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EDUCATION

University of North Carolina, Chapel Hill, NC
DrPH in Biostatistics 1994

University of North Carolina, Chapel Hill, NC
MS in Biostatistics 1990

University of North Carolina, Chapel Hill, NC
BSPH in Biostatistics 1988

EXPERIENCE

University of North Carolina, Chapel Hill, NC
Director, Collaborative Studies Coordinating Center 2012-present
Professor of the Practice, Department of Biostatistics

Quintiles, Inc. Morrisville, NC, Department of Biostatistics
Senior Director Departmental management and training; senior project leadership on design, conduct and analysis of pharmaceutical clinical trials 2008-2012
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

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 (73 PUBLISHED)

PAPERS IN PROGRESS

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1. 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. Ethnic Stress and Cardiometabolic Risk among Hispanics/Latinos in the United States. In progress.
 2. **Davis S**, Sun H, Jung K. Best Practices for Data Monitoring Committee Safety reporting. In progress.
 3. Hyams J, **Davis SM**, Denson L, Kugathasan S, , Walters T, et al. Predicting Response to Standardized Initial Therapy in Children Newly Diagnosed with Ulcerative Colitis: The PROTECT Study. In progress.
 4. 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 (2017). Serologic Reactivity Reflects Clinical and Genetic Expression of Ulcerative Colitis in Children. In progress.
 5. 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. 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. In progress.

REFEREED PAPERS IN SUBMISSION

1. 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. *Annals of Behavioral Medicine*. In submission.
2. 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. *JAHA*. In submission.
3. Afshar M, Wu D, Durazo-Arvizu R, Aguilar FG, Kalhan R, **Davis SM**, Kaplan D, Klein OL, Mendes EP, Pattany MS, Daviglius ML. Association of serum lipids and obstructive lung disease in Hispanic/Latino adults of diverse backgrounds. *Annals of ATS*. In submission.
4. 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*. In submission.
5. 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*; In submission.
6. Butler-Bente E, Laber EB, **Davis SM**, Kosorok MR. (2016) Incorporating patient preferences into estimation of optimal individualized treatment rules. *Biometrics*. In submission.
7. 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. (2016) Adiposity, metabolic dysregulation, systemic inflammation and asthma burden among Hispanic adults. *Resp. Medicine*. In submission.

REFEREED PAPERS

1. 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*. In press.
2. 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.
3. 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**
4. McClure LA, Zheng DD, Lam BL, Tannenbaum SL, Joslin CE, **Davis S**, López-Cevallos D, Youngblood, Jr. ME, Zhang Z-M, Chambers CP, Lee DJ (2016) Ocular healthcare utilization among

Hispanics/Latinos: The Ocular SOL Ancillary to the Hispanic Community Health Study/Study of Latinos. *JAMA Ophthalmology* 134(3):320-9.

