**Karen L Price, Ph.D.** Lilly Corporate Center

**Research Advisor, Lead Bayesian Methods Group** Indianapolis, IN 46285

**Science Driven Adaptive Program/Advanced Analytics** Office: 317-651-2132

**Eli Lilly and Company**  Mobile: 512-763-9720

**AREAS OF SPECIALIZATION**

* 15 years of statistical consulting experience focused in clinical trial design experience spanning Phase 1-4 of pharmaceutical drug development in therapeutic areas including diabetes, neuroscience, autoimmune and oncology, as well as global patient safety
* Areas of specialty include Bayesian methods/modeling, meta-analysis/network meta-analysis, patient safety assessment, trial design, trial simulation incorporating drug/disease modeling
* Experience in leading cross disciplinary teams within and external to the company
* Experience in developing and presenting technical and non-technical statistical training. Audiences include students, professional statisticians, clinicians, clinical trial support staff, and regulators.
* Current Society Memberships: member of American Statistical Association (ASA), member of the Drug Information Association (DIA)
* Strong interest in mentoring other statisticians and highly motivated to collaborate across the organization

**EDUCATION**

**DEGREES**

**Institution:**  **Baylor University, Waco, TX**

**Degree:** Ph.D. Statistics

 Aug. 2001

**Institution:** **Baylor University, Waco, TX**

**Degree:** M.A. Statistics

 May 1999

**Institution:** **Baylor University, Waco, TX**

**Degree:** B.A. Mathematics

 May 1997

**WORK EXPERIENCE**

**ELI LILLY AND COMPANY, Indianapolis IN (July 2001 – Present)**

 **Research Titles Held:**

Research Advisor (11/2012-Present)

 Principal Research Scientist (11/2008-10/2012)

 Sr. Research Scientist (11/2004-10/2008)

 Research Scientist (07/2001-10/2004)

**RAYTHEON, Waco TX (August 1998 - June 2001)**

 **Research Titles Held:**

Senior Factors and Formulas Analyst

Associate Factors and Formulas Analyst

**SOUTHERN METHODIST UNIVERSITY, Dallas TX (August 1997 – May 1998)**

 **Research Titles Held:**

Graduate Assistant and Tutor

**BAYLOR UNIVERSITY, Waco TX (August 1996 - May 1997)**

 **Research Titles Held:**

 Athletic Tutor

**Eli Lilly and Company Roles Held:**

**Lead of Bayesian Methods for Science-Driven Adaptive Program:**

Lead Bayesian methods efforts for Science-Driven Adaptive Program, which includes driving the use of Bayesian application throughout medical product development. Develop the Bayesian strategy related to projects and areas of focus. Lead a group of cross-functional team members to develop internal tools for implementation of Bayesian methods that enable efficient and high-quality application of complex Bayesian models that inform decision making and trial design, thereby impacting multiple compounds at all phases of development. Drive development of new Bayesian methodology to meet business needs. Consult cross-functionally on a variety of scientific problems encountered across therapeutic areas. Develop training and write white papers to facilitate an environment of learning across functional areas. Ensure Bayesian applications are utilized effectively and translated to business partners in a consistent and clear manner, thereby improving decision making and trial design. Lead DIA Bayesian Scientific Working Group.

**Lead of Bayesian Expert Team:**  Created Bayesian Expert Team by developing the business proposal for a small group of senior technical statisticians, focused on bringing value to drug development in innovative ways. Developed tools, new methods, resources, training, and provided consultation on various Bayesian needs across drug development. Identified innovative statistical approaches with high potential to impact the business and translated them into broader practice, provided impact to strategic internal decisions regarding clinical development, and worked to influence the external business environment to help bring innovative approaches into common practice. Consulted to clinical development teams and statisticians. Created and led DIA Bayesian Scientific Working Group.

