, Kalhan R, Lemus H, Ni A, Smith LJ, Talavera GA. (2017) Spirometry reference equations from the Hispanic Community Health Study/Study of Latinos. *Am J Respir Crit Care Med*; 196(8): 993-1003. DOI:10.1164/rccm.20160-1987OC.

Jarow JP, **LaVange L**, Woodcock J (2017) Multidimensional evidence generation and FDA regulatory decision making: defining and using “real-world” data. *JAMA*; 318(8):703-704. DOI:10.1001/jama.2017.9991.

Woodcock J & **LaVange LM** (2017) Master protocols to study multiple therapies, multiple diseases, or both. *NEJM*; 377:62-70. DOI: 10.1056/NEJMra1510062.

Sherman RE, Anderson SA, Dal Pan DJ, Gray GW, Gross T, Hunter NL, **LaVange L**, Marinac-Dabic D, Marks PW, Robb MA, Shuren J, Temple R, Woodcock J, Yue LQ, Califf RM (2016) Real-world evidence: What Is It and What Can It Tell Us? *NEJM*; 375(23): 2293-97.

Gamalo-Siebers M, Tiwari R, **LaVange L** (2016) Flexible shrinkage estimation of subgroup effects through Dirichlet process priors. *Journal of Biopharmaceutical Statistics*; 26(6): 1040-1055. DOI:10.1080/10543406.2016.1226327.

Barr G, Avilés-Santa L, Davis SM, Aldrich TK, Gonzalez F, Henderson AG, Kaplan RC, **LaVange L**, Liu K, Loredó JS, Mendes ES, Ni A, Ries A, Salathe M, Smith LJ (2016) *Am J Respir Crit Care Med*; 193(4): 386-95.

LaVange LM & Permutt T (2016) A regulatory perspective on missing data in the aftermath of the NRC report. *Statistics in Medicine*; 35(17): 2853-64.

Permutt T, **LaVange LM**, Wilson S, Lin DTY, Sridhara R, Chakravarty A (2016) A taxonomy of estimands for regulatory clinical trials with discontinuations. *Statistics in Medicine*; 35(17): 2865-75.

Permutt T, **LaVange LM**, Hung HMJ, Wilson S, Lin DTY, Sridhara R, Chakravarty A (2016) Sensitivity analysis for missing data in regulatory submissions. *Statistics in Medicine*; 35(17): 2876-79.

Simon R, Blumenthal GM, Rothenberg ML, Sommer J, Roberts SA, Armstrong DK, **LaVange LM**, Pazdur R (2015) The role of nonrandomized trials in the evaluation of oncology drugs. *Clinical pharmacology and therapeutics*; 97(5):502-507. DOI:10.1002/cpt86.

Amur S, **LaVange L**, Zineh I, Buckman-Garner S, and Woodcock J (2015) Biomarker qualification: toward a multiple stakeholder framework for biomarker development, regulatory acceptance, and utilization. *Clinical Pharmacology & Therapeutics*; 98 (1): 34-46. DOI: 10.1002/cpt.136.

