

Christopher S. Coffey

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EDUCATION

UNIVERSITY OF NORTH CAROLINA (Chapel Hill, North Carolina)

Ph.D. in Biostatistics, December 1999

Supporting Program: Epidemiology

Dissertation: "Internal Pilot Study Design and Analysis for Linear Models with Gaussian Errors and Fixed Predictors," K. E. Muller, chair.

UNIVERSITY OF NORTH CAROLINA (Chapel Hill, North Carolina)

M. S. in Biostatistics, December 1996

Master's Paper: "Exact Test Size and Power of a Gaussian Error Linear Model for an Internal Pilot Study," K. E. Muller, advisor.

UNIVERSITY OF TENNESSEE (Knoxville, Tennessee)

B. S. in Business Administration, December 1992

Major: Statistics, Summa cum Laude

ACADEMIC APPOINTMENTS

UNIVERSITY OF IOWA, DEPARTMENT OF BIOSTATISTICS (Iowa City, IA)

2010-Present Director, Clinical Trials Statistical and Data Management Center (CTSDMC)

2009-Present Professor

2009-2010 Deputy Director, Clinical Trials Statistical and Data Management Center (CTSDMC)

UNIVERSITY OF ALABAMA AT BIRMINGHAM, DEPARTMENT OF BIOSTATISTICS (Birmingham, AL)

2009-2014 Adjunct Professor

2004-2009 Associate Professor

2001-2004 Assistant Professor

UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL, DEPARTMENT OF BIOSTATISTICS (Chapel Hill, NC)

2005-2008 Adjunct Associate Professor

VANDERBILT UNIVERSITY MEDICAL CENTER, DIVISION OF BIOSTATISTICS (Nashville, TN)

1999-2001 Assistant Professor

TEACHING EXPERIENCE

UNIVERSITY OF IOWA

Cancer Center General Medical Education Clinical Research Conference Series

Fall 2023: Presented lectures on "Phase I & II Clinical Trials: Statistical Considerations" & "Clinical Trial Objectives & Registration"

Intervention and Clinical Trials (EPID:6900)

Doctoral Level – Epidemiology Course

Fall 2023: Presented lecture on "Adaptive Designs"

Fall 2022: Presented lecture on "Adaptive Designs"

Fall 2021: Presented lecture on "Adaptive Designs"

Fall 2019: Presented lecture on "Adaptive Designs"

Fall 2017: Presented lecture on "Adaptive Designs"

Fall 2016: Presented lecture on "Adaptive Designs"

Statistical Methods for Clinical Trials (BIOS:6610)

Master's Level – Elective Course

Spring 2023: Course Instructor

Spring 2022: Course Instructor

Spring 2021: Course Instructor

Spring 2020: Course Instructor

Spring 2018: Course Instructor

Spring 2017: Course Instructor

Spring 2016: Course Instructor

Advanced Clinical Trials (BIOS:7230)

Doctoral Level – Elective Course

Fall 2022: Course Instructor

Fall 2020: Course Instructor

Fall 2018: Course Instructor

Introduction to Translational Biomedicine (TBM:5001)

Institute for Clinical & Translational Sciences (ICTS) Course

Fall 2020: Presented lecture on “Phase II/III Clinical Trials”

Fall 2018: Presented lecture on “Phase II/III Clinical Trials”

Spring 2017: Presented lecture on “Phase II/III Clinical Trials”

Fall 2015: Presented lecture on “Phase II/III Designs”

Fall 2014: Presented lecture on “Phase I/II Designs”

Iowa Summer Institute of Biostatistics

Summer 2010-2019: Presented lecture on “Overview of Randomized Clinical Trials”

Advanced Seminars in Clinical Trials (BIOS:7600 – ‘Advanced Clinical Trials’)

Doctoral Level – Elective Course

Fall 2016: Course Instructor

Comparative Effectiveness and Patient Centered Outcomes Research (BE-8025)

Course Offered as Collaborative Effort among U. Iowa & U. Cincinnati CTSAs

Fall 2016: Presented lecture on “Conventional & Emerging Methods in the Design of Clinical Trials”

Intervention and Clinical Trials (173:290)

Doctoral Level – Epidemiology Course

Fall 2015: Presented lecture on “Adaptive Designs”

Fall 2011: Presented lecture on “Adaptive Designs”

Advanced Seminars in Clinical Trials (171:290 – ‘Advanced Clinical Trials’)

Doctoral Level – Elective Course

Fall 2014: Course Instructor

Fall 2013: Course Instructor

Fall 2011: Course Instructor

Spring 2010: Course Instructor

Applied Survival Analysis (171:242)

Doctoral Level – Required Service Course / Elective Course

Spring 2013: Course Instructor

Applied Cohort Analysis (171:243)

Doctoral Level – Required Service Course / Elective Course

Spring 2013: Course Supervisor

Applied Survival and Cohort Data Analysis (171:242)

Doctoral Level – Required Service Course / Elective Course

Spring 2011: Course Instructor

UNIVERSITY OF ALABAMA AT BIRMINGHAM**Introduction to Survival Analysis (BST 665)**

MS Level – Elective Course

Spring 2009: Course Instructor

Spring 2007: Course Instructor
Spring 2005: Course Instructor
Spring 2003: Course Instructor
Summer 2001: Co-Instructor (with Brent Shelton)

Advanced Clinical Trials II (BST 726)

Doctoral Level – Elective Course
Spring 2008: Course Instructor
Spring 2006: Developed and Organized Course; Presented 7 lectures

Advanced Clinical Trials I (BST 725)

Doctoral Level – Elective Course
Fall 2007: Presented 3 lectures – “DSMB Reports & Meetings”, “Interim Analysis”, & “Adaptive Designs”
Fall 2005: Presented four lectures on “Interim Analysis and Monitoring of Clinical Trials”

Quantitative Methods (HMG 703)

Doctoral Level – Required Course
Spring 2007: Presented lecture on “Safety Monitoring”

Theory of Linear Models (BST 723)

Doctoral Level – Required Course
Fall 2005: Course Instructor
Fall 2003: Course Instructor
Summer 2002: Course Instructor

Applied Regression Analysis

MS Level – Applied Service Course
Fall 2002 – Fall 2005: Presented two lectures on “Choosing the Best Model”

Readings Course on ‘Internal Pilot Designs’ (BST 795)

Doctoral Level – Elective Readings Course
Summer 2003: Course Instructor

Introduction to Data Management and Computing Using the SAS System (BST 626/627)

MS Level – Required Course
Fall 2001 – Fall 2002: Course Instructor

VANDERBILT UNIVERSITY

1999-2001: Statistical consultant to Radiation Oncology Fellows Journal Club

Fall 2000: Introductory Biostatistics.

Required introductory biostatistics course for first-year MPH students.

Spring 2000: Led Group Exercise on Case-Control/Cohort Studies for second year medical students at Vanderbilt University School of Medicine

UNIVERSITY OF NORTH CAROLINA

1999: Prepared and presented a lecture on "Power and Sample Size Calculations" for the course 'Introduction to Statistical Consulting'.

1997: Teaching Assistant for 'Principles of Statistical Inference'
(also presented a lecture on statistical power to the class)

SCHLEGEL, INC.

1993 - 1994: Conducted Basic Statistics and Statistical Process Control training classes for all hourly employees and new hires at Hayward, CA and Keokuk, IA plants

UNIVERSITY OF TENNESSEE

1991-1992: Teaching Assistant for 'Self Paced College Algebra' course

SHORT COURSES AND WORKSHOPS

23. *Essentials of Randomized Clinical Trials*

May 2022: Faculty Member, Workshop at Society for Clinical Trials Annual Meeting (San Diego, CA)
May 2021: Faculty Member, Workshop at Society for Clinical Trials Annual Meeting (Virtual Due to COVID-19)
May 2010: Faculty Member, Workshop at Society for Clinical Trials Annual Meeting (Baltimore, MD)

22. *Clinical Trials Methods in Neurology*

July 2022: Primary Faculty Member (Iowa City, IA)
July 2021: Primary Faculty Member (Virtual Due to COVID-19)
July 2019: Primary Faculty Member (Iowa City, IA)
August 2018: Primary Faculty Member (Ann Arbor, MI)
August 2017: Primary Faculty Member (Iowa City, IA)
July 2015-August 2016: Primary Faculty Member (Ann Arbor, MI)
August 2014: Primary Faculty Member (Iowa City, IA)
August 2008-August 2011: Primary Faculty Member (Vail, CO)

21. *Medical Monitoring*

October 2019: Short Course at Annual Northeast ALS Consortium Meeting (Clearwater, FL)
October 2018: Short Course at Annual Northeast ALS Consortium Meeting (Clearwater, FL)
October 2017: Short Course at Annual Northeast ALS Consortium Meeting (Clearwater, FL)

20. *How to Design Meaningful Clinical Trials*

May 2019: Faculty Member, Short Course at American Academy of Neurology Annual Meeting (Philadelphia, PA)

19. *Adaptive Designs – How Can We Achieve the Promise?*

May 2018: Pre-Conference Workshop, Society for Clinical Trials Annual Meeting (Portland, OR)

18. *Clinical Trials in the Drug Development Pipeline*

April 2018: Faculty Member, Short Course at American Academy of Neurology Annual Meeting (Los Angeles, CA)
April 2017: Faculty Member, Short Course at American Academy of Neurology Annual Meeting (Boston, MA)

17. *American Statistical Association Traveling Course – ‘Adaptive Designs: Overview, Hurdles, & Examples’*

April 2018: Washington Statistical Society (Washington, DC)
November 2017: Trenton/Princeton Chapter (Piscataway, NJ)
September 2017: San Diego Chapter (San Diego, CA)

16. *Adaptive Designs: Overview, Hurdles, Examples, & Software*

May 2015: Co-presenter with Daniele De Martini; Pre-Conference Workshop, Annual Meeting of the Society for Clinical Trials (Montreal, QC)

15. *Adaptive Designs: Overview, Hurdles, & Examples*

April 2015: All Day Workshop, 8th Annual ADVAMED & American Statistical Association Statistical Issues Workshop (Washington, DC)

14. *Clinical Research: Drug Development and Clinical Trials*

April 2015: Faculty Member, Short Course at American Academy of Neurology Annual Meeting (Washington, DC)

13. *Adaptive Designs*

January 2014: Two-day short course sponsored by Rho, Inc. (Chapel Hill, NC)
September 2012: Two-day short course sponsored by the University of Iowa CTSA (Iowa City, IA)

12. *Overview, Hurdles, and Future Work in Adaptive Designs*

September 2013: Short Course offered at FDA/Industry Workshop (Washington, DC)

11. *Adaptive Designs and Small Clinical Trials*

November 2012: Faculty Member; FDA-Sponsored Meeting the Challenges of Rare Disease Drug Review Short Course (Rockville, MD)

10. *Novel Designs for Rare Disorders, Including Adaptive Designs*
May 2012: Faculty Member and Workshop Organizer; NIH-Sponsored Workshop on Designing Clinical Trials in Dystonia (Bethesda, MD)
9. *Challenges in Designing Small Clinical Trials*
May 2011: Co-presenter with Janet Wittes; Pre-conference workshop held in conjunction with the Annual Meeting of the Society for Clinical Trials (Vancouver, BC)
8. *The Science of Small Clinical Trials*
April 2011: Faculty Member (Silver Spring, MD)
February 2010: Faculty Member (Silver Spring, MD)
Course, co-sponsored by the FDA Office of Orphan Products and NIH Office of Rare Diseases. (Bethesda, MD)
7. *Clinical Research Methods*
April 2010: Faculty member for this short course held in conjunction with the Annual Meeting of the American Academy of Neurology (Toronto, ON)
6. *Scientific Advances in Adaptive Clinical Trial Design*
November 2009: Co-organizer and presenter for two-day workshop (Bethesda, MD)
5. *Fundamentals of Randomized Clinical Trials*
May 2009: Co-organizer and faculty member for pre-conference workshop at the annual meeting of the Society for Clinical Trials (Atlanta, GA)
May 2008: Co-organizer and faculty member for pre-conference workshop at the annual meeting of the Society for Clinical Trials. (St. Louis, MO)
4. *Adaptive Dose-Response Studies*
August 2007: Co-taught at the annual Joint Statistical Meetings (Salt Lake City, UT)
3. *Frequentist Adaptive Designs, Internal Pilots, and Stopping Rules*
December 2006: Lecture as part of a Conference on Design, Analysis, and Interpretation of Randomized Clinical Trials in Obesity (Newark, NJ)
2. *Adaptive Designs and Clinical Trials*
May 2005: Pre-conference workshop taught with Cyrus Mehta in conjunction with the Annual Meeting of the Society for Clinical Trials (Portland, OR)
1. *Vanderbilt-Ingram Cancer Center Biostatistics Shared Resource Three Week Workshop*
March 2000: Faculty Member

WEBINARS

8. *Designing Meaningful Early Phase Clinical Trials*
March 2023: Clinical Trials Methods in Neurology Course Webinar Series (w/ Will Meurer)
April 2022: Clinical Trials Methods in Neurology Course Webinar Series (w/ Will Meurer)
7. *Rare Disease Trials*
August 2020: Clinical Trials Methods in Neurology Course Webinar Series (w/ Melanie Quintana)
6. *Ongoing Clinical Studies and Potential Collaborations for Neuroscience Research*
May 2020: Iowa Neuroscience Institute (w/ Emine Bayman, Laurie Gutmann, Kathy Matthews)
5. *Small Sample Size Clinical Trials*
May 2019: Clinical Trials Methods in Neurology Course Webinar Series
July 2018: Clinical Trials Methods in Neurology Course Webinar Series
May 2017: Clinical Trials Methods in Neurology Course Webinar Series
4. *Increasing the Practicality of Innovative Trial Design*
March 2017: Society for Clinical Trials Webinar Series
3. *Challenges in Designing Small Clinical Trials*
December 2011: Sponsored by the Association for Research in Vision and Ophthalmology
2. *Adaptive Designs for Clinical Trials: Perspectives from an NIH-Funded Workshop*
May 2011: Drug Information Association (DIA) Adaptive Design Working Group Key Opinion Leaders Lecture Series

1. Adaptive Designs in Dose-Finding Studies

November 2007: Taught w/ Brenda Gaydos and Jose Pinheiro as part of a four-part web-based training series sponsored by PhRMA and the Biopharmaceutical section of the American Statistical Association.

