Rebhi Bsharat

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# EDUCATION

# Kansas State University (KSU), Manhattan, Kansas

* **Doctorate of Philosophy in Statistics,** December 2007 GPA: 3.80/4.0

**Wichita State University (WSU), Wichita, Kansas**

* **Master of Science in Mathematics,** Summer 2002 GPA: 3.64/4.0

**Birzeit University, West Bank, Palestine**

* **Bachelor of Mathematics Applied to Economics,** Spring 2000 GPA: 3.23/4.0

EXPERTISE AND AREAS OF INTEREST

Bayesian Methods. Experimental Design. Tree Gate-keeping Strategies. Multiple Comparison procedures. Non-inferiority trials. Mixed models. CDISC, ADaM and STDM Standards. Dose-Response Methods. Leadership.

# EXPERIENCE

**Assistant Professor, An Najah National University, West Bank, Palestine, Aug 2017 – Present**

* Teaching Biostatistics classes for students in public health majors like medicine, nursing, pharmacy and clinical laboratories.
* Teaching Statistics classes for mechanical, civil and electrical engineers.
* Developing class notes using PowerPoint presentation to enhance electronic learning.
* Transforming the teaching environment to use applied and data-driven methods and techniques.

**Statistical Scientist, Quintiles, Durham, NC, Feb 2015 – May 2017**

* Acquired **SDTM** and **ADaM** certificates.
* Led a diabetes integrated efficacy and safety analysis to support **NDA** **submission**.
* Coordinated statistical reporting activities for multiple projects simultaneously.
* Developed and reviewed statistical section of protocols and statistical analysis plans in **Diabetes** based on study specific documents and sound statistical methodology.
* Wrote **Analysis Dataset and Report Specs**.
* Gave several seminars to junior and senior biostatistician about Adverse Event standards, Naming Conventions, CDISC standards.
* Took the following trainings: Blinded Data Review, Interim Analysis, Statistical Team Lead Responsibilities, ICH Guidelines, Good Clinical Practice, Oncology, Gastric Cancer, Breast Cancer, Colorectal Cancer, Working in a Regulated Environment, Business Ethics and Planning.
* Worked closely with programmers, data managers, clinicians and project managers in locking a Psoriasis phase III trial, a Diabetes phase II trial and an Oncology phase II trial.

**Senior Biostatistician, TransTech Pharma, High Point, NC, December 2013 – September 2014**

* Served as Lead Statistician for Phase I, II and III projects in Diabetes, Alzheimer, Muscle Atrophy and Weight Loss.
* Helped the Senior Management in Building the Biometrics Department by interviewing candidates and identifying department needs.
* Helped the biometrics team in following **CDISC** data standards.
* Managed CROs during several study conduct.
* Worked closely with CROs on delivering reports required for Investigational Brochures and Annual Reports.
* Helped the team in preparing concise efficacy and safety analyses for Due Diligence to attract business partners.
* Wrote a unified Statistical Analysis Plan Supporting Document to resolve common issues across different studies and programs.
* Wrote statistical sections of protocols and assisted study teams in outcome determination and sample size calculation.
* Developed and reviewed randomization schedules and implementation procedures.
* Built a risk-benefit model using a clinical utility index and bootstrap techniques to evaluate candidate treatments for phase II based on phase I data.
* Helped the team in performing PK and PK/PD analyses.
* Used JMP clinical for Visual Analytics to explore data, identify subgroups reacting to treatments and conduct efficient data reviews.

**Senior Statistician, Alcon Labs, Fort Worth, TX, May 2012 – May 2013**

* Served as Lead Statistician for Phase I, II and III projects.
* Wrote, revised and finalized Analysis Plans and shells and supported team in protocol development.
* Wrote statistical sections of protocols and assisted study teams in outcome determination and sample size calculation.
* Developed and reviewed randomization schedules and implementation procedures.
* Collaborated with Data Management and reviewed case report forms and edit checks specifications.
* Wrote specifications for datasets and study reports (tables, listings and figures).
* Attended trial team meetings and supported study teams in interim and final database locks.
* Performed Bayesian prediction analysis and helped study team in evaluating future safety concerns.
* Supported the study team in terminating a study based on scientific prediction and observing adverse events to protect patient safety.
* Conducted sensitivity analyses and evaluated study success under high dropout rates.

