

## **Todd A. Durham**

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Foundation Fighting Blindness • (919) 656-5145 • [tdurham@fightingblindness.org](mailto:tdurham@fightingblindness.org)

### **PROFILE**

- A skilled communicator who collaborates with affected individuals and their families, clinicians, and product developers to accelerate the development of treatments and cures for inherited retinal diseases.
- A biostatistician and drug developer with over 25 years of experience supporting non-clinical, Phase 1-4 clinical development, observational, and post-marketing studies in multiple therapeutic areas including ophthalmology, dermatology, and cardiovascular disease.
- Uses training in biostatistics, outcomes research, and decision science to interpret data and evidence to inform business and policy decisions.

### **EDUCATION**

*University of North Carolina at Chapel Hill, Chapel Hill, NC*

PhD, Health Policy and Management / Decision Science and Outcomes Research

MS, Biostatistics

BSPH, Biostatistics

### **WORK EXPERIENCE**

*Senior Vice President, Clinical & Outcomes Research: Foundation Fighting Blindness, Columbia, MD, January 2019-present*

- Provide senior leadership and strategic guidance to clinical research activities conducted through the Foundation's Consortium of 40 inherited retinal disease specialists
- As Principal Investigator, lead and manage a 24,000 participant registry and genetic testing program of individuals affected with inherited retinal disease
- Organize and conduct disease-specific scientific workshops that include the perspectives of affected individuals, researchers, clinicians, and regulatory representatives

*FDA Special Government Employee: Department of Health and Human Services, Food and Drug Administration, Silver Spring, MD, 2021-present*

- Represent the consumer perspective when reviewing data on safety and effectiveness as a member of the Dermatologic and Ophthalmic Drugs Advisory Committee

*Head of Biometrics: Novan, Morrisville, NC, January-December 2018*

- Provided expert level biostatistical input into study design and analysis for Phase 1-3 clinical studies in dermatology
- Managed outsourcing partners for the biostatistics and data management functions
- Supported scientific publications, business development and investor relations

*Director, Biostatistics:* QuintilesIMS, Real World Evidence Solutions, Durham, NC, February 2017-December 2017

- Served as lead statistician on large, complex real-world studies.
- Mentored junior statistical staff.
- Supported a key partnership and other business development activities.
- Advanced the science of real-world evidence through presentations at scientific conferences.

*President and Statistical Consultant:* Durham Statistical Consulting LLC, Durham, NC, 2011-2017

- Designed studies, analyzed data, and prepared manuscripts in numerous areas including glaucoma, dry eye, cystic fibrosis, and manufacturing quality.
- Used Phase 2 data and Monte Carlo simulation to estimate the Phase 3 probability of technical success and select an optimal multiple testing strategy.
- Served as a statistical panelist for mock FDA Advisory Committees.
- Provided statistical writing services for joint regulatory and industry collaborations.
- Conducted statistical education workshops for non-statistical audiences.

*Doctoral Fellow:* Bristol Myers Squibb, Worldwide Health Economics and Outcomes Research, Princeton, NJ, August 2014 – July 2016

- Assisted with the development of protocols, manuscripts, and posters for observational studies using administrative claims data and electronic health records.
- Conducted literature reviews to identify priorities for real-world research opportunities.

*Director, Eastern Operations:* Axio Research LLC, Seattle, WA, 2011-2013

- Provided statistical consulting and analysis services to developers of drugs, devices, and biologics.
- Developed business opportunities and partnerships.

*Senior Director/Director, Biostatistics and Data Management:* Inspire Pharmaceuticals, Inc., Durham, NC, 2003-2011

- Provided statistical design and analysis expertise in ophthalmology, respiratory, and cardiovascular programs.
- Recruited and managed department staff of 4 statisticians, 2 statistical programmers and a data manager.
- Championed the adoption of statistical approaches to estimate the probability of success as a portfolio management tool.

*Associate Director/Senior Biostatistician/Biostatistician:* Quintiles, Inc., Durham, NC, 1995-2003

- Managed, mentored and trained a staff of 9 statisticians.
- Served in lead technical roles on 4 new drug applications and 5 FDA Advisory Committee meetings.