PUBLICATIONS AND PRESENTATIONS

PEER REVIEWED PUBLICATIONS

195. Leroux A, Crainiceanu C, Zeger S, Taub M, Ansari B, Wager TD, Bayman E, **Coffey C**, Langefeld C, McCarthy R, Tsodikov A, Brummet C, Clauw DJ, Edwards RR, and Lindquist MA (2024). "Statistical Modeling of Acute and Chronic Pain Patient Reported Outcomes (PROs) Obtained from Ecological Momentary Assessment," *PA/N*, in press.
194. Cousins KAQ, Irwin DJ, Tropea TF, Rhodes E, Phillips JS, Chen-Plotkin AS, Brumm MC, **Coffey CS**, Kang JH, Simuni T, Foroud T, Toga AW, Tanner CM, Kieburtz K, Mollenhauer B, Galasko DR, Hutten S, Weintraub D, Siderowf A, Marek K, Kollmorgen G, Poston KL, and Shaw LM on behalf of the Parkinson's Progression Marker Initiative (2023). "Evaluation of ATN_{PD} Framework and Biofluid Markers to Predict Cognitive Decline in Early Parkinson's Disease," *Neurology*, in press.
193. Berry-Kravis E, Abbeduto L, Hagerman R, **Coffey CS**, Cudkowicz M, Erickson CA, McDuffie A, Hessl D, Ethridge L, Tassone F, Kaufmann WE, Friedmann K, Bullard L, Hoffmann A, Veenstra-VanderWeele J, Staley K, Klements D, Moshinsky M, Harkey B, Long J, Fedler J, Klingner E, Ecklund D, Costigan M, Huff T, Pearson B and the NeuroNEXT FXLEARN Investigators (2023). "Effects of AFQ056 on Language Learning in Fragile X Syndrome," *Journal of Clinical Investigation*, Published 08/31/2023 (EPub ahead of print). PMID: 37651202.
192. Simuni T, Chahine LM, Poston K, Brumm M, Buracchio T, Campbell M, Chowdhury S, **Coffey C**, Concha-Marambio L, Dam T, DiBiaso P, Foroud T, Frasier M, Gochanour C, Jennings D, Kieburtz K, Kopil CM, Merchant K, Mollenhauer B, Montine T, Nudelman K, Pagano G, Seibyl J, Sherer T, Singleton A, Stephenson D, Stern M, Soto C, Tanner CM, Tolosa E, Weintraub D, Xiao Y, Siderowf A, Dunn B, and Marek K (2024). "Biological Definition of Neuronal Alpha-Synuclein Disease: Towards an Integrated Staging System for Research," *Lancet Neurology*, 23: 178-190.
191. Smith AG, Singleton JR, Aperghis A, **Coffey CS**, Creigh P, Cudkowicz M, Conwit R, Ecklund D, Fedler JK, Gudjonsdottir A, Hauer P, Herrmann DN, Kearney M, Kissel J, Klingner E, Quick A, Revere C, and Stino A for the NeuroNEXT NN108 TopCSPN Study Team (2023). "Safety and Efficacy of Topiramate in Individuals with Cryptogenic Sensory Peripheral Neuropathy with Metabolic Syndrome: The TopCSPN Randomized Clinical Trial," *JAMA Neurology*, 80(12): 1334-1343. PMID: 37870862.
190. Gonzalez NR, Amin-Hanjani S, Bang OY, **Coffey C**, Du R, Fierstra J, Fraser JF, Kuroda S, Tietjen GE, and Yaghi S on behalf of the American Heart Association Stroke Council, Council on Cardiovascular and Stroke Nursing, and Council on Clinical Cardiology (2023). "Adult Moyamoya Disease and Syndrome: Current Perspectives and Future Directions: A Scientific Statement From the American Heart Association/American Stroke Association," *Stroke*, 54(10): e465-e479. PMID: 37609846.
189. Brumm MC, Siderowf A, Simuni T, Burghardt E, Choi SH, Caspell-Garcia C, Chahine LM, Mollenhauer B, Foroud T, Galasko D, Merchant K, Arnedo V, Hutten SJ, O'Grady AN, Poston KL, Tanner CM, Weintraub D, Kieburtz K, Marek K, and **Coffey CS** on behalf of the Parkinson's Progression Markers Initiative (2023). "Parkinson's Progression Markers Initiative: A Milestone-Based Strategy to Monitor PD Progression," *Journal of Parkinson's Disease*, 13(6): 899-916. PMID: 37458046.
188. Siderowf A, Concha-Marambio L, Lafontant DE, Farris CM, Ma Y, Urenia PA, Nguyen H, Alcalay RN, Chahine LM, Foroud T, Galasko D, Kieburtz K, Merchant K, Mollenhauer B, Poston KL, Seibyl J, Simuni T, Tanner CM, Weintraub D, Videncovic A, Choi SH, Kurth R, Caspell-Garcia C, **Coffey CS**, Frasier M, Oliveira LMA, Hutten SJ, Sherer T, Marek K, Soto C and the Parkinson's Progression Markers Initiative (2023). "Assessment of Heterogeneity and Disease Onset in the Parkinson's Progression Markers Initiative (PPMI) Cohort Using the α -Synuclein Seed Amplification Assay: A Cross-Sectional Study," *Lancet Neurology*, 22(5): 407-417. PMID: 37059509.

187. Sluka KA, Wager TD, Sutherland SP, Labosky PA, Balach T, Bayman EO, Berardi G, Brummett CM, Burns J, Buvanendran A, Caffo B, Calhoun VD, Clauw D, Chang A, **Coffey CS**, Dailey DL, Ecklund D, Fiehn O, Fisch KM, Frey Law LA, Harris RE, Harte SE, Howard TD, Jacobs J, Jacobs JM, Jepsen K, Johnston N, Langefeld CD, Laurent LC, Lenzi R, Lindquist MA, Lokshin A, Kahn A, McCarthy RJ, Olivier M, Porter L, Qian WJ, Sankar CA, Satterlee J, Swensen AC, Vance CGT, Waljee J, Wandner LD, Williams DA, Wixson RL, Zhou ZJ and the A2CPS Consortium (2023). "Predicting Chronic Postsurgical Pain: Current Evidence and a Novel Program to Develop Predictive Biomarker Signatures," *Pain*, 164(9):1912-1926. PMID: 37326643.

186. Merchant K, Simuni T, Fedler J, Caspell-Garcia C, Brumm M, Nudelman K, Tengstrand E, Hsieh F, Alcalay R, **Coffey C**, Chahine L, Foroud T, Singleton A, Weintraub D, Hutten S, Sherer T, Siderowf A, Mollenhauer B, Tanner C, and Marek K (2023). "LRRK2 and GBA1 Variant Carriers Have Higher Urinary Bis(Monacylglycerol) Phosphate Concentrations in PPMI Cohorts," *NPJ Parkinson's Disease*, 9, 30(23). <https://doi.org/10.1038/s41531-023-00468-2>.

185. Weintraub D, Picillo M, Cho HR, Caspell-Garcia C, Blauwendraat C, Brown E, Chahine L, **Coffey C**, Dobkin R, Foroud T, Galasko D, Kieburtz K, Marek K, Merchant K, Mollenhauer B, Poston K, Simuni T, Siderowf A, Singleton A, Seibyl J, and Tanner C (2023). "Impact of the Dopamine System on Long-Term Cognitive Impairment in Parkinson Disease: An Exploratory Study," *Movement Disorders Clinical Practice*, 10(6): 942-954. doi: 10.1002/mdc3.13751.

184. Chahine LM, Beach T, Adler C, Hepker M, Kanthasamy A, Appel S, Pritzkow S, Pinho M, Mosovsky S, Serrano G, **Coffey C**, Brumm M, Oliveira L, Eberling J, and Mollenhauer B (2023). "Central and Peripheral α -Synuclein in Parkinson Disease Detected by Seed Amplification Assay," *Annals of Clinical and Translational Neurology*, 10(5): 696-705. doi:10.1002/acn3.51753.

183. Gibler RC, Peugh JL, **Coffey CS**, Chamberlin L, Ecklund DE, Klingner EA, Korbee LL, Kabbouche MA, Kacperski J, Porter LL, Reidy BL, Hershey AD, and Powers SW (2023). "Impact of Preventive Pill-Based Treatment on Migraine Days: A Secondary Outcome Study of the Childhood and Adolescent Migraine Prevention (CHAMP) Trial and a Comparison of Self-Report to Nosology-Derived Assessments," *Headache*, 63(6): 805-812. PMID: 36757131. Doi:10.1111/head.14474

182. Brumm MC, Pierz KA, Lafontant DE, Caspell-Garcia C, **Coffey CS**, Siderowf A, and Marek KL (2023). "Updated Percentiles for the University of Pennsylvania Smell Identification Test in Adults 50 Years of Age and Older," *Neurology*, Published 02/27/2023 (EPub ahead of print). PMID: 36849448

181. Simuni T, Merchant K, Brumm MC, Cho H, Caspell-Garcia C, **Coffey CS**, Chahine LM, Alcalay RN, Nudelman K, Foroud T, Mollenhauer B, Siderowf A, Tanner C, Iwaki H, Sherer T, and Marek K on behalf of the Parkinson's Progression Marker Initiative (2022). "Longitudinal Clinical and Biomarker Characteristics of Non-Manifesting LRRK2 G2019S Carriers in the PPMI Cohort," *NPJ Parkinson's Disease*, 8(1): 140. PMID: 36273008

180. Macklin EA, **Coffey CS**, Brumm MC, and Seibyl JP (2022). "Statistical Considerations in the Design of Clinical Trials Targeting Prodromal Parkinson Disease," *Neurology*, 99(7 Suppl 1): 68-75. PMID: 35970588.

179. Saunders-Pullman R, Ortega RA, Wang C, Raymond D, Elango S, Urval KLN, Katsnelson V, Gerber R, Swan M, Shanker V, Alcalay RN, Mirelman A, Brumm MC, Meijia-Santana H, **Coffey CS**, Marek K, Ozelius LJ, Giladi N, Marder KS, and Bressman SB (2022). "Association of Olfactory Performance with Motor Decline and Age at Onset in People with Parkinson's Disease and the LRRK2 G2019S Variant," *Neurology*, 99(8): e814-e823. PMID 35995594.

178. Berardi G, Frey-Law L, Sluka KA, Bayman EO, **Coffey CS**, Ecklund D, Vance CGT, Dailey DL, Burns J, Buvanendran A, McCarthy RJ, Jacobs J, Zhou XJ, Wixson R, Balach T, Brummett CM, Clauw D, Colquhoun D, Harte SE, Harris RE, Williams DA, Chang AC, Waljee J, Fisch KM, Jepsen K, Laurent LC, Olivier M, Langefeld CD, Howard TD, Fiehn O, Jacobs JM, Dakup P, Qian WJ, Swensen AC, Lokshin A, Lindquist M, Caffo BS, Crainiceanu C, Zeger S, Kahn A, Wager T, Taub M, Ford J, Sutherland SP, and Wandner LD (2022). "Multi-Site Observational Study to Assess Biomarkers for Susceptibility or Resilience to Chronic Pain: The Acute to Chronic Pain Signatures (A2CPS) Study Protocol," *Frontiers in Medicine*, 9: 849214. PMID: 3554720

177. Signaevsky M, Marami B, Prastawa M, Tabish N, Iida MA, Zhang XF, Sawyer M, Duran I, Koenigsberg DG, Bryce CH, Chahine LM, Mollenhauer B, Mosovsky S, Riley L, Dave KD, Eberling J, **Coffey CS**, Adler CH, Serrano GE, White CL, Koll J, Fernandez G, Zeineh J, Cordon-Cardo C, Beach TG, Crary JF (2022). "Antemortem Detection of Parkinson's Disease Pathology in Peripheral Biopsies Using Artificial Intelligence," *Acta Neuropathologica Communications*, 10(1): 21. PMID: 35164870

176. Griguer CE, Oliva CR, **Coffey CS**, Cudkowicz ME, Conwit RA, Gudjonsdottir AL, Ecklund DJ, Fedler JK, Neill-Hudson TM, Nabors LB, Benge M, Hackney JR, Chase M, Leonard TP, Patel T, Colman H, De la Fuente M, Chaudhary R, Marder K, Kreisl T, Mohlie N, Chheda MG, McNeil K, Kumthekar P, Dogan A, Drappatz J, Puduvalli V, Kowalska A, Gruber J, Gerstner E, Clark S, Salacz M, and Markert J (2022). "Prospective Biomarker Study in Newly Diagnosed Glioblastoma: Cyto-C Clinical Trial," *Neurooncology Advances*, 4(1): 1-10. PMID: 35088051

175. Reidy BL, Powers SW, **Coffey CS**, Chamberlin LA, Ecklund DJ, Klingner EA, Yankey JW, Korbee LL, Porter LL, Peugh J, Kabbouche MA, Kacperski J, and Hershey AD for the CHAMP Investigators (2022). "Multimodal Assessment of Medication Adherence Among Youth with Migraine: An Ancillary Study of the CHAMP Trial," *Journal of Pediatric Psychology*, 47(4): 376-387. PMID: 34865085.

174. Reidy BL, Peugh J, Hershey AD, **Coffey CS**, Chamberlin LA, Ecklund DJ, Klingner EA, Yankey JW, Korbee LL, Porter LL, Kabbouche MA, Kacperski J, and Powers SW (2022). "Trajectory of Treatment Response in the Child and Adolescent Migraine Prevention (CHAMP) Study, A Randomized Clinical Trial," *Cephalgia*, 42(1): 44-52. PMID: 34404270.

173. Nowak RJ, **Coffey CS**, Goldstein JM, Dimachkie MM, Benatar M, Kissel JT, Wolfe GI, Burns TM, Freimer ML, Nations S, Granit V, Smith AG, Richman DP, Ciafaloni E, Al-Lozi MT, Sams LA, Quan D, Ubogu E, Pearson B, Sharma A, Yankey JW, Uribe L, Shy M, Amato AA, Conwit R, O'Connor KC, Hafler DA, Cudkowicz ME and Barohn RJ on behalf of the NN103 BeatMG Study Team (2021). "Phase 2 Trial of Rituximab in Acetylcholine Receptor Antibody-Positive Generalized Myasthenia Gravis: The BeatMG Study," *Neurology*, 98(4): e376-e389. PMID: 34857535

172. Espay AJ, Lafontant DE, Poston KL, Caspell-Garcia C, Marsili L, Cho HR, Daniel C, Kim N, **Coffey CS**, Mahajan A, Ezzat K, and Sturchio A for the Parkinson's Progression Markers Initiative (2021). "Low Soluble Amyloid-Beta 42 is Associated with Smaller Brain Volume in Parkinson's Disease," *Parkinsonism and Related Disorders*, 92: 15-21. PMID: 34656902

171. Picillo M, LaFontant DE, Bressman S, Caspell-Garcia C, **Coffey C**, Cho HR, Burghardt EL, Dahodwala N, Sanders-Pullman R, Tanner CM, and Amara AW for the Parkinson's Progression Markers Initiative (2021). "Sex-Related Longitudinal Change of Motor, Non-Motor, and Biological Features in Early Parkinson Disease," *Journal of Parkinson Disease*, 12(1): 421-436. PMID: 34744052

170. Russo MJ, Orru CD, Concha-Marambio L, Giaisi S, Groveman BR, Farris CM, Holguin B, Hughson AG, LaFontant DE, Caspell-Garcia C, **Coffey CS**, Mollon J, Hutten SJ, Merchant K, Heym RG, Soto C, Caughey B, and Kang UJ (2021). "High Diagnostic Performance of Independent Alpha-Synuclein Seed Amplification Assays for Detection of Early Parkinson's Disease," *Acta Neuropathologica Communications*, 9(1): 179. PMID: 34742348

169. Carillo N, Malicdan MC, Leoyklang P, Shrader JA, Joe G, Slota C, Perreault J, Heiss JD, Class B, Liu CY, Bradley K, Jodarski C, Ciccone C, Driscoll C, Parks R, Van Wart S, Bayman L, **Coffey CS**, Quintana M, Berry SM, Huizing M, and Gahl WA (2021). "Safety and Efficacy of N-Acetylmannosamine (ManNAc) in Patients with GNE Myopathy: An Open-Label Phase 2 Study," *Genetics in Medicine*, 23(11): 2067-2075. PMID: 34257421.

