

CURRICULUM VITAE

Rafe Michael Joseph Donahue
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Education

Ph.D., Statistics, 1992

Colorado State University, Fort Collins, Colorado

- Doctoral Dissertation: *Estimation for Nearest 1-Neighbor Processes*

B.S., Mathematics, 1987

University of Dayton, Dayton, Ohio

- *magna cum laude*, University Honors Program, biology minor
- Undergraduate Honors Thesis: *The Development of a Transform Method for Use in Solving Difference Equations*

Employment

Associate Director for Statistics

BioMimetic Therapeutics, Inc., 2008 – present

Adjunct Associate Professor

Vanderbilt University School of Medicine, Department of Biostatistics, 2008 – present

Research Associate Professor

Vanderbilt University School of Medicine, Department of Biostatistics, 2005 – 2008

Principal Consultant Data Mining

GlaxoSmithKline, 2001 – 2005

Senior Statistician I, then Senior Statistician II, then Principal Statistician

Glaxo Wellcome, Inc., 1996 – 2001

Senior Statistician, then Statistical Scientist

Marion Merrell Dow, Inc. (Hoechst Marion Roussel), 1992 – 1996

Graduate Student Statistics Instructor and Consultant

Colorado State University, 1987 – 1992

Undergraduate Mathematics Teaching Assistant

University of Dayton, 1985 – 1987

Research Assistant

University of Dayton Research Institute, 1985 – 1986

Selected Talks, Presentations, Posters, Abstracts, Classes, and such things

On Permissible Correlations for a Class of Stationary Spatial Processes — presented at the Kansas–Western Missouri Chapter of the American Statistical Association Summer Meeting, July 1993.

Standardizing Clinical Study Designs for Accelerating Drug Development (with S.J. Ruberg) — presented at the 32nd Annual Meeting of the Drug Information Association as part of the Statistical Track: Statistical Strategies for Accelerating Clinical Development, June 1996.

Adjunctive Lamictal (LTG) Treatment Is Associated With Stable Body Weight in Patients With Epilepsy (with J.A. Messenheimer, P.A. Burns, G.D. Rudd, and M.E. Risner) — presented at American Epilepsy Society Meeting, December 1996.

Adult Patients with Epilepsy Maintain Stable Weight During Lamotrigine Therapy: A Review of Data From 30 Clinical Trials (with O. Devinsky, J. Gallagher, and B. Clements) — presented at American Academy of Neurology Meeting, April 1997.

Clinician and Caregiver Assessments of Global Response to Therapy Strongly Agree in a Double-Blind, Placebo-Controlled Trial of Lamotrigine in the Lennox-Gastaut Syndrome (with J. Gallagher, L. Mullens, and G. Rigdon) — presented at American Academy of Neurology Meeting, April 1997.

Evaluation of the Safety and Efficacy of Bupropion SR 150 mg Once Daily and Twice Daily Versus Placebo in Outpatients with Moderate to Severe Depression (with S.R. Batey and J.A. Ascher) — presented at American College of Neuropsychopharmacology Meeting, December 1997.

Estimating Rankings Under A Stochastic Ordering — presented at Twenty-first Annual Midwest Biopharmaceutical Statistics Workshop, May 1998.

Comparison of the Safety and Efficacy of Bupropion Sustained Release and Paroxetine in Elderly Depressed Outpatients (with K. Weihs, E. Settle, T.L. Houser, S.R. Batey, J.A. Ascher, and L.L. Alvarez) — presented at American Psychiatric Association Meeting, June 1998.

Comparison of the Efficacy and Safety Including Sexual Functioning of Bupropion SR and Sertraline in Depressed Outpatients (with R. Kavoussi, R.T. Seagraves, S.R. Batey, A. Hughes, and J.A. Ascher) — presented at American Psychiatric Association Meeting, June 1998.

Clinical Statistics for Non-Statisticians (with C. Chuang-Stein, K. Gordon, M. Mosier, and/or J. Whitmore) — 1- and 2-day short courses taught in the US and in Europe through the Drug Information Association (June 1998, March 1999, May 1999, March 2000, June 2000, March 2001, July 2001, March 2002, April 2003, March 2004, September 2004, October 2004, May 2005, October 2005, June 2006, September 2006).