**Project Statistician supporting Global Patient Safety:** Provided technical leadership to global patient safety organization. Member of EXPERT research design network, providing technical leadership, protocol reviews, and development of new methods for safety studies, particularly in the observational setting. Lead patient exposure estimates working group, developing methods for estimating the number of patients prescribed Lilly compounds which is important for evaluating active surveillance safety data. Member of PhRMA pharmacovigilance working group.

**Lead Project Statsitician for Diabetes Neuropathy indication:** Responsible for all Diabetic Neuropathy-related activities, including three phase 3 Global studies and one Japan study. Lead statistician for all tasks related to key safety topics, including cardiovascular-related analyses. Also served as lead statistician for other indications, including nephrapthy and erectile dysfuction, and provided support for diabetic retinopathy and macular edema.

**AWARDS**

* Lilly Top 100 Innovator Award (2015)
* LRL President’s Scientific Award for Innovation (2013)
* SPAIG ASA Award: Lilly/Baylor Collaboration (2012)
* Individual Leadership Award for Innovation (2006 and 2007)
* GBD Component Brand Champion Award (2005)
* Quarterly Arxxant Team Award (2004 and 2005)

**PROFESSIONAL ACTIVITIES**

Founder and Chair of the DIA Bayesian Scientific Working Group (01/2012- present)

Appointed (11/2012-present) Adjunct Associate Professor of Statistics, Baylor University

Co-chair Joint AD/Bayes workshop

DER, FDA

Co-chair of Joint Adaptive Design and Bayesian Statistics Conference: Drivers of Efficiency in Modern Medical Product Development

ASA Biopharmaceutical Section Committee Member: Scientific Working Group

Associate Editor for *Pharmaceutical Statistics*

ASA Committee Member: WJ Dixon Award Committee

Co-editor (with Lisa LaVange) Special Issue on Bayesian methods for *Pharmaceutical Statistics*

DIA Bayesian Scientific Working Group Chair and founder; member and/or co-chair for several subteams

Core member of OMOP

ENAR Regional Advisory Board

Adjunct Professor Department of Statistical Sciences, Baylor University

Central Indiana American Statistical Association (ASA) Chapter Past President

Central Indiana ASA Chapter President

Central Indiana ASA Chapter Vice-President

DIA member

ENAR Member

Bayesian ASA Section member

Biopharm ASA Section member

ASA Member

**PRESENTATIONS & PANELS**

Oura T and **Price KL**. East Asia Regional Biometric Conference: Encore of *Implementation of Bayesian Network Meta-analysis to Improve Medical Product Development*, December 2015

**Price KL**. DIA Japan (Tokyo): *Implementation of Bayesian Network Meta-analysis to Improve Medical Product Development*, November 2015

**Price KL.** Bayesian opportunities in clinical trials from an industry perspective, August 2015

**Price KL**. Presentation at opening session Joint Adaptive Design/Bayesian Workshop, February 2015

**Price KL** and Carlin B. Network meta-analysis , DIA Short course , June 2014

**Price KL**. DIA invited discussant, June 2014

**Price KL**. DIA: invited panelist (only representative from industry) on trends within medical product decision (others on panel included Lisa LaVange, Estelle Russek-Cohen, Steve Wilson), June 2014.

**Price KL**. Overview of Bayesian Methods for Safety Assessment, MBSW, May 2014.

**Price KL**. FDA/DIA Statistics Forum Session on Leadership in a Collaborative Environment: invited panelist and presenter, April 2014.

Seifert H, Siemers E, Sundell K, **Price KL**, Han B, D’Souza D, Raskin J, Mohs R. *Relationship Between Cognitive and Functional Progression in Patients with Mild Alzheimer’s Disease*, November 2013.

Kahle D, Stamey J, Natanegara F, **Price KL**, Han B. *Advances in Facilitated Prior Elicitation*, August 2013 JSM.

**Price KL**, Chen F, Han B. *Bayesian Approaches in Clinical Development Using SAS*, August 2013 JSM.

**Price KL**. *Overview of DIA Bayesian Scientific Working Group*, June 2013 DIA.

**Price KL** and Ohlssen D. *Recent Developments of Bayesian Meta-analysis for Safety Evaluation in Randomized Clinical Trials*, July 2012 JSM.