## **RESEARCH EXPERIENCE**

*Doctoral Research:* Department of Health Policy and Management, Gillings School of Global Public Health, University of North Carolina, August 2014-August 2016

- Described general practitioners' prescribing patterns of oral anticoagulants in a retrospective cohort of patients in the United Kingdom with newly diagnosed non-valvular atrial fibrillation.
- Developed new prediction models for the one-year competing risks of stroke, intracranial hemorrhage, extracranial hemorrhage, and death in a retrospective cohort of patients in the United Kingdom with newly diagnosed non-valvular atrial fibrillation.
- Used individual-based simulation to examine the population health impact of using the new predictive risk models to identify a preferred oral anticoagulant for individual patients.

*Graduate Research Assistant:* Department of Health Policy and Management, Gillings School of Global Public Health, University of North Carolina, January 2014-May 2014

- Used published literature and existing datasets to parameterize an agent-based model designed to evaluate the impact and cost-efficiency of four interventions to improve compliance with colorectal cancer screening in North Carolina.
- Prepared technical documentation for the agent-based model to be included in scientific manuscripts.

## **RESEARCH INTERESTS**

- Disease progression modeling
- Outcomes research
- Decision analysis
- Individual-based modeling and simulation

## **TEACHING EXPERIENCE**

*Course Director and Lecturer:* Campbell University, Clinical Research Program, 2005-2008

- Introduction to Biostatistics and Experimental Design

*Teaching Assistant:* University of North Carolina

- Math/Stata Tutorial, Fall 2013
- Leadership and Workforce Management Strategies in Healthcare Organizations, Spring 2013

*Guest Lecturer*

- Public Health Intervention and Evaluation, University of North Carolina, Fall 2015
  - Introduction to Economic Evaluation of Health Programs
- Health Services/Health Policy Research Methods, University of North Carolina, Fall 2013
  - Meta-Analysis of Data from a Systematic Review – Practical Considerations and Controversies
- Design and Analysis of Clinical Trials, University of North Carolina, Spring 2008
  - Clinical Trials and New Drug Development
- Statistics in Pharmaceutical Research, North Carolina State University, Spring 2008
  - Early Clinical Studies