**Research Scientist, Lilly, Indianapolis, IN, December 2007 – April 2012**

* Served as Lead Statistician for several phase II, III and IV projects.
* Conducted sample size calculation and wrote statistical section of protocols and analysis plans.
* Participated in and supported a Biologic License Application submission.
* Learned about the Electronic Common Technical Document (eCTD) and its structure and contents.
* Participated with the compound team in preparing documents for type A, type B and type C meetings with the regulatory agency.
* Chaired a Weekly Diabetes Stat Seminar and organized a Stat Lunch & Learn.
* Managed vendor and CRO during several study conduct.
* Had weekly meeting with CRO statistician and programmer to plan timely and quality delivery of protocols, analysis plans, analysis dataset specifications, programming requirements, table shells and clinical study reports.
* Planned and wrote schedules for timely delivery of different work products by CRO.
* Worked with management and team members on developing an efficient standard operating procedure to communicate with CRO.
* Reviewed documents after being delivered by CRO and verified accuracy and integrity of work products.
* Conducted efficacy and safety meta-analyses.
* Wrote, revised and finalized Analysis Plans and shells and supported team in protocol development.
* Wrote statistical sections of protocols and assisted study teams in outcome determination and sample size calculation.
* Developed and reviewed randomization schedules and implementation procedures.
* Collaborated with Data Management and reviewed case report forms and edit checks specifications.
* Worked with SAS programmers on development of analysis database specifications and programming of tables, listings and figures.
* Validated programs and did quality control of tables, listings and figures produced by programmers.
* Assisted programmers in development, testing and maintenance of SAS macros to program tables, figures and listings.
* Designed dose-response, non-inferiority and superiority clinical trials.
* Worked with teams on several studies from design to reporting phase.
* Used SAS Drug Development in simulations and research.
* Participated in and used Critical Chain training in assigned projects.
* Collaborated with Center for Advanced Statistical Expertise and developed a tree gatekeeping multiplicity adjustment strategy for a phase 3 program.
* Participated in improving Standard Operating Procedures used in Global Statistical Sciences.
* Used subgroup tools to search for subgroups to detect safety concerns.
* Performed Bayesian indirect comparisons, Bayesian prediction of trail success given interim results, and Bayesian enrollment projection.
* Took trainings about Leadership, Communication, and Critical Chain.
* Supported the team in designing a Cardiovascular phase III trial to evaluate effect of drug on major Cardiovascular events.

**Summer Intern, Lilly, Indianapolis, IN, Summer 2006**

* Compared several dose-response methods using simulation to find the minimum effective dose of a drug.
* Took short and online courses about leadership skills, team-building skills, self-improvement, performance management, drug development, phases of clinical trials, clinical ethics and integrity.

