Mike Henderson

{{Creative, Curious, Compassionate},{Leader, Father, Husband},{Coder, Data Gentleman, Swell Bayesian}}

PROFILE

I am a lifetime learner with a background in statistics. My passion is for quantifying the patient experience in healthcare through better drug and device evaluation in research, development, clinical, and market settings. My career started with over a decade of clinical trial research covering drugs, devices, and combinations. I focused on inferential methods for patient-reported outcomes, efficient trial design and conduct, and the application of Bayesian methods. The most recent years have built on this experience in a customer advisory role at SAS to help life science, care providers, and healthcare companies apply analytical techniques to understand better and predict the impact of care on the patient experience.

I am passionate about computational engineering and work tirelessly to broaden my exposure. I utilize a wide range of skills and tools to enable deeper inferential and predictive health data evaluations in highly creative ways. I believe cloud computing is the radical change of our generation that gives us a chance to skip rethinking what we do and think new all over again.

Leadership Statement

The last 19 years have been a blast! Two companies, 11 years at one of the world's largest pharmaceutical companies and eight at one of the largest privately-held software companies, each with entirely different cultures. I have continuously reshaped my style and approach to match as well as counter-balance many types of leadership. My actions and words consistently focus on customers' interests, empowering direct reports, and growing the corporation before my own. I view leadership as a path that is continually unfolding from all directions.

EXPERIENCE

Current Public-Facing Work Leadership and a daily contributor to data for good collaboration between SAS and Cleveland Clinic. A multi-stage project started as a COVID-19 scenario tool focused on helping hospitals project and plan daily occupancy during the epidemic. It has expanded to a visual user-interface being used globally and extended to include resource optimization tools for reopening care facilities for surgical procedures. I continue to be a daily contributor to the public GitHub repository for these efforts and enjoy working with and learning from a fantastic team of caring people.

SAS; CARY, NORTH CAROLINA - OCTOBER 2012 - PRESENT

Senior Manager — April 2015 - PRESENT
Leadership for a group of statisticians and specialists focused on solving problems facing hospital systems, health insurance companies, pharmaceutical, device, and clinical research organizations. A focus on automating processes, augmenting decision making, and efficient architectures that work in the cloud and are scalable.

- Industry Focus Examples:

  - Member of SAS Global Industry Advisory Board for Health Care and Life Sciences focused on strategy for product development, organizational focus, partnerships and industry engagement
  - Speaker at a public workshop sponsored by the FDA: Improving the Implementation of Risk-Based Monitoring Approaches of Clinical Investigations
  - Maintain public GitHub repositories focused on the application and adoption of modern analytical methods for better inference and prediction
- Additional Sample Projects include:
  - Architecting a bursting model of distributed and parallelized computation for statistical simulations where users simply call functions that initiate, start, orchestrate, and shutdown clusters of computing across cloud services (AWS, Azure, GCP)
  - Scoring predictive models in a stream of data to trigger integrity feedback to providers
  - Building models with combinations of business rules and machine learning to detect fields needing review in electronic case report forms
  - Building a missing data imputation system using Bayesian MCMC methods
  - Setting up a parallel execution system for sample size simulations of adaptive clinical trial designs
  - Creating a tipping point analysis system that runs in a parallel computing environment
  - Building a missing value imputation system to examine the effect of dropout rates on outcomes for treatment groups and subgroups in clinical trials
  - Designing a Bayesian computation simulation to examine the response rate relative to dosing in early phase clinical trials

Manager - October 2013 - March 2015
Promoted to manage a team focused on solving problems for all business areas of pharmaceutical, device, and CRO companies. I continued to be hands-on and solve problems while also mentoring and coaching a team focused on data management, analytics, and decision delivery challenges. Worked with multiple companies to covert text from open narratives in adverse event reports to concepts and build predictive models that categorize events on risk of medically serious for expedited review and reporting. Implemented forecast models for adverse events to show new ways to determine when particular drug/event combinations were anomalous and trigger an investigation.