Bupropion Sustained Release and Paroxetine Demonstrate Equivalent Quality of Life in Elderly Depressed Outpatients (with L. Herrero, Z.M. Khan, S. Batey, and J. Ascher) — presented at New Clinical Drug Evaluation Unit Program Annual Meeting, June 1998.

Data Issues in International Clinical Trials — invited presentation as part of Regulatory Affairs Professionals Society conference on International Clinical Trials Today and in the 21st Century, August 1998.

Time Course of Effectiveness with Bupropion, Nicotine Replacement, and Combination Therapy for Smoking Cessation (with B.D. Jamerson, D. Jorenby, J.A. Johnson, M. Fiore, M. Nides, S. Rennard, and S Leischow) — presented at American Society of Addiction Medicine National Conference, November 1998.

A Comparison of the Efficacy and Safety, Including Sexual Functioning, of Bupropion SR, Sertraline, and Placebo in Depressed Outpatients (with J. Ascher, S. Batey, T. Houser, and A. Metz) — presented at American College of Neuropsychopharmacology Annual Meeting, December 1998.

Pretreatment Anxiety Does Not Predict Response to Bupropion or Sertraline (with J. Rush, T. Carmody, S. Batey, J. Ascher, and V. Lackey) — presented at American Psychiatric Association Annual Meeting, Summer 1999.

Pretreatment Anxiety Does Not Predict Response to Bupropion SR or Sertraline (with J. Rush, S. Batey, J. Ascher, and T. Carmody) — presented at New Clinical Drug Evaluation Unit Program Annual Meeting, June 1999.

A Darwinian Scheme for Estimating Rankings under a Stochastic Ordering — presented in part at the Joint Statistical Meetings, Indianapolis, August 2000.

Randomness and Probability for First and Second Graders — presented as part of Catholic Schools Week at The Franciscan School, Raleigh, February 2001.

How Statisticians Think and Why it Matters — invited presentation as part of Drug Information Association Annual Meeting, Denver, July 2001.

Fundamentals of Statistical Thinking — presented as part of the Vanderbilt University Medical Center Department of Ophthalmology seminar series, Nashville, July 2001.

Comparing R&D and Commercial: Are All Data Created Equal? — invited presentation as part of the Twenty-fifth Annual Midwest Biopharmaceutical Statistics Workshop, Muncie, Indiana, May 2002.

Statistical Issues in Research Preparation and Review — two lectures as part of Campbell University's Clinical Research Seminar (CLNR 534), Raleigh, September 2002 and September 2004.

Statistics in Clinical Research: Godsend or Necessary Evil? — invited presentation as part of Regulatory Affairs Professionals Society Clinical Research Meeting, San Diego, April 2003.

Data Issues in Multinational Trials — invited presentation as part of Regulatory Affairs Professionals Society Clinical Research Meeting, San Diego, April 2003.

Using Data Mining Techniques to Harvest Information from Clinical Trials (with R. De Veaux and R. Small) — presented by R. De Veaux as part of DIMACS Working Group on Privacy / Confidentiality of Health Care Data, Rutgers University, December 2003.

Advanced Clinical Statistics for Non-Statisticians (with C. Chuang-Stein, M. Mosier, and/or J. Whitmore) — a 2-day short courses taught through the Drug Information Association (November 2004, May 2005, October 2006).

Statistics as a Career — part of Wakefield Middle School Career Day, Raleigh, March 2005.

Multiple Inferences in Early Phase II Clinical Trials — Performance of Exact Methods for Dose Response (with A. Krishen) — presented at the Joint Statistical Meetings, Minneapolis, August 2005.

Fundamental Statistics Concepts in Understanding and Presenting Data — presented at Section of Surgical Sciences Research Conference (6 January 2006); Department of Anesthesiology Seminar (18 January 2006); General Clinical Research Center Skills Workshop (20 January 2006), Vanderbilt University Medical Center, Nashville; Clinical Research Seminar, University of Texas Southwestern Medical Center (8 June 2006); Atherogenics, Atlanta (14 June 2006).

Blood Pressure Variability: A Biomarker for Mortality in 1852 Trauma Patients (with H. Cao, P. Norris, N. Mowery, and J. Morris) — abstract in *Shock*, **25(6)** (2006), 54.

(Musings on) the nature of data analysis — Department of Biostatistics Seminar/Workshop Series, Vanderbilt University (11 October 2006); invited presentation at Vanderbilt Kennedy Center for Research on Human Development seminar (28 April 2007); invited Department of Pathology seminar (14 May 2007); invited monthly MS-level biostatisticians seminar (9 July 2007).