- Marchenko O & LaVange LM (2015) Guest Editors' Note: Special Issue on Challenges, Trends, and Innovation in Clinical Trial Statistics. *Statistics in Biopharmaceutical Research*; 7(4): 251-252.
- Zhao Y, Zalkikar J, Tiwari T, **LaVange LM** (2014) A Bayesian approach for benefit-risk assessment. *Statistics in Biopharmaceutical Research*; 6(4): 326 -37. DOI: 10.1080/19466315.2014.965845.
- Gamalo MA, Tiwari RA, **LaVange LM** (2014) Bayesian approach to the design and analysis of non-inferiority trials for anti-infective products. *Pharmaceutical Statistics*; 13(1): 25-40. DOI: 10.1002/pst.1588.
- Couper D, LaVange LM, Barr RG, Bleecker E, Hoffman EA, Kanner R, Kleerup E, Martinez FJ, Woodruff PG, Rennard S (2014) Design of the subpopulations and intermediate outcomes in COPD study (SPIROMICS). *Thorax* 69(5): 491-4. Doi: 10.1136/thoraxjnl-2013-203897.
- Wassertheil-Smoller S, Arredondo EM, Cai J, Castañeda SF, Choca JP, Gallo LC, Jung M, **LaVange LM**, Lee-Rey ET, Mosley T, Penedo FJ, Santistaban DA, Zee PC (2014) Depression, anxiety, antidepressant use, and cardiovascular disease among Hispanic men and women of different national backgrounds: results from the Hispanic Community Health Study/Study of Latinos. *Annals of Epidemiology*; 24(11): 822-30.
- Schneiderman N, Llabre M, Cowie CC, Barnhart J, Carnethon M, Gallo LC, Giachello AL, Heiss G, Kaplan RC, **LaVange LM**, Teng Y, Villa-Caballero L, M Avilés-Santa L (2014) *Diabetes Care*; 37(8): 2233-9.
- Sorlie PD, Allison MA, M Avilés-Santa L, Cai J, Daviglus ML, Howard AG, Kaplan R, **LaVange LM**, Raij L, Schneiderman N, Wassertheil-Smoller S, Talavera GA (2014) Prevalence of hypertension, awareness, treatment, and control in the Hispanic Community Health Study/Study of Latinos. *Am J Hypertens*; 27(6): 793-800.
- Price K, **LaVange L**. Bayesian methods in medical product development and regulatory reviews. *Pharmaceutical statistics*. Jan-Feb 2014;13(1):1-2.
- LaVange LM** (2013) The role of statistics in regulatory decision making. *Therapeutic Innovation & Regulatory Science*; 48(1): 12-19.
- Cao H, **LaVange LM**, Heyse JF, Mast TC, Kosorok MR. (2013) Medical records-based postmarketing safety evaluation of rare events with uncertain status. *Journal of Biopharmaceutical Statistics*; 23(4): 744-755. DOI: 10.1080/10543406.2013.789886.
- Leigh MW, Hazucha MJ, Chawla KK, Baker BR, Shapiro AJ, Brown DE, **LaVange LM**, Horton BJ, Qaqish B, Carson JL, Davis S, Dell SD, Ferkol TW, Atkinson JJ, Olivier KN, Sagel SD, Rosenfeld M, Milla C, Lee H-S, Krischer J, Zariwala MA, Knowleds MR (2013) Standardizing nasal nitric oxide measurement as a test for primary ciliary dyskinesia. *Annals of the American Thoracic Society*;10(6):574-581. 3960971.
- Jarskog LF, Hamer RM, Catellier DJ, Stewart DD, **LaVange L**, Golden RN, Lieberman JA, Stroup TS, METS Investigators (2013). Metformin for weight loss and metabolic control in overweight outpatients with schizophrenia and schizoaffective disorder. *The American journal of psychiatry*; 170(9):1032-1040. 3874085.
- Stürmer T, Marquis MA, Zhou H, Meigs JB, Lim S, Blonde L, Macdonald E, Wang R, **LaVange LM**, Pate V, Buse JB (2013) Cancer incidence among those initiating insulin therapy with glargine versus human NPH insulin. *Diabetes Care*; 36(11): 3517-25. doi: 10.2337/dc13-0263. Epub 2013 Jul 22.
- Rubin E, **LaVange L**, DeGruttola V (2013) University of Pennsylvania 5th annual conference on statistical issues in clinical trials: emerging statistical issues in biomarker validation (afternoon session). *Clinical trials*; 10(5):701-708.
- Daviglus ML, Talavera GA, M Avilés-Santa L, Allison M, Cai J, Criqui MH, Gellman M, Giachello AL, Goukova N, Kaplan RC, **LaVange L**, Penedo F, Perreira K, Pirzada A, Schneiderman N, Wassertheil-Smoller S, Sorlie PD, Stamler J (2012) Prevalence of major cardiovascular risk factors and cardiovascular diseases among Hispanic/Latino individuals of diverse backgrounds in the United States. *JAMA*; 308(17): 1775-84.
- Nelson SB, **LaVange LM**, Nie Y, Walsh JW, Enright PL, Martinez FJ, Mannino DM, Thomashow BM (2011) Questionnaires and pocket spirometers provide an alternative approach for COPD screening in the general population. *Chest*; 142(2):358-366. doi: 10.1378/chest.11-1474.
- Stroup TS, McEvoy JP, Ring K, Hamer R, **LaVange L**, Swartz M, Rosenheck R, Perkins D, Nussbaum AM, Lieberman JA., and the Schizophrenia Trials Network (2011) A randomized trial examining the effectiveness of switching from olanzapine, quetiapine, or risperidone to aripiprazole to reduce metabolic risk: Comparison of Antipsychotics for Metabolic Problems (CAMP). *American Journal of Psychiatry*; 168(9): 947-956.

- Muhlebach MS, Miller M, **LaVange LM**, Mayhew G, Goodrich JS, Miller MB. (2011) Treatment intensity and characteristics of MRSA infection in CF. *Journal of Cystic Fibrosis*; 10(3):201-206.
- LaVange LM** and Preisser JS. (2011) A conversation with Gary Grove Koch. *Statistics in Biopharmaceutical Research*; 3(2): 124-138.
- Greenberg J, Deshmukh R, Huang L, Mostafa J, **LaVange L**, Carretta E and O'Neal W. (2010) The COPD Ontology and Toward Empowering Clinical Scientists as Ontology Engineers. *Journal of Library Metadata*; 10(2): 173-187.
- Saville BR, **LaVange LM**, and Koch GG. (2011) Estimating covariate-adjusted incidence density ratios for multiple time intervals in clinical trials using nonparametric randomization based ANCOVA. *Statistics in Biopharmaceutical Research*; 3(2): 242-252.
- LaVange L**, Kalsbeek W, Sorlie P, Avilés-Santa L, Kaplan R, Barnhart J, Liu K, Giachello A, Lee D, Ryan J, Criqui M, Elder J. (2010) Sample design and cohort selection in the Hispanic Community Health Study/Study of Latinos. *Annals of Epidemiology*; 20(8): 642-649.
- Sorlie P, Avilés-Santa L, Wassertheil-Smoller S, Kaplan R, Daviglus M, Giachello A, Schneiderman N, Raij L, Talavera G, Allison M, **LaVange L**, Chambless L, Heiss G. (2010) Design and implementation of the Hispanic Community Health Study / Study of Latinos. *Annals of Epidemiology*; 20(8): 629-641.
- Deterding RR, **LaVange LM**, Engels JM, Mathews DW, Coquillette SJ, Brody AS, Millard SP, Ramsey BW. (2007) Phase 2 randomized safety and efficacy trial of nebulized denufosal tetrasodium in cystic fibrosis. *Am. J. Respir Crit Care Med*; 176: 362-369.
- LaVange LM** and Koch GG. (2007) Statistical projection of clinical subsample estimates to a survey population. *J Periodontol*; 78(7s): 1400-06.
- White WB, West CR, Borer JS, Gorelick PB, **LaVange L**, Pan SX, Weiner E, and Verburg KM. (2007) Risk of cardiovascular events in patients receiving celecoxib: A meta-analysis of randomized clinical trials. *Am. J. of Cardiology*; 99: 91-98.
- LaVange LM** and Koch GG. (2006) Rank score tests. Statistical primer for cardiovascular research series. *Circulation*; 114: 2528-2533.
- LaVange LM**, Durham TA, Koch GG. (2005) Randomization-based nonparametric analysis of multicentre trials. *Statistical Issues in Medical Research*; 14: 1-21.
- Deterding R, Retsch-Bogart G, Milgram L, Gibson R, Daines C, Zeitlin P, Milla C, Marshall B, **LaVange L**, Engels J, Mathews D, Schaberg A, Williams J, Ramsey B. (2005) Safety and tolerability of denufosal tetrasodium inhalation solution, a novel P2Y₂ receptor agonist: Results of a phase 1/phase 2 multi-center study in mild to moderate cystic fibrosis. *Pediatric Pulmonology*; 39: 339-348.
- Tauber J, Davitt WF, Bokosky JE, Nichols KK, Yerxa BR, Schaberg AE, **LaVange LM**, Mills-Wilson MC, Kellerman DJ. (2004) Double-masked, placebo-controlled safety and efficacy trial of diquafosol tetrasodium (INS365) Ophthalmic Solution for the treatment of dry eye. *Cornea*; 23(8): 784-792.
- Davis SM, Koch GG, Davis CE, and **LaVange L**. (2003) Statistical approaches to effectiveness measurement and outcome-driven re-randomizations in the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) studies. *Schizophrenia Bulletin*; 29(2): 73-80.
- Thase ME, Rush AJ, Howland RH, Kornstein SG, Kocsis JH, Gelenberg AJ, Schatzberg AF, Koran LM., Keller MB, Russell JM, Hirschfeld R, **LaVange L**, Klein DN, Fawcett J, and Harrison W. (2002) Double-blind switch study of imipramine or sertraline treatment of antidepressant-resistant chronic depression. *Archives of General Psychiatry*; 59: 233-240.
- Koran LM, Gelenberg AJ, Kornstein SG, Howland RH, Friedman RA, DeBattista C, Klein D, Kocsis JH, Schatzberg AF, Thase ME, Rush AJ, Hirschfeld RMA, **LaVange L**, Keller MB. (2001) Sertraline versus imipramine to prevent relapse in chronic depression. *J. of Affective Disorders*; 65: 27-36.
- LaVange LM**, Koch GG, and Schwartz TA. (2000) Applying sample survey methods to clinical trials data. *Statistics in Medicine*; 20: 2609-2623.
- Klein DN, Schatzberg AF, McCullough JP, Dowling F, Goodman D, Howland RH, Markowitz JC, Smith C, Thase ME, Rush AJ, **LaVange L**, Harrison WM, Keller MB. (1999) Age of onset in chronic major depression; relation to demographic and clinical variables, family history, and treatment response. *J. of Affective Disorders*; 55: 149-157.