Gao A, Natanegara F, and **Price KL**. *Frequentist Conditional Power, Bayesian Predictive Power and their Applications and Implementations*, July 2012 JSM.

**Price KL**. *DIA Bayesian scientific working group*, June 2012 DIA invited presentation

Price KL. Chair: Impact of Bayesian methods in drug development, June 2012 DIA.

**Price KL**. *Bayesian meta-analysis*, June 2012, Baylor University.

Price KL. Chair: Bayesian methods in safety detection and evaluation, April 2012 FDA/DIA workshop.

Fu H, **Price KL**, Nilsson M, and Ruberg S. *Identifying Potential Adverse Events Dose-Response Relationships Via Bayesian Indirect And Mixed Treatment Comparison Models*. April 2012 FDA/DIA workshop.

**Price KL**. *Bayesian DIA Scientific Working Group*. January 2012 Bayesian Biostatistics Conference.

Natanegara F, **Price KL**, Heilmann C, Belger M, and Fu H. *Quantitative Decision Making Using Bayesian Approach to Synthesize Information from Multiple Clinical Studies*. January 2012 Bayesian Biostatistics Conference.

Fu H and **Price KL**. *Evaluating Probability of Study Success Through Bayesian Evidence Synthesis Techniques*. January 2012 Bayesian Biostatistics Conference.

Baygani S and **Price KL**. *Using Bayesian Methods to Enhance Data Monitoring Committee (DMC) Decision Making and Application*. January 2012 Bayesian Biostatistics Conference.

**Price KL**. Invited panelist, FDA/DIA Workshop, Bayesian Methods in Drug Development, April 2011.

**Price KL**. Chair: FDA/DIA Session on Bayesian Methods in Drug Development, April 2011.

**Price KL** and Fu H. The Impact of Bayesian Methods in Drug Development: An Industry Perspective. January 2011 Bayesian Biostatistics Conference.

**Price KL**. Invited discussant: Bayesian methods in drug development, January 2010 Bayesian Biostatistics Conference.

**Price KL** and the Meta-Analysis Working Group. *Meta-Analysis: To Believe or Not to Believe, That is the Question*. Invited presentation, 2008 Midwest-Biopharmaceutical Statistics Workshop.

Bastyr EJ, Cheng C, **Price KL**, Kles KA, Skljarevski V, Lledo A, Ruboxistaurin Treatment of DPN Study Group. *Lack of Diabetic Peripheral Neuropathy (DPN) Progression After Three Years in Patients with Early Mild DPN: Experience from the Ruboxistaurin Clinical Trial*. EASD 10/2007.

Bastyr EJ, Cheng C, **Price KL**, Kles KA, Skljarevski V, Lledo A, Ruboxistaurin Treatment of DPN Study Group. *Lack of Diabetic Peripheral Neuropathy (DPN) Progression After Three Years in Patients with Early Mild DPN: Experience from the Ruboxistaurin Clinical Trial*. Neurodiab 10/2007.

**Price KL**. Post-marketing Patient Exposures Estimation, Baylor University 5/2007.

**Price KL**. A Day in the Life of a Pharmaceutical Statistician, Baylor University 3/2007.

McGill J, King GL, Hyslop D, Berg PH, **Price KL**, Kles KL, Bastyr EJ, Vignati L. Safety of Ruboxistaurin, a Selective PKC β Isoform Inhibitor, in Patients with Diabetic Microvascular Complications. Program of the International Diabetes Federation 19th World Diabetes Congress; Cape Town, South Africa December 3rd-7th, 2006.

King GL, McGill J, Hyslop D, Berg PH, **Price KL**, Kles KA, Bastyr EJ, Vignati L. Evaluation of the Clinical Safety of the Selective PKC ß Isoform Inhibitor, Ruboxistaurin, in Patients with Diabetic Microvascular Complications. Program of the 42nd European Association for the Study of Diabetes (EASD), Copenhagen-Malmoe, September 14th-17th, 2006.