5. Arredondo EM, Sotres-Alvarez D, Stoutenberg M, **Davis SM**, Crespo NC, Carnethon MR, Castañeda SF, Isasi CR, Espinoza, RA, Daviglius ML, Perez LG, Evenson KR (2016) Physical activity levels in US Latino/Hispanic adults: Results from the HCHS/SOL. *American Journal of Preventive Medicine*. 50(4):500-8. **PMCID: PMC4801731**
6. Ramos AR, Tarraf W, Daviglius M, **Davis S**, Gallo LC, Mossavar-Rahmani Y, Penedo FJ, Redline S, Rundek T, Sacco RL, Sotres-Alvarez D, Wright CB, Zee PC, Gonzalez HM (2016). Sleep Duration and Neurocognitive Function in the Hispanic Community Health Study/Study of Latinos. *Sleep*. 39(10):1843-1851. **PMCID: PMC5020366**
7. Singer RS, Stoutenberg M, Gellman MD, Archer E, **Davis SM**, Gotman NM, Marquez DX, Buelna C, Deng Y, Hosgood HD, Zambrana RE (2016). Occupational Physical Activity and Body Mass Index: Results from the Hispanic Community Health Study / Study of Latinos. *PLOS ONE*; 11(3): e0152339. doi:10.1371/journal.pone.0152339. **PMCID: PMC4816339**
8. Barr RG, Avilés-Santa L, **Davis SM**, Aldrich T, Gonzalez F, Henderson AG, Kaplan RC, LaVange L, Liu K, Loredó JS, Mendes ES, Ni A, Ries A, Salathe M, Smith LJ (2016). Pulmonary Disease and Age at Immigration among Hispanics: Results from the Hispanic Community Health Study/Study of Latinos (HCHS/SOL). *American Journal of Respiratory and Critical Care Medicine*. 193(4):386-395. **PMCID: PMC4803083**
9. Ornelas IJ, Lapham GT, Salgado H, Williams EC, Gotman N, Womack V, **Davis S**, Penedo F, Smoller S, Gallo LC. (2016) Binge Drinking and Perceived Ethnic Discrimination among Hispanics/Latinos: Results from the Hispanic Community Health Study/Study of Latinos Sociocultural Ancillary Study. *Journal of Ethnicity in Substance Abuse*.15(3):223-239..
10. Nuñez A, Gonzalez P, Talavera G, Sanchez-Johnson L, Roesch SC, **Davis S**, Arguelles W, Womack VY, Ostrovsky NW, Ojeda L, Penedo FJ, Gallo LC (2015) Machismo, Marianismo, and Negative Cognitive-Emotional Factors: Findings from the Hispanic Community Health Study / Study of Latinos (HCHS/SOL) Sociocultural Ancillary Study. *Journal of Latina/o Psychology*; E-pub ahead of print: <http://dx.doi.org/10.1037/lat0000050>.
11. Palta P, McMurray RG, Gouskova NA, Sotres-Alvarez, D, **Davis SM**, Carnethon M, Castaneda SF, Gellman MD, Hankinson AL, Isasi CR, Schneiderman N, Talavera GA, Evenson KR. (2015) Self-reported and accelerometer-measured physical activity by body mass index in US Hispanic/Latino adults. *Preventive Medicine Report*; 2:824-828. **PMCID: PMC4721348**
12. González HM, Tarraf W, Gouskova N, Gallo LC, Penedo FJ, **Davis SM**, Arguelles W, Mattson SN, Choca JP, Catellier DJ, Mosley TH (2015). Correlates of cognitive function among Latino adults: Results from the Hispanic Community Health Study/Study of Latinos. *Archives of Clinical Neuropsychology*; 30(1):68-77. **PMCID: PMC4351363**
13. Evenson KR, Sotres-Alvarez D, Deng Y, Marshall SJ, Isasi CR, Esliger DW, and **Davis S** (2015). Accelerometer adherence and performance in a population-based cohort study of US Hispanic adults. *Medicine and Science in Sports and Exercise*. 47(4):725–734. **PMCID: PMC4333140**
14. O'Neal WK, Anderson W, Basta PV, Carretta EE, Doerschuk CM, Barr RG, Bleecker ER, Christenson SA, Curtis JL, Han MK, Hansel NN, Kanner RE, Kleerup EC, Martinez FJ, Miller BE, Peters SP, Rennard SI, Scholand MB, Tal-Singer R, Woodruff PG, Couper DJ, **Davis SM**. (2014) Comparison of serum, EDTA plasma and P100 plasma for luminex-based biomarker multiplex assays in patients with chronic obstructive pulmonary disease in the SPIROMICS study. *Journal of Translational Medicine*; 12(1):9. **PMCID: PMC3928911**
15. **Davis SM**, Stroup TS, Koch GG, Davis CE, Rosenheck RA, Lieberman JA. (2011). Time to all-cause treatment discontinuation as the primary outcome in the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) schizophrenia study. *Statistics in Biopharmaceutical Research*; 3(2):253-265.
16. Hermes E, Nasrallah H, Davis V, Meyer J, McEvoy J, Goff D, **Davis S**, Stroup TS, Swartz M, Lieberman J, Rosenheck R. (2011). The association between weight change and symptom reduction in the CATIE schizophrenia trial. *Schizophrenia Research*; 128(1-3):166-170. **PMCID: PMC3789238**
17. Addington D, Mohamed S, Rosenheck RA, **Davis SM**, Stroup TS, McEvoy J, Swartz M, Lieberman JA. (2011). Impact of second generation antipsychotics and perphenazine on depressive symptoms in a randomized trial for chronic schizophrenia. *Journal of Clinical Psychiatry*; 72(1):75-80. **PMCID: PMC5052810**
18. Carof SB, Davis VG, Miller DD, **Davis SM**, Rosenheck RA, McEvoy JP, Saltz BL, Riggio S, Chakos MH, Swartz MS, Keefe RS, Stroup TS, Lieberman JA. (2011). Treatment outcomes of patients with tardive dyskinesia in the CATIE schizophrenia trial. *J Clin Psych*; 72(3):295-303. **PMCID: PMC3825701**