- Keller MB, Kocsis JH, Thase ME, Gelenberg AJ, Rush AJ, Koran L, Schatzberg A, Russell J, Hirschfield R, Klein D, McCullough JP, Fawcett JA, Kornstein S, **LaVange L**, Harrison W. (1998) Maintenance phase efficacy of sertraline for chronic depression. *J. of the American Medical Association*; 280(19): 1665-1672.
- Jhingran P, Davis SM, **LaVange LM**, Miller DW, Helms RW. (1998) Migraine-specific quality of life questionnaire: Further investigation of the factor structure. *Pharmacoeconomics*; 13(6): 707-717.
- NIMH Multisite HIV Prevention Trial Group. (1998) The NIMH multisite HIV prevention trial: Reducing HIV sexual risk behavior. *Science*; 280: 1889 - 94.
- NIMH Multisite AIDS Prevention Trial. (1997) *AIDS*; 11, Supplement 2: S51-S63. Included eight manuscripts concerning study design and baseline data.
- Wallace JM, Hansen NI, **LaVange L**, Glassroth J, Browdy BL, Rosen MJ, Kvale PA, Mangura BT, Reichman LB, Hopewell PC, and the Pulmonary Complications of HIV Infections Study Group. (1997) Respiratory disease trends in the pulmonary complications of HIV infection study cohort. *Am. J. of Respiratory and Critical Care Medicine*; 155: 72-80.
- Margolis PA, Keyes LL, Greenberg RA, Bauman KE, and **LaVange LM**. (1997) Urinary cotinine and parent history (questionnaire) as indicators of passive smoking and predictors of lower respiratory illness in infants. *Pediatric Pulmonology*; 23: 417-423.
- Litz BT, Schlenger WE, Weathers FW, Cadell JM, Fairbank JA, and **LaVange LM**. (1997) Predictors of emotional numbing in post-traumatic stress disorder. *J. of Traumatic Stress*; 10(4): 607-618.
- LaVange LM**, Stearns SC, Lafata JE, Koch GG, and Shah BV. (1996) Innovative strategies using SUDAAN for analysis of health surveys with complex samples. *Statistical Methods in Medical Research*; 5: 311-329.
- LaVange LM**, Keyes LL, Koch GG, and Margolis PA. (1994) Application of sample survey methods for modeling ratios to incidence densities. *Statistics in Medicine*; 13(4):343-355.
- Greenberg RA, Strecher VJ, Bauman KE, Boat B, Fowler MG, Keyes LL, Denny FW, Chapman RS, Stedman HC, **LaVange LM**, Glover LH, Haley NJ, and Loda FA. (1994) Evaluation of a home-based intervention program to reduce infant passive smoking and lower respiratory illness. *J. of Behavioral Medicine*; 17(3): 273-290.
- Muller KE, **LaVange LM**, Ramey CT, and Ramey SL. (1992) Power calculations for general linear multivariate models including repeated measures applications. *J. of the American Statistical Association*; 87(420): 1209-1226.
- Margolis PA, Greenberg RA, Keyes LA, **LaVange LM**, Chapman RS, Denny FW, Bauman KE, Boat BW. (1992) Lower respiratory illness in infants and low socioeconomic status. *Am. J. of Public Health*; 82(8): 1119-1126.
- Ramey CT, Bryant DM, Wasik BH, Sparling J, Fendt KH, & **LaVange LM**. (1992) The infant health and development program for low birth weight, premature infants: Program elements, family participation, and child intelligence. *Pediatrics*; 89(3): 454-465.
- Schmid JE, Koch GG, & **LaVange LM**. (1991) An overview of statistical issues and methods of meta-analysis. *J. of Biopharmaceutical Statistics*; 1: 103-120.
- Sparling J, Lewis I, Ramey CT, Wasik BH, Bryant DM, & **LaVange LM**. (1991) Two curricula to help low-birth-weight, premature infants get off to a good start. *Topics in Early Childhood Education*; 11: 36-55.
- LaVange LM**. (1990) Review of Analyzing Quantitative Behavioral Observation Data by H.K. Suen & D. Ary. *J. of the American Statistical Association*; 89: 278.