- Phase 2 Studies
- Phase 3 Studies
- NDAs and Advisory Committee Meetings

## **PUBLICATIONS AND PRESENTATIONS**

### *Peer-Reviewed Journal Articles*

- Hufnagel RB, Liang W, Duncan JL, Brewer CC, Audo I, Ayala AR, Branham K, Cheetham JK, Daiger SP, **Durham TA**, Guan B, Heon E, Hoyng CB, Iannaccone A, Kay CN, Michaelides M, Pennesi ME, Singh MS, Ullah E; Foundation Fighting Blindness Consortium Investigator Group. Tissue-specific genotype-phenotype correlations among USH2A-related disorders in the RUSH2A study. *Hum Mutat.* 2022 May;43(5):613-624. doi: 10.1002/humu.24365. Epub 2022 Mar 21. PMID: 35266249; PMCID: PMC9018588.
- Lad EM, Duncan JL, Liang W, Maguire MG, Ayala AR, Audo I, Birch DG, Carroll J, Cheetham JK, **Durham TA**, Fahim AT, Loo J, Deng Z, Mukherjee D, Heon E, Hufnagel RB, Guan B, Iannaccone A, Jaffe GJ, Kay CN, Michaelides M, Pennesi ME, Vincent A, Weng CY, Farsiu S; Foundation Fighting Blindness Consortium Investigator Group. Baseline Microperimetry and OCT in the RUSH2A Study: Structure-Function Association and Correlation with Disease Severity. *Am J Ophthalmol.* 2022 Aug 22:S0002-9394(22)00318-X. doi: 10.1016/j.ajo.2022.08.013. Epub ahead of print. PMID: 36007554.
- Hufnagel RB, Liang W, Duncan JL, Brewer CC, Audo I, Ayala AR, Branham K, Cheetham JK, Daiger SP, **Durham TA**, Guan B, Heon E, Hoyng CB, Iannaccone A, Kay CN, Michaelides M, Pennesi ME, Singh MS, Ullah E; Foundation Fighting Blindness Consortium Investigator Group. Tissue-specific genotype-phenotype correlations among USH2A-related disorders in the RUSH2A study. *Hum Mutat.* 2022 May;43(5):613-624. doi: 10.1002/humu.24365. Epub 2022 Mar 21. PMID: 35266249; PMCID: PMC9018588.
- Birch DG, Samarakoon L, Melia M, Duncan JL, Ayala AR, Audo I, Cheetham JK, **Durham TA**, Iannaccone A, Pennesi ME, Stingl K; Foundation Fighting Blindness Consortium Investigator Group. The RUSH2A Study: Dark-Adapted Visual Fields in Patients With Retinal Degeneration Associated With Biallelic Variants in the USH2A Gene. *Invest Ophthalmol Vis Sci.* 2022 Mar 2;63(3):17. doi: 10.1167/iovs.63.3.17. PMID: 35293952; PMCID: PMC8944389.
- Iannaccone A, Brewer CC, Cheng P, Duncan JL, Maguire MG, Audo I, Ayala AR, Bernstein PS, Bidelman GM, Cheetham JK, Doty RL, **Durham TA**, Hufnagel RB, Myers MH, Stingl K, Zein WM; Foundation Fighting Blindness Consortium Investigator Group. Auditory and olfactory findings in patients with USH2A-related retinal degeneration-Findings at baseline from the rate of progression in USH2A-related retinal degeneration natural history study (RUSH2A). *Am J Med Genet A.* 2021 Dec;185(12):3717-3727.
- Gong J, Cheung S, Fasso-Opie A, Galvin O, Moniz LS, Earle D, **Durham T**, Menzo J, Li N, Duffy S, Dolgin J, Shearman MS, Fiorani C, Banhazi J, Daly A. The Impact of Inherited Retinal Diseases in the United States of America (US) and Canada from a Cost-of-Illness Perspective. *Clin Ophthalmol.* 2021 Jul 1;15:2855-2866. doi: 10.2147/OPHTH.S313719. PMID: 34234408; PMCID: PMC8257071.
- Sofia F, Cerolini S, **Durham T**. Report from a Workshop on Accelerating the Development of Treatments for Inherited Retinal Dystrophies Associated with Mutations in the RDH12 Gene. *Transl Vis Sci Technol.* 2020 Jul 17;9(8):30. doi: 10.1167/tvst.9.8.30. PMID: 32855876; PMCID: PMC7422783.
- Birch DG, Cheng P, Duncan JL, Ayala AR, Maguire MG, Audo I, Cheetham JK, **Durham TA**, Fahim AT, Ferris FL 3rd, Heon E, Huckfeldt RM, Iannaccone A, Khan NW, Lad EM,

