Mike Henderson

{{Creative, Curious, Compassionate},{Leader, Father, Believer},{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 also utilize a wide range of skills and tools to enable deeper inferential and predictive evaluations of health data in highly creative ways.

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 for 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; 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 get a view of 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; 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 in use 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 the creation of 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 as well as work conducted at CRO's and independent partners. I managed team growth through hiring, training, and coaching, as well as collaboration with adjacent departments. Additional responsibilities included participation in reviewing investigator-initiated research proposals and developing best practices for research centers doing contract research as an extension of 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 the creation of a Patient-Reported Outcomes 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.

EDUCATION

UNIVERSITY OF GEORGIA, ATHENS, GEORGIA

M.S. Statistics, Graduated August 2001

- **Coursework:** Tools for Statistical Theory, Theory of Linear Models, Statistical Inference, Statistical Consulting, 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

- **Highlight:** 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

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STACK

Primary Skills

Leadership	Inference	Prediction / Mining / Learning / Understanding	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
SQL	R	TensorFlow	Perl
Python	Docker	Golang	Matlab
SAS 9 / STAT & ETS	Ansible	Kubernetes	C
SAS Viya / CASL	HTML & CSS	PyTorch	Ruby & JS

Familiar Technologies

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

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