19. Meyer JM, McEvoy JP, Davis VG, Goff DC, Nasrallah HA, **Davis SM**, Hsiao JK, Swartz MS, Stroup TS, Lieberman JA. (2009). Inflammatory markers in schizophrenia: comparing antipsychotic effects in Phase 1 of the CATIE schizophrenia study. *Biological Psychiatry*; 66(11):1013-22. **PMCID: PMC3743723**
20. Penn D, Keefe RSE, **Davis SM**, Meyer PS, Perkins DO, Losardo D, Lieberman JA. (2009) The effects of antipsychotic medications on emotion perception in patients with chronic schizophrenia in the CATIE trial. *Schizophrenia Research*; 115(1):17-23. **PMCID: PMC2765056**
21. Rosenheck RA, Davis VG, **Davis SM**, Stroup TS, McEvoy J, Swartz M, Lieberman J. (2009) Can a non-equivalent choice of dosing regimen bias the results of flexible dose double-blind trials? The CATIE schizophrenia trial. *Schizophrenia Research*; 113:12-18.
22. Rosenheck RA, **Davis S**, Covell N, Essock S, Swartz M, Stroup S, McEvoy J, Lieberman J. (2009) Does switching to a new antipsychotic improve outcomes? *Schizophrenia Research*; 107(1):22-29.
23. Stroup TS, Lieberman JA, McEvoy JP, **Davis SM**, Swartz MS, Keefe RSE, Miller AL, Rosenheck RA, Hsiao JK for the CATIE Investigators. (2009) Results of Phase 3 of the CATIE schizophrenia trial. *Schizophrenia Research*; 107(1):1-12. **PMCID: PMC2675163**
24. Chwastiak LA, Rosenheck RA, McEvoy JP, Stroup TS, Swartz MS, **Davis SM**, Lieberman JA. (2009) The impact of obesity on health care costs among persons with schizophrenia. *Gen Hosp Psychiatry*; 31(1):1-7. **PMCID: PMC2660565**
25. Daumit GL, Davis VG, Goff DG, McEvoy JP, **Davis SM**, Nasrallah HA, Meyer JM, Rosenheck RA, Hsio J, Stroup TS, Lieberman JA. (2008) Antipsychotic effects on estimated 10 year coronary heart disease risk in the CATIE Schizophrenia Study. *Schizophrenia Research*; 105(1):175-187. **PMCID: PMC2614656**
26. Miller DD, Caroff SN, **Davis SM**, Rosenheck RA, McEvoy JP, Saltz BL, Riggio S, Chakos MH, Swartz MS, Keefe RSE, Stroup TS, Lieberman JA. (2008) Extrapyramidal side effects of antipsychotics in a randomized trial: Findings from the CATIE schizophrenia trial. *British Journal of Psychiatry*; 193:279-288. **PMCID: PMC2801816**
27. Meyer JM, Davis VG, McEvoy JP, Goff DG, Nasrallah HA, **Davis SM**, Daumit GL, Hsio J, Swartz MS, Stroup TS, Lieberman JA. (2008) Impact of antipsychotic treatment on nonfasting triglycerides in the CATIE schizophrenia trial Phase 1. *Schizophrenia Research*; 103(1):104-109. **PMCID: PMC2583138**
28. Meyer JM, Davis VG, Goff DG, McEvoy JP, Nasrallah HA, **Davis SM**, Rosenheck RA, Daumit GL, Hsio J, Swartz MS, Stroup TS, Lieberman JA. (2008). Change in metabolic syndrome parameters with antipsychotic treatment in the CATIE schizophrenia trial: prospective data from Phase 1. *Schizophrenia Research*; 101:273-286. **PMCID: PMC3673564**
29. Swartz MS, Stroup TS, McEvoy JP, **Davis SM**, Rosenheck RA, Keefe R, Hsiao J, Lieberman JA. (2008) What CATIE found: results from the Schizophrenia Trial. *Psychiatric Services*; 59(5):500-506. **PMCID: PMC5033643**
30. Resnick SG, Rosenheck RA, Canive JM, De Souza C, Stroup TS, McEvoy JP, **Davis SM**, Keefe RSE, Swartz M, Lieberman JA. (2008) Employment outcomes in a randomized trial of second-generation antipsychotics and perphenazine in the treatment of individuals with schizophrenia. *Journal of Behavioral Health Services and Research*; 35(2):215-225.
31. Swartz MS, Wagner HR, Swanson JW, Stroup TS, McEvoy JP, Reimherr F, Miller DD, McGee M, Khan A, Canive JM, **Davis SM**, Hsiao JK, Lieberman JA. (2008) The effectiveness of antipsychotic medications in patients who use or avoid illicit substances: results from the CATIE study. *Schizophrenia Research*; 100:39-52.
32. Sultzer DL, **Davis SM**, Tariot PN, Dagerman KS, Lebowitz BD, Lyketsos CG, Rosenheck RA, Hsiao JK, Lieberman JA, Schneider LS for the CATIE-AD Study Group. (2008) Clinical symptom responses to atypical antipsychotic medications in Alzheimer's disease: Phase 1 outcomes from the CATIE-AD effectiveness trial. *American Journal of Psychiatry*; 165(7):844-854. **PMCID: PMC2714365**
33. Rosenheck RA, Leslie DL, Sindelar J, Miller EA, Tariot PN, Dagerman KS, **Davis S**, Lebowitz BD, Rabins P, Hsiao JK, Lieberman JA, Schneider LS for the Clinical Antipsychotic Trials of Intervention Effectiveness – Alzheimer's Disease (CATIE-AD) investigators. (2007) Cost-benefit analysis of second generation antipsychotics and placebo in a randomized trial of the treatment of psychosis and aggression in Alzheimer's disease. *Archives of General Psychiatry*; 64(11):1259-1268.
34. Keefe RSE, Bilder RM, **Davis SM**, Harvey PD, Palmer BW, Gold JM, Meltzer H, Green MF, Capuano G, Stroup TS, McEvoy JP, Swartz MS, Rosenheck RA, Perkins DO, Davis CE, Hsiao JK, Lieberman JA for the CATIE Investigators and the Neurocognitive Working Group. (2007) Neurocognitive effects of antipsychotic medications in patients with chronic Schizophrenia in the CATIE Trial. *Archives of General Psychiatry*; 64(6):633-647.