BOOK CHAPTERS

- Durham TA, Koch GG, **LaVange LM** (2012) Introductory statistics in medical research. In PG Suppino & JS Borer (Eds.), *Principles of Research Methodology: A Guide for Clinical Investigators*. New York: Springer.
- LaVange LM** and Koch GG. (2008). Randomization-based nonparametric Analysis of Covariance (ANCOVA). *Wiley Encyclopedia of Clinical Trials*. Eds. D'Agostino, Sullivan, Massaro. 1st Edition. 4 vols. Hoboken: John Wiley & Sons, Inc.
- Meyerson LJ, Wiens BL, **LaVange LM**, and Koutsoukos AD. (2000) Quality control of oncology clinical trials. In C. J. Allegra and B. S. Kramer (Eds.), *Hematology/Oncology Clinics of North America* (953-971). Philadelphia: W.B. Saunders Co.
- Corder LS, **LaVange LM**, Bryan FA. (1992) Projections of the aged supplementary security income population: The implications of uncertainty. In K.E. Manton (Ed.), *Forecasting the Health of the Elderly Population*.

California: Springer-Verlag.

- LaVange LM**, Shah BV, Barnwell BG, & Killinger JF. (1990) SUDAAN: A comprehensive package for survey data analysis. In GE Liepins and VRR Uppuluri (Eds.), *Data Quality Control: Theory and Pragmatics*. New York: Marcel Dekker.
- Pfeffermann D & **LaVange LM**. (1989) Regression models for stratified multistage cluster samples. In C. J. Skinner, D. Holt, and T.M.F. Smith (Eds.), *Analysis of Complex Surveys (237-270)*. New York: Wiley & Sons.
- Folsom RE, **LaVange LM**, & Williams RL. (1989) A probability sampling perspective on panel data analysis. In D. Kasprzyk, G. Duncan, G. Kalton, & M.P. Single (Eds.), *Panel Surveys (108-138)*. New York: Wiley & Sons.
- Williams RL, Folsom RE, & **LaVange LM**. (1983) The implications of sample design on survey data analysis. In T. Wright (Ed.), *Statistical Methods and the Improvement of Data Quality (267-295)*. New York: Academic Press.

SELECTED ABSTRACTS AND PRESENTATIONS

- LaVange LM**. Platform trial designs: Benefits, efficiencies, and applications. Discussant at the ENAR Spring Meeting, Washington, DC: March 12-15, 2017.
- LaVange LM**. Examining the feasibility of real-world evidence through pilot studies. Panelist at the Friends of Cancer Research Annual Meeting, Washington, DC: Nov.16, 2016.
- LaVange LM**. Adaptive trials, platform trials, master protocols, and beyond. Panelist at the Partnering for Cures Annual Meeting, New York: Nov. 15, 2016.
- LaVange LM**. Precision medicine initiatives at FDA. **Keynote Address** for the Duke-Industry Symposium, Durham, NC: Sep 14-16, 2016.
- LaVange LM**. Innovative trial designs for pediatric and rare diseases. **Keynote Address** for the PharmSci Conference, UNC-Chapel Hill School of Pharmacy, Chapel Hill, NC: May 12-13, 2016.
- LaVange LM**. Bayesian methods for clinical trials: CDER and CBER experience. Presentation for the ACDRS Special Workshop on Substantial Evidence in 21st Century Regulatory Science. Washington, DC: April 21, 2016.
- LaVange LM**. Recent advances in subgroup identification for clinical trials. Presented at the ENAR Spring Meeting, Austin, TX: March 5-9, 2016.
- LaVange LM**. Quantitative versus qualitative approaches to benefit-risk. Presentation at the DIA Workshop on Benefit-Risk. Washington, DC: Sep. 18, 2015.
- LaVange LM**. Personalized medicine initiatives at FDA. **Plenary Address** at the ASA Biopharm/Industry Workshop, Washington, DC: Sep. 16-18, 2015.
- LaVange LM**. Practical ethics for statisticians working in drug regulation. Presentation at the Joint Statistical Meetings, Seattle, WA: August 9-13, 2015.
- LaVange LM**. New challenges for a data monitoring committee. Presentation at the DIA Annual Meeting, Washington, DC: June 14-18, 2015.
- LaVange LM**. The role of statistics in regulatory decision-making. 12th Annual Biostatistics and Computational Biology Lecture, Dana Farber Cancer Institute, Boston, MA: Oct. 28, 2014.
- LaVange LM** & Sridhara R. Statistical considerations in designing master protocols. Presentation at the Innovations in Breast Cancer Drug Development – Next Generation Oncology Trials Workshop, Bethesda, MD: Oct. 21, 2014.
- LaVange LM**. Statistics and the FDA: Where we've been and where we are today. **Keynote Address** at the FDA/ASA/Industry Workshop, Washington, DC: Sep. 22-24, 2014.
- LaVange LM**. Influence as a key component of statistical leadership. Lecture for the 1st Annual ASA Leadership Workshop, held in conjunction with the Joint Statistical Meetings, Boston, MA: August 2-7, 2014.
- LaVange LM**. Statistical considerations in designing master protocols. Presented at the NIH-FDA Workshop on Developing New Antibiotic Products: Charting a Course for the Future. Bethesda, MD: July 30-31, 2014.
- LaVange LM**. Statistical issues in drug regulation. Presentation at the Quantitative Issues in Regulatory Science Symposium of the Committee on Applied and Theoretical Statistics of the National Academy of Science, Washington, DC: May 30, 2014.
- LaVange LM**. Missing data in regulatory clinical trials. Presentation at the DIA China Statistics Community January 2018