###### SEMINARS

* Robust Estimation, Ph.D. Proposal, Dept of Statistics, KSU, August 2005
* Assessment of Dose-Response Methods, Lilly, August 2006
* Evaluation of nCk Estimators, Ph.D. Defense, Dept of Statistics, KSU, October 2007
* Bioequivalence Trails, Clinical Statistics Team, Lilly, April 2008
* Dose-Response Methods, GLP Investigator Start-Up Meeting, Lilly, October 2008
* International Conference of Harmonization Guidelines (E9), Global Statistical Sciences, Lilly, November 2008
* Introduction to Nonparametric Statistics, Clinical Stat Team, Lilly, February 2009
* Hypotheses Testing and Power, Clinical Extended Core Team, Lilly, April 2009
* Type I error Calculation for Non-inferiority Testing, Clinical Stat Team, Lilly, July 2009
* Tree Gate-keeping Procedures, Center for Advanced Statistical Expertise, Lilly, November 2009
* Longitudinal Categorical Data Analysis, Endosprom, Lilly, December 2009
* Statistical Analyses in Phase 3 Non-inferiority trial, Phoenix, AZ, January 2010
* Tree Gate-keeping Procedures, Diabetes Statistics, Lilly, March 2010
* Bayesian Enrollment Prediction, Clinical Core Team, Lilly, September 2010
* Compound PR Interval Analysis; Heart Conduction Safety Evaluation, Clinical Stat Team, Lilly, May 2011
* Generalized Estimating Equations, Clinical Stat Team, Lilly, August 2011
* Bayesian Indirect Comparisons to Predict Probability of Study Success in Diabetes, Diabetes Statistics, Lilly, January 2012
* Predicting Observing Drug Precipitates to protect Patient Safety using Bayesian Methods, Alcon Labs, December 2012
* Using Clinical Utility Index and Bootstrap to evaluate risk-benefit of a GLP compound, TransTech Pharma, May 2014
* Final Report Convention, Quintiles, April 2015
* Collapsing Adverse Events in ADAEME dataset, Quintiles May 2015
* Global Biostatistics Requirements, Quintiles, July 2015
* Using Utility Index to Evaluate Risk-Benefit of Several Doses to Help in Dose Selection, Duke-Industry Statistics Symposium, October 2015

###### PUBLICATIONS

* Grunberger G, Chang A, Garcia Soria G, Botros FT, Bsharat R and Milicevic Z.

Monotherapy with the once weekly GLP-1 analogue dulaglutide for 12 weeks in patients with type 2 diabetes: dose-dependent effects on glycaemic control in a randomized, double-blind, placebo-controlled study. Diabet Med. 2012 Oct; 29(10):1260-7

###### CONFERENCES and MEETINGS

* Applied Stat in agriculture, KSU, April 2004
* Applied Stat in agriculture, KSU, April 2005
* Midwest Biopharm Stat Conference, May 2008&2011
* Advisory Committee meeting for Liraglitude, July 2008
* Joint Statistical Meeting, August 2009
* Joint Statistical Meeting, August 2014
* Duke-Industry Statistical Symposium, October 2015

###### COMPUTER AND PROGRAMMING SKILLS

* SAS. Had 10-year experience with SAS on Windows. Used SAS daily to handle most of statistical work. Can manipulate large datasets, generate graphs, transfer data and files between SAS and other Softwares, design experiments and conduct simulation
* Splus/R. Used R for computational intensive simulations especially in resampling. Wrote high-level user-defined R functions
* JMP clinical. Used JMP clinical for exploratory analyses, modeling and visual analytics
* Minitab and Excel. Proficient in statistical analysis and graphing. Taught undergraduate classes using Minitab and Excel

###### SHORT COURSES

* Multiplicity, Discrete Repeated Measures, Bayesian Meta-Analysis, Bayesian Adaptive Methods, Leadership and Communication

**AWARDS**

* Outstanding Graduate Student Scholarship, $2,000, 2005, Dept of Statistics, KSU
* Recognition Award for organizing a Stat Lunch & Learn, 2010, Lilly
* Jefferson Outstanding Community Service Award, 2011, Lilly

**REFERENCES**

* Doug Moore, Statistical Programming Scientist, QuintilesIMS, Overland Park, Kansas, USA , dcmpvks@gmail.com, 913-708-9963
* Aditi Acharya, Biostatistician II, QuintilesIMS, Durham, North Carolina, USA, aditiacharya06@hotmail.com, 402-547-9963
* Imogene Dunn, Senior VP, Biometrics and Regulatory Affairs, vTv Therapeutics, High Point, North Carolina, USA,  IDunn@vTvTherapeutics.com, 336-880-8864