35. Rosenheck R, Swartz M, McEvoy J, Stroup TS, **Davis S**, Keefe RSE, Hsiao J, Lieberman J. (2007) Second-generation antipsychotics: reviewing the cost-effectiveness component of the CATIE trial. *Expert Review of Pharmacoeconomics & Outcomes Research*; 7(2):103-111.
36. Swartz MS, Perkins DO, Stroup TS, **Davis SM**, Capuano G, Rosenheck RA, Reimherr F, McGee MF, Keefe RS, McEvoy JP, Hsiao JK, Lieberman JA for the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) investigators. (2007) Effects of antipsychotic medications on psychosocial functioning in patients with chronic schizophrenia: findings from the NIMH CATIE study. *American Journal of Psychiatry*; 164(3):428-36.
37. Stroup TS, Lieberman JA, McEvoy JP, Swartz MS, **Davis SM**, Capuano GA, Rosenheck RA, Keefe RS, Miller AL, Belz I, Hsiao JK for the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) investigators. (2007) Effectiveness of olanzapine, quetiapine, and risperidone in patients with chronic schizophrenia after discontinuing perphenazine: a CATIE study. *American Journal of Psychiatry*; 164(3):415-27.
38. Schneider LS, Tariot PN, Dagerman KS, **Davis S**, Hsiao JK, Ismail MS, Lebowitz BD, Constantine J, Lyketsos G, Ryan M, Stroup TS, Sultzer DL, Weintraub D, Lieberman JA for the Clinical Antipsychotic Trials of Intervention Effectiveness – Alzheimer's Disease (CATIE-AD) investigators. (2006) Effectiveness of atypical antipsychotic drugs for patients with Alzheimer's disease. *New England Journal of Medicine*; 355(15):1525-1537.
39. Essock SM, Covell NH, **Davis SM**, Stroup TS, Rosenheck RE, Lieberman JA. (2006) Effectiveness of switching antipsychotic medications. *American Journal of Psychiatry*; 163(12):2090-2095.
40. Rosenheck RA, Leslie D, Sindelar J, Miller EA, Lin H, Stroup TS, McEvoy JP, **Davis SM**, Keefe RSE, Swartz MS, Perkins DO, Hsiao JK, Lieberman JA. (2006) Cost effectiveness of second generation antipsychotics and perphenazine in a randomized trial of treatment for chronic schizophrenia. *American Journal of Psychiatry*; 163(12):2080-2089.
41. Keefe RSE, Bilder RM, Harvey PD, **Davis SM**, Palmer BW, Gold JM, Meltzer HY, Green MF, Miller DD, Canive JM, Adler LW, Manschreck TC, Swartz M, Rosenheck R, Perkins DO, Walker TM, Stroup TS, McEvoy PP, Lieberman JA. (2006) Baseline neurocognitive deficits in the CATIE Schizophrenia Trial. *Neuropsychopharmacology*; 31(9):2033-46.
42. McEvoy JP, Lieberman JA, Stroup TS, **Davis SM**, Meltzer HY, Rosenheck RA, Swartz MS, Perkins DO, Keefe RSE, Davis CE, Severe J, Hsiao JK for the CATIE Investigators. (2006) Effectiveness of clozapine versus olanzapine, quetiapine and risperidone in patients with chronic schizophrenia who did not respond to prior atypical antipsychotic treatment. *American Journal of Psychiatry*; 163(4): 600-610.
43. Stroup TS, Lieberman JA, McEvoy JP, Swartz MS, **Davis SM**, Rosenheck RA, Perkins DO, Keefe RSE, Davis CE, Severe J, Hsiao JK for the CATIE Investigators. (2006) Effectiveness of olanzapine, quetiapine, risperidone, and ziprasidone in patients with chronic schizophrenia following discontinuation of a previous atypical antipsychotic. *American Journal of Psychiatry*; 163(4):611-622.