- Michaelides M, Pennesi ME, Stingl K, Vincent A, Weng CY; Foundation Fighting Blindness Consortium Investigator Group. The RUSH2A Study: Best-Corrected Visual Acuity, Full-Field Electroretinography Amplitudes, and Full-Field Stimulus Thresholds at Baseline. *Transl Vis Sci Technol.* 2020 Oct 8;9(11):9. doi: 10.1167/tvst.9.11.9. PMID: 33133772; PMCID: PMC7552938.
- Duncan JL, Liang W, Maguire MG, Audo I, Ayala AR, Birch DG, Carroll J, Cheetham JK, Esposti SD, **Durham TA**, Erker L, Farsiu S, Ferris FL 3rd, Heon E, Hufnagel RB, Iannaccone A, Jaffe GJ, Kay CN, Michaelides M, Pennesi ME, Sahel JA; Foundation Fighting Blindness Consortium Investigator Group. Baseline Visual Field Findings in the RUSH2A Study: Associated Factors and Correlation With Other Measures of Disease Severity. *Am J Ophthalmol.* 2020 Nov;219:87-100. doi: 10.1016/j.ajo.2020.05.024. Epub 2020 May 22. PMID: 32446738.
  - Tying SK, Rosen T, Berman B, Stasko N, **Durham T**, Maeda-Chubachi T. A phase 2 controlled study of SB206, a topical nitric oxide-releasing drug for extragenital wart treatment. *Journal of Drugs Dermatology.* 2018; 17(10):1100-1105.
  - **Durham TA**, Hassmiller Lich K, Viera AJ, Fine JP, Mukherjee J, Weinberger M, Dusetzina SB. Utilization of standard and target-specific oral anticoagulants among adults in the United Kingdom with incident non-valvular atrial fibrillation: a retrospective cohort study. *American Journal of Cardiology* 2017. 120(10):1820-1829.
  - Hassmiller Lich K, Cornejo DA, Mayorga ME, Pignone M, Tangka FK, Richardson LC, Kuo TM, Meyer AM, Hall IJ, Smith JL, **Durham TA**, Chall SA, Crutchfield TM, Wheeler SB. Cost-Effectiveness Analysis of Four Simulated Colorectal Cancer Screening Interventions, North Carolina. *Prev Chronic Dis.* 2017 Feb 23;14:E18. doi: 10.5888/pcd14.160158. PMID: 28231042; PMCID: PMC5325466.
  - Goldstein MH, Martel JR, Sall K, Goldberg D, Abrams M, Rubin J, Sheppard J, Tauber J, Korenfeld M, Agahigian J, **Durham TA**, Furfine E. Multicenter study of a novel topical interleukin-1 receptor inhibitor, isunakinra, in subjects with moderate to severe dry eye disease. *Eye & Contact Lens: Science & Clinical Practice.* 2017; 43(5):287-296.
  - Ratjen F, **Durham T**, Navratil T, Schaberg A, Accurso FJ, Wainwright C, Barnes M, Moss RB, the TIGER-2 Study Investigator Group. Long term effects of denufosol tetrasodium in patients with cystic fibrosis. *Journal of Cystic Fibrosis.* 2012; 11:539-549.
  - Satin LZ, Turner RJ, **Durham T**. Assessing a drug's proarrhythmic liability: an overview of computer simulation modeling, nonclinical assays, and the thorough QT/QTc study. *DIJ.* 2011; 45:357-375.
  - Accurso FJ, Moss RB, Wilmott RW, Anbar RD, Schaberg AE, **Durham TA**, Ramsey BW. Denufosol tetrasodium in patients with cystic fibrosis and normal to mildly impaired lung function. *Am J Respir Crit Care Med.* 2011 March 1; 183(5): 627-634.
  - Johnson F, Boyer J, Leese P, Crean C, Krishnamoorthy R, **Durham T**, Fox A, Kellerman D. Rapid and reversible modulation of platelet function in man by a novel P2Y12 ADP-receptor antagonist, INS50589. *Platelets.* 2007 August; 18(5): 346-356.
  - LaVange LM, **Durham TA**, and Koch GG. Randomization-based nonparametric methods for the analysis of multicentre trials. *Stat Methods Med Res.* 2005 Jun;14 (3): 281-301.

#### *Books and Book Chapters*

- Ayala A, Cheetham J, **Durham T**, Maguire M. The Importance of Natural History Studies in Inherited Retinal Diseases. *Cold Spring Harb Perspect Med.* 2023 Jan 23:a041297. doi: 10.1101/cshperspect.a041297. Epub ahead of print. PMID: 36690461.
- **Durham T**, Banhazi J, Patalano F, Jayasundera T. Beyond the NEI-VFQ: Recent Experience in the Development and Utilization of Patient-Reported Outcomes for Inherited Retinal Diseases. *Cold Spring Harbor Perspectives in Medicine.* 2022 Oct:a041298. DOI:

10.1101/cshperspect.a041298. PMID: 36220332.