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18. Dutta SC, Chang SC, **Coffey CS**, Smith JA Jr, Jack G, and Cookson MS. (2002) "Health Related Quality of Life Assessment after Radical Cystectomy: Comparison of Ileal Conduit with Continent Orthotopic Neobladder," *Journal of Urology*, **168**(1): 164-167.
17. Griffin MR, **Coffey CS**, Neuzil KM, Mitchel EF, Wright PF, and Edwards KM. (2002) "Winter Viruses: Influenza and Respiratory Syncytial Virus-Related Morbidity in Chronic Lung Disease," *Archives of Internal Medicine*, **162**(11): 1229-1236.
16. Allison DB and **Coffey CS**. (2002) "Two-Stage Testing in Microarray Analysis: What is Gained?" *Journal of Gerontology: Biological Sciences*, **57**: B189-B192.
15. Grossklaus DJ, **Coffey CS**, Shappell SB, Jack GS, Chang SS, and Cookson MS. (2002) "Percent of Cancer in the Biopsy Set Correlates with Pathologic Findings after Prostatectomy," *Journal of Urology*, **167**(5), 2032-2036.
14. Grossklaus DJ, **Coffey CS**, Shappell SB, Jack GS, and Cookson MS. (2001) "Prediction of Tumor Volume and Pathologic Stage in Radical Prostatectomy Specimens is not Enhanced by Increasing the Number of Prostate Needle Biopsy Cores," *BJU International*, **88**, 722-726.
13. Hemminger BM, Zong S, Muller KE, **Coffey CS**, DeLuca MC, Johnston RE, and Pisano ED. (2001) "Improving the Detection of Simulated Masses in Mammograms Through Two Different Image Processing Techniques," *Academic Radiology*, **8**, 845-855.
12. Shappell SB, Manning S, Boeglin WE, Guan YF, Roberts RL, Davis L, Olson SJ, Jack GS, **Coffey CS**, Wheeler TM, Breyer MD, and Brash AR. (2001) "Alterations in Lipoxygenase and Cyclooxygenase-2 Catalytic Activity and mRNA Expression in Prostate Carcinoma," *Neoplasia*, **3**, 287-303.
11. Dutta SC, Smith JA, Shappell SB, **Coffey CS**, Chang SS, and Cookson MS. (2001) "Clinical Understaging of High Risk Nonmuscle Invasive Urothelial Carcinoma Treated with Radical Cystectomy," *Journal of Urology*, **166**, 490-493.
10. **Coffey CS** and Muller KE. (2001) "Controlling Test Size While Gaining the Benefits on an Internal Pilot Design," *Biometrics*, **57**, 625-631.
9. Cardin S, Jackson PA, Edgerton DS, Neal DW, **Coffey CS**, and Cherrington AD. (2001) "Effect of Vagal Cooling on the Counterregulatory Response to Hypoglycemia Induced by a Low Dose of Insulin in the Conscious Dog," *Diabetes*, **50**, 558-564.
8. Jackson PA, Cardin S, **Coffey CS**, Neal DW, Allen EJ, Penalosa AR, Snead WL, and Cherrington AD (2000). "Effect of Hepatic Denervation on the Counterregulatory Response to Insulin-Induced Hypoglycemia in the Dog," *American Journal of Physiology – Endocrinology and Metabolism*, **279**, E1249-E1257.
7. **Coffey CS** and Muller KE. (2000) "Some Distributions and Their Implications for an Internal Pilot Study with a Univariate Linear Model," *Communications in Statistics-Theory and Methods*, **29**(12), 2677-2691.
6. Jack GS, Brash AR, Olson SJ, Manning S, **Coffey CS**, Smith J, and Shappell SB. (2000). "Reduced 15-lipoxygenase-2 Immunostaining in Prostate Adenocarcinoma: Correlation with Grade and Expression in High Grade Prostatic Intraepithelial Neoplasia," *Human Pathology*, **31**(9), 1146-1154.
5. **Coffey CS** and Muller KE. (2000) "Properties of Doubly-Truncated Gamma Variables," *Communications in Statistics-Theory and Methods*, **29**(4), 851-857.
4. Hemminger BM, Dillon A, Johnston RE, Muller KE, Pisano E, Deluca M, and **Coffey C** (1999). "Effect of Display Luminance on the Feature Detection Rates of Masses in Mammograms," *Medical Physics*, **26**(11), 2266-2272.
3. **Coffey CS** and Muller KE. (1999) "Exact Test Size and Power of a Gaussian Error Linear Model for an Internal Pilot Study," *Statistics in Medicine*, **18**, 1199-1214.
2. Bullitt E, Liu A, Aylward S, **Coffey C**, Stone J, Mukherji SK, Muller K, and Pizer SM. (1999) "Registration of 3D Cerebral Vessels with 2D Digital Angiograms: Clinical Evaluation," *Academic Radiology*, **6**, 539-546.
1. Boxwala AA, Chaney EL, Fritsch DS, Raghavan S, **Coffey CS**, Major SA, and Muller KE. (1999) "Comparison of Computer Workstation with Light Box for Detecting Setup Errors from Portal Images," *International Journal of Radiation Oncology, Biology, Physics*, **44**, 711-716.

INVITED BOOK CHAPTERS

2. **Coffey CS**. "Adaptive Design across Stages of Development." *Clinical Trials in Neurology*. Eds: Ravina B, Cummings MP, McDermott MP, and Poole M. Cambridge University Press, 2012, 91-100.
1. **Coffey CS** and Cofield SS. "Parametric Linear Models." *DNA Microarrays and Related Genomic Techniques: Design, Analysis, and Interpretation of Experiments*. Eds: Allison DB, Page GP, Beasley TM, and Edwards JW. Boca Raton: Chapman & Hall/CRC, 2005, 223-243.

OTHER PUBLICATIONS

7. Hoffman EP on behalf of **Workshop Participants** and the TREAT-NMD Alliance (2017). "Facilitating Orphan Drug Development: Proceedings of the TREAT-NMD International Conference, December 2015, Washington, DC, USA," *Neuromuscular Disorders*, 27(7): 693-701.
6. **Coffey CS** (2010). "Power Analysis," In *Encyclopedia of Research Design*, NJ Salkind (ed.), Publisher: Sage, Thousand Oaks, CA.
5. Kairalla JA, **Coffey CS**, and Muller KE (2010). "Achieving the Benefits of Both an Internal Pilot and Interim Analysis in Small Samples," *2010 Proceedings of the Joint Statistical Meetings*, ENAR Section, 5239-5252.
4. Ritchie MD, **Coffey CS**, and Moore JH. (2005) "Genetic Programming Neural Networks as a Bioinformatics Tool for Human Genetics," *Lecture Notes in Computer Science: Genetic and Evolutionary Computation – GECCO 2004 Conference Proceedings*, **3102**: 438-448.
3. **Coffey CS** and Muller KE. (2003) "Practical Methods for Bounding Test Size with an Internal Pilot Design," *2003 Proceedings of the Joint Statistical Meetings*, Biopharmaceutical Section [CD-ROM].
2. **Coffey CS** and Muller KE. (2001) "GLUMIP 1.0: Free SAS IML Software for Internal Pilots," *2001 Proceedings of the Joint Statistical Meetings*, Biometrics Section [CD-ROM].
1. Bullitt E, Aylward S, Liu A, Stone J, Mukherji S, **Coffey C**, Gerig G, and Pizer SM. (1999) "3D Graph Description of the Intracerebral Vasculature from Segmented MRA and Tests of Accuracy by Comparison with X-Ray Angiograms," *Lecture Notes in Computer Science*, **1613**, 308-321.

INVITED PRESENTATIONS

75. *Statistical Design Considerations*
January 2024: BIG10 Neurosurgery Consortium Meeting (Los Angeles, CA)
74. *Achieving the Promise of Innovative Clinical Designs in an Academic Setting*
October 2022: Icahn School of Medicine at Mt. Sinai (Virtual)
June 2020: University of Alabama at Birmingham (Birmingham, AL – Virtual Due to COVID-19)
January 2019: Duke University (Durham, NC)
August 2018: University of Minnesota (Minneapolis, MN)
73. *Study Design & Statistical Issues*
October 2022: Planning for Prevention of Parkinson's: A Trial Design Forum (Boston, MA)
72. *Trial Design & Statistics*
September 2022: International Linked Clinical Trials (iLCT) Meeting (Grand Rapids, MI)
71. *Running Up That Hill: Navigating the Upside Down World of Coordinating Clinical Trials*
August 2022: University of Iowa College of Public Health Spotlight Series (Iowa City, IA)
70. *Clinical Trials Regulatory Overview*
July 2022: Keynote Address, 2022 Clinical Trials Methodology Course (Iowa City, IA)
69. *We Built This Network: How NeuroNEXT Increases Innovative Design in Neurology*
April 2022: University of Rochester Michael P. McDermott Endowed Lectureship in Experimental Therapeutics (Virtual Due to COVID-19)
68. *Planning for Success: Clinical Trial Design*
November 2021: Panelist, Alpha Synuclein Summit: Clinical Development of Alpha-Synuclein Therapeutics (Virtual Due to COVID-19)
67. *Data Coordinating Centers: Telling the Story of Research*
August 2021: Panelist, Joint Statistical Meetings (Virtual Due to COVID-19)

66. *Is Sample Size Re-Estimation Controversial? – Well, Yes & No*
May 2021: Society for Clinical Trials Annual Meeting (Virtual Due to COVID-19)

65. *Designing Meaningful Early Phase Clinical Trials*
April 2021: American Academy of Neurology Annual Meeting (Virtual Due to COVID-19)

64. *How to Measure Prevention? Selecting an Intervention – Study Design/Statistical Foundation*
April 2021: Planning for Prevention of Parkinson's: A Trial Design Symposium and Workshop (Virtual Due to COVID-19)

63. *An Overview of Adaptive Designs*
February 2020: University of Iowa Institutional Review Board (Iowa City, IA)

62. *Increasing the Chances of Finding Effective Treatments*
November 2019: NIH Workshop – Improving the Identification of Disease Modification PD Targets and Their Testing in Early Phase Clinical Trials (Bethesda, MD)

61. *The Clinical Trials Statistical & Data Management Center (CTSDMC) – History & Current Neurological Activities*
July 2019: University of Iowa Department of Neurology Grant Rounds (Iowa City, IA)

60. *An Overview of Data Sharing*
May 2019: Society for Clinical Trials Annual Meeting (New Orleans, LA); Part of an Invited Session on "Preparing and Submitting Data to Open and Limited-Access Repositories" (Organizer: Janel Fedler, University of Iowa)

59. *An Overview of NeuroNEXT*
May 2019: Society for Clinical Trials Annual Meeting (New Orleans, LA); Part of an Invited Session on "Switching Boats Mid-Stream: Maintaining Continuity in a Large Clinical Trials Network in the Face of Change" (Organizer: Julie Qidwai, University of Iowa)

58. *Novel Trial Designs of 'Disease Modifying Therapy' in Oncology (e.g., I-SPY2) and Other Diseases*
April 2019: The Krembil Knowledge Gaps in Parkinson's Disease Symposium (Toronto, Canada)

57. *Innovative Statistical Design and Analysis in ALS*
November 2018: Massachusetts ALS Partnership Symposium (Boston, MA)
October 2018: 17th Annual Northeast ALS Consortium Annual Meeting (Clearwater, FL)

56. *Design Considerations When Planning Clinical Trials*
September 2018: "Enhancing Natural Products Clinical Trials" Workshop (Bethesda, MD)

55. *We Built This Network: How NeuroNEXT Increases Innovative Design in Academic Trials*
August 2018: University of Iowa College of Public Health Distinguished Faculty Lecture (Iowa City, IA)

54. *What We Measure and How: Outcomes Panel*
July 2018: ALS Community Workshop – Therapy Development & Regulatory Discussion; Panel Discussion w/ Drs. Jeremy Shefner (Barrow Neurological Institute), Steve Hersch (Voyager Therapeutics), and Madeline Kennedy (Person w/ ALS; Washington, DC)

53. *Adaptive Timing of Interim Analysis: DSMB Perspective*
May 2018: Society for Clinical Trials Annual Meeting (Portland, OR)

52. *University of Iowa Clinical Trials Statistical & Data Management Center – Overview of Ongoing Parkinson's Disease Research Efforts*
April 2018: University of Iowa, Parkinson's Foundation Center of Excellence Evaluation Site Visit (Iowa City, IA)

51. *University of Iowa Clinical Trials Statistical & Data Management Center – Overview of Ongoing Collaborations with the Michael J. Fox Foundation*
April 2018: Eastern Iowa Parkinson's Symposium (Cedar Rapids, IA)

50. *Innovative Statistical Design and Analysis in PD*
February 2018: The International Society for CNS Clinical Trials & Methodology Annual Meeting (Washington, DC)

49. *Utilizing NIH Networks for Clinical Trials: Lessons from the Trenches*
July 2017: Cleveland Clinic (Cleveland, OH – Co-Presenter w/ Merit Cudkowicz, MGH; Robin Conwit, NINDS; Codrin Lungu, NINDS)

48. *Implementing Adaptive Designs: Balancing the Practical with the Statistical*
May 2017: Discussant, Society for Clinical Trials Annual Meeting (Liverpool, UK)

47. *Statistical Aspects of the Childhood & Adolescent Migraine Prevention (CHAMP) Study*
April 2017: UAB Department of Biostatistics (Birmingham, AL)

46. *Increasing the Practicality of Innovative Trial Designs*
April 2017: DIA Adaptive Design Scientific Working Group Key Opinion Leaders Webinar Series
March 2017: The Society for Clinical Trials Webinar Series
March 2017: Iowa Department of Biostatistics Seminar Series (Iowa City, IA)
December 2016: National Institute of Neurological Disorders & Stroke (Bethesda, MD)
April 2016: University of Florida Department of Biostatistics (Gainesville, FL)
October 2015: UAB Department of Biostatistics (Birmingham, AL)
April 2015: Keynote Address at 8th Annual ADVAMed & American Statistical Association Statistics Workshop (Washington, DC)

45. *Challenges and Experience in Designing Small Clinical Trials*
August 2016: Invited Session at Joint Statistical Meetings (Chicago, IL)

45. *NeuroNEXT Overview & Accomplishments*
July 2016: The Ohio State University School of Medicine (Columbus, OH)

44. *Adaptive & Bayesian Trial Design*
February 2016: ICTS Sponsored Workshop on Patient-Centered Outcomes and Comparative Effectiveness Research (Cincinnati, OH)

43. *The State of the Clinical Trials Statistical and Data Management Center*
February 2016: Iowa Department of Biostatistics Seminar Series (Iowa City, IA)

42. *Innovative Trial Designs for Rare Disease*
December 2015: TREAT-NMD International Conference (Washington, DC)

41. *Common Data Elements: The User's Perspective*
May 2015: Invited Session at Annual Society for Clinical Trials Meeting (Washington, DC)

40. *Overview of the Clinical Trials Statistical and Data Management Center & NeuroNEXT*
April 2015: Iowa Department of Epidemiology Seminar Series (Iowa City, IA)

39. *Re-Estimating Sample Size Midtrial: The SPS3 Experience*
April 2015: 8th Annual ADVAMed & American Statistical Association Workshop (Washington, DC)

38. *Small Phase II Trials*
March 2015: ALS Association Patient Webinar Series

37. *Overview, Hurdles, and Future Work in Adaptive Designs*
August 2014: American Statistical Association Webinar Series

36. *Adaptive Trial Designs*
February 2014: Alpha-One Foundation Sponsored Workshop on 'Clinical Trial Design for Alpha-1 Antitrypsin Deficiency: A Model for Rare Diseases' (Bethesda, MD)

35. *Challenges in Designing Clinical Trials for Rare Diseases*
September 2013: FDA/Industry Workshop (Washington, DC)

34. *Overview of Adaptive Designs, and Extensions beyond Clinical Trials*
July 2013: East Tennessee State University College of Public Health (Johnson City, TN)

33. *Revolutionizing Clinical Trials by Creating Infrastructure for Phase 2 Trials in Neurological Disorders*
May 2013: Invited Session at Annual Society for Clinical Trials Meeting (Panel with Cudkowicz M, Kearney M, Ecklund D, McNeil E; Boston, MA)

