

**Sonia Thomas, DrPH**  
(Formerly Sonia Davis, Sonia Kropp)

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**Senior Research Statistician**  
**RTI International**

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SUMMARY

Rigorous applied biostatistician with exceptional collaborative and leadership skills for the design, implementation and analysis of clinical trials and observational studies.

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EDUCATION

<b>DrPH in Biostatistics</b> , University of North Carolina, Chapel Hill, NC	<b>1994</b>
<b>MS in Biostatistics</b> , University of North Carolina, Chapel Hill, NC	<b>1990</b>
<b>BSPH in Biostatistics</b> , University of North Carolina, Chapel Hill, NC	<b>1988</b>

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EXPERIENCE

*RTI International, Durham, NC*

**Senior Research Statistician**, *Division of Biostatistics and Epidemiology* **2017-**

Principal Investigator and/or lead statistician of NIH-funded Data Coordinating Centers (DCCs) for clinical trials or clinical research networks. Projects include Administrative Coordinating Center PI of a \$500m NHLBI-wide program of multi-center adaptive COVID-19 clinical trials and research studies, DCC PI of an NHLBI-funded double-blind clinical trial for HHT (a rare bleeding disorder), DCC Alternate PI of an NICHD clinical research network of surgical interventions for women's pelvic floor disorders, principal statistician of a PCORI-funded clinical trial of behavioral interventions with EHR data collection, and DCC Deputy PI of DoD clinical trial consortium for Gulf War Illness.

*University of North Carolina, Chapel Hill, NC*

**Professor of the Practice**, Department of Biostatistics **2012-2017**  
**Director, Collaborative Studies Coordinating Center**

Directed a research data coordinating center comprised of 80 faculty, staff, and students with \$14 million annual expenditures. Led strategic planning, oversaw operations, mentored junior faculty. Led development of SOPs and improved processes. Wrote NIH grant proposals for data coordinating centers. Collaborated with UNC medical and dental faculty. Led clinical trial and observational study projects as Data Coordinating Center PI or co-Investigator. Contributed to clinical trial design and co-authored protocols. Designed interim analyses for efficacy, futility, and sample size re-estimation. Led statistical analyses including multiple imputation, inverse probability weighting, multivariable prediction modeling. Authored a book chapter on MMRM. Co-authored collaborative manuscripts. Led independent DSMB reporting of pharmaceutical clinical trials. Member of multiple DSMBs. Taught clinical trial statistical methods and leadership to graduate students. Gave short courses and presentations at national conferences. Therapeutic areas included Alzheimer's disease, neurocognitive functioning, pulmonary functioning, pediatric ulcerative colitis, Type 2 diabetes in pregnancy, physical activity measured by accelerometer, microbiome, burn scars, ADHD, acute critical care, dental health.

*Quintiles, Inc. Morrisville, NC, Department of Biostatistics*

**Senior Director** **2008-2012**

Departmental management with emphasis on staff training. Senior statistical leadership on design, implementation, analysis and reporting of multi-center pharmaceutical Phase II-IV clinical trials. Mentored staff and customers. Provided senior statistical reviews. Led independent DSMB and interim analysis reporting. Co-authored collaborative manuscripts. Interacted with expert consultants. Led development of ISE/ISS reports for NDA submissions and participated in regulatory and advisory meetings. Provided statistical

training seminars worldwide within the company. Statistical expertise including DSMBS, futility analysis, MMRM, equivalence and non-Inferiority, multiple comparisons, complex randomizations. Therapeutic areas included schizophrenia, Alzheimer's disease, depression, bipolar, alcohol dependence, Parkinson's disease, rheumatoid arthritis, benign prostatic hyperplasia

**Director** 2002-2008  
**Associate Director** 2000-2002  
**Manager** 1997-2000  
**Senior Statistician** 1996-1997  
**Biostatistician II** 1995

*University of North Carolina, Chapel Hill, NC*

**Visiting Associate Professor**, Department of Psychiatry 2005-2009

Conducted statistical analysis and prepared manuscripts for the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) program