44. Nasrallah HA, Meyer JM, Goff DC, McEvoy JP, **Davis SM**, Stroup TS, Lieberman JA. (2006) Low rates of treatment for hypertension, dyslipidemia and diabetes in schizophrenia: data from the CATIE schizophrenia trial sample at baseline. *Schizophrenia Research*; 86(1-3):15-22.
45. Goff DC, Sullivan L, McEvoy JP, Meyer JM, Nasrallah H, Daumit GL, Lambert S, D'Agostino RB, Stroup TS, **Davis S**, Lieberman J (2005) A comparison of ten-year cardiac risk estimates in schizophrenia patients from the CATIE Study and matched controls. *Schizophrenia Research*; 80(1): 45-53.
46. Meyer JM, Nasrallah HA, McEvoy JP, Goff DC, **Davis SM**, Chackos M, Patel JA, Keefe RSE, Stroup TS, Lieberman JA. (2005) The Clinical Antipsychotic Trials of Intervention effectiveness (CATIE) Schizophrenia Trial: clinical comparison of subgroups with and without the metabolic syndrome. *Schizophrenia Research*; 80(1):9-18.
47. McEvoy J, Meyer J, Goff D, Nasrallah H, **Davis SM**, Sullivan L, Meltzer HY, Hsiao J, Stroup TS, Lieberman JA. (2005) Prevalence of the metabolic syndrome in patients with schizophrenia: baseline results from the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) Schizophrenia trial and comparison with national estimates from NHANES III. *Schizophrenia Research*; 80(1):19-32.
48. Miller DD, McEvoy JP, **Davis SM**, Caroff SN, Saltz BL, Chakos M, Swartz MS, Keefe RS, Stroup TS, Rosenheck RA, Lieberman JA. (2005) Clinical Correlates of tardive dyskinesia in schizophrenia: Baseline data from the CATIE Schizophrenia Trial. *Schizophrenia Research*; 80(1):33-43.
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52. Rush AJ, Sackeim HA, Marangell LB, George MS, Brannan SK, **Davis SM**, Lavori P, Howland R, Kling MA, Rittberg B, Carpenter L, Ninan P, Moreno F, Schwartz T, Conway C, Burke M, Barry JJ. (2005) Effects of 12 months of vagus nerve stimulation in treatment-resistant depression: A naturalistic study. *Biological Psychiatry*; 58(5):355-363.
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57. Russell JM, Koran LM, Rush J, Hirschfeld R, Harrison W, Friedman ES, **Davis S**, Keller M. (2001) Effect of concurrent anxiety on response to sertraline and imipramine in patients with chronic depression. *Depression and Anxiety*; 13(1):18-27.
58. Schneider LS, Tariot PN, Lyketos CG, Dagerman KS, Davis KL, **Davis S**, Hsiao JK, Jeste DV, Katz IR, Olin JT, Pollock BG, Rabins PV, Small GW, Lebowitz B, Lieberman JA. (2001) National Institute of Mental Health Clinical Antipsychotic Trials in Intervention Effectiveness (CATIE) Alzheimer's disease trial methodology. *American Journal of Geriatric Psychiatry*; 9(4):1-15.
59. Kornstein SG, Schatzberg AF, Thase ME, Yonkers KA, McCullough JP, Keitner GI, Gelenberg AJ, **Davis SM**, Harrison WH, Keller MB. (2000) Gender differences in treatment response to sertraline versus imipramine in chronic depression. *American Journal of Psychiatry*; 157(9):1445-1452.
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66. Miller CA, Richards TB, **Davis SM**, McKaig CA, Koch GG, Sharp TG, Christenson GG. (1995) Validation of a screening survey to assess local public health performance. *Journal of Public Health Management and Practice*; 1(1):63-71.