Seminar Series, Beijing, China: May 15, 2014.

- LaVange LM.** Statistical leadership in drug regulation. Presentation at the DIA China Annual Meeting, Shanghai, China: May 13, 2014.
- LaVange LM.** Problem-solving and effective leadership in regulatory statistics. **Keynote Address** at the Trends and Innovation in Clinical Trials Statistics Conference, Raleigh, NC: April 21-23, 2014.
- LaVange LM.** Data standards, data quality, and data sharing as integral components of statistical research. **Keynote Address** for the CDISC International Interchange. Bethesda, MD: Nov. 6-7, 2013.
- LaVange LM.** Regulatory statistics and its place in FDA's Center for Drug Evaluation and Research. Presentation at the Center for Drug Safety and Effectiveness Seminar Series, Johns Hopkins Bloomberg School of Public Health, Baltimore MD: October 28, 2013.
- LaVange LM.** The role of quantitative sciences in US regulatory decision-making. **Keynote Address** for the DIA China Quantitative Science Forum, Beijing, China: October 20-21, 2013.
- LaVange LM.** Bayesian methods in medical product development and comparative effectiveness. Panel Discussant for the DIA Annual Meeting, Boston, MA: June 24-27, 2013.
- LaVange LM.** Health disparities: Statistical considerations. Presentation for the DIA Annual Meeting, Boston, MA: June 24-27, 2013.
- LaVange LM.** The role of statistics at FDA. **Keynote address** for the International Chinese Statistical Association's Applied Statistics Forum, Bethesda, MD: June 9-12, 2013.
- LaVange LM.** Regulatory and statistical issues in multi-regional clinical trials. Presentation for the International Chinese Statistical Association's Applied Statistics Forum, Bethesda, MD: June 9-12, 2013.
- LaVange LM.** Statistical considerations for Data Monitoring Committees in Adaptive clinical trials. Presentation for the DAGStat Conference, University of Freiburg, Germany: March 18-22, 2013.
- LaVange LM.** Statistical aspects of well-designed and well-conducted clinical trials. Presentation at the US Conference on Rare Diseases and Orphan Products. Washington, DC: October 21, 2012.
- LaVange LM.** Current statistical challenges in the US regulatory environment. **Keynote address** for the BfArM/DIA Statistics Workshop, Bonn, Germany: October 16-19, 2012.
- LaVange LM.** Covariate adjustment in regulatory clinical trials. Presentation for the BfArM/DIA Statistics Workshop, Bonn, Germany: October 16-19, 2012.
- LaVange LM.** Report on the CTTI Statistics Think Tank for anti-bacterial drug development. Presented at the Brookings Institute, Washington, DC: August 30, 2012.
- LaVange LM.** Advances in missing data prevention and analysis. Presentation for the International Chinese Statistical Association's Applied Statistics Forum, Boston, MA: June 24, 2012.
- LaVange LM.** Current regulatory statistical challenges. **Keynote address** for the 35th Annual Midwest Biopharmaceutical Statistics Workshop, Muncie IN: May 21-23, 2012.
- LaVange LM.** A US regulatory perspective on statistical issues in drug development. **Keynote address** for the Drug Information Association (DIA) Statistics Forum, Bethesda, MD: April 23-25, 2012.
- Sieren J, Hoffman EA, Baumhauer H, Barr G, Goldin JG, Rennard S, **LaVange L**, et al. CT Imaging Protocol Standardization for Use in a Multicenter Study: SPIROMICS. Presented at the Radiological Society of North America meeting, Chicago, IL; November 27 – December 2, 2011.
- LaVange L.** Relationship between Diabetes and Metabolic Syndrome in the Hispanic Community Health Study/ Study of Latinos (HCHS/SOL). Presented at the American Diabetes Association conference, San Diego, CA: June 24-28, 2011.
- LaVange L**, Greenberg J, Carretta E, Mostafa J, Deshmukh R, O'Neal W, Rennard S, and the SPIROMICS Investigators. The COPD Ontology and Its Role in the Subpopulations and Intermediate Outcome Measures in COPD Study (SPIROMICS). Presented at the American Thoracic Society conference, Denver, CO: May 13-18, 2011.
- Czaja CA, Stewart D, Levin AR, Aksamit TR, **LaVange L**, O'Donnell AE, Knowles MR, Thomashow B, and C.L. Daley for the Bronchiectasis Research Consortium. Prevalence and Clinical Significance of Mucoid Pseudomonas aeruginosa Infection in Adults with Non-Cystic Fibrosis Bronchiectasis: Results from the Bronchiectasis Research Registry. Presented at the American Thoracic Society conference, Denver, CO: May

13-18, 2011.