Multiple Lagged Differences in Spatial Times Series (with J. Horner) — presented at the Joint Statistical Meetings, Seattle, August 2006.

Data Display Principles Revealed in the NASA Data — presented at the Joint Statistical Meetings, Seattle, August 2006.

Heart Rate Variability Signals Adrenal Insufficiency in the Critically Ill: A Study of 1871 Trauma Patients (with J. Morris, O. Guillaumondegui, A. Ozdas, H. Cao, P. Norris, L. Waitman, and J. Jenkins) — presented at Southern Surgical Association, One Hundred Eighteenth Annual Session, December 2006.

Achieving GBC Reliability — invited presentation at Brickworld, Chicago, June 2007.

Bivariate Baseball Score Plots — presented at the Joint Statistical Meetings, Salt Lake City, July 2007.

Publications

On Permissible Correlations for Locally Correlated Stationary Processes (with P. J. Brockwell and R. A. Davis) — *Statistics and Probability Letters*, **22** (1995), 49–53.

A Summary Statistic for Measuring Change from Baseline — *Journal of Biopharmaceutical Statistics*, **7**(2) (1997), 287–299.

Standardizing Clinical Study Designs for Accelerating Drug Development (with S.J. Ruberg) — *Drug Information Journal*, **31** (1997), 655–663.

Costs of Epilepsy in an Intermediate Care Facility for the Mentally Retarded (ICF/MR) (with T.A. Burke, J.R. McKee, D.S. Pathek, T.V. Parasuraman, and A.S. Batenhorst) — *The American Journal of Mental Retardation*, **104** (1999), 148–157.

A Note on Information Seldom Reported Via the P-value — *The American Statistician*, **53** (1999), 303–306.

Reply to Langbehm’s Comment on A Note on Information Seldom Reported Via the P-value — *The American Statistician*, **54** (2000), 227–228.

Anxiolysis Associated with Antidepressant Response to bupropion Sustained Release or Sertraline (with A.J. Rush, M.H. Trivedi, S.R. Batey, T.J. Carmody, T.L. Houser, J.A. Ascher, C. Bolden-Watson, and A. Metz) — *International Journal of Neuropsychopharmacology*, **3** Supplement 1, (2000), S235.

A Placebo-controlled Comparison of the Antidepressant Efficacy and Effects on Sexual Functioning of Sustained-release Bupropion and Sertraline (with H. Croft, E. Settle, T. Houser, S.R. Batey, and J.A. Ascher) — *Clinical Therapeutics*, **21** (1999), 643–658.

Sexual Dysfunction Associated with the Treatment of Depression: A Placebo-controlled Comparison of Bupropion Sustained Release and Sertraline Treatment (with C.C. Coleman, L.A. Cunningham, V.J. Foster, S.R. Batey, T.L. Houser and J.A. Ascher) — *Annals of Clinical Psychiatry*, **11**, (1999), 205–215.

A Comparison of Time-and-motion and Self-reporting Methods of Work Measurement (with T.A. Burke, J.R. McKee, H.C. Wilson, D.S. Pathek, and A.S. Batenhorst) — *Journal of Nursing Administration*, **30** (2000), 118–125.

Evaluation of Sexual Functioning in Depressed Outpatients: A Double-Blind Comparison of Bupropion Sustained Release and Sertraline Treatment (with R.T. Segraves, R. Kavoussi, A.R. Hughes, S.R. Batey, J.A. Johnston, and J.A. Ascher) — *The Journal of Clinical Psychopharmacology*, **20**, (2000), 122–128.

Some Commentary on Maximizing the Statistician’s Value to the Pharmaceutical Industry — *Drug Information Journal*, **34**, (2000), 1261–1264.

Bupropion Sustained-Release Versus Paroxetine for the Treatment of Depression in the Elderly (with K.L. Weihs, E.C. Settle, S.B. Batey, T.L. Houser, and J.A. Ascher) — *The Journal of Clinical Psychiatry*, **61**, (2000), 196-202.

Improved Health-related Quality of Life and Reduced Productivity Loss after Treatment with Wellbutrin SR: A Study in Patients with Major Depression (with D.L. Dunner, W.J. Kwong, T. Houser, N.E. Richard, and Z.M. Khan) — *Primary Care Companion to the Journal of Clinical Psychiatry*, **3**, (2001), 10-16.