- **Durham T** and Turner JR. Introduction to Statistics in Pharmaceutical Clinical Trials. London: Pharmaceutical Press; 2008. ISBN: 978-0-85369-714-5.
- Turner JR and **Durham TA**. Integrated Cardiac Safety: Assessment Methodologies for Noncardiac Drugs in Discovery, Development, and Postmarketing Surveillance. New York: John Wiley & Sons; 2009. ISBN: 978-0-470-22964-4.
- **Durham T**, Koch G, LaVange L. Introduction to Statistics in Medical Research in Principles of Research Methodology: a Guide for Clinical Professionals. Supino PG and Borer JS (Eds). New York: Springer; 2012. ISBN: 978-1-4614-3359-0.

### *Oral Presentations*

- **Durham T**. Setting Up and Contributing to a Patient Registry. Oral presentation at ARVO Learn's virtual conference, Getting the Most from Big Datasets: Where to Find them and How to Use them Effectively; December 9, 2020.
- **Durham T**. Utilizing Natural History Studies to Inform Clinical Trial Design. Oral presentation at Gene Therapy for Ophthalmic Disorders; August 6, 2020.
- **Durham T**. Studies using Real-World Data in the Product Lifecycle: Frequently Useful, Sometimes Necessary, and Occasionally Dangerous. Oral presentation at PhUSE US Connect 2018; June 4, 2018; Raleigh, NC.
- **Durham T**. Novel prediction models for the one-year competing risks of stroke, intracranial hemorrhage, extracranial hemorrhage, and death in adults with incident non-valvular atrial fibrillation. Oral presentation at Duke-Industry Statistics Symposium. September 6, 2017; Durham, NC.
- **Durham T**. Using Real World Data to Simulate Clinical Trial Enrollment: Benefits and Challenges. Oral presentation at ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop. September 27, 2017; Washington DC.
- **Durham T**. Thoughts on the use of decision analysis in the review of new drug applications. Oral presentation at the meeting of the Statistical and Applied Mathematical Sciences Institute (SAMSI); October 3, 2007; Durham NC.

### *Editorials and Commentary*

- **Durham TA**, Duncan JL, Ayala AR, Birch DG, Cheetham JK, Ferris FL 3<sup>rd</sup>, Hoyng CB, Pennesi ME, Sahel JA; Foundation Fighting Blindness Consortium Investigator Group. Tackling the Challenges of Product Development Through a Collaborative Rare Disease Network: The Foundation Fighting Blindness Consortium. *Transl Vis Sci Technol.* 2021 Apr 1;10(4):23. doi: 10.1167/tvst.10.4.23.
- Shaberman B, **Durham T**. The Foundation Fighting Blindness Plays an Essential and Expansive Role in Driving Genetic Research for Inherited Retinal Diseases. *Genes.* 2019; 10(7):511. <https://doi.org/10.3390/genes10070511>.
- **Durham TA**. (2018). How did these data get here? Recommendations for the analysis of data from clinicaltrials.gov. *Therapeutic Innovation & Regulatory Science.*
- Turner JR and **Durham TA**. (2015). Must new drugs be superior to those already available? The role of noninferiority clinical trials. *The Journal of Clinical Hypertension.* 17(4):319-21.

- Turner JR and **Durham TA**. (2014), Meta-methodology: conducting and reporting meta-analyses. *The Journal of Clinical Hypertension*. 16(2):91-3.

### **AWARDS AND HONORS**

*Harry T. Phillips Award for Outstanding Teaching by a Doctoral Student*: University of North Carolina, Gillings School of Global Public Health, University of North Carolina, 2014

*Richard Evans Team Award*: Inspire Pharmaceuticals, 2009

- This award was given annually to an Inspire team that demonstrates exemplary performance in effort and outcome. The criteria for the award include: synergy; resourcefulness and creativity; accountability; determination; and quality. The Biostatistics Department was recognized with this award.

*Leigh Thompson Science Award*: Inspire Pharmaceuticals, 2008

- The Leigh Thompson Science Award was given annually to an Inspire employee for overall excellence in scientific achievement. The award recipient will have played a primary role in conducting scientific research resulting in significant, positive impact on the organization while also making valuable contributions to scientific dialogue.