**Statistician II**, Collaborative Studies Coordinating Center 1990-1991

**Graduate and Undergraduate Research Assistant**, Biometric Consulting Lab. 1991-1994

Analyzed data from research studies under the direction of Gary Koch 1986-1990

#### AWARDS AND HONORS

RTI President's Award 2020

RTI Career Author Award 2018

Doctoral written examination Special Commendation 1993

Delta Omega Public Health Honor Society 1990

US Public Health Service Training Grant 1988-1994

BSPH graduated with Highest Distinction 1988

Delta Omega Undergraduate Award for Excellence 1988

#### PUBLICATIONS (113 PUBLISHED)

##### REFEREED PAPERS

1. Mo A, Nagpal S, Gettler K, Haritunians T, Giri M, Haberman Y, Karns R, Prince J, Arafat D, Hsu NY, Chuang LS, Argmann C, Kasarskis A, Suarez-Farinas M, Gotman N, Mengesha E, Venkateswaran S, Rufo PA, Baker SS, Sauer CG, Markowitz J, Pfefferkorn MD, Rosh JR, Boyle BM, Mack DR, Baldassano RN, Shah S, LeLeiko NS, Heyman MB, Griffiths AM, Patel AS, Noe JD, **Davis Thomas S**, Aronow BJ, Walters TD, McGovern DPB, Hyams JS, Kugathasan S, Cho JH, Denson LA, Gibson G. Stratification of risk of progression to colectomy in ulcerative colitis via measured and predicted gene expression. *Am J Hum Genet.* 2021 Sep 2;108(9):1765-1779. doi: 10.1016/j.ajhg.2021.07.013. Epub 2021 Aug 26. PMID: 34450030.
2. Rogers RG, Meyer I, Smith AL, Ackenbom M, Barden L, Korbly N, Mazloomdoost D, **Thomas S**, Nager C. Improved body image after uterovaginal prolapse surgery with or without hysterectomy. *International Urogynecology Journal.* 2021 Aug 25. doi: 10.1007/s00192-021-04954-0. Epub ahead of print. PMID: 34432089.
3. Nager CW, Visco AG, Richter HE, Rardin CR, Komesu Y, Harvie HS, Zyczynski HM, Paraiso MFR, Mazloomdoost D, Sridhar A, **Thomas S**. Effect of sacrospinous hysteropexy with graft vs vaginal hysterectomy with uterosacral ligament suspension on treatment failure in women with uterovaginal prolapse: 5 year results of a randomized clinical trial. *American Journal OF Obstetrics and Gynecology.* 2021 Aug;225(2):153.e1-153.e31. doi: 10.1016/j.ajog.2021.03.012. Epub 2021 Mar 12. PMID: 33716071; **PMCID: PMC8328912**.
4. **Thomas SM**, Jung K, Sun, H, Psioda MA, Quibera PM, Strakowski S (2020). Enhancing clarity of clinical trial safety reports for Data Monitoring Committees. *Journal of Biopharmaceutical Statistics.* 2020 Nov 1;30(6):1147-1161. doi: 10.1080/10543406.2020.1815034. Epub 2020 Sep 8. PMID: 32897808.

5. Mack D, Saul B, Boyle B, Griffiths A, Sauer C, Markowitz J, LeLeiko N, Keljo D, Rosh J, Baker S, Steiner S, Heyman M, Patel A, Baldassano R, Noe J, Rufo P, Kugathasan S, Walters T, Marquis M, **Thomas S**, Denson L, Hyams J, PROTECT STUDY GROUP (2020) Analysis of Using the Total White Blood Cell Count to Define Severe New Onset Ulcerative Colitis in Children. *Journal of Pediatric Gastroenterology and Nutrition*. 2020 Sep;71(3):354-360. doi: 10.1097/MPG.0000000000002797. PMID: 32520830.
6. Sung VW, Menefee S, Dunivan G, Richter HE, Moalli P, Weidner A, Andy UU, Jelovsek E, Mazloomdoost D, Whitworth R, **Thomas S**, NICHD Pelvic Floor Disorders Network. Design of a study to measure patient-perspectives in adverse event reporting (the PPAR study): Supplementary study to the ASPIRE trial. *Female Pelvic Med Reconstr Surg*. 2021 Jan 1;27(1):e112-e117. doi: 10.1097/SPV.0000000000000845. PMID: 32487881; **PMCID: PMC8087185**.
7. Menefee S, Richter HE, Myers D, Weidner A, Moalli P, Harvie H, Rahn D, Jeppson P, Paraiso M, **Thomas S**, Mazloomdoost D. Design of a 3-Arm Randomized Trial for Posthysterectomy Vault Prolapse Involving Sacral Colpopexy, Transvaginal Mesh, and Native Tissue Apical Repair: The Apical Suspension Repair for Vault Prolapse in a Three-Arm Randomized Trial. *Female Pelvic Med Reconstr Surg*. 2020 Jul;26(7):415-424. doi: 10.1097/SPV.0000000000000803. PMID: 31860566; **PMCID: PMC7326314**.
