

Melissa E. Spann, PhD

Contact Information

Melissa E. Spann
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Education

PhD. Statistics, Baylor University, Waco, Texas May 2006
M.A. Statistics, Baylor University, Waco, Texas December 2003
B.A. Mathematics, Cum Laude, University of North Texas, Denton, Texas August 1997

Profile

In my current role, I provide consultation across multiple therapeutic areas and phases of development for clinical trial and clinical program optimization utilizing various tools and methods for adaptive study designs and adaptive clinical programs. Previously, I was the lead statistician for early phase assets and a key contributor to successful US and global submissions, regulatory interactions, and commercialization work products. While possessing strong technical skills I also have a passion for education and assisting my colleagues, who may or may not have formal statistical training, understand complex statistical concepts. In addition, I am a skilled public speaker and enjoy presenting in a various types of venues.

Employment

Senior Research Scientist, Eli Lilly & Company, Indianapolis, Indiana 2011-present
Current Role in Advanced Analytics:
Advanced Analytics Clinical Trial Optimization for Science Drive Adaptive Programs (SDAP) providing consultation across multiple therapeutic areas and phases of development in addition to the development SDAP tools

Previous Contributions as Project Statistician:

- Phase I & III Immunology Statistics – Lead Statistician for multiple indications
- Deliverables: Protocols, analysis plans, database locks, study reports, CTR summaries
- Due diligence assessment of potential new asset acquisitions

Manager, Biostatistics, Alcon Laboratories, Fort Worth, Texas 2010 – 2011
Key Contributions:
Managed Biostatistics direct reports and programming resources to support multiple therapeutic areas and US submissions.

Other Contributions:

- Established summer Biostatistics internship program
- Developed junior statisticians
- Developed educational materials for statisticians and non-statisticians
- Championed process improvement initiatives

Research Scientist, Eli Lilly & Company, Indianapolis, Indiana 2005 – 2010
Key Contributions:

- Phase III & IV Neuroscience Statistics – Lead Statistician for multiple indications
- EU and US submission planning and execution; regulatory interactions and label negotiations
- Managing statistical resources in the presence of competing priorities
- Deliverables: Protocols, analysis plans, database locks, study reports, CTR summaries

Other Contributions:

- Chair of Bayesian Education Team responsible for the development of companywide Bayesian educational curriculum
- Speaker Trainings - Explained to clinicians statistical concepts used in clinical research
- Mentor/coach to statistical colleagues, clinical colleagues, and statistics intern
- Responsible for arrangement of team building events

Summer Intern

Developed Bayesian adaptive dose selection design and simulation program which was presented at a contributed session at the 2006 Joint Statistical Meetings and multiple internal Lilly venues.

Statistical Consultant, Office of Strategic Planning - Baylor University, Waco, Texas

2003-2005

- Developed statistical model for the purpose of enrollment prediction and planning.
- Developed classification model and tool to aid the Financial Aid Office in determining the appropriate amount of financial assistance to offer a potential student in order to achieve the desired shape and size of an incoming freshmen class.
- Implemented student and faculty surveys to aid in development plans; led team in analysis and interpretation of survey results

Statistical Consultant, Self-Employed, Waco, Texas

2003-2005

- Developed analysis plans and models to assist investment strategy
- Developed model to assess if students participating in an honorary program is a contributing factor in the success of the college student.
- Used statistical models to determine if an alternative form of education produces positive long-term results in elementary school students' progress.
- Assisted in the interpretation of analyses resulting from the research of the benefits of four year old children attending preschool.

Statistics Teaching Assistant, Psychology Department & Economics Department - Baylor University, Waco, Texas

2002-2003

- *Introduction to Statistics* – Responsible for delivering lectures and grading homework
- *Econometrics* – Responsible for grading homework and developing tests

Teacher and Tennis Coach, Vanguard College Preparatory, Waco, Texas

1999-2002

Teaching responsibilities: Advanced Placement Statistics, Algebra II, Computer Science, and Environmental Science

Other Responsibilities:

- Middle School Tennis Coach
- Junior Class Sponsor – responsible for managing and coordinating students, student affairs, fund raising, and community involvement

Mathematics Teacher, La Vega Independent School District, Waco, Texas

1998-1999

- *Teaching responsibilities*
 - 6th & 8th Grade Mathematics
 - 6th Grade Gifted & Talented Mathematics
- *University Interscholastic League: Number Sense* - Faculty Sponsor

Tennis Coach, University of North Texas, Denton, Texas

1997

Interim Head Coach/Assistant Coach Women's Tennis Team

Relevant Skills, Experience & Accomplishments

Skills & Strengths

Instruction/Teaching, Team collaboration, Adaptive designs & clinical trial optimization, Bayesian methods, Presentation skills, Statistical, analytical, and problem solving skills, Time management, Study design, SAP and protocol development, Regulatory response and submission planning

Systems Mastery: FACTS, R, ADDPLAN, EAST, WinBUGS, PC-SAS, PC-SAS/WinBUGS Interface, nQuery, Mathcad, JMP, Microsoft Office