Bastyr EJ, Kles KL, Skljarevski V, **Price KL**, for the Ruboxistaurin Study Group. The Impact of the Standard of Care on Symptoms in Placebo-treated Patients with Diabetic Peripheral Neuropathy from a 1-Year Clinical Trial. Program of the 16th Neurodiab, Diabetic Neuropathy Study Group of the EASD NEURODIAB XVI, Ystad, Sweden, September 10-13th 2006

Tesfaye S, Skljarevski V, **Price KL**, Kles KA, Bastyr EJ. Marked Placebo Effect at the end of a 1-year Clinical Trial: Clues to the Nature of Symptoms in Diabetic Peripheral Neuropathy? Diabetes 2006; 55(suppl 1): A190.

King GL, Hyslop DL, Berg PH, **Price KL**, Kles KA, Bastyr EJ, Vignati L. Evaluation of the Clinical Safety of the PKC-β Inhibitor, Ruboxistaurin in Patients with Diabetic Microvacsular Complications. Diabetes 2006; 55(suppl 1): A121.

Tandan R, Skljarevski V, **Price KL**, Kles KA, Bastyr EJ, for the Ruboxistaurin Treatment of DPN Study Group. Neuropathy Progressionin Patients with Symptomatic Diabetic Peripheral Neuropathy: Experience from Phase 3 Ruboxistaurin Clinical Trials. Neurology. 2006;66(5) Suppl 2:A191.

Tesfaye S, for the Ruboxistaurin Treatment of Diabetic Peripheral Neuropathy Study Group. Symptomatic Diabetic Peripheral Neuropathy (SDPN) Treatment with the PKC ß Inhibitor Ruboxistaurin: Trial Design. European Association for the Study of Diabetes (EASD), Athens, Greece, September 10-15th, 2005.

Tesfaye S, for the Ruboxistaurin Treatment of Diabetic Peripheral Neuropathy Study Group. Symptomatic Diabetic Peripheral Neuropathy (SDPN) Treatment with the PKC ß Inhibitor Ruboxistaurin: Trial Design. Neurodiab, Porto Heli, Greece, September 8-11th, 2005.

**Price KL** and Seaman JW. Graphical Methods For Time-to-Pregnancy Data, JSM August 2004.

Skljarevski V, **Price KL**, Amador A, Bai S, Bastyr EJ. Diabetic Peripheral Neuropathy (DPN): Abnormalities of Vibration Detection Threshold (VDT) and their Correlation with Composite Score of Nerve Function and Electrophysiologic Attributes. Presentation American Diabetes Association National Meeting Orlando, Fla. Diabetes 53 (suppl 2): A214, 2004.

Skljarevski V, **Price KL**, Amador AG, Lledo A, Bastyr E, Ruboxistaurin-Induced Reduction of Symptoms of Diabetic Peripheral Neuropathy Is Not Associated With Use of Palliative Oral Medications, AAPM.

Bastyr EJ, **Price KL**, Skljarevski V, Lledo A, Vignati L. Ruboxistaurin (RBX) Mesylate Improves Diabetic Peripheral Neuropathy (DPN) Signs and Symptoms. Diabetologia 46 (suppl 2):A316, 2003.

**Price KL** and Seaman JW. Bayesian Analysis of Time-to-Pregnancy Data. JSM 2003.

Skljarevski V, **Price KL**, Bastyr EJ, Lledo A. Ruboxistaurin Mesylate Improves Signs and Symptoms of Diabetic Peripheral Neuropathy. Eur J Neurol 10 (suppl 1): 181, 2003.

Bastyr EJ, **Price KL**, Skljarevski V, Lledo A, Vignati L. Ruboxistaurin Mesylate Treatment in Patients with Diabetic Peripheral Neuropathy Improves Clinical Global Impression and Correlates with Change in Patient Positive Sensory Symptoms and Neurological Signs. Neurodiab Meeting St. Malo, France. Journal of the Peripheral Nervous System 8: 190, 2003.