8. Harvie HS, Amundsen CL, Neuwahl SJ, Honeycutt AA, Lukacz ES, Sung VW, Rogers RG, Ellington D, Ferrando CA, Chermansky CJ, Mazloomdoost D, **Thomas S**. Cost-Effectiveness of Sacral Neuromodulation versus OnabotulinumtoxinA for Refractory Urgency Urinary Incontinence: Results of the ROSETTA Randomized Trial. *J Urol*. 2020 May;203(5):969-977. doi: 10.1097/JU.0000000000000656. Epub 2019 Nov 18. PMID: 31738113; **PMCID: PMC7204548**.
9. González HM, Schneiderman N, Fornage M, Zeng D, Youngblood M, Gallo LC, Daviglius ML, Kaplan R, Ramos AR, Vasquez PM, Lamar M, **Thomas S**, Chai A, DeCarli C, Tarraf W. (2019) Prevalence and Risks for Mild Cognitive Impairment among diverse middle-aged and older Hispanics/Latinos: Hispanic Community Health Study/Study of Latinos-Investigation of Neurocognitive Aging results (SOL-INCA). *Alzheimer's Disease and Dementia*. 2019 Dec;15(12):1507-1515. doi: 10.1016/j.jalz.2019.08.202. Epub 2019 Nov 18. **PMCID: PMC7171942**.
10. González HM, Tarraf W, Fornage M, Trujillo González K, Chai A, Youngblood M, Abreu M, Zeng D, **Thomas S**, Talavera GA, Gallo LC, Kaplan R, Daviglius M, Schneiderman N. (2019) A research framework for cognitive aging and Alzheimer's disease among diverse US Latinos: Design and implementation of the Hispanic Community Health Study/Study of Latinos – Investigation of Neurocognitive Aging (SOL-INCA). *Alzheimer's Disease and Dementia* 2019 Dec;15(12):1624-1632. doi: 10.1016/j.jalz.2019.08.192. Epub 2019 Nov 20. **PMCID: PMC6925624**
11. Murillo R, Pirzada A, Wu, D, Gallo L, **Davis S**, Ostrovsky NW, Penedo FJ, Perreira K, Reina SA, Van Horn L, Stamler J, Daviglius ML (2019). The Association between Social Network Size and Healthy Lifestyle Factors: Results from the Hispanic Community Health Study/Study of Latinos (HCHS/SOL). *Journal of Behavioral Medicine*. 2020 Apr;43(2):198-208. doi: 10.1007/s10865-019-00082-9. Epub 2019 Jul 26 **PMCID: PMC7340005**.
12. Andy U, Amundsen C, Honeycutt E, Markland A, Dunivan G, Dyer K, Korbly N, Bradley M, Vasavada S, Mazloomdoost D, **Thomas S** (2019). Impact of Refractory Urgency Urinary Incontinence treatment on fecal incontinence symptoms and sexual function. *American Journal of Obstetrics and Gynecology*. 2019 Nov;221(5):513.e1-513.e15. doi: 10.1016/j.ajog.2019.06.018. Epub 2019 Jun 15. **PMCID: PMC6911169**.
13. Patel MD, Platts-Mills TF, Grover JM, **Thomas SM**, Rossi JS. A pilot study of the feasibility of prehospital delivery of remote ischemic conditioning by emergency medical services in chest pain patients. (2019) *Pilot and Feasibility Studies*. 5:42 <https://doi.org/10.1186/s40814-019-0431-8> **PMCID: PMC6415490**
14. Fox RS, Carnethon MR, Gallo LC, Wiley JF, Isasi CR, Daviglius ML, Cai J, **Davis SM**, Giachello AL, Gonzalez P, McCurley JL, Schneiderman N, Penedo FJ (2019). Perceived Discrimination and Cardiometabolic Risk among U.S. Hispanics/Latinos in the HCHS/SOL Sociocultural Ancillary Study. *International Journal of Behavioral Medicine*. 2019 Aug;26(4):331-342. doi: 10.1007/s12529-019-09782-7 **PMCID: PMC7294575**.
15. Haberman Y, Karns R, Dexheimer PJ, Bauman L, Collins MH, Rosen M, Bonkowski E, Gotman N, Marquis A, Rufo PA, Baker SS, Sauer CG, Markowitz J, Pfeifferkorn MD, Rosh JR, Boyle BM, Mack DR, Baldassano RN, Keljo DJ, Leleiko NS, Heyman MB, Griffiths AN, Patel AS, Noe JD, Aronow BJ, Kugathasan S, Walters TD, **Davis Thomas S**, Hyams JS, Denson LA. (2019) The Ulcerative Colitis Mucosal Transcriptome Reveals a Profound Mitochondriopathy and Personalized Mechanisms Underlying Disease Severity and Treatment Response. *Nature Communications*. 2019 Jan 3;10(1):38. doi: 10.1038/s41467-018-07841-3.