32. *An Overview of Adaptive Designs*
March 2013: College of Nursing Seminar Series, University of Iowa (Iowa City, IA)

31. *Overview, Hurdles, and Future Work in Adaptive Designs*
February 2013: Department of Statistics, University of Iowa (Iowa City, IA)
May 2011: Mackey Cancer Center, University of Kentucky (Lexington, KY)

30. *Overview of Randomized Clinical Trials*
September 2012: Department of Obstetrics/Gynecology Seminar, University of Iowa (Iowa City, IA)

29. *Quantitative Pitfalls in Comparative Effectiveness Research and How to Avoid Them*
February 2012: Department of Internal Medicine Grand Rounds, University of Florida
(with KE Muller & RI Shorr; Gainesville, FL)

28. *Building a Clinical Studies Database*
December 2011: NINDS Sponsored Parkinson's Disease Biomarkers Resource Data Management Workshop (Bethesda, MD)

27. *Use of Adaptive Designs in Clinical Effectiveness Trials*
November 2011: University of Iowa CTSA Lecture Series (Iowa City, IA)

26. *Adaptive Designs and Small Clinical Trials*
October 2011: FDA/Industry Workshop (Washington, DC)
October 2011: US Conference on Rare Diseases and Orphan Products (Washington, DC)
March 2011: US FDA Center for Biologics Evaluation and Research (Rockville, MD)
March 2011: US FDA Center for Drug Evaluation and Research Office of Biostatistics (Silver Spring, MD)

25. *Adaptive Design for Clinical Trials: Perspectives from an NIH-Funded Workshop*
May 2011: Drug Information Association (DIA) Adaptive Design Working Group KOL Lecture Series (webinar)

24. *Hurdles and Future Work in Adaptive Designs*
April 2011: University of Pennsylvania Clinical Trials Symposium (Philadelphia, PA)

23. *Biostatistics*
October 2010: Fourth Annual Iowa Mathematical Field of Dreams Conference (Iowa City, IA)

22. *Adaptive Designs*
November 2009: Huntington Disease Study Group (Baltimore, MD)

21. *The Emerging Role of the Data and Safety Monitoring Board: Implications of Adaptive Clinical Trial Designs*
Oct 2009: University of Rochester (Rochester, NY)
June 2009: Annual Meeting of the Southern Research Council on Statistics (Jekyll Island, GA)

20. *Avoiding the Pitfalls of a Meta-Analysis*
April 2009: Third Annual Methods in Epidemiology and Outcomes Research Symposia, University of Alabama at Birmingham (Birmingham, AL)

19. *Internal Pilot Designs: They're Not Just for Clinical Trials Anymore*
December 2008: Department of Biostatistics, The University of Iowa (Iowa City, IA)

18. *Internal Pilot Designs: An Overview and Recent Extensions*
November 2008: Department of Public Health Sciences, University of Virginia (Charlottesville, VA)
October 2008: College of Public Health, The Ohio State University (Columbus, OH)

17. *Internal Pilot Designs for Cluster Samples*
August 2008: Joint Statistical Meetings (Denver, CO)

16. *Advantages and Disadvantages When Implementing an Adaptive Design in an NIH-Funded Study*
August 2007: Joint Statistical Meetings (Salt Lake City, UT)

15. *Treatment Effect in Sample Size Determination: Clinical vs. Statistical Significance*
May 2007: Annual Meeting of the Society for Clinical Trials (Montreal, Quebec, Canada)

14. *Activities of the Statistical Center for the Secondary Prevention of Small Subcortical Strokes (SPS3) Trial*
May 2007: Clinical Trials and Data Management Center, Department of Biostatistics, University of Iowa (Iowa City, IA)

13. *Clarifying the Controversy Surrounding Adaptive Designs for Sample Size Re-Estimation*
May 2007: Department of Biostatistics, University of Iowa (Iowa City, IA)
March 2007: Department of Epidemiology and Health Policy Research, University of Florida (Gainesville, FL)

12. *An Introductory Overview Lecture on Adaptive Designs/Internal Pilots*
August 2006: Annual Joint Statistical Meetings (Seattle, WA)

11. *Adaptive and Internal Pilot Designs*
 - December 2006:** Department of Neurology, Columbia University Medical Center (New York, NY)
 - June 2006:** Department of Epidemiology and Health Policy Research, University of Florida (Gainesville, FL)
 - April 2006:** Department of Public Health, East Tennessee State University (Johnson City, TN)
10. *Internal Pilot Designs for Medical Imaging Studies*
 - March 2006:** Department of Biostatistics, University of North Carolina at Chapel Hill (Chapel Hill, NC)
9. *An Overview of Adaptive Designs with Emphasis on Internal Pilots*
 - March 2006:** Health Services Administration Doctoral Seminar, University of Alabama at Birmingham (Birmingham, AL)
 - November 2005:** Medical Statistics Section Seminar, University of Alabama at Birmingham Comprehensive Cancer Center (Birmingham, AL)
 - October 2005:** Center for Nursing Research Seminar, University of Alabama at Birmingham (Birmingham, AL)
 - June 2004:** National Institute of Neurological Disorders and Stroke, Clinical Trials Program (Bethesda, MD)
8. *Using Internal Pilot Designs with Repeated Measures*
 - August 2005:** Annual Joint Statistical Meetings (Minneapolis, MN)
7. *Sample Size Adjustments Using Internal Pilot Designs for Repeated Measures ANOVA*
 - April 2005:** Department of Biostatistics, University of North Carolina at Chapel Hill (Chapel Hill, NC)
6. *Internal Pilots and Power Adjustments for Controlled Clinical Trials*
 - January 2005:** Center for Aging/VA GRECC, University of Alabama at Birmingham (Birmingham, AL)
5. *Promises and Pitfalls of Modifying the Sample Size during a Study: Adaptive and Internal Pilot Designs*
 - November 2004:** Department of Biostatistics, University of North Carolina at Chapel Hill (Chapel Hill, NC)
4. *Exact and Approximate Methods for Internal Pilots: Beyond Two Group Comparisons*
 - April 2003:** Annual Meeting of the Eastern North American Region (ENAR) of the Biometrics Society (Tampa, FL)
3. *GLUMIP 1.0: Free SAS IML Software for Planning Internal Pilots.*
 - August 2001:** Annual Joint Statistical Meetings (Atlanta, GA)
2. *Is There an Interaction between the ACE I/D and PAI-1 4G/5G Gene Polymorphisms on Risk of Myocardial Infarction?*
 - (Joint presentation with Patricia Hebert, Yale, and Jason Moore, Vanderbilt)
 - August 2001:** Joint with P Hebert (Yale) and J Moore (Vanderbilt), Section of Cardiovascular Medicine, Department of Internal Medicine, Yale University School of Medicine (New Haven, CT)
1. *Internal Pilot Study Design and Analysis for Gaussian Error Linear Models with Fixed Predictors.*
 - April 2000:** Department of Biostatistics, University of Alabama at Birmingham (Birmingham, AL)
 - October 1999:** Middle Tennessee Chapter, American Statistical Association, (Nashville, TN)
 - September 1999:** Gertrude M. Cox Building Dedication and Statistical Symposium, Research Triangle Institute (Research Triangle Park, NC)
 - August 1999:** Annual Meeting of General Clinical Research Center Statisticians (Baltimore, MD)

CONTRIBUTED PRESENTATIONS

13. *Adaptive Design for Clinical Trials: Perspectives from an NIH-Sponsored Workshop*
 - May 2011:** Annual Meeting of the Society for Clinical Trials (Vancouver, BC)
12. *Power in Time to Event Trials: Bigger Isn't Always Better*
 - September 2006:** 4th Annual SPS3 Investigator's Meeting (San Antonio, TX)
11. *Premature Termination of Clinical Trials*
 - September 2005:** 3rd Annual SPS3 Investigator's Meeting (Scottsdale, AZ)
10. *Internal Pilot Designs with Compound Symmetric and Gaussian Repeated Measures*
 - August 2004:** Annual Joint Statistical Meeting (Toronto, Ontario)

9. *Controlling Bias in Internal Pilots with the Univariate Approach to Repeated Measures*
March 2004: Annual Meeting of the Eastern North American Region (ENAR) of the Biometrics Society (Pittsburgh, PA)
8. *Practical Methods for Bounding Test Size with an Internal Pilot Design*
August 2003: Annual Joint Statistical Meeting (San Francisco, CA)
7. *Reporting of Internal Prediction Errors in Case-Control Studies of Genetic Interactions* (Joint presentation with Patricia Hebert, Yale)
May 2003: Annual Meeting of the Society for Clinical Epidemiology and Health Care Research (Vancouver, BC)
Abstract Published: *Journal of Clinical Epidemiology*, **56(9)**:922-3.
6. *A Comparison of Two Methods for Detecting Interactions among Genetic Polymorphisms in Matched Case-Control Studies*
March 2002: Annual Meeting of the Eastern North American Region (ENAR) of the Biometrics Society (Crystal City, VA)
5. *Internal Pilot for the Univariate Approach to Repeated Measures*
March 2001: Annual Meeting of the Eastern North America Region (ENAR) of the Biometrics Society (Charlotte, NC)
4. *Controlling Test Size While Gaining the Benefits of an Internal Pilot Design.*
March 2000: Annual Meeting of the Eastern North America Region (ENAR) of the Biometrics Society (Chicago, IL)
3. *The Impact on Power of Controlling Test Size for an Internal Pilot Study.*
August 1999: Annual Joint Statistical Meeting (Baltimore, MD)
2. *Approximations and Bounds on Test Size for an Internal Pilot Study.*
March 1999: Annual Meeting of the Eastern North America Region (ENAR) of the Biometrics Society (Atlanta, GA)
1. *Exact Test Size and Power of a Gaussian Error Linear Model for an Internal Pilot Study.*
March 1997: Annual Meeting of the Eastern North America Region (ENAR) of the Biometrics Society (Memphis, TN)

CONTRIBUTED POSTER PRESENTATIONS

7. *The Parkinson's Progression Markers Initiative: A Prospective Biomarkers Study.*
May 2011: Annual Meeting of the Society for Clinical Trials (Vancouver, BC)
6. *Development of an Advanced Clinical Trials Course in a Biostatistics Doctoral Program.*
May 2009: Annual Meeting of the Society for Clinical Trials (Atlanta, GA)
5. *The Metabolic Syndrome and its Association with PAI-1 and t-PA Antigen Levels in a Population-Based Study.*
April 2005: Annual Conference on Cardiovascular Disease Epidemiology and Prevention (Washington DC)
4. *The Effects of Intentional Weight Loss as a Latent Variable Problem.* **November 2003:** North American Association for the Study of Obesity Annual Scientific Meeting (Ft. Lauderdale, FL)
3. *The Importance of Model Validation in Determining the Clinical Utility of Genetic Interactions on Disease Risk.* **October 2002:** Annual Meeting of the American Society for Human Genetics (Baltimore, MD)
2. *Safety of an Herbal Formulation Including Ephedra Alkaloids Dosed Intermittently or Continuously for Weight Control.* **April 2002:** Annual Meeting of the Federation of American Societies for Experimental Biology (New Orleans, LA)
1. *A Comparison of Two Methods for Detecting Interactions among Genetic Polymorphisms in Matched Case-Control Studies.* **October 2001:** Annual Meeting of the American Society for Human Genetics (San Diego, CA)

ABSTRACTS (CO-AUTHORED PRESENTATIONS/POSTERS)

191. *Path to Prevention (P2P) Therapeutics Platform Trial in Stage 2B Neuronal Alpha-Synuclein Disease: Study and Timeline*
Simuni T, **Coffey C**, Siderowf A, Tanner C, Chowdhury S, Kopil C, Sherer T, Brumm M, Kieburtz K, Fabrizio K, Saville B, Allen-Savietta C, Wendelberger B, Crawford A, and Marek K on behalf of the PPMI Investigators
March 2024: Poster Presentation, To be presented at International Conference on Alzheimer's and Parkinson's Diseases & Related Disorders (AD/PD: Lisbon, Portugal)

190. *Path to Prevention (P2P) Therapeutics Platform Trial in Biomarker Defined Prodromal Parkinson's Disease: Study Design*
Simuni T, **Coffey C**, Siderowf A, Tanner C, Chowdhury S, Kopil C, Sherer T, Brumm M, Kieburtz K, Fabrizio K, Saville B, Allen-Savietta C, Wendelberger B, Crawford A, and Marek K on behalf of the PPMI Investigators
October 2023: Poster Presentation, Michael J. Fox Foundation Therapeutics Conference (New York, NY)

189. *Estimating Power Under Differences in Placebo Response in a Platform Trial*
McCabe ME, **Coffey CS**, and Bayman EO
October 2023: Poster Presentation, College of Public Health Research Day (Iowa City, IA)

188. *The ExTINGUISH Trial: A Phase-2B Randomized Placebo-Controlled Trial of Inebilizumab in Anti-NMDA Receptor Encephalitis*
Wong KH, Day GS, Torner J, Cudkowicz M, **Coffey C**, Cho S, Ohayon J, Klawiter E, Singleton JR, Mitchell D, Cahalan S, Fedler J, Ecklund DJ, Klements D, Costigan M, Pearson B, Steinhart E, Desir C, Titulaer MJ, and Clardy SL
October 2023: Poster Presentation, World Congress of Neurology (Montreal, Canada)
October 2023: Poster Presentation, European Committee for Treatment & Research in Multiple Sclerosis (ECTRIMS) Meeting (Milan, Italy)

187. *ATN_{PD} Framework Using Biofluid Markers Predicts Cognitive Decline in Early Parkinson's Disease*
Cousins KAQ, Irwin DJ, Tropea TF, Rhodes E, Phillips JS, Chen-Plotkin AS, Brumm MC, **Coffey CS**, Kang JH, Simuni T, Foroud T, Toga AW, Tanner CM, Kieburtz K, Mollenhauer B, Galasko DR, Hutten S, Weintraub D, Siderowf A, Marek K, Poston KL, and Shaw LM on behalf of the Parkinson's Progression Marker Initiative
September 2023: Poster Presentation, American Neurological Association Annual Meeting (Philadelphia, PA)

186. *Widespread Synuclein Pathology in Hypotheses Precedes Dopamine Transporter Deficit in PARS*
Marek K, Russell D, Concha L, Choi C, Jennings D, Brumm M, **Coffey C**, Brown E, Stern M, Seibyl J, Soto C, and Siderowf A for the PARS Investigators
August 2023: Virtual Poster Presentation, International Congress of Parkinson's Disease & Movement Disorders (Copenhagen, Denmark)

185. *Digital Mobility Sub-Study in the Parkinson's Progression Marker Initiative (PPMI) Study*
Mirelman A, Simuni T, Tanner C, Flagg E, Lorenzo A, Dimos J, **Coffey C**, Siderowf A, Marek K, and The Parkinson's Progression Markers Initiative
August 2023: Poster Presentation, International Congress of Parkinson's Disease & Movement Disorders (Copenhagen, Denmark)

184. *Comparison of Original and Revised Versions of the University of Pennsylvania Smell Identification Test*
Brumm MC, Pierz K, Aamodt W, Gochanour C, Kurth R, **Coffey CS**, Foroud T, Brown E, Doty R, Simuni T, Tanner CM, Marek K, Siderowf A
August 2023: Virtual Poster Presentation, International Congress of Parkinson's Disease & Movement Disorders (Copenhagen, Denmark)