- Stewart D, **LaVange L**, Thomashow B, Daley C, Knowles M, Olivier K, O'Donnell A, and Aksamit T for the Bronchiectasis Research Consortium. Bronchiectasis Research Registry: Added Perspective of Changes Over Time. Presented at the American Thoracic Society conference, Denver, CO: May 13-18, 2011.
- Barr RG, **LaVange LM**, Henderson A, Aviles-Santa L, Kaplan R, Aldrich T, Liu K, Smith LJ, Mendes ES, Salathe M, Ries A, Lored J. Prevalence Of Pulmonary Symptoms And Disease In Hispanic Subgroups: Results From The Hispanic Community Health Study / Study Of Latinos (HCHS/SOL). Presented at the American Thoracic Society conference, Denver, CO: May 13-18, 2011.
- Donohue KM, **LaVange LM**, Henderson A, Aviles-Santa L, Kaplan R, Aldrich TE, Liu K, Smith LJ, Mendes ES, Salathe M, Ries A, Lored J, Barr RG. Prevalence of Rhinitis in Hispanic Subgroups: Results From The Hispanic Community Health Study / Study Of Latinos (HCHS/SOL). Presented at the American Thoracic Society conference, Denver, CO: May 13-18, 2011.
- Talavera G, Allison M, Avilés-Santa L, **LaVange L**, et al. Prevalence of Coronary Heart Disease and Stroke in the Hispanic Community Health Study/Study of Latinos (HCHS/SOL). Presented at the American Heart Association conference, Atlanta, GA: March 22 - 25, 2011.
- Wassertheil-Smoller S, Arredondo E, Avilés-Santa L, Choca J, **LaVange L**, Lee-Rey E, Mosley T, Penedo F, Santisteban D, Talavera G, Zee P. Depression and Anxiety in Hispanic/Latino Subgroups in the United States and in Relation to Acculturation: Results from the Hispanic Community Health Study / Study of Latinos (HCHS/SOL). Presented at the American Heart Association conference, Atlanta, GA: March 22 - 25, 2011.
- Sorlie P, **LaVange L**, Allison M, Avilés-Santa L, et al. Prevalence of Hypertension, Awareness, Treatment and Control: Preliminary Results from the Hispanic Community Health Study/Study of Latinos (HCHS/SOL). Presented at the American Heart Association conference, Atlanta, GA: March 22 - 25, 2011.
- LaVange LM**, Statistics training in a data-centric world. Invited panelist, Joint Statistical Meetings, Vancouver, BC: August 1-5, 2010.
- LaVange LM**, Stewart D, Thomashow B, Olivier K, Knowles M, Daley C, Barker A. The Bronchiectasis Research Registry: A resource for collaborative research in non-cystic fibrosis bronchiectasis. Poster presented at American Thoracic Society conference, New Orleans, LA: May 14-19, 2010.
- O'Connell MT, Prevots DR, Olivier K, **LaVange LM**, Thomashow B, Knowles M, Daley C, Askamit T, O'Donnell A. The Bronchiectasis Research Registry: Clinical, microbiologic, and treatment characteristics. Poster presented at American Thoracic Society conference, New Orleans, LA: May 14-19, 2010.
- Donaldson SH, Bendahmane N, Zeman K, Wu J, Alexis N, **LaVange L**, Bordonali E, Boucher RC, Bennett WD. Longitudinal assessment of mucociliary clearance: repeatability and impact of CF exacerbations. Presented at the North American Cystic Fibrosis conference, Orlando, FL: October 23 – 25, 2009.
- LaVange LM**. Margins and Monitoring of non-inferiority clinical trials. Discussant for an Invited Session, Eastern North American Region of the International Biometric Society Spring meeting, San Antonio, TX: March 15-18, 2009.
- LaVange LM**. Dichotomizing continuous variables in clinical trials. Discussant for an Invited Session, Joint Statistical Meetings, Washington, DC: August 2-6, 2009.
- LaVange LM**. Model- versus randomization-based inference from group randomized trials. Topic-contributed Panel Session, Joint Statistical Meetings, Washington, D.C.: August 2-6, 2009.
- LaVange LM**. The use of survey samples in epidemiological follow-up studies. Invited Panel Session, Annual meeting of the Eastern North American Region of the International Biometric Society, Crystal City, VA: March 16-19, 2008.
- LaVange L**, Engels J, Accurso FA. Analyzing percent change in cystic fibrosis clinical trials. *Pediatric Pulmonology*; Supplement 30:290, Abstract 252. Presented at the North American Cystic Fibrosis (NA CF) Conference, Anaheim, CA: October 4-7, 2007.
- LaVange LM**. Conflict of interest concerns in medical statistics. Invited Panel Session, Joint Statistical Meetings, Salt Lake City, UT: July 29 - August 2, 2007
- LaVange LM**. Statistical projection of clinical subsample estimates to a survey population. Presented at the American Association of Dental Research (AADR) Symposium: Development of self-reported measures for surveillance of periodontics. Orlando, FL: March 9, 2006.