Systems Working Knowledge: SDD (SAS Drug Development), Project Office, Pro Chain Enterprise

Publications – Statistical Methodology Research

- “Bayesian Adaptive Non-inferiority with Safety Assessment: Retrospective Case Study to Highlight Potential Benefits and Limitations of the Approach”, *Journal of Psychiatric Research* (2008); Author list: Melissa Spann, Stacy R. Lindborg, John W. Seaman Jr., Robert W. Baker, Eduardo Dunayevich, Alan Breier
- “Bayesian Adaptive Non-Inferiority Design with Safety Assessment: Retrospective Analysis of Zyprexa IM Data”; *Joint Statistical Meetings 2006 Proceedings*; Author List: Melissa Spann, Stacy R. Lindborg, John W. Seaman, Jr.
- “Bayesian Adaptive Dose Selection Design: Utilizing Effect Sizes to Identify the Most Efficacious Dose”; *Joint Statistical Meetings 2006 Proceedings*; Author List: Melissa Spann, David H. Manner, John W. Seaman, Jr.

Publications- Clinical Research

- “Estrogen receptor beta agonist LY500307 fails to improve symptoms in men with enlarged prostate secondary to benign prostatic hypertrophy”, *Prostate Cancer and Prostatic Disease* (2015) 18, 43–48; Author list: Claus Roehrborn, Melissa Spann, Myers, Cynthia Serviss, Leijun Hu, and Yan Jin
- “Predictors of relapse in a study of duloxetine treatment for patients with generalized anxiety disorder”, *Human Psychopharmacology* (2011); Author list: J. Bodkin, Christer Allgulander, P. Llorca, Melissa Spann, Daniel Walker, James Russell, Susan Ball.
- “Assessing remission in major depressive disorder and generalized anxiety disorder clinical trials with the discan metric of the Sheehan disability scale”, *International Clinical Psychopharmacology* (2011) Mar26(2):75-83; Author list: David Sheehan, Kathy Harnett-Sheehan, Melissa Spann, Harry Thompson, Apuvura Prakash.
- “Sexual Function during Long-Term Duloxetine Treatment in Patients with Recurrent Major Depressive Disorder”, *Journal of Sexual Medicine* (2011) Mar;8(3):773-82; Author list: A Montejo, D Perahia, Melissa Spann, F Wang, D Walker, C. Yang, M Detke
- “Duloxetine 60 mg/day for the prevention of depressive recurrences: post hoc analyses from a recurrence prevention study”, *International Journal of Clinical Practice*. (2010); Author list: K. Kelin, M. Berk, Melissa Spann, D. Sagman D, Joel Raskin, Daniel Walker, David Perahia.
- “Relationship between TSH levels in the normal range and short-term duloxetine efficacy”, *Journal of Affective Disorders*. (2010); Author list: E. Corruble, Celine Goldberger, Melissa Spann.
- “A continuous responder analysis from a long-term trial of duloxetine treatment for generalized anxiety disorder: implications for the randomized withdrawal relapse prevention study design”, *Journal of Clinical Psychopharmacology* (2009); Author list: P. Llorca, J. Bodkin, Melissa Spann, Susan Ball, James Russell.
- “The short- and long-term effect of duloxetine on painful physical symptoms in patients with generalized anxiety disorder: results from three clinical trials”, *Journal of Anxiety Disorders*. (2009); Author list: K. Beesdo, J. Hartford, James Russell, Melissa Spann, Susan Ball, H. Wittchen.
- “Duloxetine in the prevention of depressive recurrences: A randomized, double blind, placebo-controlled trial”, *Journal of Clinical Psychiatry* (2009); Author List: David Perahia, Giuseppe Maina, Michael Thase, Melissa Spann, Fujun Wang, Daniel Walker, Michael Detke.
- “A non-inferiority comparison of duloxetine and venlafaxine in the treatment of adult patients with generalized anxiety disorder”, *Journal of Psychopharmacology*, (2008); Author list: Christer Allgulander, D. Nutt, Michael Detke, Janelle Erickson, Melissa Spann, Daniel Walker, Susan Ball, James Russell.
- “Comparison of Duloxetine and Venlafaxine in the Treatment of Adult Patients with Generalized Anxiety Disorder”, *Journal of Psychopharmacology* (2008); Author List: Christer Allgulander, David Nutt, Michael Detke, Janelle Erickson, Melissa Spann, Daniel Walker, Susan G Ball, James M Russell.
- “Improvement of psychic and somatic symptoms in adult patients with generalized anxiety disorder: examination from a duloxetine, venlafaxine extended-release and placebo-controlled trial”, *Psychological Medicine*, (2008); Author List: H. Nicolini, D. Bakish, H. Duenas, Melissa Spann, Janelle Erickson, Cynthia Hallberg, Susan Ball, D. Sagman, James Russell.