**PMCID: PMC6318335.**

16. Hyams J, **Davis Thomas S**, Gotman N, Haberman Y, Karns R, Schirmer M, Mo A, Mack D, Boyle B, Griffiths A, Leleiko N, Sauer C, Keljo D, Markowitz J, Baker S, Rosh J, Baldassano R, Patel A, Pfefferkorn M, Otley A, Heyman M, Noe J, Oliva-Hemker M, Rufo P, Strople J, Ziring D, Guthery S, Sudel B, Benkov K, Wali P, Moulton D, Evans J, Kappelman M, Marquis A, Sylvester F, Collins M, Venkateswaran S, Dubinsky M, Tangpricha V, Spada K, Saul B, Wang J, Serrano J, Hommel K, Marigorta U, Gibson G, Xavier R, Kugathasan S, Walters T, Denson L (2019) Clinical and Biological Predictors of Response to Standardised Paediatric Colitis Therapy: A Multicentre Inception Cohort Study. *Lancet* 2019 Apr 27;393(10182):1708-1720. doi: 10.1016/S0140-6736(18)32592-3. Epub 2019 Mar 29. **PMCID: PMC6501846**
17. Berry DC, **Davis Thomas S**, Dorman K, Ivins A, Abreu MIA, Young L, Boggess K (2018). Rationale, Design, and Methods for the Medical Optimization and Management of Pregnancies with Overt Type 2 Diabetes (MOMPOD). *BMC Pregnancy and Childbirth*. 18:488. <https://doi.org/10.1186/s12884-018-2108-3> **PMCID: PMC6292086**
18. Schirmer M, Denson, L, Vlamakis H, Franzosa EA, **Thomas SM**, Gotman NM, Rufo P, Baker S, Sauer C, Markowitz J, Pfefferkorn M, Oliva-Hemker M, Rosh J, Otley A, Boyle B, Mack D, Baldassano R, Keljo D, Leleiko N, Heyman M, Griffiths A, Patel A, Noe J, Kugathasan S, Walters T, Huttenhower C, Hyams J, Xavier RJ (2018) Gut microbial factors implicated in disease progression and treatment response in pediatric ulcerative colitis. *Cell Host and Microbes*. 2018 Oct 10;24(4):600-610.e4. doi: 10.1016/j.chom.2018.09.009. **PMCID: PMC6277984**
19. Deal JA, Sharrett AR, Albert M, Bandeen-Roche K, Burgard S, **Davis Thomas S**, Gottesman RF, Knopman D, Mosley T, Klein B, Klein R (2018). Retinal Signs and Risk of Incident Dementia in the Atherosclerosis Risk in Communities Study. *Alzheimer's and Dementia*. 2019 Mar;15(3):477-486. doi: 10.1016/j.jalz.2018.10.002. Epub 2018 Nov 12. **PMCID: PMC6408967**
20. Deal JA, Goman AM, Albert MS, Arnold ML, Burgard S, Chisolm T, Couper D, Glynn NW, Gmelin T, Hayden KM, Mosley T, Pankow JS, Reed N, Sanchez VA, Sharrett AR, **Thomas SD**, Coresh J, Lin FR. Hearing Treatment for Reducing Cognitive Decline: Design and Methods for the Aging and Cognitive Health Evaluation in Elders (ACHIEVE) Randomized Controlled Trial. *Alzheimer's & Dementia: Translational Research & Clinical Interventions*. 2018 Oct 5;4:499-507 PMID [30364572](https://pubmed.ncbi.nlm.nih.gov/30364572/) DOI: [10.1016/j.trci.2018.08.007](https://doi.org/10.1016/j.trci.2018.08.007) **PMCID: PMC6197326**
21. Muhlebach M, Tunney M, Hatch J, Gotman J, **Davis Thomas S**, Mirkovic B, McElvaney NG, Lavelle G, Elborn S, Wolfgang M, Boucher RC. (2018) Anaerobic bacteria cultured from CF airways correlate to milder disease-a multisite study. *European Respiratory Journal*. 2018 Jul;52(1). doi: 10.1183/13993003.00242-2018. Print 2018 Jul. **PMCID: PMC6376871**.
22. Guo Y, Moon J, Laurie C, North K, Sanchez-Johnsen L, **Davis S**, Nyenhuis S, Kaplan R, Rastogi D, Qibin Qi (2018). Genetic Predisposition to Obesity is associated with Asthma in US Hispanics/Latinos: Results from the Hispanic Community Health Study/Study of Latinos (HCHS/SOL). *Allergy*. 2018 Jul;73(7):1547-1550. doi: 10.1111/all.13450. Epub 2018 Apr 22 **PMCID: PMC6019147**.
23. Knopman D, Gottesman R, Sharret R, Tapia A, **Davis Thomas S**, Windham G, Coker L, Schneider A, Alonso A, Coresh J, Albert M, Mosley T (2018) Midlife vascular risk factors and midlife cognitive status in relation to Prevalence of Mild Cognitive Impairment and Dementia in later life. *Alzheimer's and Dementia*. 14(11):1406-1415 doi: 10.1016/j.jalz.2018.03.011 **PMCID: PMC6231996**
24. González HM, Tarraf W, Vásquez P, Sanderlin AH, Rosenberg NI, **Davis S**, Rodríguez CJ, Gallo LC, Thyagarajan B, Daviglius M, Khambaty T, Cai J, Schneiderman N (2018). Metabolic Syndrome and Neurocognition Among Diverse Middle-Aged and Older Hispanics/Latinos: HCHS/SOL Results. *Diabetes Care* 2018 Apr; dc171896. <https://doi.org/10.2337/dc17-1896> **PMCID: PMC6014545**
25. Burkart KM, Sofer T, London SJ, Manichaikul A, Hartwig FP, Yna Q, Artigas MS, Avila L, Chen W, **Davis Thomas SM**, Diaz, AA, Hall IP, Horta, BL, Kaplan RC, Laurie CC, Menezes AM, Morrison JV, Oelsner EC, Rastogi D, Rich SS, Soto-Quiros M, Stilp AM, Tobin MD, Wain LV, Celedón JC, Barr, RG. (2018) Genome-Wide Association Analyses in Hispanics/Latinos identify novel signals for Lung Function: The Hispanic Community Health Study/Study of Latinos. *Am J of Respiratory and Critical Care Medicine*. 2018 Jul 15;198(2):208-219. doi: 10.1164/rccm.201707-1493OC. **PMCID: PMC6058984**.
26. Hibbard JC, Friedstadt JS, **Thomas SM**, Edkins RE, Hultman CS, Kosorok MR (2018). LIBERTI: A SMART Study in plastic surgery. *Clinical Trials*. 15(3): 286-293. <https://doi.org/10.1177/1740774518762435> **PMCID: PMC5990436**
27. Spencer E, **Davis S**, Mack D, Boyle B, Griffiths A, LeLeiko N, Sauer C, Keljo D, Markowitz J, Baker S, Rosh J, Baldassano R, Oliva-Hemker M, Pfefferkorn M, Otley A, Heyman M, Noe J, Patel A, Rufo P,