Quality of Life in Geriatric Depression: A Comparison of Remitters, Partial Responders, and Nonresponders (with P.M. Doraiswamy, N.E. Richard, and Z.M. Khan) — *American Journal of Geriatric Psychiatry*, **9**, (2001), 423-428.

The Development of a Darwinian Scheme for Estimating Rankings Under a Stochastic Ordering — *2000 Proceedings of the Section on Statistics in Sports of the American Statistical Association*, (2001), 64-69 (not refereed).

Response in Relation to Baseline Anxiety Levels in Major Depressive Disorder Treated with Bupropion Sustained Release or Sertraline (with A.J. Rush, M.H. Trivedi, T. Carmody, T.L. Houser, C. Bolden-Watson, S.R. Batey, J.A. Ascher, and A. Metz) — *Neuropsychopharmacology*, **25**, (2001), 131-138.

Does Pretreatment Anxiety Predict Response to Bupropion SR or Sertraline? (with J. Rush, S.Batey, J. Ascher, T. Carmody, and A. Metz) — *Journal of Affective Disorders*, **64**, (2001), 81-87.

Do Bupropion SR and Sertraline Differ in Their Effects on Anxiety in Depressed Patients? (with A.J. Rush, M.H. Trivedi, T. Carmody, T.L. Houser, and C. Bolden-Watson) — *Journal of Clinical Psychiatry*, **62**, (2001), 776-781.

Late-Term Smoking Cessation Despite Initial Failure: An Evaluation of Bupropion Sustained Release, Nicotine Patch, Combination Therapy, and Placebo (with B.D. Jamerson, M. Nides, D.E. Jorenby, P. Garrett, J.A. Johnston, M.C. Fiore, S.I. Rennard, and S.J. Leischow) — *Clinical Therapeutics*, **23**, (2001), 744-752.

The Spectrum of Quality-of-life Impairments in Recurrent Geriatric Depression (with P.M. Doraiswamy, N.E. Richard, and Z.M. Khan) — *Journal of Gerontology Medical Sciences*, **57**, (2002), M134-M137.

Effect on Body Weight of Bupropion Sustained-Release in Patients with Major Depression Treated for 52 Weeks (with H. Croft, T.L. Houser, B. Jamerson, R. Leadbetter, C. Bolden-Watson, and A. Metz) — *Clinical Therapeutics*, **24**, (2002), 662-672.

Continuation Phase Treatment with Bupropion SR Effectively Decrease the Risk for Relapse of Depression (with K.L. Weihs, T.L. Houser, S.R. Batey, J.A. Ascher, C. Bolden-Watson, and A. Metz) — *Biological Psychiatry*, **51**, (2002), 753-761.

Prevalence of Sexual Dysfunction Among Newer Antidepressants (with A. Clayton, J. Pradko, H. Croft, B. Montano, R. Leadbetter, C. Bolden-Watson, K. Bass, B. Jamerson, and A. Metz) — *Journal of Clinical Psychiatry*, **63**, (2002), 357-366.

Statistics in Clinical Research: Godsend or Necessary Evil? — *Regulatory Affairs Focus*, (December 2003), 37-39 (not refereed).

Cost-effective use of breast biopsy techniques in a Veterans health care system (with A. Hatmaker, J. Tarpley, and A. Pearson) — *American Journal of Surgery*, **192**, (2006), e37-41.

Miscellany

Member of Editorial Board for *Drug Information Journal*

Referee for *The American Statistician*
Member of the American Statistical Association
Member of the Drug Information Association
Member of the National Geographic Society
Developer of Donahue Darwinian Ranking Scheme
Born 8 January 1965, Milwaukee, Wisconsin
Private pilot's license, 1989
Grand Knight, Knights of Columbus Council #9709, 1999–2000
Happily married; two wonderful sons, one beautiful daughter
Basketball coach, St Francis Youth Basketball League, Raleigh, 1999–2005
Award for Best GBC Module, Brickfest, August 2005, Washington, D.C.
Basketball coach, Youth Incorporated, Brentwood, 2005–2006
Assistant baseball coach, Brentwood Civitan Youth Baseball, Brentwood, 2006
Award for Best GBC Module, Brickfest, August 2006, Washington, D.C.
Assistant baseball coach, Brentwood Babe Ruth Baseball, Brentwood, 2006–2008