183. *Parkinson's Progression Markers Initiative (PPMI): Defining PD Biology to Accelerate PD Therapeutics*
McMahon B, Siderowf A, Simuni T, Tanner C, Mollenhauer B, **Coffey C**, Galasko D, Poston K, Chahine L, Dobkin R, Foroud T, Kieburtz K, Weintraub D, Merchant K, Frasier M, Sherer T, Chowdhury S, Brown E, Alcalay R, Videnvic A, Fabrizio K, Flagg E, & Marek K
August 2023: Poster Presentation, International Congress of Parkinson's Disease & Movement Disorders (Copenhagen, Denmark)

182. *Path to Prevention (P2P) Therapeutics Platform Trial in Biomarker Defined Prodromal Parkinson's Disease: Study Design*
Simuni T, **Coffey C**, Siderowf A, Tanner C, Chowdhury S, Kopil C, Sherer T, Brumm M, Kieburtz K, Fabrizio K, Saville B, Allen-Savietta C, Wendelberger B, Crawford A, and Marek K on behalf of the PPMI Investigators
August 2023: Poster Presentation, International Congress of Parkinson's Disease & Movement Disorders (Copenhagen, Denmark)

181. *10 Year Longitudinal Change in Clinical and Biological Characteristics of Sporadic Parkinson Disease PPMI Cohort*
Gonzalez-Latapi P, Simuni T, Siderowf A, Fedler J, Brumm M, Gochanour C, **Coffey C**, and Marek K on behalf of the PPMI Investigators
August 2023: Poster Presentation, International Congress of Parkinson's Disease & Movement Disorders (Copenhagen, Denmark)

180. *Longitudinal Clinical and Biomarker Characteristics of Non-Manifest GBA1 N40S Carriers: The PPMI Cohort*
Gonzalez-Latapi P, Harvell D, Simuni T, Merchant K, Brumm MC, Alcalay RN, Cho H, Caspell-Garcia C, Gochanour C, **Coffey C**, and Marek K on behalf of the PPMI Investigators
August 2023: Poster Presentation, International Congress of Parkinson's Disease & Movement Disorders (Copenhagen, Denmark)

179. *Long-Term Dementia Prevalence in Parkinson Disease: Glass Half-Full?*
Gallagher J, Gochanour C, Caspell-Garcia C, Dobkin R, Aarsland D, Alcalay R, Barrett M, Chahine LM, Chen-Plotkin A, **Coffey C**, Dahodwala N, Eberling J, Espay A, Leverenz JB, Litvan I, Mamikonyan E, Morley JF, Richard I, Rosenthal L, Siderowf A, Simuni T, York M, Willis A, Xie SX, & Weintraub D
July 2023: Poster Presentation, World Parkinson's Congress (Barcelona, Spain)

178. *Evaluation of Current Practices in the Reporting of Results from Platform Trials*
McCabe ME, **Coffey CS**, and Bayman EO
May 2023: Poster Presentation, Society for Clinical Trials Annual Meeting (Baltimore, MD)

177. *Acute to Chronic Pain Signatures (A2CPS) Thoracic Enrollment*
Bayman EO, Nadel L, **Coffey C**, Sluka K, Dailey D, McCarthy, and Brummett C
April 2023: Poster Presentation at United States Association for the Study of Pain Annual Meeting (Durham, NC)

176. *Longitudinal Clinical and Biomarkers Characteristics of Non-Manifest GBA1 N40S Carriers: The PPMI Cohort*
Gonzalez-Latapi P, Simuni T, Merchant K, Brumm M, Alcalay RN, Cho H, Caspell-Garcia C, Gochanour C, **Coffey C**, and Marek K on behalf of the PPMI Investigators
March 2023: Poster Presentation, ADPD 2023 – International Conference on Alzheimer's and Parkinson's Disease and Related Neurological Disorders (Gothenberg, Sweden)

175. *An Overview of Statistical Approaches and Operational Challenges Related to Non-Concurrent Controls in Platform Trials*
McCabe ME, **Coffey CS**, and Bayman EO
February 2023: Poster Presentation, American Statistical Association Conference on Statistical Practice (San Francisco, CA)

174. *The ExTINGUISH Trial: A Multi-Site Phase-2B Randomized Placebo-Controlled Trial to Study the Safety and Efficacy of Inebiliizumab in Anti-NMDA Receptor Encephalitis*
Day GS, Titulaer MJ, Wong KH, Torner J, Cudkowicz M, **Coffey C**, Lungu C, Klawiter E, Singleton JR, Mitchell D, Fedler J, Ecklund DJ, Klements D, Costigan M, and Clardy SL
October 2022: American Neurological Association Annual Meeting (Chicago, IL)
April 2022: Poster Presentation, American Academy of Neurology Annual Meeting (Seattle, WA)

173. *Acute to Chronic Pain Signatures Program (A2CPS): An Update on Study Enrollment and Data Completion*
Berardi G, Frey-Law L, Vance CGT, Bayman EO, **Coffey CS**, Dailey DL, Ecklund D, Sluka KA, Burns J, Buvanendran A, Jacobs J, McCarthy RJ, Wixson R, Zhou WJ, Brummett CM, Clauw D, Harris RE, Harte S, Crainiceanu C, Ford J, Kahn A, Lindquist M, Sutherland S, Taub M, Wager T, Wandner LD and The Acute to Chronic Pain Signatures Consortium
September 2022: Poster Presentation, IASP 2022 World Congress of Pain (Toronto, Canada)

172. *Acute to Chronic Pain Signature Program Powered for Discovery and Prediction Modeling*
Bayman EO, Langefeld CD, Lindquist M, **Coffey C**, Leroux A, Crainiceanu C, McCarthy R, Tsodikov A, Zeger SL, Berardi G, Brummett C, Burns J, Clauw D, Johnston N, Porter L, Sluka K, and Wager TD
September 2022: Poster Presentation, IASP 2022 World Congress of Pain (Toronto, Canada)

171. *Longitudinal Clinical and Biological Characteristics of LRRK2 Non-Manifest Carriers: PPMI Cohort*
Simuni T, Merchant K, Brumm MC, Cho H, Caspell-Garcia C, **Coffey C**, Chahine LM, Alcalay RN, Nudelman K, Foroud T, Mollenhauer B, Siderowf A, Tanner C, Iwaki H, Sherer T, and Marek K on behalf of the PPMI Investigators
September 2022: Poster Presentation, International Congress of Parkinson's Disease and Movement Disorders (Madrid, Spain)

170. *Parkinson's Progression Markers Initiative (PPMI) Online Identifies People with Features of Prodromal Parkinson's Disease Through Online Questionnaires*
Brown E, Chahine L, Alonso D, **Coffey CS**, Dobkin R, Korell M, Lorenzo A, Marras C, Poewe W, Sherer T, Siderowf A, Simuni T, Tolosa E, Twiggs JV, Weintraub D, Chowdhury S, Marek K, and Tanner CM
September 2022: Poster Presentation, International Congress of Parkinson's Disease and Movement Disorders (Madrid, Spain)

169. *Parkinson's Progression Markers Initiative (PPMI) Online Expands Biomarker Research in Parkinson's Disease (PD)*
Brown E, Alonso D, Chahine L, **Coffey CS**, Dobkin R, Korell M, Lorenzo A, Marras C, Poewe W, Sherer T, Siderowf A, Simuni T, Tolosa E, Twiggs JV, Weintraub D, Chowdhury S, Marek K, and Tanner CM
September 2022: Poster Presentation, International Congress of Parkinson's Disease and Movement Disorders (Madrid, Spain)

168. *Bis(Monoacylglycerol) Phosphate Levels are Elevated at Baseline in Carriers of Pathogenic Variants in LRRK2 and GBA1 and Do Not Predict Progression of PD in PPMI Cohorts*
Merchant KM, Simuni T, Fedler J, Caspell-Garcia C, Brumm M, Nudelman K, Tengstrandt E, Hsieh F, Alcalay RN, **Coffey C**, Chahine L, Foroud T, Singleton A, Sherer T, Siderowf A, Tanner C and Marek K on behalf of the PPMI Investigators
September 2022: Poster Presentation, International Congress of Parkinson's Disease and Movement Disorders (Madrid, Spain)

167. *FX LEARN Trial: Effects of AFQ0566 on Language Learning in Fragile X Syndrome*
Berry-Kravis E, McDuffie A, Hessl D, Ethridge L, Erickson C, Kaufmann W, Friedmann K, Bullard L, Hagerman R, Cudkowicz M, Staley K, Klements D, Moshinsky M, Harkey B, **Coffey C**, Long J, Fedler J, Klingner E, Ecklund D, Costigan M, Huff T, Pearson B, Abbeduto L, and the NeuroNEXT FXLEARN Investigators
July 2022: Presented at National Fragile X Foundation Meeting (San Diego, CA)

166. *Topiramate as a Disease Modifying Therapy for Cryptogenic Sensory Peripheral Neuropathy (CSPN): A NeuroNEXT Trial*
Smith AG, Singleton JR, Chase M, **Coffey CS**, Conwit R, Cudkowicz M, Ecklund D, Fedler J, Gudjonsdottir A, Greene T, Hauer P, Klingner L, Revere C, and the NN108 Study Team
May 2022: Presented at Peripheral Nerve Society Annual Meeting (Miami, FL)

165. *Clinical Trials Methodology Course: What Is It? Who Is It For?*
Meurer W, **Coffey C**, Gutmann L, and Conwit R
April 2022: Presented at American Academy of Neurology Annual Meeting (Seattle, WA)

164. *Parkinson's Progression Markers Initiative (PPMI) Online Expands Biomarker Research in Parkinson's Disease (PD)*
Brown E, Alonso D, Chahine L, **Coffey C**, Dobkin R, Korell M, Lorenzo A, Marras C, Poewe W, Sherer T, Siderowf A, Simuni T, Tolosa E, Weintraub D, Chowdhury S, Marek K, and Tanner C
April 2022: Presented at the American Academy of Neurology Annual Meeting (Seattle, WA)

163. *High Diagnostic Performance of Independent Alpha-Synuclein Seed Amplification Assays for Detection of Early Parkinson's Disease*
Russo MJ, Orru CD, Concha-Marambio L, Giaisi S, Groveman BR, Farris CM, Holguin B, Hughson AG, LaFontant DE, Caspell-Garcia C, **Coffey CS**, Mollon J, Hutten SJ, Merchant K, and Heym RG
April 2022: Poster Presentation at Synuclein 2022 Meeting (Belgium, Germany)

162. *A Milestone-Based Approach to Monitoring Disease Progression in Parkinson's Disease*
Brumm MC, Siderowf A, Simuni T, Burghardt E, Caspell-Garcia C, Toga AW, Galasko D, Mollenhauer B, Chahine LM, Foroud T, Arnedo V, Frasier M, Reimer A, Tanner C, Poston K, Weintraub D, Hutten SJ, Kieburtz K, Marek K, and **Coffey CS**
September 2021: Guided Poster Tour, Movement Disorder Society Virtual Congress

161. *Parkinson Progression Marker Initiative – New Science/New Cohorts*
Marek K, Siderowf A, Simuni T, **Coffey C**, Foroud T, Flagg E, Chowdhury S, Mollenhauer B, Galasko D, Merchant K, Kieburtz K, Brown E, Poston K, Chahine L, Tanner C, and the Parkinson's Progression Markers Initiative
September 2021: Guided Poster Tour, Movement Disorder Society Virtual Congress

160. *Conceptual Design and Protocol for the Acute to Chronic Pain Signatures Program (A2CPS)*
Sluka KA, Frey Law L, **Coffey C**, Bayman E, Ecklund D, Vance CGT, Dailey DL, Wager T, Lindquist MA, Kahn A, Burns JW, McCarthy RJ, Jacobs JJ, Buvanendran A, Zhou X, Brummett C, Clauw D, Chang W, Waljee J, Harris R, Williams D, Harte S, Olivier M, Langefeld CD, Howard T, Jepsen K, Laurent L, Fisch KM, Jacobs J, Qian W, Loshkin A, Sankar C, Lenzi R, Wandner L, Saterlee J, Labosky P, and Porter L
December 2020: Poster Presentation, Inaugural Meeting of the US Association for the Study of Pain

159. *NILO-PD: A Phase 2A Study of Nilotinib in Patients with Advanced Parkinson's Disease: Final Study Results*
The Parkinsons Study Group / NILO-PD Investigators (Simuni T – PI)
September 2020: American Academy of Neurology Emerging Science Virtual Live Presentation
May 2020: Poster Presentation, American Academy of Neurology Virtual Annual Meeting

158. *Sample Size Estimates for Optical Coherence Tomography Outcome Measures Based on Trends Observed in the SPRINT-MS Trial*
Fedler JK, Bermel RA, **Coffey CS**, Klingner E, Yankey J, Fox RJ
August 2020: Society for Clinical Trials Virtual Meeting

157. *Rates of Pharmacological Treatment of Neuropsychiatric Symptoms in Early Parkinson's Disease*
Kulick-Soper CV, Caspell-Garcia C, **Coffey C**, Picillo M, Weintraub D, Dahodwala N, and the Parkinson Progression Markers Initiative
August 2020: Guided Poster Tour, Movement Disorder Society Virtual Congress

156. *Longitudinal Clinical and DAT Imaging Characteristics of Non-Manifest LRRK2 Carriers: The PPMI Cohort*
 Simuni T, Siderowf A, Brumm M, Caspell-Garcia C, **Coffey C**, Chahine LM, Merchant K, Trojanowski JQ, Shaw LM, Seibyl J, Singleton A, Toga AW, Galasko D, Foroud T, Tosun-Turgut D, Poston K, Poewe W, Weintraub D, Mollenhauer B, Tanner CM, Kieburtz K, Reimer A, Hutten S, Marek K and the Parkinson's Progression Markers Initiative
August 2020: Guided Poster Tour, Movement Disorder Society Virtual Congress

155. *Physiologically-Based Pharmacokinetic Modeling of Nilotinib to Determine Serum, Cerebrospinal Fluid, and Brain Exposures*
 Venuto C, Simuni T, Fiske B, **Coffey C**, Matthews H, Wyse R, Brundin P, Simon D, Schwarzschild M, Weiner D, Adams J, Trusso L, Kostrzebski M, Ward T, Rafaloff G, and Merchant K
August 2020: Guided Poster Tour, Movement Disorder Society Virtual Congress

154. *Feasibility of Studying Microbiome in Frozen Saliva and Formalin-Fixed Colon in PD Using Systemic Synuclein Sampling Study (S4) Samples*
 Mosovsky S, Methé B, Beach TG, Adler CH, **Coffey CS**, Foroud T, Eberling J, Mollenhauer B, & Chahine L for the Systemic Synuclein Sampling Study
August 2020: Guided Poster Tour, Movement Disorder Society Virtual Congress

153. *NILO-PD: A Phase 2A Study of Nilotinib in Patients with Moderately Advanced Parkinson's Disease: Exploratory Efficacy Outcomes*
 Simuni T, **Coffey CS**, Klingner E, Caspell-Garcia C, Lafontant DE, Merchant K, Fiske B, Matthews H, Wyse R, Brundin P, Simon DK, Schwarzschild M, Weiner D, Adams J, Trusso L, Baker L, Kostrzebski M, Venuto C, Rafaloff G, and Ward T on behalf of the NILO-PD Investigators
August 2020: Guided Poster Tour, Movement Disorder Society Virtual Congress

152. *Childhood and Adolescent Migraine Prevention [CHAMP] Trial: The 3-Yea Follow-Up Survey Results*
 Powers SW, Chamberlin L, Peugh J, Reidy BL, Klingner EA, Yankey J, Porter LL, Kabbouche M, Kacperski J, Ecklund D, **Coffey CS**, and Hershey AD.
June 2020: Virtual Platform Presentation, American Headache Society Virtual Annual Meeting