67. Taylor DF, Bayne SC, Leinfelder KF, **Davis S**, Koch GG. (1994) Pooling of long term clinical wear data for posterior composites. *American Journal of Dentistry*; 7(3):167-174.
68. McKee SP, Schor CM, Steinman SB, Wilson N, Koch GG, **Davis SM**, Hsu-Winges C, Day SH, Chan C.L, Movshon JA, Flom MC, Levi DM, Flynn JT. (1992) The classification of amblyopia on the basis of visual and oculomotor performance. *Optical Society of America Technical Digest: Non-invasive Assessment of the Visual System*; 1: 60-63. **PMCID: PMC1298430**
69. Steckler A, Goodman RM, McLeroy KR, **Davis S**, Koch G. (1992) Measuring the diffusion of innovative health promotion programs. *American Journal of Health Promotion*; 6:214-224.
70. Blanton KJ, Biswas GD, Tsai J, Adams J, Dyer DW, **Davis SM**, Koch GG, Sen PK, Sparling PF. (1990) Genetic evidence that neisseria gonorrhoeae produces specific receptors for transferrin and lactoferrin. *Journal of Bacteriology*; 172(9):5225-5235. **PMCID: PMC213184**
71. Sheps DS, Herbst MC, Hinderliter AL, Adams K, Ekelund LG, O'Neil JJ, Goldstein GM, Bromberg PA, Dalton J, Ballenger M, **Davis SM**, Koch GG. (1990) Production of arrhythmias by elevated carboxy-hemoglobin in patients with coronary artery disease. *Annals of Internal Medicine*;113:343-351.
72. Sheps DS, Maxner W, Hinderliter AL, Herbst MC, Bragdon EE, Herdt J, **Kropp S**, Adams KF, Koch G G, Ekelund LG. (1989) The relationship between systolic blood pressure, ventricular volume, and ischemic pain perception in patients with angina pectoris: a potential role for baroreceptors. *Israel Journal of Medical Science*; 25:482-487.
73. Hiramatsu Y, Buchanan JW Jr., Knisley SB, Koch GG, **Kropp S**, Gettes L. (1989) Influence of rate-dependent cellular uncoupling of conduction change during simulated ischemia in guinea pig papillary muscles: effect of verapamil. *Circulation Research*; 65(1):95-102.