Solutions Architect — October 2012 - October 2013
Joined SAS and enjoyed the opportunity to view how clinical processes worked across many different device and pharmaceutical companies and work on the most challenging analytical problems they face. Projects included:

- Validating a signal detection system for drug adverse events while implementing the Bayesian MGPS method in SAS with PROC MCMC.
- Implementing a drug combination and sequencing model in a high-performance computing environment
- Parallelizing code for a Bayesian clinical trial simulation tool and a trial subgroup detection method to work on a cluster of computers using SAS.

JOHNSON & JOHNSON; JACKSONVILLE, FLORIDA - SEPTEMBER 2001 - OCTOBER 2012

Manager, Biostatistics — February 2011 - October 2012
Reported to the chief medical officer and worked to make the members of my team leaders of clinical programs. I partnered to build a new data management group focused on expanding clinical data collection to instrument data and PRO data acquisition programs. We developed a data stage with versioning that allowed analysis from any point in time to be recreated, differenced to any other point in time, and trigger onboard data integrity checks to give partners faster feedback through automation. We created a two-layer approach to our clinical data model from the data stage, the first step to an internal model that made queries across studies simple and a second step to SDTM. Participated in multiple FDA submissions and reviews and prepared materials for panel presentations. Involved in legal review and preparation of evidence to support product development representation in defenses.

Group Leader, Biostatistics — February 2008 - January 2011

Completed the creation and validation of a PRO instrument trademarked as CLUE: Contact Lens User Experience (now published and used across the industry). Further developed the tool for computer-adaptive testing to minimize the number of evaluations a patient needed to participate in and implemented direct data collection outside of clinical visits via SMS and web portals. This opened up a window into the patients' full day experiences throughout clinical trials and led to creating a new data management strategy. My role expanded to managing the statistical leads for all platforms covering the design of contact lenses, materials development, drug development, and combination drug/device development. I led a team of statisticians and statistical programmers and work conducted at CRO's and independent partners. I managed team growth through hiring, training, and coaching and collaboration with adjacent departments. Additional responsibilities included participating in reviewing investigator-initiated research proposals and developing best practices for research centers doing contract research to extend our internally lead clinical trial programs. I acted as lead statistician for all pediatric programs as we developed drug and device-based approaches to controlling myopia progression.

Senior Biostatistician — February 2006 - February 2008
An expanded role to include lead biostatistician responsibilities on new pharmaceutical development for vision care. Initiated a project that started as the quality of life assessment for contact lens wearers. After showing clinical value, this expanded to begin creating a Patient-Reported Outcomes (PRO) instrument designed along the NIH project PROMIS methodology to create a psychometric tool for accurate and continual patient experiences assessments. My work as a biostatistician expanded to include:

- signal detection methods for interactions between manufacturing variability and in-market adverse events
- managing the work of CRO's on multiple clinical platforms
- implementation of data standards
- leading the adoption of electronic data capture and direct data capture initiatives

Biostatistician II — July 2002 - February 2006
Promoted to be the lead statistician for all trials related to the design aspect of contact lenses: optical, geometry, stabilization, vision, comfort, handling. In this role, I guided CRO's on statistical analysis plans and data management plans. Involved in numerous FDA submissions and reviews that led to multiple new products going to market. Completed projects related to increasing the measurement accuracy of patients' perception of vision and comfort outside of controlled clinical environments.

Biostatistician — September 2001 - June 2002
Lead statistician for a new program for cosmetic contact lenses. While learning the on the job skills of biostatistician and statistical programming, I gained valuable experience including FDA submissions, measuring the impact of a manufacturing change on patient experience, working with marketing to accurately message clinical attributes, learning the data workflow of clinical trial processes.

Foundations - Jobs Before Graduating

I grew up in a diverse and very rural area. Attending a public school with the same classmates from kindergarten through high-school was a unique and fun experience. My first jobs were helping put up fences and cleaning floors after school. High-school summers played out assembling air conditioners in an unairconditioned plant. I started as an exam proctor in college and moved up to grader and eventually at honors calculus homework grading and tutoring. Graduate school was a progression from teaching undergraduates to assisting with graduate classes. Success in this was quickly followed by consulting projects with professors across the business school, social sciences, and agriculture. Continued success led to funding for becoming a research assistant, where I encountered the project that led me to bayesian statistics.