151. *Pharmacokinetics and Biomarker Changes in NILO-PD, A Phase 2A Study of Nilotinib in Patients with Moderate to Advanced Parkinson's Disease*
 Merchant K, Simuni T, Fiske B, **Coffey CS**, Matthews H, Wyse RK, Brundin P, Simon DK, Schwarzschild M, Weiner D, Adams J, Trusso L, Baker L, Kostrzebski M, Ward T, Rafaloff G, and Venuto C on behalf of the NILO-PD PSG Investigators
April 2020: Poster Presentation, Advances in Alzheimer's and Parkinson's Therapies; An AAT-AD/PD Virtual Focus Meeting

150. *Modeling Outcomes in the PPMI Cohort: Implications for Clinical Trial Design*
 Brumm MC, **Coffey CS**, Siderowf A, Simuni T, Galasko D, Mollenhauer B, Chahine LM, Arnedo V, Daegele N, Frasier M, Tanner C, Poston K, Weintraub D, Hutten S, Kieburtz K, Marek K, and the Parkinson's Progression Markers Initiative
April 2020: Poster Presentation, Advances in Alzheimer's and Parkinson's Therapies; An AAT-AD/PD Virtual Focus Meeting

149. *NILO-PD: A Phase 2A Study of Nilotinib in Patients with Advanced and Early Parkinson's Disease – Final Study Results*
 Simuni T, Fiske B, Merchant K, **Coffey CS**, Matthews H, Wyse RK, Brundin P, Simon DK, Schwarzschild MA, Weiner D, Adams J, Venuto C, Trusso L, Baker L, Kostrzebski M, Ward T, & Rafaloff G on behalf of the NILO-PD PSG Investigators
February 2020: Poster Presentation, Pan American Parkinson's Disease and Movement Disorders Congress (Miami, FL)

148. *Analyses of Pharmacokinetics, CSF Exposures and CSF Dopamine and its Metabolite Levels in NILO-PD, A Phase 2A Study of Nilotinib in Moderate to Advanced Parkinson's Disease*
 Merchant KM, Simuni T, Fiske B, **Coffey C**, Matthews H, Wyse RK, Brundin P, Simon DK, Schwarzschild MA, Weiner D, Adams J, Trusso L, Baker L, Kostrzebski M, Ward T, Rafaloff G, and Venuto C on behalf of the NILO-PD Steering Committee
October 2019: Poster Presentation, Society for Neuroscience Annual Meeting (Chicago, IL)

147. *Rituximab Response in Patients with Moderate to Severe Myasthenia Gravis (MG): A Subgroup Analysis of the BeatMG Study*
 Nowak RJ, **Coffey C**, Goldstein JM, Yankey JW, Uribe L, Dimachkie MM, Benatar M, Wolfe GI, Burns T, Pearson B, O'Connor KC, Conwit R, Kissel JT, Hafler DA, Cudkowicz ME, and Barohn RJ on behalf of the NeuroNEXT NN103 BeatMG Study Team
October 2019: Platform Presentation, American Association of Neuromuscular and Electrodiagnostic Medicine Annual Meeting (Austin, TX)

146. *Evaluation of Continual Reassessment Method with Lagged Group: A Study Design for Early Phase Dose-Finding Clinical Trials*
 Welhaven A, **Coffey C**, and Foster E.
October 2019: Oral Presentation, Women in Statistics and Data Science Conference (Bellevue, WA)

145. *PPMI 2.0 – Transforming PPMI – New Cohorts, New Science – Focus on Prodromal PD*
 Marek K, Siderowf A, Simuni T, **Coffey C**, Foroud T, Arnedo V, Flagg E, Chowdhury S, Kieburtz K, Chahine L, Tanner C, and the Parkinson's Progression Markers Initiative
September 2019: Poster Presentation, Movement Disorders Society Meeting (Nice, France)

144. *Clinical and DAT Imaging Characteristics of Participants with Scans without Evidence of Dopaminergic Deficit (SWEDDs): PPMI Cohort 2 Year Follow-Up*
 Marek K, Simuni T, Siderowf A, Lafontant DE, Caspell-Garcia C, **Coffey C**, Mollenhauer B, Tanner C, Kieburtz K, Chahine L, & Seibyl J on behalf of the PPMI Investigators
September 2019: Poster Presentation, Movement Disorders Society Meeting (Nice, France)

143. *Identifying Incident Cases of Neurodegenerative Parkinsonism in a Large Observational At-Risk Cohort: The PPMI Study*
 Chahine L, Kieburtz K, Brumm M, Caspell-Garcia C, **Coffey C**, Siderowf A, Weintraub D, Tanner C, Foroud T, Galasko D, Mollenhauer B, Simuni T, Marek K, and the Parkinson's Progression Markers Initiative
September 2019: Poster Presentation, Movement Disorders Society Meeting (Nice, France)

142. *Neuropsychiatric Symptoms Over the Initial Lustrum of Parkinson Disease: Common, Increasing, Comorbid & Varied*
 Weintraub D, Caspell-Garcia C, Simuni T, Cho R, **Coffey C**, Aarsland D, Alcalay R, Barrett M, Chahine LM, Eberling J, Espay A, Hamilton J, Hawkins K, Leverenz J, Litvan I, Richard I, Rosenthal L, Siderowf A, York M, and the Parkinson's Progression Markers Initiative
September 2019: Poster Presentation, Movement Disorders Society Meeting (Nice, France)

141. *NILO-PD: A Phase 2A Study of Nilotinib in Patients with Advanced Parkinson's Disease – Study Design and Status Update*
 Simuni T, Fiske B, Merchant K, **Coffey CS**, Matthews H, Wyse RK, Brundin P, Simon DK, Schwarzschild M, Weiner D, Adams J, Venuto C, Trusso L, Baker L, Kostrzebski M, Ward T, and Rafaloff G on behalf of the NILO-PD PSG Investigators
September 2019: Poster Presentation, Movement Disorders Society Meeting (Nice, France)

140. *Highlights From a Workshop on Enhancing Natural Product Clinical Trials*
 Pauli G, Kuszak A, Bloss G, Fukagawa N, Jafari M, Walters M, Barrett B, Bushman F, Casper S, Chilton F, **Coffey C**, Feruzzi M, Hopp C, Kiely M, Lakens D, MacMillan J, Meltzer D, Paul J, Pritchett-Corning K, Quinney S, Ross S, Seifried H, Setchell K, Sipes N, Stephens J, Taylor D, Tiriac H, Xi D, Hoffman FA, and Sorkin B
July 2019: Poster Presentation, American Society of Pharmacognosy Meeting (Madison, WI)

139. *Evaluation of Continual Reassessment Method with Lagged Cohort*
 Wellhaven AE, **Coffey CS**, and Foster EF.
May 2019: Oral Presentation, Society for Clinical Trials Annual Meeting (New Orleans, LA)

138. *Response to Treatment According to Progressive Disease Type: Analysis from a Phase II Progressive MS Trial of Ibutidilast*
 Goodman A, Barnes J, Yankey J, Zahn E, Natarajan S, Bermel R, **Coffey CS**, Klawiter EC, Matsuda K, Naismith RT, & Fox RJ on behalf of the SPRINT-MS Investigators
May 2019: Platform Presentation, American Academy of Neurology Annual Meeting (Philadelphia, PA)

137. *Effect of Ibudilast on Macular Measures in Progressive MS: OCT Analysis from a Phase II Trial*
 Bermel RA, Barnes J, Yankey J, Zahn E, Natarajan S, **Coffey CS**, Goodman A, Klawiter EC, Matsuda K, Naismith RT, and Fox RJ on behalf of the SPRINT-MS Investigators
May 2019: Poster Presentation, American Academy of Neurology Annual Meeting (Philadelphia, PA)

136. *Effect of Ibudilast on Serum Neurofilament in Progressive MS: Analysis from a Phase II Trial*
 Fox RJ, Kuhle J, Karafa M, Konig V, Natarajan S, Bermel RA, **Coffey CS**, Goodman A, Klawiter EC, Matsuda K, and Naismith RT on behalf of the SPRINT-MS Investigators
May 2019: Poster Presentation, American Academy of Neurology Annual Meeting (Philadelphia, PA)

135. *NILO-PD: A Phase 2 Study of Nilotinib in Patients with Advanced and Early Parkinson's Disease: Study Design and Status Update*
 Simuni T, Fiske B, Merchant K, **Coffey CS**, Matthews H, Wyse RK, Brundin P, Simon DK, Schwarzschild M, Weiner D, Adams J, Venuto C, Trusso L, Baker L, Kostrzebski M, Ward T, and Rafaloff G on behalf of the NILO-PD PSG Investigators
May 2019: Poster Presentation, American Academy of Neurology Annual Meeting (Philadelphia, PA)

134. *NILO-PD: A Phase 2A Study of Nilotinib in Patients with Advanced and Early Parkinson's Disease: Study Design and Status Update*
 Simuni T, Fiske B, Merchant K, **Coffey C**, Matthews H, Wyse R, Brundin P, Simon DK, Schwarzschild M, Weiner D, Venuto C, Trusso L, Baker L, Kostrzebski M, Ward T, and Rafaloff G on behalf of the NILO-PD Steering Committee
March 2019: Poster Presentation, Alzheimer's & Parkinson's Disease Congress (Portugal, Spain)

133. *Irritability in Huntington's Disease: A Phase 2 Exploratory Clinical Trial with a Novel Vasopressin 1a Antagonist SRX246*
 Simon N, Hersch S, Anderson K, Long J, Ecklund D, Costigan M, Thornell B, Gladden C, Coffey C, Cudkowicz M, & Brownstein M
December 2018: Poster Presentation, American College of Neuropsychopharmacology Annual Meeting (Hollywood, FL)

132. *Multisite Tissue and Biofluid Sampling for Alpha-Synuclein in Parkinson's Disease: The Systemic Synuclein Sampling Study (S4)*
 Chahine LM, Beach T, **Coffey C**, Caspell-Garcia C, Adler C, Serrano G, Mosovsky S, Foroud T, Linder C, Riss H, Ecklund D, Seibyl J, Mallya A, Arnedo V, Riley L, Dave K, Jennings D, & Mollenhauer B
October 2018: Poster Presentation, Annual Movement Disorders Society Meeting (Hong Kong)

131. *The National Institute of Neurological Disorders and Stroke Clinical Trials Methodology Course: Outcomes of Trainees After 3 Years*
 Seedorff N, Black J, Conwit R, Lewis R, **Coffey C**, Gutmann L, & Meurer W
May 2018: Poster Presentation, Society for Clinical Trials Annual Meeting (Portland, OR)

130. *A Phase II Trial of Ibudilast in Progressive Multiple Sclerosis*
 Fox RJ, **Coffey CS**, Cudkowicz ME, Gleason T, Goodman A, Klawiter EC, Matsuda K, McGovern M, Conwit R, Naismith R, Ashokkumar A, Barnes J, Ecklund D, Klingner E, Koepp M, Natarajan S, Thornell B, Yankey J, Bermel RA, Huang X, Lowe MJ, Nakamura K, Narayanan S, Sakaie KE, Debbins JP, Zhou X, Alvarez E, Apperson M, Bashir K, Cohen B, Coyle P, Delgado S, Dewitt D, Flores A, Giesser B, Goldman M, Jubelt B, Lava N, Lynch S, Moses H, Ontaneda D, Perumal J, Racke M, Repovic P, Riley C, Severson C, Shinnar S, Suski V, Weinstock-Guttman B, Yadav V, & Zabeti A on behalf of the NN102/SPRINT-MS Investigators
April 2018: Clinical Trials Plenary Session, American Academy of Neurology Annual Meeting (Los Angeles, CA)

129. *B Cell Targeted Treatment in Myasthenia Gravis (BeatMG) – A Phase 2 Trial of Rituximab in MG: Topline Results*
 Nowak RJ, **Coffey C**, Goldstein JM, Dimachkie MM, Benatar M, Huq SN, Pearson B, Herbelin L, O'Connor KC, Conwit R, Kissel JT, Hafler DA, Cudkowicz ME, & Barohn RJ on behalf of the NeuorNEXT NN013 BeatMG Study Team
April 2018: Poster Presentation, American Academy of Neurology Annual Meeting (Los Angeles, CA)

128. *Network for Excellence in Neuroscience Clinical Trials, NeuroNEXT: Update on Success and Five-Year Renewal Application*
Qidwai J, Kearney Chase M, Ecklund D, Bosch M, Thornell B, **Coffey C**, & Cudkowicz M.
March 2018: Poster Presentation, American Society for Experimental Neurotherapeutics (ASENT) Meeting (Washington, DC)

127. *SPRINT-MS/NN012 Phase II Trial of Ibdilast in Progressive MS: Top-Line Results*
Naismith R, **Coffey CS**, Cudkowicz ME, Gleason T, Goodman AD, Klawiter EC, Matsuda K, McGovern MM, Conwit R, Ashokkumar A, Ecklund DJ, Klingner E, Koepp M, Natarajan S, Thornell B, Yankey JW, Bermel R, Huang X, Lowe M, Nakamura K, Narayanan S, Sakaie K, Debbins J, Zhou X, Alvarez E, Apperson ML, Bashir K, Cohen BA, Coyle PK, Delgado S, Dewitt D, Flores A, Giesser B, Goldman M, Jubelt B, Lava N, Lynch SG, Moses H, Ontaneda DD, Perumal JS, Racke MK, Repovic P, Riley CS, Severson CA, Shinnar S, Suski V, Weinstock-Gutman B, Yadav V, Zabeti A, & Fox RJ.
February 2018: Poster Presentation, American Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Annual Meeting (San Diego, CA)

126. *Final Results of the RHAPSODY Trial*
Lyden P, Coffey CS, Cudkowicz M, Conwit RA, & Pryor KE on behalf of the RHAPSODY Investigators
January 2018: Plenary Presentation at the International Stroke Conference (Los Angeles, CA)

125. *Safety and Tolerability of SRX246 in Irritable/Aggressive Subjects with Huntington's Disease (STAIR): A Phase II Exploratory Clinical Trial*
Raulerson S, Berg S, Costigan M, Hersch SM, Anderson KE, Long J, **Coffey CS**, Yankey J, Cudkowicz M, Conwit R, Lungu C, Brownstein MJ, & Simon NG
November 2017: Poster Presentation, Huntington's Study Group Annual Meeting (Denver, CO)

124. *Measurement of Huntington's Irritability and Aggression in the Azevan Pharmaceuticals-NeuroNEXT STAIR Study*
Anderson K, Hersch S, Long J, Cudkowicz M, **Coffey C**, Yankey J, Costigan M, Raulerson S, Berg S, Conwit R, Lungu C, Brownstein M, & Simon L.
November 2017: Poster Presentation, Huntington's Study Group Annual Meeting (Denver, CO)

123. *SPRINT-MS/NN012 Phase II Trial of Ibdilast in Progressive MS: Top-Line Results*
Fox RJ, **Coffey CS**, Cudkowicz ME, Gleason T, Goodman A, Klawiter EC, Matsuda K, McGovern M, Conwit R, Naismith R, Ashokkumar A, Ecklund D, Koepp M, Long J, Natarajan S, Skaramagas T, Thornell B, Yankey J, Bermel R, Huang X, Lin J, Lowe M, Nakamura K, Narayanan S, Sakaie KE, Debbins JP, Zhou X, Alvarez E, Apperson M, Bashir K, Cohen B, Coyle P, Delgado S, Dewitt D, Flores A, Giesser B, Goldman M, Jubelt B, Lava N, Lynch S, Moses H, Ontaneda D, Perumal J, Racke M, Repovic P, Riley C, Severson C, Shinnar S, Suski V, Weinstock-Gutman B, Yadav V, & Zabeti A on behalf of the NN102/SPRINT-MS Study Investigators.
October 2017: Plenary Presentation at European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) Annual Meeting (Paris, France)