- “Early Improvement during Duloxetine Treatment of Generalized Anxiety Disorder Predicts Response and Remission at Endpoint”, *Journal of Psychiatric Research*, (2008); Author List: Mark H. Pollack, Susan G. Kornstein, Melissa Spann, Paul Crits-Christoph, Joel Raskin, James M. Russell.
- “Examining quality of life in patients with generalized anxiety disorder: Clinical relevance and response to duloxetine treatment”, *Journal of Psychiatric Research*, (2007); Author List: Mark H Pollack, Jean Endicott, Michael Liebowitz, James Russell, Michael Detke, Melissa Spann, Susan Ball, Ralph Swindle.

Conferences

- Biopharmaceutical Applied Statistics Symposium, Orlando, Florida 2013; Speaker
- American College of Rheumatology, San Diego, California 2013; Attendee
- MD Anderson Bayesian Biostatistics Conference 2012; Attendee
- International Association for the Study of Pain Conference 2012; Attendee
- Conference of Texas Statisticians 2011; Poster Presentation
- Joint Statistical Meetings, 2005, 2010; Attendee
- FDA/Industry Workshop, 2009; Round Table Discussion Leader
- NCDEU 2009; Poster Presentation
- European Congress of Neuropsychopharmacology, 2008; Attendee
- Adaptive Designs in Clinical Drug Development, 2008 - Invited Speaker
- Midwest Biopharmaceutical Statistics Workshop 2007; Poster Presentation
- Joint Statistical Meetings 2006- Presentation & multiple proceedings papers
- Midwest Biopharmaceutical Statistics Workshop 2006; Poster Presentation
- Midwest Biopharmaceutical Statistics Workshop 2005; Attendee
- International Biometric Society, Eastern North American Region 2005; Volunteer Coordinator & Diversity Workshop Attendee
- Conference of Texas Statisticians, 2003, 2005; Attendee
- Erich Lehmann Symposium, 2004; Attendee
- College Board of Advanced Placement Statistics Workshop, 1999, 2000, 2001; Attendee

Public Speaking

- Biopharmaceutical Applied Statistics Symposium, Orlando, Florida – Speaker 2013
- Baylor University, Waco, Texas – Invited Speaker, 2009 & 2011
- Midway Independent School District, Waco, Texas– Invited Speaker, May 2009
- Lilly Speaker Trainings 2009: San Diego, California & Jacksonville Florida
Explained to clinicians statistical concepts used in neuroscience clinical research
- 5th Annual Statistics Career Day, Indianapolis, Indiana –Speaker 2008
- Adaptive Designs in Clinical Drug Development, London 2008 - Invited Speaker
- Scientech, Indianapolis, Indiana - Invited Speaker, Feb 2008
- Cedar Hill High School, Cedar Hill, Texas - Invited Speaker, Apr 2008
- IUPUI, Indianapolis, Indiana - Instructor Fall 2007
- University of Indianapolis, Indianapolis, Indiana - Invited Speaker, Apr & Dec 2007
- American Society of Quality, Indianapolis, Indiana - Invited Speaker, Apr 2007
- Joint Statistical Meetings 2006- Contributed Session
- Vanguard College Preparatory, Waco, Texas - Invited Speaker, Mar 2005

Professional Memberships

American Statistical Association:

Sections: Biometrics Section, Biopharmaceutical Section, Statistical Consulting, Section on Statistical Graphics, Section on Bayesian Statistical Science, Section on Statistics in Sports, Section for Statistical Programmers and Analysts

Chapters: Austin, Central Indiana, North Texas

Institute of Mathematical Statistics

International Society for Bayesian Analysis

International Biometric Society – Eastern North American Region

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- Awards & Honors**
- Midwest Biopharmaceutical Statistic Workshop-** 2006 Charles B. Sampson Student Poster Competition-1st place
 - Joint Statistical Meetings-** 2006 ASA Biopharmaceutical Section Student Paper Competition – Honorable Mention
 - Texas Knight’s Templar Educational Foundation Scholarship-** 2003, 2004
 - Who’s Who Among High School Teachers-** 2002, 2004
 - Golden Key National Honor Society**
 - Big West Conference Female Student Athlete of the Year -** 1997

Community Involvement

Social Order of the Beauceant: Organization is actively involved in contributing to Knight’s Templar Eye Foundation, dyslexia programs, local shut-ins, and other philanthropic endeavors.

- National Level Appointed Officer: 2007-2008 & 2015-2016
- Past President of Waco Assembly #199: 2005 & 2012
- Member and Officer of Waco Assembly #199: 1997 – present
- Member of Dallas Assembly #63: 2009 – present

Cottonwood Baptist Church, Lorena, Texas: Member since 2012

Upward Bound Basketball Coach, Mansfield, Texas – Spring 2011

Western Heights Baptist Church: Member and Sunday school teacher 2009-2010

Woodway Community Center Basketball Coach, Waco, Texas - Spring 2010

Carmel Dad’s Club Basketball Coach, Carmel, Indiana – Spring 2009

Zionsville Christian Church, Zionsville, Indiana

- Member and regular attendee, 2006 - 2009
- Served as Deacon, 2007-2009
- Steering Committee Member, 2007 - 2009

Toastmasters International

- Vice President of Public Relations, 2007
Region V, District 11, Division C, Area 20, Club # 7594