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.
- McKee SP, Schor CM, Steinman SB, Wilson N, Koch GG, **Davis SM**, Hsu-Winges C, Day SH, Chan C L, Movshon JA, Flom MC, Levi DM, Flynn JT. (1992) The classification of amblyopia on the basis of visual and oculomotor performance. *Transactions of The American Ophthalmological Society*; 90:123-146.
- Lewis KE, **Davis SM**, Koch GG. (1993) Evaluating clinical equivalence of treatments from a repeated measures design. *American Statistical Association 1993 Proceedings of the Biopharmaceutical Section*; 300-305.

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.

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.

PRESENTATIONS

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. October **2015 (Invited)**.

Robert Califf, **Sonia Davis**, Tom Fleming, Jeffrey Helderbrand, 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. October **2014 (Invited)**.

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)**.

SHORT COURSES

O'Kelly M, **Davis SM**. Handling Missing Data in Clinical Trials short course. **2014-2015**
ASA Biopharmaceutical Section Statistics Workshop. Sept, 2015 (Invited)
SAS Global Forum. April 2015 (Invited).
Trends and Innovations in Statistics Conference. April 2014 (Invited).

Koch GG, **Davis SM**. Advanced Topics in Categorical Data Analysis. Two-day short course. **1998**
Finish Society of Biostatistics. Turku, Finland. May 1998 (Invited).