122. *Biological Analyses of PPMI Samples*
Mollenhauer B, Caspell-Garcia CJ, **Coffey CS**, Taylor P, Shaw LM, Trojanowski JQ, Singleton A, Naito A, Reimer A, Frasier M, Marek K, and Galasko D for the Parkinson Progression Marker Initiative
October 2017: PD Therapeutics Conference (New York, NY)

121. *Feasibility and Safety of Multisite Tissue and Biofluid Sampling for Alpha-Synuclein in Parkinson's Disease: The Systemic Synuclein Sampling Study (S4)*
Linder C, Mollenhauer B, **Coffey C**, Beach T, Foroud T, Adler C, Riss H, Ecklund D, Caspell-Garcia C, Dave K, Deshpande S, Lasch S, Arnedo V, Riley L, Kopil C, Jennings D, & Chahine L
June 2017: Poster Presentation, Annual Movement Disorders Society Meeting (Vancouver, BC)

120. *Network for Excellence in Neuroscience Clinical Trials, NeuroNEXT: Pre-Award Process and Experiences*
Foster E, Mahoney K, Ecklund D, Kearney Chase M, Bosch M, Thornell B, **Coffey C** & Cudkowicz M
May 2017: Poster Presentation, Society for Clinical Trials Annual Meeting (Liverpool, UK)

119. *Feasibility and Safety of Multisite Tissue and Biofluid Sampling for Alpha-Synuclein in Parkinson's Disease: The Systemic Synuclein Sampling Study (S4)*
 Linder C, Mollenhauer B, **Coffey C**, Beach TG, Foroud T, Adler CH, Riss H, Ecklund D, Caspell-Garcia C, Dave KD, Deshpande S, Lasch S, Arnedo V, Riley L, Jennings D, & Chahine L
April 2017: Poster Presentation, American Academy of Neurology Annual Meeting (Boston, MA)

118. *The Systemic Synuclein Sampling Study*
 Mollenhauer B, **Coffey C**, Beach TG, Foroud T, Adler CH, Ecklund D, Dave KD, Deshpande S, Lasch S, Arnedo V, Riley L, Jennings D, & Chahine L.
March 2017: Poster Presentation, Alzheimer's & Parkinson's Disease Congress (Vienna, Austria)

117. *Network for Excellence in Neuroscience Clinical Trials, NeuroNEXT: Increasing Efficiency in Clinical Trials*
 Kearney Chase M, Ecklund D, Bosch M, Thornell B, **Coffey C**, & Cudkowicz M.
October 2016: Poster, American Neurological Association Annual Meeting (Baltimore, MD)

116. *Longitudinal Evolution of Possible REM Sleep Behavior Disorder in Early Parkinson's Disease*
 Oertel W, Simuni T, Caspell-Garcia C, Long J, **Coffey CS**, Iranzo A, Mayer G, Chahine L, Lasch S, & Marek K on behalf of the PPMI Sleep Working Group
June 2016: International Movement Disorders Congress (Berlin, Germany)

115. *The Systemic Synuclein Sampling Study (S4)*
 Jennings D, **Coffey C**, Beach T, Foroud T, Adler CH, Mollenhauer B, Seibyl J, Ecklund D, Lasch S, Arnedo V, & Kopil C
June 2016: International Movement Disorders Congress (Berlin, Germany)

114. *Longitudinal Cerebrospinal Fluid Biomarkers in Early Parkinson's Disease and Healthy Controls*
 Mollenhauer B, Caspell-Garcia CJ, **Coffey CS**, Taylor P, Shaw LM, Trojanowski JQ, Singleton A, Frasier M, Marek K, & Galasko DR
June 2016: International Movement Disorders Congress (Berlin, Germany)

113. *Baseline Prevalence and Longitudinal Evolution of Non-Motor Symptoms in Early Parkinson's Disease – PPMI Cohort*
 Simuni T, Weintraub D, Caspell-Garcia C, Walker M, **Coffey CS**, Lasch S, Tanner C, Jennings D, Kieburtz K, & Marek K on behalf of the PPMI Investigators
June 2016: International Movement Disorders Congress (Berlin, Germany)

112. *Longitudinal Evolution of Excessive Daytime Sleepiness in Early Parkinson's Disease*
 Simuni T, Caspell-Garcia C, Long J, **Coffey CS**, Oertel W, Lasch S, & Marek K on behalf of the PPMI Sleep Working Group
June 2016: International Movement Disorders Congress (Berlin, Germany)

111. *Clinical and Biological Predictors of Time to Initiation of Symptomatic Therapy in Early Parkinson's Disease*
 Simuni T, Long J, Caspell-Garcia C, **Coffey CS**, Lasch S, Tanner C, Jennings D, Kieburtz K, & Marek K on behalf of the PPMI Investigators
June 2016: International Movement Disorders Congress (Berlin Germany)

110. *Physician-Pharmacist Collaboration: Overcoming Socioeconomic Barriers*
 Gums TH, Anderegg MD, Uribe L, **Coffey C**, and Carter BL.
May 2016: Annual Meeting of the American Society for Hypertension (New York, NY)

109. *Selecting Patients for Intra-Arterial Therapy in the Context of a Clinical Trial for Neuroprotection*
 Lyden P, Weymer S, **Coffey C**, Cudkowicz M, Fisher M, Haley EC, Khatri P, Saver J, Levine S, Levy H, Pryor K, Rymer M, and Wechsler L.
February 2016: International Stroke Conference (Los Angeles, CA)

108. *A Phase 2 Trial of Rituximab in Myasthenia Gravis: Study Update*
 Nowak RJ, **Coffey C**, Goldstein JM, Dimachkie M, Benatar M, O'Connor KC, Kissel J, Hafler DA, Barohn R, and Cudkowicz for the NeuroNEXT NN103 Study Team.
September 2015: Annual Meeting of the American Neurological Association (Chicago, IL)

107. *Can We Reliably Establish Parkinson's Disease Subtypes in De Novo Patients: Follow Up Results from the PPMI Study*
 Simuni T, Caspell-Garcia C, **Coffey C**, Lasch S, Jennings D, Tanner C, Kieburtz K, and Marek K.
June 2015: 19th Int. Congress of Parkinson's Disease and Movement Disorders (San Diego, CA)

106. *Initial Results from the NeuroNEXT SMA Infant Biomarker Study*
 Kolb SJ, **Coffey CS**, Yankey JW, Arnold D, Rutkove SB, Bartlett A, Renusch S, Wang S, Snyder PJ, Prior TW, and Kissel JT for the NeuroNEXT Clinical Trial Network and on behalf of the NN101 SMA Biomarker Investigators.
June 2015: Cure SMA Annual Researcher Meeting (Kansas City, MO)

105. *Including Uncertainty in the Target Probability of Dose Limiting Toxicity in Phase I/II Studies with a Dose Finding Component*
 Foster E, Thomann MA, and **Coffey CS**.
May 2015: Society for Clinical Trials Annual Meeting (Washington, DC)

104. *The NINDS Clinical Trials Methodology Course: Approach and Lessons from Year 1*
 Meurer WJ, Mawocha S, Conwit R, Lewis R, **Coffey C**, and Gutmann L.
May 2015: Society for Clinical Trials Annual Meeting (Washington, DC)

103. *The Network for Excellence in Neuroscience Clinical Trials (NeuroNEXT) Protocol Working Group Design Phase Experiences*
 Foster E, **Coffey CS**, Cudkowicz ME, Ecklund DJ, Bosch MJ, Thornell BJ, Kearney M, Littizzio E, Ashokkumar A, and Mahoney K
May 2015: Society for Clinical Trials Annual Meeting (Washington, DC)

102. *NN102/SPRINT-MS Phase II Trial of Ibudilast in Progressive MS: Baseline Characteristics*
 Fox R, **Coffey C**, Cudkowicz M, Gleason T, Goodman A, Klawiter E, Matsuda K, McGovern M, McNeil E, Naismith R, and Yankey J.
April 2015: Annual Meeting of the American Academy of Neurology (Washington, DC)

101. *Initial Results from the NeuroNEXT SMA Infant Biomarker Study*
 Kolb SJ, **Coffey CS**, Arnold WD, Rutkove SB, Bartlett A, and Kissel JT from the NeuroNEXT Clinical Trial Network and on behalf of the NN101 SMA Biomarker Investigators
April 2015: Annual Meeting of the American Academy of Neurology (Washington, DC)

100. *Network for Excellence in Neuroscience Clinical Trials, NeuroNEXT: Increasing Efficiency in Clinical Trial Management*
 Kearney M, Ecklund D, Bosch M, Thornell B, McNeil E, Cordell J, **Coffey C**, and Cudkowicz M
April 2015: Annual Meeting of the American Academy of Neurology (Washington, DC)

99. *Multicenter Evaluation of Parkinson's Disease Progression using 123-I-Ioflupane SPECT: Update from the Parkinson's Progression Marker Initiative Trial*
 Seibyl J, Jennings D, **Coffey C**, and Marek K
June 2014: 18th Int. Congress of Parkinson's Disease and Movement Disorders (Stockholm, Sweden)

98. *Excessive Day Time Sleepiness Is Not Part of Parkinson's Disease Disability in De Novo Patients: Results from the PPMI Study*
 Simuni T, Caspell C, **Coffey C**, Chahine LC, Lasch S, Oertel W, and Marek K for the PPMI Investigators.
June 2014: 18th Int. Congress of Parkinson's Disease and Movement Disorders (Stockholm, Sweden)

97. *Degeneration of Corticostriatal Fibers in Parkinson's Disease and Their Differential Relations to Cognitive and Motor Deficits*
 Zhang Y, Wu K, Buckley S, Mendick S, Seibyl J, Foster E, **Coffey C**, Marek K, and Schuff N for the Parkinson's Progression Markers Initiative (PPMI).
June 2014: 18th Int. Congress of Parkinson's Disease and Movement Disorders (Stockholm, Sweden)

96. *Cognitive Performance and Psychiatric Symptoms in De Novo, Untreated Parkinson's Disease: Results from the PPMI Study*
 Weintraub D, Simuni T, **Coffey C**, Caspell-Garcia C, Foster E, Barone P, Leverenz J, Burn D, Eberling J, Chahine L, Litvan T, Troyer M, Siderowf A, Aarsland D, and Hawkins K for the PPMI Cognitive Behavioral Working Group
June 2014: 18th Int. Congress of Parkinson's Disease and Movement Disorders (Stockholm, Sweden)

95. *Can We Reliably Establish Parkinson's Disease Subtypes in De Novo Patients: Results from the PPMI Study*
 Simuni T, **Coffey C**, Uribe L, Lasch S, Jennings D, Tanner C, and Marek K for the PPMI Investigators
June 2014: 18th Int. Congress of Parkinson's Disease and Movement Disorders (Stockholm, Sweden)

94. *Coordinating Center Support Required for an Academic Central IRB: The NeuroNEXT Network Experience*
 Kearney M, Flynn K, Huq S, Ashokkumar A, Simpson E, McCourt M, Ecklund D, Bosch M, **Coffey C**, and Cudkowicz M.
May 2014: Society for Clinical Trials Annual Meeting (Philadelphia, PA)

93. *The NeuroNEXT Experience of Patient Engagement in Protocol Development*
 Kearney M, Thornell B, Mahoney K, Ecklund D, **Coffey C**, and Cudkowicz M
May 2014: Society for Clinical Trials Annual Meeting (Philadelphia, PA)

92. *Assessment of Site Feasibility: The NeuroNEXT Network Experience*
 Kearney M, McCourt M, Huq S, Strodel R, Thornell B, Ecklund D, Bosch M, **Coffey C**, & Cudkowicz M.
May 2014: Society for Clinical Trials Annual Meeting (Philadelphia, PA)

91. *Simulation Study to Assess an A Priori Decision Algorithm for a Randomized Three-Armed Clinical Trial*
 Zahn E and **Coffey C**
May 2014: Society for Clinical Trials Annual Meeting (Philadelphia, PA)

90. *Network for Excellence in Neuroscience Clinical Trials, NeuroNEXT: Increasing Efficiency in Clinical Trial Management*
 Kearney M, Ecklund D, Bosch M, Thornell B, McNeil E, Koroshetz W, Kaufmann P, **Coffey C**, Cudkowicz M
April 2014: Annual Meeting of the American Academy of Neurology (Philadelphia, PA)

89. *Risk of Stroke and Vascular Events and Response to Antiplatelet Therapy in Young Adults with Recent Lacunar Strokes: The SPS3 Study*
 Pikula A, **Coffey CS**, Lau HW, White CL, Kase CS, and Benavente O
February 2014: International Stroke Congress (San Diego, CA)

88. *Benefits of Clinical Trial Participation for Risk Factor Control: Experience from the SPS3 Study*
 Lau H, White C, **Coffey C**, Romero J, Pikula A, Babikian V, and Benavente O
February 2014: International Stroke Congress (San Diego, CA)

87. *Rapid Rollout of a Pediatric Migraine Prevention Study Conducted in Academic Research Centers*
 Korbee L, Powers S, Hershey A, Chamberlin L, Allen J, LeCates S, White S, Kroner J, Sullivan S, **Coffey C**, and Ecklund D.
November 2014: International Headache Congress (Scottsdale, AZ)

86. *123-I Ioflupane SPECT Measures of Parkinson Disease Progression in the Parkinson Progression Marker Initiative (PPMI) Trial*
 Seibyl JP, Jennings D, Grachev, I, **Coffey C**, & Marek K on behalf of the PPMI Investigators
June 2013: Annual Meeting of the Movement Disorders Society (Sydney, Australia)

85. *Relationship Between Serum Urate and Clinical Features in Early Parkinson's Disease: PPMI Baseline Data*
 Constantinescu R, Jennings D, Foster ED, Auinger P, **Coffey CS**, & Marek K for the Parkinson's Progression Markers Initiative
June 2013: Annual Meeting of the Movement Disorders Society (Sydney, Australia)

84. *Cognitive Performance and Psychiatric Symptoms in De Novo, Untreated Parkinson's Disease: Results from the PPMI Study*
 Weintraub D, Jennings D, Foster ED, Auinger P, **Coffey CS**, & Marek K for the Parkinson's Progression Markers Initiative
June 2013: Annual Meeting of the Movement Disorders Society (Sydney, Australia)

83. *Rapid Rollout of a Pediatric Migraine Prevention Study Conducted in Academic Research Centers*
 Korbee L, Powers S, Hershey A, Chamberlin L, Allen J, LeCates S, White S, Kroner J, Sullivan S, **Coffey C**, and Ecklund D
June 2013: International Headache Congress (Boston, MA)

82. *Internal Pilot Design for Cluster Randomized Trials with Unequal Cluster Sizes*
Ranjan A, McClure LA, and **Coffey CS**
May 2013: Society for Clinical Trials Annual Meeting (Boston, MA)

81. *Network for Excellence in Neuroscience Clinical Trials, NeuroNEXT: Concept to Implementation*
Kearney M, Ecklund D, Simpson E, Bosch M, Sweet B, Jackson K, Mahoney K, McCourt M, Thornell B, Titus S, Soodoo N, O'Brien J, Gloer K, Costigan M, Logsden-Sackett N, Huff T, Shefner J, Staley K, Guttman L, Clarke W, Torner J, Long J, Chaloner K, Bayman E, McNeil E, Kaufmann P, Koroshetz W, Cudkowicz M, and **Coffey CS**
March 2013: American Academy of Neurology Annual Meeting (San Diego, CA)