- Strople J, Ziring D, Guthery S, Benkov K, Wali P, Sudel B, Moulton D, Marquis A, Collins M, Venkateswaran S, Denson L, Kugathasan S, Dubinsky MC, Hyams J (2018). Serologic Reactivity Reflects Clinical Expression of Ulcerative Colitis in Children. *Inflammatory Bowel Diseases*. 24(6), 1335-1343. DOI: 10.1093/ibd/izy009 **PMCID: PMC6093192**
28. Venkateswaran S, Prince J, Cutler DJ, Marigorta UM, Okou1 DT, Prahalad S, Mack D, Boyle B, Walters T, Griffiths A, Sauer C, LeLeiko N, Keljo D, Markowitz J, Baker S, Rosh J, Pfefferkorn M, Heyman M, Patel A, Otle A, Baldassano R, Noe J, Rufo P, Oliva-Hemker M, **Davis S**, Zwick ME, Gibson G, Denson LA, Hyams J, Kugathasan S (2018). Enhanced Contribution of HLA in Childhood Onset Ulcerative Colitis. *Inflammatory Bowel Diseases*. 24(4): 829-838 doi: 10.1093/ibd/izx084. **PMCID: PMC6350448**
29. Hernandez R, González, HM, Tarraf W, Carnethon MR, Gallo LC, Penedo FJ, Isasi CR, Ruiz JM, Arguelles W, Buelna C, **Davis S**, Gonzalez F, Wu D, McCurley J, Daviglius ML (2018). The Association of Disposition Optimism and Life's Simple 7's Cardiovascular Health Index: Results from the Hispanic Community Health Study/Study of Latinos (HCHS/SOL) Sociocultural Ancillary Study. *BMJ Open*, 8(3): e019434 [10.1136/bmjopen-2017-019434](https://doi.org/10.1136/bmjopen-2017-019434). **PMCID: PMC5875660**
30. Tarraf W, Criqui MH, Allison MA, Wright CB, Fornage M, Daviglius M, Kaplan RC, **Davis S**, Conceicao AS, Gonzalez HM (2018) Ankle Brachial Index and cognitive function among Hispanics/Latinos: Results from the Hispanic Community Health Study/Study of Latinos. *Atherosclerosis*. 271:61-69 DOI: <https://doi.org/10.1016/j.atherosclerosis.2018.02.016> **PMCID: PMC6467470**
31. Sauer, GC, Loop M, Venkateswaran S, Tangpricha V, Ziegler TR, Dhawan A, McCall C, Bonkowski E, Mack D, Boyle B, Griffiths A, LeLeiko N, Keljo D, Markowitz J, Baker S, Rosh J, Baldassano R, **Davis, S**, Patel A, Wang J, Marquis A, Spada K, Kugathasan S, Walters T, Hyams J, Denson LA (2018). Free and Bioavailable 25-Hydroxy Vitamin D Concentrations are Associated with Disease Activity in Pediatric Patients with Newly Diagnosed Treatment Naïve Ulcerative Colitis. *Inflammatory Bowel Diseases*. 24(3):641-650 doi: <https://doi.org/10.1093/ibd/izx052> **PMCID: PMC6176888**
32. Butler-Bente E, Laber EB, **Davis SM**, Kosorok MR. (2018) Incorporating patient preferences into estimation of optimal individualized treatment rules. *Biometrics*. 74:18–26 doi: 10.1111/biom.12743. **PMCID: PMC5785589**
33. Afshar M, Wu D, Durazo-Arvizu R, Aguilar FG, Kalhan R, **Davis SM**, Kaplan D, Klein OL, Mendes EP, Pattany MS, Daviglius ML. (2017) Association of serum lipids and obstructive lung disease in Hispanic/Latino adults of diverse backgrounds. *Journal of Pulmonary and Respiratory Medicine*. 7: 419. doi: 10.4172/2161-105X.1000419. **PMCID: PMC5619869**
34. Hyams J, **Davis S**, Mack D, Boyle B, Griffiths A, Leleiko N, Sauer C, Keljo D, Markowitz J, Baker S, Rosh J, Baldassano R, Patel A, Pfefferkorn M, Otle A, Heyman M, Noe J, Oliva-Hemker M, Rufo P, Strople J, Ziring D, Guthery S, Sudel B, Benkov K, Wali P, Moulton D, Evans J,, Kappelman M, Marquis A, Sylvester F, Collins M, Venkateswaran S, Dubinsky M, Tangpricha V, Spada K, Britt A, Saul B, Gotman N, Wang J, Serrano J, Kugathasan, S, Walters T, Denson L (2017). Factors associated with early outcomes following standardized initial therapy in children with ulcerative colitis (PROTECT): a multicentre inception cohort study. *The Lancet Gastroenterology & Hepatology*. 2(12): 855-868. DOI 10.1016/ S2468-1253(17)30252-2. **PMCID: PMC5695708**
35. Alcantara C, Patel SR, Carnethon M, Castañeda S, Isasi CR, **Davis S**, Ramos A, Arredondo E, Redline S, Zee P, Gallo L (2017) Stress and Sleep: Results from the Hispanic Community Health Study/Study of Latinos Sociocultural Ancillary Study. *SSM - Population Health*. 3C: 713-721 DOI 10.1016/j.ssmph.2017.08.004 **PMCID: PMC5663240**
36. Gottesman R, Albert M, Coker L, Coresh J, **Davis SM**, Deal JA, McKhann GM, Mosley TH, Selnes O, Sharrett AR, Schneider ALC, Windham BG, Wruck LM, Knopman DS.(2017) Midlife vascular risk factors and incident dementia in the ARIC cohort. *JAMA Neurology*. 74(10):1246-1254. doi:10.1001/jamaneurol.2017.1658. **PMCID: PMC5710244**
37. Deal J, Albert MS, Bangidwala S, Chisolm T, **Davis S**, Glynn NW, Minotti M, Mosely T, Rebok G, Reed N, Sharrett AR, Coresh J, Lin FR. (2017) A Randomized Pilot Trial of Hearing Treatment for Reducing Cognitive Decline: Results from the Aging, Cognition, and Hearing Evaluation in Elders Pilot (ACHIEVE-P) Study. *Alzheimers & Dementia Translational Research & Clinical Interventions*, 3(3):410-415. DOI: 10.1016/j.trci.2017.06.003. **PMCID: PMC5651440**
38. LaVange L, **Davis SM**, Hankinson J, Enright P, Wilson R, Barr RG, Aldrich TK, Kalhan R, Lemus H, Ni A, Smith LJ, Talavera GA. (2017) Spirometry Reference Equations from the Hispanic Community Health Study/Study of Latinos (HCHS/SOL). *Am J of Respiratory and Critical Care Medicine*. 196(8):993-1003. doi: 10.1164/rccm.201610-1987OC. **PMCID: PMC5649980**