- Deterding RR and **LaVange LM**. Improving patient care: Academic and industry partnerships for therapeutic product development. Presented as part of the Study Group: Topical Issues in Clinical Research at the North American Cystic Fibrosis (NAFC) Conference, Baltimore, MD: October 20-23, 2005.
- LaVange LM**. CT Parameters as clinical trial endpoints in CF drug development: Practical and statistical considerations. Presented at the Imaging Endpoints for Cystic Fibrosis Clinical Trials Workshop, Chantilly, VA: September 7-8, 2005.
- LaVange L**, Knowles M, Mathews D, Engels J, Kellerman D. Safety and efficacy of INS37217 Inhalation Solution in patient subgroups: Results of a phase 2 multicentre trial. Presented at the 28th European Cystic Fibrosis Conference, Crete: June 22-25, 2005.
- Deterding R, **LaVange L**, Mathews D, Engels J, Gorden J, Shaffer C, Coquillet S, Ramsey B. Safety and efficacy of INS37217 Inhalation Solution, a novel P2Y₂ receptor agonist, in patients with mild cystic fibrosis: Results of a Phase 2 Multi-Center Study. Abstract # 177. *Pediatric Pulmonology*, Suppl. 27, pp. 249, and presented at the North American Cystic Fibrosis (NAFC) Conference, St. Louis, MO: October 14-17, 2004.
- Brody AS, Robinson TE, Knowles M, Goris M, **LaVange LM**, Engels JE. The use of high resolution CT in intervention studies of cystic fibrosis. Abstract # 321. *Pediatric Pulmonology*, Supplement 27, pp. 299, and presented at the North American Cystic Fibrosis (NAFC) Conference, St. Louis, MO: October 14-17, 2004.
- Donshik P, Tauber J, Schaberg A, Durham TA, **LaVange LM**, Yerxa BR, Kellerman DJ. Diquafosol tetrasodium reduces corneal and conjunctival staining in subjects with dry eye, with the largest benefit relative to placebo observed in subjects with severe disease. Presented at 23rd Biennial Corneal Conference, Boston, MA: October 3-4, 2003.
- Tauber J, Davitt WF, Bokosky JE, Nichols K, Mills-Wilson MC, Schaberg AE, Yerxa B, **LaVange LM**, Kenny SJ, Kellerman DJ. Double masked, placebo-controlled safety and efficacy trial of diquafosol tetrasodium (INS365) ophthalmic solution for the treatment of dry eye. Presented at the Association for Research in Vision and Ophthalmology (ARVO) annual meeting: May 4-9, 2003, Ft. Lauderdale, FL., abstract 3738.
- Schaberg AE, Meltzer EO, LaForce CF, Pearlman DS, Ice JC, **LaVange L**, Kellerman DJ. INS37217 Intranasal, a P2Y₂ receptor agonist, is a novel treatment for allergic rhinitis. Presented at the American Academy of Allergy, Asthma, and Immunology (AAAI) 60th annual meeting, March 7-12, 2003, Denver, CO. *Journal of Allergy and Clinical Immunology*; 11(2), S74.
- Deterding R, Mundahl J, Shaffer C, Kellerman D, Mathews D, **LaVange L**, Gorden J, Quittner A, Williams J, Ramsey B. Safety and tolerability of INS37217 inhalation solution, a novel P2Y₂ receptor agonist, in patients with mild to moderate cystic fibrosis: Results of a phase 1/2 multi-center study. *Pediatric Pulmonology*, Supplement 24, 2002; Sixteenth Annual North American Cystic Fibrosis (NAFC) Conference: October 3-6, 2002; page 258; poster 231.
- LaVange LM**, Friedman C, Smith-Hinton S, Koch GG, Durham T, Hare JS. The design of actual use studies to support an over-the-counter switch. Presented at the Society for Clinical Trials meeting, Denver, CO: May 21, 2001.
- LaVange LM**. Applying sample survey methods to clinical trials data. Invited presentation at Statistical Issues in Biopharmaceutical Environments: Towards the new Millennium, Leicester, England: July 28-30, 1999.
- LaVange LM**. Generalized estimating equations (GEE): An Industry perspective. Invited presentation at the FDA & Industry Workshop, Arlington, VA: September 24-25, 1998.
- LaVange LM**. Analysis of sample survey data from longitudinal studies. Invited workshop presented at the Symposium on Longitudinal Analysis for Complex Surveys, Statistics Canada, Ottawa, Canada: May 19-22, 1998.
- Stokes ME & **LaVange LM**. Applications of GEE methodology using the SAS system. Short course presented at the Joint Statistical Meetings, Anaheim, CA: August 10-14, 1997.
- LaVange LM** & Shah BV. Statistical methods in SUDAAN for survey data analysis. Presented as an invited paper at the Joint Statistical Meetings, Chicago, IL: August 4-8, 1996.
- LaVange LM**, Helms LE, Kessler LG. Power and cost issues in evaluating state-based intervention studies. Presented at the Joint Statistical Meetings, Orlando, FL: August 13-17, 1995.
- LaVange LM** & Koch GG. Analysis of repeated measures studies with multiple regression methods for sample survey data. Presented at the Drug Information Association's 30th Annual Meeting, Washington, DC: June 5-9,

1994.

- LaVange LM**, Follmann DA, Osmond D, Glassroth J, Rao AV. Decline in CD4 T-lymphocyte cells by mode of transmission, gender, and race. Poster presentation at the Ninth International Conference on AIDS, Berlin, Germany: June 6-11, 1993.
- LaVange LM** & Koch GG. Exploring the utility of survey analysis strategies for a multivisit follow-up study to compare two treatments in AIDS patients. Panel Discussion: Answering questions in an AZT clinical trial, the American Public Health Association Annual Meeting, Washington, DC: August 8-12, 1992.
- Muller KE & **LaVange LM**. Sample size determination for multivariate models. Presented as an invited paper at the Eastern North American Regional Meeting of the International Biometric Society, Houston, TX: March 24-27, 1991.
- Ramey CT & **LaVange LM**. The Infant Health and Development Program. Presented at the Society for Research in Child Development Biennial Meeting, Seattle, WA: April 16-18, 1991.
- Ramey CT, Ramey SL, Sparling J, **LaVange LM**, Bryant DM, and Wasik BH. Altering intergenerational transmission of intellectual competence. Presented at the Society for Research in Child Development Biennial Meeting, Seattle, WA: April 16-18, 1991.
- Folsom RE, Horvitz DG, & **LaVange LM**. (1990) The design of surveys using measurement design standards. *Statistics of Income and Related Administrative Record Research: 1988-1989* (pp. 211-218). Department of the Treasury, Internal Revenue Service, Statistics of Income Division, Publication No. 1299.
- Pfeffermann D & **LaVange L**. (1986). The analysis of survey data using stochastic regression coefficients models with application to health surveys. *Proceedings of the American Statistical Association, Section on Survey Research Methods* (pp. 264-269). Washington, DC: American Statistical Association.
- LaVange LM**, Iannachione VG, & Garfinkel SA. (1986) An application of logistic regression methods to survey data: Predicting high costs users of medical care. *Proceedings of the American Statistical Association, Section on Survey Research Methods* (pp. 270-273). Washington, DC: American Statistical Association.
- LaVange LM** & Folsom RE. (1985) Regression estimates of National Crime Survey operations effects: Adjustments for nonsampling bias. *Proceedings of the Washington, DC: American Statistical Association.*