Skljarevski V, **Price KL**, Bastyr EJ, Litchy W, Dyck PJ. Limited Neurological Examination of the Legs Correlates with Composite Measures of Nerve Conduction in Patients with Diabetic Peripheral Neuropathy. Eur J Neurol 10 (suppl 1): 122, 2003.

Skljarevski V, **Price KL**, Bastyr EJ, Vignati L. The Relative Impact of Individual Symptoms and Signs on Clinical Global Impression in Patients with Diabetic Peripheral Neuropathy Treated with Ruboxistaurin Mesylate. European Association for the Study of Diabetes Meeting Paris, France. Diabetologia 46 (suppl 2): A340, 2003.

Bastyr EJ, **Price KL**, Skljarevski V, Lledo A, Vignati L. Ruboxistaurin Mesylate Treatment in Patients with Diabetic Peripheral Neuropathy Improves Clinical Global Impression and Correlates with Change in Patient Symptoms and Signs. Diabetes 52 (suppl 1): A191-192, 2003.

**PUBLICATIONS**

# Hong H, Fu H, Price K, and Carlin B. Incorporation of individual-patient data in network meta-analysis for multiple continuous endpoints, with application to diabetes treatment. Statistics in Medicine, 2015.

Xia A and Price K. Bayesian Applications for Drug Safety Evaluation. Chapter in Quantitative Evaluation of Safety in Drug Development. CRC Press, edited by Jiang and Xia, 2015.

Liu-Siefert H, Siemers E, Price K, Han B, Selzler K, Henley D, Sundell K, Aisen P, Cummings J, Raskin J, Mohs R, and the Alzheimer’s Disease Neuroimaging Initiative. "Cognitive Impairment Precedes and Predicts Functional Impairment in Mild Alzheimer’s Disease." Journal of Alzheimer's Disease. 47: 205-214, 2015.

Liu-Seifert H, Simers E, Sundell K, Price K, Han B, Selzler K, Aisen P, Cummings J, Raskin J, Mohs R.

"Cognitive and Functional Decline and Their Relationship in Patients with Mild Alzheimer's Dementia."

Journal of Alzheimer's Disease. 43: 949-955, 2015.

Price K and LaVange L. Bayesian Methods in Medical Product Development and Regulatory Review. Pharmaceutical Statistics, 2014.

Price K, Xia A, Lakshminarayanan M, Madigan D, Manner D, Scott J, Stamey J, and Thompson L. Bayesian methods for design and analysis of safety trials. Pharmaceutical Statistics, 2014

Ohlssen D, Price K, Xia A, Hong H, Kerman J, Fu H, Quartey G, Heilmann C, Ma H, Carlin B. Guidance on the implementation and reporting of a drug safety Bayesian network meta-analysis. Pharmaceutical Statistics, 2014.

Stamey J, Beavers D, Faries D, Price K, Seaman J. Bayesian modeling of cost-effectiveness studies with unmeasured confounding: a simulation study. Pharmaceutical Statistics, 2014.

Fu H, Price K, Nilsson M, and Ruberg S. Identifying Potential Adverse Events Dose-Response Relationships Via Bayesian Indirect And Mixed Treatment Comparison Models. Journal of Biopharmaceutical Statistics.

Bennett M, Crowe B, Price K, Stamey J, Seaman J. Comparison of Bayesian and Frequentist Meta-Analytical Approaches for Analyzing Time to Event Data. Journal of Biopharmaceutical Statistics.

Myers J, Wielage R, Han B, Price K, Gahn J, Paget M-A, Happich M. The Efficacy of Duloxetine, Non-steroidal Anti-inflammatory Drugs, and Opioids in Osteoarthritis: A Systematic Literature Review and Meta-analysis. Submitted to Osteoarthritis and Cartilage.