39. Rastogi D, Jung M, Strizich G, Shaw PA, **Davis SM**, Klein OL, Penedo FJ, Ries AL, Daviglius ML, Moreiras JJ, Salathe MA, Celedón JC, Isasi CR, Kaplan RC. (2017) Association of systemic inflammation, adiposity, and metabolic dysregulation with asthma burden among Hispanic adults. *Resp. Medicine*. 125:72-81. doi: 10.1016/j.rmed.2017.03.003. **PMCID: PMC5395248**
40. Qureshi W, Kaplan R, Swett K, Burke G, Daviglius M, Jung M, Talavera G, Chirinos D, Reina S, **Davis S**, Rodriguez C. (2017) ACC/AHA Class I Guidelines for the Treatment of Cholesterol to Reduce Atherosclerotic Cardiovascular Risk: Implications for US Hispanics/Latinos based on findings from the HCHS-SOL. *Journal of the American Heart Association*. 6(5):e005045 DOI 10.1161/JAHA.116.005045. **PMCID: PMC5524073**
41. López-Cevallos DF, Gonzalez P, Bethel JW, Castañeda SF, Isasi CR, Penedo FJ, Ojeda L, **Davis SM**, Chirinos DA, Molina KM, Teng Y, Bekthesi V, Gallo LC. (2017) Is there a link between wealth and cardiovascular disease risk factors among Hispanic/Latinos? Results from the HCHS/SOL Sociocultural Ancillary Study. *Ethnicity and Health*. 2018 Nov;23(8):902-913. doi: 10.1080/13557858.2017.1315370. Epub 2017 Apr 6. **PMCID: PMC5796865**
42. González HM, Tarraf W, Rodríguez CJ, Gallo LC, Sacco RL, Talavera GA, Heiss G, Kizer JR, Hernandez R, **Davis S**, Schneiderman N, Daviglius ML, Kaplan RC (2016) Cardiovascular health among diverse Hispanics/Latinos: Hispanic Community Health Study/Study of Latinos Results. *American Heart Journal*. 176:134-44. **PMCID: PMC5479416** <https://doi.org/10.1016/j.ahj.2016.02.008>
43. Wong WW, Strizich G, Heo M, Heymsfield SB, Himes JH, Rock CL, Gellman MD, Siega-Riz AM, Sotres-Alvarez D, **Davis SM**, Arredondo EM, Van Horn L, Wylie-Rosett J, Sanchez-Johnsen L, Kaplan R, Mossavar-Rahmani Y (2016). Relationship between body fat and BMI in a US Hispanic population-based cohort study: Results from HCHS/SOL. *Obesity*. 24(7):1561-71. **PMCID: PMC4925254**
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## PROCEEDINGS

Collier AM, Goldstein GM, Shrewsbury RP, **Davis SM**, Koch GG, Zhang C, Benowitz NL, Lewtas J, Williams RW. (1993) Cotinine Elimination Following ETS Exposure in Young Children as a Function of Age, Sex, and Race. *Proceedings of the 6th International Conference on Indoor Air Quality and Climate*; 1:669-674.

Lewis KE, **Davis SM**, Koch GG. (1993) Evaluating clinical equivalence of treatments from a repeated measures design. *American Statistical Assoc. Proceedings of the Biopharmaceutical Section*; 300-305.

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## BOOK CHAPTERS

**Davis SM**. Chapter 5: Mixed models for repeated measures with categorical time effects (MMRM). In Clinical Trials with Missing Data: a Guide for Practitioners. O'Kelly, M and Ratitch B. Wiley. 2014.

**Davis SM**, Koch GG, Rosenheck RA, Davis VG. Chapter 2: Statistical Considerations. In Antipsychotic Trials in Schizophrenia: the CATIE Project. Stroup TS and Lieberman JA, editors. Cambridge University Press. 2010:22-38.

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## DISSERTATION AND THESIS

**Davis, Sonia**. Statistical Methods for Evaluating Multiple Response Criteria from Bioequivalence and Clinical Equivalence Trials. Dissertation for DrPH degree. University of North Carolina Dept. of Biostatistics, Chapel Hill, NC. Advisor: Gary G. Koch, Ph.D. May 1994.

**Davis, Sonia**. Statistical Strategies for Analyzing Bacterial Genetic Transformation Experiments through Structures for Interactions in Log-linear ANOVA Models. Master's Paper for MS degree. University of North Carolina, Chapel Hill, NC. Advisor: Gary G. Koch, Ph.D. May 1990.

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## PRESENTATIONS

**Thomas SM**, Bernard G. Launching CONNECTS: A Partnership Between Research Triangle Institute, Vanderbilt University Medical Center, and NHLBI. NIH Collaboratory Grand Rounds. Sept **2020 (Invited)**.

**Thomas, SM**. Giving a scientific presentation. North Carolina Chapter of ASA workshop for young professionals. Nov **2018 (Invited)**.

**Thomas, SM**. Prediction Modeling of Outcomes in a Clinical Trial with Missing Baseline Data. Society for Clinical Trials. April **2018 (Contributed)**.

Ivanova A, **Davis Thomas S**. Solving Clinical Trial Problems by using Novel Designs. Duke Industry Statistics Symposium. Sept **2017**.

**Davis SM**, Sun H, Jung K. Best Practices for Reporting Safety Data to Data Monitoring Committees. Society for Clinical Trials. April **2017 (Contributed)**

**Davis SM**. Best Practices for Reporting Safety Data to Data Monitoring Committees. Exl Pharma Interim Analysis Symposium. March **2017 (Invited)**

**Davis SM**. Raising Statisticians to Lead. Quintiles Innovation and Collaboration Workshop. Oct **2015 (Invited)**.

Robert Califf, **Sonia Davis**, Tom Fleming, Jeffrey Helterbrand, Lisa LaVange, Bob Temple, Janet Wittes, Town Hall Panel: Roles of Statisticians in Academia, Regulatory and Pharmaceuticals Industry, ASA Biopharmaceutical Section Statistics Workshop. Sept **2015 (Invited)**.