EDUCATION

UNIVERSITY OF GEORGIA, ATHENS, GEORGIA

M.S. Statistics, Graduated August 2001
Coursework: Tools for Statistical Theory, Theory of Linear Models, Statistical Inference, Statistical Con-

sulting, Statistical Analysis II, Special Topics in Statistics (Genetics), Probability Distributions, Multivariate Theory and Methods, Doctoral Research, Computing Techniques in Statistics, Clinical Trials Design and Inference, Categorical Data Analysis, Generalized Linear Models, Advanced Statistical Inference I, Advanced Applications and Computing in S/R
Honors: Outstanding Graduate Teaching Award
Published: Exploring the Confidence Interval for a Binomial Parameter in a First Course in Statistical Computing, The American Statistician, 2001

B.S. Mathematics, Graduated May 1999
Coursework: Calculus, Differential Equations, Partial Differential Equations, Linear Algebra, Numerical Analysis, Number Theory, Complex Analysis, Mathematical Statistics I and II, Probability

Primary Skills

Leadership	Inference & Prediction	Mining & Learning	Industry
Communication	Inferential Statistics	Boosting	Clinical Trial Design
Change Management	Bayesian Analysis	Neural Networks	Sample Size Estimation & Randomization
Presentation	Survival Analysis	Clustering Techniques	Parallel and Threaded Computing
Education	Forecasting	Probabilistic Graph Models	Anomaly Detection in Health Data
Delegation	Bayesian Filtering	Text Topic Discovery	Psychometric Scale Creation & Item-Response Theory
Strategic Thinking	Resampling Methods	Simulation Methods	Clinical Data Quality - Automated Detection & Monitoring

Tools Used

Expert Skills	Frequently Used	Developing Skills	Periodic Use Currently
git / GitHub / GitLab	SAS 9 / IML	Swift	SAS 9 / OR
SAS 9 / STAT	R	Tensorflow	Perl
Python	Docker	Golang	Matlab
SAS 9 / ETS	Ansible	Kubernetes	C
SAS Viya / CASL	HTML & CSS	PyTorch	Ruby & JS

Data

My experience covers data of all sizes and shapes: more rows than columns and more columns than rows. From dozens of values from research experiments to distributed data tables measured in terabytes. I am comfortable with accessing data from files, blobs, relational databases, and dozens of cloud technologies. I consider data access, preparation, quality, and governance to be core skills to be a great statistician. It is essential to be able to adapt to data stored in any location, in any format, and any volatility. Including subscribing and publishing to streaming data for near real-time inference and prediction. Authenticating and querying databases, NoSQL sources, Hadoop ecosystem components like HDFS and HIVE, flat files on drives, parallel access of parquet files, or anything needed to make data as close to the analysis runtime as possible. I am incredibly comfortable across the range of SQL writing to engineering a custom parsing engine in the language closest to the data source technology.

Data Architecture skills for designing

Familiar Technologies

Server and Virtual Machine	Public Cloud	Containerization	Hybrid Designs
Windows Server	Azure	Docker	On-Premises and Public Cloud
Linux (Redhat, Centos)	Amazon Web Services	Kubernetes	Multi-Cloud Bursting Models
	Google Cloud Platform		

CONTACT

CONTACT ME

COMMUNITY

Member of American Statistical Association since 2001

Joint Statistical Meeting Activities: * 2017 - Session Chair - Interim Monitoring and Analyses: Two-Stage, Multi-Stage, and Group Sequential Designs
* 2018 - Session Chair - Bayesian Clustering and Variable Selection * 2019 - Mentoring Program * 2020 - Panel participant for “Big Data, Technology Platform and Digital Innovation with Measurable Impact,” hosted by the ASA’s Text Analytics Interest Group