Faries D, Peng X, Pawaskar M, Price K, Stamey J, and Seaman J. Evaluating the Impact of Unmeasured Confounding with Internal Validation Data: An Example Cost Evaluation in Type 2 Diabetes. Accepted Value In Health.

Mehta N, Sheetz M, Price K, Comiskey L, Amruita S, Iqbal N, Mohler E, Reilly M. Selective PKC b Inhibition with Ruboxistaurin and Endothelial Function in Type-2 diabetes, submitted to *Diabetes Care*.

Tesfaye S, Tanden R, Bastyr EJ III, Kles KA, Skljarevski V, Price KL, Ruboxistaurin Study Group. Factors the Impact Symptomatic Diabetic Peripheral Neuropathy in Placebo-Administered Patients From Two 1-Year Clinical Trials. *Diabetes Care*. 2007; 30: 2626-2632.

Kincaid J, Price K, Jimenez M, Skljarevski V. Correlation of Vibratory Quantitative Sensory Testing and Nerve Conduction Studies in Patients with Diabetes. *Muscle and Nerve*. 2007; 36: 821-827.

McGill JB, King GL, Berg PH, Price KL, Kles KA, Bastyr EJ, and Hyslop DL. Clinical safety of the selective PKC-β inhibitor, Ruboxistaurin. [*Expert Opinion on Drug Safety*](http://www.expertopin.com/loi/eds). 2006; 5(6): 835-845.

King GL, McGill JB, Hyslop DL, Berg PH, Price KL, Kles KA, Bastyr EJ, Vignati L. Clinical Safety of the PKC-β Inhibitor, Ruboxistaurin in Patients with Diabetic Microvacsular Complications. Diabetologia 2006; 49(suppl 1): 657.

Price KL and Seaman JW. Bayesian modeling of retrospective time-to-pregnancy data with digit preference bias. [*Mathematical and Computer Modelling*.](http://www.sciencedirect.com/science?_ob=JournalURL&_cdi=5656&_auth=y&_acct=C000024438&_version=1&_urlVersion=0&_userid=499562&md5=5310228c64b1c7e8fc268006be200e0e)[2006 June:43(11-12):1424-1433.](http://www.sciencedirect.com/science?_ob=IssueURL&_tockey=%23TOC%235656%232006%23999569988%23621696%23FLA%23&_auth=y&view=c&_acct=C000024438&_version=1&_urlVersion=0&_userid=499562&md5=4e653741924e3c13a1e8a4d25c9f0fa5)

Vinik AI, Bril V, Litchy WJ, Price KL, Bastyr EJ 3rd; MBBQ Study Group. Sural sensory action potential identifies diabetic peripheral neuropathy responders to therapy. *Muscle Nerve*. 2005 Nov;32(5):619-25.

Vinik AI, Bril V, Kempler P, Litchy WJ, Tesfaye S, Price KL, Bastyr EJ 3rd for the MBBQ Study Group. Treatment of Symptomatic Diabetic Peripheral Neuropathy with the Protein Kinase C ß-Inhibitor Ruboxistaurin Mesylate During a One-Year Randomized, Placebo-Controlled, Double-Blind Clinical Trial. *Clinical Therapeutics.* 2005 Aug; 27(8):1164-1180.

Bastyr EJ, Price KL, Bril V for the MBBQ Study Group. Development and Validity Testing of the Neuropathy Total Symptom Score-6: Questionnaire for the Study of Sensory Symptoms of Diabetic Peripheral Neuropathy. *Clinical Therapeutics.* 2005 Aug; 27(8):1278-1294.

Price, K. and Seaman, J.W. (2004) "Graphical Methods for Time-to-Pregnancy Data," Proceedings of the American Statistical Association, Section on Bayesian Statistics, [CD-ROM], Toronto, Canada: American Statistical Association, 2004.

Price, K. and Seaman, J.W. (2003) "Bayesian modeling of retrospective time-to-pregnancy data with digit preference bias," Proceedings of the American Statistical Association, Section on Bayesian Statistics, [CD-ROM], San Francisco, California: American Statistical Association, 2003.