APPENDIX: ADDITIONAL ACADEMIC SERVICE INFORMATION

DATA AND SAFETY MONITORING BOARDS (SELECTED EXPERIENCE 2005 – 2011)

- 2010-2011 GlaxoSmithKline, Protocol NAI114373: Phase III international, randomized, double-blind, double-dummy study to evaluate the efficacy and safety of 300 mg or 600 mg of intravenous zanamivir twice daily compared to 75 mg or oral oseltamivir twice daily in the treatment of hospitalized adults and adolescents with influenza; Data Monitoring Committee.
- 2009-2011 MAP Pharmaceuticals, Inc., Protocol MAP0004-CL-P301: A randomized, double-blind, placebo-controlled, parallel-group, phase 3 study of MAP0004 in adult migraineurs for a single migraine followed by open-label extension; Data and Safety Monitoring Board
- 2006-2009 Merck, Post Marketing Evaluation of the Short-Term Safety of RotaTeq®; Safety Monitoring Committee
- 2006-2008 Juvenile Diabetes Research Foundation, Continuous Glucose Monitoring Randomized Clinical Trial; Data and Safety Monitoring Board
- 2005-2008 Salix Pharmaceuticals, Inc., Protocol RFHE3001: A multi-center, randomized, double-blind, placebo-controlled trial to evaluate the efficacy, safety, and tolerability of Rifaximin 550 mg BID for 6 months in preventing hepatic encephalopathy; Data and Safety Monitoring Board.

BIostatistics DOCTORAL COMMITTEES (2005 – 2011)

- Yiyun Tang (2010) – Tailoring Therapy for Better Long Term Outcome: Reinforcement Learning in Cystic Fibrosis
- Eugenio Andracas (2008) – Approaches to Parameter and Variance Estimation in Generalized Linear Models
- Ben Saville (2008) – Bayesian Hierarchical Models and Medical and Medical Applications
- Jackie Johnson (2007) – Fixed Effects Inference for Clustered Data in Gaussian Linear Models
- John Kairalla (2007) - Internal Pilot Study with Interim Analysis for Linear Models with Gaussian Errors and Fixed Predictions
- Rebekkah Dann (2006) – Methods for Strengthening the Design and Analysis of Clinical Trials to Show Non-Inferiority of a New Treatment to a Reference Treatment for a Binary Response Variable

BIostatistics MASTER PAPERS (2005 – 2011)

- Brian Smith (2009) - Very Late Onset Sepsis in the Neonatal Intensive Care (Role: Advisor)
- Jamie Perin (2005) – Analysis of Correlated Health Care Outcomes from the Mountain Accessibility Project Cluster Sample Survey in Rural North Carolina (Role: Reader)

GRANT AND CONTRACT SUPPORT (Active in 2011)

- HHSN268200900020C, National Heart, Lung and Blood Institute: SubPopulations and Intermediate Outcome Measures In COPD Study (SPIROMICS): Genomics and Informatics Center (2/1/09 - 1/31/16). PI: Dr. Lisa LaVange (30%).
- HHSN268200625233C, National Heart, Lung and Blood Institute: Hispanic Community Health Study: Coordinating Center (9/30/06 – 3/31/13). PI: Dr. Lisa LaVange (30%).
- Sanofi-aventis: Risks of Cancers in Relation to Insulin Therapy in People with Diabetes (7/1/09 – 12/31/11). PI: Dr. Lisa LaVange (11%).
- 5 UL1-RR025747-02, National Center for Research Resource: UNC Clinical Translation Science Award - Clinical Data Management Group (5/19/08 - 4/30/13). PI: Dr. Marshall Runge; My Role: Deputy Director (8%).
- 5 ULI RR025747-02, National Center for Research Resources: UNC Clinical Translation Science Award – Biostatistics Core (5/19/08 – 4/30/13). PI: Dr. Marshall Runge; My Role: Associate Director (8%).
- Chronic Obstructive Pulmonary Disease Foundation: Bronchiectasis Patient Registry (11/1/07 – 3/31/12). PI: Dr. Lisa LaVange (3%).

1 RC2 HL101649-01, National Heart, Lung and Blood Institute: Ancillary to HCHS/SOL: Sociocultural Factors and CVD Risk/Prevalence in Hispanics (9/30/09 - 7/31/11). Coordinating Center PI: Dr. Lisa LaVange (2%).

Merck & Co.: Methods for Interim Analysis with Incomplete Adjudication of Events (7/1/09 – 6/30/11). PI: Dr. Joe Ibrahim; My Role: Co-investigator (1%).

5 P50 HL 084934-04, National Heart, Lung and Blood Institute: SCCOR in Host Factors in Chronic Lung Diseases- Core A Administrative & Biostatistics Core (9/15/06 – 7/31/11). PI: Dr. Ric Boucher; My Role: Co-investigator (1%).

MUHLEB08A0, Characterization of MRSA infection/colonization in CF (9/1/08 – 8/31/11). PI: Dr. Marianne Muhlebach. My Role: Co-investigator (0%), supervising a Biostatistics GRA.