**Davis SM**. Some Design Approaches to Address Missing Data Due to Early Discontinuation in Clinical Trials. ENAR March **2015 (Invited)**.

**Davis SM**. Time to Discontinuation as a Primary Outcome in Clinical Trials. International Conference on Advances in Interdisciplinary Statistics and Combinatorics. Oct **2014 (Invited)**.

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**Davis SM.** Some Approaches to Address the Problem of Missing Data in CNS Clinical Trials. Trends and Innovations in Statistics Conference. April **2014 (Invited)**.

**Davis SM.** 3-stage Multiple Imputation (MI) - Inverse Probability Weighting (IPW) - Multiple Imputation (MI) Adjustment for missing data in prevalence estimates of COPD from the Hispanic Community Health Study / Study of Latinos. UNC Department of Biostatistics Seminar. Nov **2013 (Invited)**.

**Davis SM.** DSMBs and Interim Analysis. NCTraCS Biostatistics Seminar. **2013 and 2016 (Invited)**.

**Davis SM, Koch GG.** Some innovative approaches to handling missing data problems in clinical trials. Drug Information Association Annual Meeting. June **2013 (Invited)**.

**Davis SM.** Beyond tables and P-values: Enhancing the role of the clinical trial team statistician. FDA/Industry Statistics workshop. Sept **2011 (Invited)**.

**Davis SM.** Time to discontinuation: primary outcome in the CATIE study. FDA/Industry Statistics workshop. Sept **2010 (Invited)**.

**Davis SM.** Time to all-cause discontinuation as the primary outcome in the CATIE schizophrenia study. UNC Biostatistics Festschrift honoring Gary Koch. Oct **2009 (Invited)**.

**Davis SM.** Design, primary effectiveness outcome, and key results for the NIMH CATIE schizophrenia trial. Society for Clinical Trials Annual Meeting May **2006 (Invited)**.

**Davis SM.** Statistician's comments on design issues and consequences in the NIMH CATIE trial. International Society for CNS Drug Development Annual meeting March **2006 (Invited)**.

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#### **SHORT COURSES**

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O'Kelly M, <b>Davis SM.</b> Handling Missing Data in Clinical Trials short course. ASA Biopharmaceutical Section Statistics Workshop. Sept, 2015 (Invited) SAS Global Forum. April 2015 (Invited). Trends and Innovations in Statistics Conference. April 2014 (Invited).	<b>2014-2015</b>
Koch GG, <b>Davis SM.</b> Advanced Topics in Categorical Data Analysis. Two-day short course. Finish Society of Biostatistics. Turku, Finland. May 1998 (Invited).	<b>1998</b>

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#### **PROFESSIONAL ACTIVITIES**

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<b>Adjunct Associate Professor</b> , UNC Department of Biostatistics	<b>2004-2009</b>
<b>Adjunct Assistant Professor</b> , UNC Department of Biostatistics	<b>1995-2004</b>
<b>Adjunct Professor</b> , UNC Department of Biostatistics	<b>2018-present</b>
<b>Good Clinical Practice for Clinical Trials certificate</b> , Barnett Educat. Services	<b>2011</b>
<b>ULEAD University Leadership Education and Development program</b> , UNC	<b>2014</b>

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#### **TEACHING**

*University of North Carolina, Chapel Hill, NC*

**BIOS 844 (Leadership in Biostatistics)** **2013-2016**

**Guest Lecturer**, Departments of Biostatistics, Epidemiology, Pharmacy, NC TraCS **2007-present**

Each of the following courses taught on a regular basis:

Consulting In Industry (Bios 841 Stat Consulting)

Missing Data Methods (Bios 752 Clinical Trials)

Non-Inferiority and Equivalence (Bios 752 Clinical Trials; EPID 733 Clinical Trials;

DPET 833 Experimental Design in Clinical Research)

Interim analysis and DSMBs (Bios 752, EPID 733 Clinical Trials; NC TraCS)

*Campbell University School of Pharmacy*

**Co-Lecturer**, Advanced Statistics (CLN 524). Masters of Clinical Research Program, **2001-2005**  
with Tony Segreti. ANCOVA, Regression, DSMBs, Interim Analysis

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**STUDENT ADVISING**

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

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**Masters Paper Advisor**, Department of Biostatistics

Evan Zucker (MS): Analyzing the Effect of Differential Dropout on Prevalence of a Negative Endpoint	<b>2016</b>
Kwanye Jung (MPH): Advanced Adverse Events Reporting for Data and Safety Monitoring Boards (DSMB)	<b>2016</b>
Wei Xue (MPH): The Association of Postprandial Lipemia and Cardiovascular Outcomes in the ARIC study.	<b>2013</b>
Mukesh Patel (MPH): Predictors of the MacCAT-CR in the CATIE Schizophrenia Trial.	<b>2005</b>
Reader for three MPH papers and advisor for two Bios 342 consulting projects	<b>2000-2004</b>

**Dissertation Committee Member**, Department of Biostatistics

Rebecca Wilson (DrPH)	<b>2017</b>
Jon Hibbard (PhD): Harnessing heterogeneity to improve patient outcomes	<b>2017</b>
Emily Butler (PhD): Using patient preferences to estimate optimal treatment strategies for competing outcomes	<b>2016</b>
Hengrui Sun (DrPH): Controlling Multiplicity in Confirmatory Clinical Trials	<b>2016</b>
Eunjee Lee (PhD – STOR department): Advanced Bayesian Models for High Dimensional Biomedical Data	<b>2016</b>