PROFESSIONAL ACTIVITIES

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

TEACHING

University of North Carolina, Chapel Hill, NC

BIOS 844 (Leadership in Biostatistics) 2013-present

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

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)

DSMBs (Bios 752, 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

STUDENT ADVISING

University of North Carolina, Chapel Hill, NC:

Masters Paper Advisor, Department of Biostatistics

Evan Zucker (MS): Analyzing the Effect of Differential Dropout on Prevalence of a Negative Endpoint 2016

Kwanye Jung (MPH): Advanced Adverse Events Reporting for Data and Safety Monitoring Boards (DSMB) 2016

Wei Xue (MPH): The Association of Postprandial Lipemia and Cardiovascular Outcomes in the ARIC study. 2013

Mukesh Patel (MPH): Predictors of the MacCAT-CR in the CATIE Schizophrenia Trial. 2005

Reader for three MPH papers and advisor for two Bios 342 consulting projects 2000-2004

Dissertation Committee Member, Department of Biostatistics

Rebecca Wilson (DrPH) Current

Jon Hibbard (PhD) Current

Emilily Butler (PhD): Using patient preferences to estimate optimal treatment strategies for competing outcomes 2016

Hengrui Sun (DrPH): Controlling Multiplicity in Confirmatory Clinical Trials 2016

Eunjee Lee (PhD – STOR department): Advanced Bayesian Models for High Dimensional Biomedical Data 2016

MAJOR GRANTS

University of North Carolina, Chapel Hill, NC

NICHD MOMPOD (R01): Medical Optimization of Management of Type 2 Diabetes Complicating Pregnancy Double-blind clinical trial of metformin (**Data Coordinating Center PI**) 2016-2021

NICHD ECHO-ELGAN (UH3/UG3): Environmental Influences of Children's Health Outcomes Cohort study of the impact of neonatal inflammation on adolescent neurodevelopmental outcomes for teens born as extremely low gestational age neonates (**Data Coordinating Center PI**) 2016-2023

NIA SOL-INCA (R01): Study of Latinos Investigation of Neurocognitive Aging Ancillary to HCHS/SOL (**Data Coordinating Center PI**) 2015-2019

NIMHD PREMIERS (R01): Periodontal treatment to eliminate minority inequality and rural disparities in stroke randomized clinical trial (**Data Coordinating Center PI**) 2015-2019

Sunovion Pharmaceuticals ISAC: DSMB Independent Statistical Analysis Center for a Phase II/III program of a treatment for ADHD (adult and pediatric) and Binge Eating Disorder (PI)	2014-2018
NIDDK PROTECT (U01): Predicting Response to Standard Pediatric Colitis Therapy Non-randomized Clinical trial of treatment for pediatric Ulcerative Colitis (Data Coordinating Center PI) <i>Quintiles, Inc.</i>	2012-2017
NIMH Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) U01: Clinical trials of schizophrenia and psychosis associated with Alzheimer's Disease (Lead Statistician and Steering Committee Member)	1999-2009

SERVICE

Clinical Trials Transformation Initiative

Data Monitoring Committee Expert Panel, participant	2015
...Steering Committee Representative for UNC	2015-present

American Statistical Association

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

National Institutes of Health

NIAID Panel Reviewer: Clinical Trial Units for NIAID Networks (UM1)	2013
NHLBI Panel Reviewer: Molecular Atlas of Lung Development Data Coordinating Center (U01)	2013
NHLBI Panel Reviewer: Data Coordinating Center for Sickle Cell Disease Implementation Consortium (U24)	2016

DATA AND SAFETY MONITORING BOARD (DSMB) MEMBERSHIPS

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

UNIVERSITY SERVICE

NC TraCS CTSA

Biostatistics Associate Director	2013-present
CTSA Domain Task Force on Integration across the Human Lifespan UNC representative	2015-present
Clinical Trials Transformation Initiative UNC Steering Committee Representative	2015-present

Department of Biostatistics

CSCC Faculty Search Committee Chair	2016
CSRL 5-year review committee member	2012
Academic Advisor	2012- present
Junior Faculty Mentoring Committee	2012- present

JOURNAL REVIEWS

Journal of the Royal Statistical Society
International Journal of Clinical Practice
BMJ Open

MEMBERSHIPS

American Statistical Association
Biometrics ENAR
Drug Information Association
International Society for CNS Clinical Trials and Methodology
Society for Clinical Trials