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**MAJOR NIH GRANTS**

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NHLBI ACTIV Integration of Host-targeting COVID-19 Therapies Administrative Coordinating Center. Administration of CONNECTS multiple COVID-19 Adaptive Clinical trials Program ( <b>PI</b> )	<b>2020-</b>
NHLBI Pomalidomide for the Treatment of HHT Data Coordinating Center. PATH-HHT double-blind multi-center randomized trial under an FDA IND and REMS program( <b>PI</b> )	<b>2019-</b>
PCORI Integrated Health Services to Reduce Opioid Use While Managing Chronic Pain. INSPIRE multi-center randomized clinical trial comparing two behavioral interventions with primary data collection via EMR extraction using the PCORI CDM. ( <b>Principal Statistician</b> )	<b>2018-</b>
NICHD Pelvic Floors Disorders Network Data Coordinating Center. ( <b>Alternate PI</b> )	<b>2017 -</b>
NIA ACHIEVE (R01): Aging and Cognitive Health Evaluation in Elders. Multicenter randomized clinical trial of hearing aids for reducing decline of neurocognitive functioning in 850 Elders ( <b>Data Coordinating Center PI</b> )	<b>2017</b>
NICHD MOMPOD (R01): Medical Optimization of Management of Type 2 Diabetes Complicating Pregnancy. Multicenter double-blind clinical trial of metformin in 1200 pregnant women under an IND ( <b>Data Coordinating Center PI</b> )	<b>2016-2017</b>
NHLBI ARIC NCS: Atherosclerosis Risk in Communities Neurocognitive Study. Cohort study of midlife risk factors for mild cognitive impairment and dementia in 16,000 adults followed for 30+years in 4 US communities ( <b>DCC co-Investigator</b> )	<b>2016-2017</b>
NIA SOL-INCA (R01): Study of Latinos Investigation of Neurocognitive Aging Ancillary to HCHS/SOL. Study of neurocognitive functioning ( <b>Data Coordinating Center PI</b> )	<b>2015-2017</b>
NIMHD PREMIERS (R01): Periodontal Treatment to Eliminate Minority Inequality and Rural Disparities in Stroke. Multicenter biased-coin randomized clinical trial of periodontal treatment to reduce risk of stroke ( <b>Data Coordinating Center PI</b> )	<b>2015-2017</b>
Sunovion Pharmaceuticals ISAC: DSMB Independent Statistical Analysis Center for a program of 9 Phase II/III studies of a proposed treatment for ADHD (adult and pediatric) and Binge Eating Disorder ( <b>PI</b> )	<b>2014-2017</b>

NIDDK PROTECT (U01): Predicting Response to Standard Pediatric Colitis Therapy Non-randomized Clinical trial of treatment for pediatric Ulcerative Colitis under and IND ( <b>Data Coordinating Center PI</b> )	<b>2012-2017</b>
NHLBI HCHS/SOL: Hispanic Community Health Study/Study of Latinos. Population- based cohort study of 16,000 Hispanic/Latino adults in 4 US communities. ( <b>Data Coordinating Center co-Investigator</b> )	<b>2012-2017</b>
NIMH Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) U01: Clinical trials of schizophrenia and psychosis associated with Alzheimer's disease ( <b>Lead Statistician and Steering Committee Member</b> )	<b>1999-2009</b>

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## SERVICE

### *Clinical Trials Transformation Initiative*

Data Monitoring Committee Expert Panel, participant	<b>2015</b>
Steering Committee Representative for UNC	<b>2015-2017</b>

### *American Statistical Association*

Biopharmaceutical Section Regulatory/Industry Statistics Workshop Planning Committee	<b>2010-2011</b>
Steering Committee and Session Chair	<b>2009, 2017</b>

### *National Institutes of Health*

NIAID Panel Reviewer: Clinical Trial Units for NIAID Networks (UM1)	<b>2013</b>
NHLBI Panel Reviewer: Molecular Atlas of Lung Development DCC (U01)	<b>2013</b>
NHLBI Panel Reviewer: DCC - Sickle Cell Disease Implementation Consortium (U24)	<b>2016</b>
NIAID Panel Reviewer: Clinical trials for COVID-19 vaccines and therapies	<b>2021</b>

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## DATA AND SAFETY MONITORING BOARD (DSMB) MEMBERSHIPS

Phase III pragmatic study of cord-milking for non-vigorous infants	<b>2018 - present</b>
Phase II study of a proposed treatment for ulcerative colitis, Lycera Corp.	<b>2016-2018</b>
Probiotics to Reduce Impact of Diarrhea and Enteropathy in Children-Peru (PRIDEC- Peru) NIDDK U01	<b>2015-2019</b>
Phase III studies of a proposed treatment for Alzheimer's disease, Eli Lilly.	<b>2012-2016</b>
Phase II study of a proposed treatment for ADHD, Sunovion, Inc.	<b>2013-2014</b>
Phase II study of a proposed treatment for ulcerative colitis, Nutr. Science Partners	<b>2014</b>

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## UNIVERSITY SERVICE

### *NC TraCS CTSA*

Biostatistics Associate Director	<b>2013-2017</b>
CTSA Domain Task Force -Integration across the Lifespan UNC representative	<b>2015-2017</b>
Clinical Trials Transformation Initiative UNC Steering Committee Representative	<b>2015-2017</b>

### *Department of Biostatistics*

CSCC Faculty Search Committee Chair	<b>2016</b>
CSRL 5-year review committee member	<b>2012</b>
Academic Advisor	<b>2012- 2017</b>
Junior Faculty Mentor	<b>2012- 2017</b>

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## JOURNAL REVIEWS

Journal of the Royal Statistical Society  
International Journal of Clinical Practice  
BMJ Open  
Therapeutic Innovation and Regulatory Science

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**MEMBERSHIPS**

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American Statistical Association  
Society for Clinical Trials  
International Biometric Society ENAR