80. *The Coalition Against Major Diseases: Dopamine Transporter Imaging as an Enrichment Biomarker to Enable Parkinson's Disease Clinical Trials*
Gordon M, Stephenson D, **Coffey C**, Cole PE, Comery TA, Grachev I, Grosset D, Harbron C, Kuoppamaki M, Lindstedt K, Meibach R, Marek K, Matthews D, Romero K, Russell D, Seibyl J, Sherer T, Stark Y, Subramaniam R, and Walton M for the Coalition Against Major Diseases (CAMD)
March 2013: American Academy of Neurology Annual Meeting (San Diego, CA)

79. *Factors Affecting Time to Achieve Blood Pressure Targets in the Secondary Prevention of Small Subcortical Strokes (SPS3) Trial*
Szychowski JM, McClure LA, White CL, Pergola PE, Benavente O, and **Coffey CS**
February 2013: International Stroke Conference (Honolulu, HI)

78. *Increasing the Sample Size in the Secondary Prevention of Small Subcortical Strokes (SPS3) Study: What Did We Gain?*
McClure LA, Szychowski JM, Benavente O, Hart RG, and **Coffey CS**
February 2013: International Stroke Conference (Honolulu, HI)

77. *The NIHSS Supplementary Motor Scale: A Valid Tool for Multidisciplinary Recovery Trials*
Leira EC, **Coffey CS**, Jorge RE, Morton SM, Froehler MT, Davis PH, and Adams HP
February 2013: International Stroke Conference (Honolulu, HI)

76. *Factors Affecting Time to Achieve Blood Pressure Targets in the Secondary Prevention of Small Subcortical Strokes (SPS3) Trial*
Szychowski JM, McClure LA, White CL, Pergola PE, Benavente OR, and **Coffey CS**
February 2013: International Stroke Conference (Honolulu, HI)

75. *Adaptive Designs for Comparative Effectiveness Trials*
Kairalla JA, **Coffey CS**, Thomann MA, and Muller KE
August 2012: Joint Statistical Meetings (San Diego, CA)

74. *CSF Biomarkers in Early Parkinson's Disease: Predictors of Risk for Disease Progression*
Kang JH, Chen-Plotkin A, Irwin D, Siderowf A, Caspell C, **Coffey C**, Taylor P, Frasier M, Marek K, Trojanowski J, Shaw LM, and the Parkinson's Progression Marker Initiative
July 2012: Alzheimer's Association International Conference (Vancouver, BC)

73. *Diurnal and Intersubject Variability of Cerebrospinal Fluid Biomarkers in Parkinson's Disease and Healthy Volunteers*
Frasier MA, Marek K, Taylor P, Caspell C, **Coffey C**, Ereshefsky L, Yen M, and Sherer T
June 2012: Annual Meeting of the Movement Disorders Society (Dublin, Ireland)

72. *Association Between CSF Biomarkers and Clinical Phenotype of Early Parkinson's Disease*
Kang JH, Caspell C, **Coffey C**, Taylor P, Frasier M, Marek K, Trojanowski JQ, Shaw LM, and the Parkinson's Progression Marker's Initiative
June 2012: Annual Meeting of the Movement Disorders Society (Dublin, Ireland)

71. *Adaptive Designs for Clinical Comparative Effectiveness Research: Are We Ready?*
Kairalla JA, Thomann MA, **Coffey CS**, Shorr RI, and Muller KE.
May 2012: Society for Clinical Trials Annual Meeting (Miami, FL).

70. *NeuroNEXT: Developing Infrastructure for Phase 2 Clinical Trials in Neurological Disorders.*
Ecklund D, Kearney M, **Coffey CS**, Cudkowicz M, and McNeil E
May 2012: Society for Clinical Trials Annual Meeting (Miami, FL).

69. *A Class of Two-Stage Internal Pilot with Interim Analysis Designs for Two Group Comparative Effectiveness Trials.*
 Kairalla JA, Thomann MA, **Coffey CS**, and Muller KE.
March 2012: Annual Meeting of the Eastern North American Region (ENAR) of the Biometric Society (Washington, DC).

68. *Diurnal Fluctuations of Parkinson's Disease Biomarkers in Healthy Volunteers*
 Frasier M, Marek K, Schlossmacher M, Yen M, Taylor P, Caspell C, and **Coffey C**
June 2011: International Congress of Parkinson's Disease and Movement Disorders (Toronto, ON)

67. *Some Strategies for Report Generation by Biostatisticians in Clinical Trials.*
 Yankey J, **Coffey CS**, and Clarke WR.
May 2011: Society for Clinical Trials Annual Meeting (Vancouver, BC)

66. *Predictors of Blood Pressure Control at 6 and 12 Months in the Secondary Prevention of Small Subcortical Strokes (SPS3) Study*
 Hornung LN, Szychowski J, White CL, Graves JW, Pergola PE, McClure LA, **Coffey CS**, Hart RG, and Benavente OR.
May 2011: Society for Clinical Trials Annual Meeting (Vancouver, BC).

65. *Benefits of Clinical Trial Participation for Risk Factor Control: Experience from the SPS3 Study*
 Lau H, White C, **Coffey C**, Romero J, Pikula A, Babikian V, Kase C, and Benavente O
February 2011: International Stroke Conference (New Orleans, LA)

64. *The Use of an Unplanned Adaptive Design in an NIH-Sponsored Stroke Prevention Trial*
 McClure LA, Szychowski JM, Benavente O, Hart RG, Conwit R, and **Coffey CS**
February 2011: International Stroke Conference (Los Angeles, CA)

63. *Achieving the Benefits of Both an Internal Pilot and Interim Analysis in Small Samples*
 Kairalla JA, Muller KE, and **Coffey CS**
August 2010: Joint Statistical Meetings (Vancouver, BC).

62. *The Parkinson's Progression Marker's Initiative: A Prospective Biomarkers Study*
 Frasier M, Chowdury S, Sherer T, Eberling J, Meunier C, Ravina B, Siderowf A, Scherzer C, Jennings D, Tanner C, Kieburz K, **Coffey C**, Poewe W, Mollenhauer B, Seibyl J, Toga A, Ansbach A, De Blasio P, Piovella M, Trojanowski J, Shaw L, Singleton A, and Marek K
June 2010: Annual Movement Disorders Society Meeting (Buenos Aires, Argentina).

61. *Survey on the Use of Adaptive Designs in the Journal of the American Medical Association (2007-2008)*
 Mbowe O, Birkner T, and **Coffey CS**.
May 2010: Society for Clinical Trials Annual Meeting (Baltimore, MD)

60. *The Effect of an Unplanned Sample Size Re-Estimation on the Type I Error Rate*
 McClure LA, Szychowski JM, Benavente O, and **Coffey CS**
May 2010: Society for Clinical Trials Annual Meeting (Baltimore, MD)

59. *Achieving the Benefits of an Internal Pilot with Interim Analysis While Controlling Type I Errors for Gaussian Linear Models*
 Kairalla JA, Muller KE, and **Coffey CS**
August 2009: Joint Statistical Meetings (Washington, DC).

58. *Ambulatory Blood Pressure as Related to White Matter Hyperintensity*
 Howard KP and **Coffey CS**
May 2009: Society for Clinical Trials Annual Meeting (Atlanta, GA)

57. *Monitoring Futility in Two-by-Two Factorial Studies*
 McClure LA, Howard G, and **Coffey CS**
May 2009: Society for Clinical Trials Annual Meeting (Atlanta, GA).

56. *Factors Affecting Time to In-Target Blood Pressure Status in a Multicenter International Trial.*
 Szychowski J, McClure L, White C, Pergola P, Graves J, Hart R, Benavente O, and **Coffey CS**
May 2009: Society of Clinical Trials Annual Meeting (Atlanta, GA).

55. *Predicting Survival in Pulmonary Arterial Hypertension Using the REVEAL Database*
Benza RL, Foreman AJ, Prucka WR, Gomberg-Maitland M, Frantz RP, Miller DP, **Coffey CS**, Elliott CG, and McGoon MD.
May 2009: Annual Meeting of the American Thoracic Society (San Diego, CA).

54. *Are Lacunar Strokes Different in Hispanic Patients? The SPS3 Study.*
Benavente O, Del Brutto O, Arauz A, Ruiz-Sandoval JL, Roldan A, Szychowski J, Peri K, **Coffey CS**, White C, and Hart RG. **February 2009:** American Stroke Association Annual Meeting (San Diego, CA).

53. *Cytokine SNP's and Their Relationship to the Development of Peripartum Cardiomyopathy.*
Pekarek D, Barchue J, Grenett H, Biggio J, Robin N, **Coffey CS**, and Benza R.
January 2009: Annual Meeting of the Society for Maternal and Fetal Medicine (San Diego, CA).

52. *Estimating Predictive Error for Left- and Right-Censored Survival Data with Time-Varying Covariates.*
Prucka WR and **Coffey CS**
August 2008: Joint Statistical Meetings (Denver, CO).

51. *GLUMIP 2.0: SAS/IML Software for Planning Internal Pilots.*
Kairalla JA, **Coffey CS**, and Muller KE. **August 2008:** Joint Statistical Meetings (Denver, CO).

50. *Potential Outcomes Applied to an Intentional Weight Loss Application.*
Supapkorn T, Gadbury GL, **Coffey CS**, Keith SW, and Allison DB.
August 2008: Joint Statistical Meetings (Denver, CO).

49. *ET-1 Polymorphism and Functional Capacity Interactions in PAH Patients Treated with Endothelin Antagonists.*
Benza R, Prucka W, Frost A, Gomberg M, Lawrence E, Barchue J, **Coffey CS**, and Grenett H.
May 2008: American Thoracic Society Annual Meeting (Toronto, Canada)

48. *eNOS Polymorphism and 6MWD Interactions in PAH Patients on Endothelin Antagonists.*
Benza R, Prucka W, Torbicki A, Pulido R, Langleben D, Barchue J, **Coffey CS**, and Grenett H.
May 2008: American Thoracic Society Annual Meeting (Toronto, Canada)

47. *Atypical Lacunar Syndromes: Same Disease as Classical Lacunar Infarcts? The Secondary Prevention of Small Subcortical Strokes (SPS3) Study.*
Benavente OR, Arboix A, Bazan C, Rubio F, **Coffey CS**, McClure L, Nair N, Roldan A, White C, and Hart R.
May 2008: European Stroke Meeting (Nice, France)

46. *HsCRP and SAA among Patients with Lacunar Stroke: Preliminary Findings from the Levels of Inflammatory Markers in Treatment of Ischemic Stroke (LIMITS) Study.*
Luna J, McClure LA, Szychowski JM, **Coffey CS**, Benavente O, White C, Roldan A, Liu K, Wang H, Fink DJ, and Elkind MSV.
April 2008: American Academy of Neurology Meeting (Chicago, IL)

45. *A Two-Stage Procedure for Factorial Designs Utilizing a Formal Futility Rule.*
Nair NK and **Coffey CS**
March 2008: Annual Meeting of the Eastern North American Region (ENAR) of the Biometrics Society (Alexandria, VA)

44. *GLMIP 1.0: SAS/IML Software for Planning Repeated Measures Internal Pilots.*
Muller KE, **Coffey CS**, Kairalla JA, and Johnson JL.
March 2008: Annual Meeting of the Eastern North American Region (ENAR) of the Biometrics Society (Alexandria, VA)

43. *Adjusting for Covariates in the Analysis of Microarray and Other High Dimensional Biological Data.*
Chen L, Beasley MB, **Coffey CS**, and Page GP.
March 2008: Annual Meeting of the Eastern North American Region (ENAR) of the Biometrics Society (Alexandria, VA)

42. *Internal Pilot Designs for Observational Studies.*
Gurka MJ and **Coffey CS**
March 2008: Annual Meeting of the Eastern North American Region (ENAR) of the International Biometric Society (Alexandria, VA)

41. *Internal Pilot with Interim Analysis for Single Degree of Freedom Hypothesis Tests*
 Kairalla JA, Muller KE, and **Coffey CS**
March 2008: Annual Meeting of the Eastern North American Region (ENAR) of the International Biometric Society (Alexandria, VA)

40. *Single vs. Multiple Lacunar Infarcts: Are They Caused by Different Diseases? The SPS3 Study.*
 Benavente O, Bazan C, Nair N, McClure L, **Coffey C**, Pretel J, Krupinski Y, Vaishnav A, Hart R, and Roldan A.
February 2008: American Stroke Association Annual Meeting (New Orleans, LA)

39. *An Internal Pilot Study with Interim Analysis for Gaussian Linear Models*
 Kairalla J, Muller KE, and **Coffey CS**
August 2007: Annual Joint Statistical Meetings (Salt Lake City, UT)

38. *Small Sample Properties of Information-Based Monitoring*
 Sawrie D and **Coffey CS**.
August 2007: Annual Joint Statistical Meetings (Salt Lake City, UT)

37. *Bayesian Analysis of the Effect of Intentional Weight Loss on Mortality Rate*
 Yi N, Ding S, Keith SW, **Coffey CS**, and Allison DB.
August 2007: Annual Joint Statistical Meetings (Salt Lake City, UT)

36. *Wavelet-Based Modeling of Clinical Outcomes Using Diffusion Tensor Image Data*
 Prucka W, **Coffey CS**, Cutter G, and Reich DS.
August 2007: Annual Joint Statistical Meetings (Salt Lake City, UT)

35. *Internal Pilot Designs and Mixed Models*
 Gurka M, **Coffey CS**, and Muller KE.
August 2007: Annual Joint Statistical Meetings (Salt Lake City, UT)

34. *Monitoring Serious Adverse Events via a Web-Based System*
 Guyton F, Allcorn C, Stern B, McCarthy S, and **Coffey CS**.
May 2007: Society for Clinical Trials Annual Meeting (Montreal, Quebec, Canada)

33. *TGF-Beta Polymorphisms, Gender, Age, and Their Effect on Acute Cardiac Rejection.*
 Pekarek D, **Coffey CS**, Barchue J, Grennett H, Tallaj J, Rayburn B, Kirklin J, and Benza RL.
April 2007: Annual Meeting of the International Society for Heart and Lung Transplantation (San Francisco, CA)

32. *Relationship between u-PA and TGF-Beta Genotypes and Allograft Coronary Disease.*
 Pekarek D, **Coffey CS**, Barchue J, Grennett H, Tallaj J, Rayburn B, and Benza RL.
April 2007: Annual Meeting of the International Society for Heart and Lung Transplantation (San Francisco, CA)

31. *A Wavelet Based Method for Determining Persistent DNA Copy Number Variation Across Multiple Subjects.*
 Prucka WR and **Coffey CS**
March 2007: Annual Meeting of the Eastern North America Region (ENAR) of the Biometrics Society (Atlanta, GA)

30. *Internal Pilot Design with Interim Analysis.*
 Kairalla JA, Muller KE, **Coffey CS**.
March 2007: Annual Meeting of the Eastern North America Region (ENAR) of the Biometrics Society (Atlanta, GA)

29. *Preemptive Power and the Consulting Statistician.*
 Sawrie DF and **Coffey CS**
March 2007: Annual Meeting of the Eastern North America Region (ENAR) of the Biometrics Society (Atlanta, GA)

28. *DWI Overestimates the Ultimate Size of Lacunar Infarcts.*
 Benavente O, Bazan C, Tonarelli S, Pergola G, McClure L, **Coffey C**, and Hart RG.
February 2007: American Stroke Association Annual Meeting (San Francisco, CA)

27. *Orthostatic Hypotension (OH) at Six and Twelve Months in the Secondary Prevention of Small Subcortical Strokes (SPS3) Study.*
 Graves JW, Wochos DN, and **Coffey CS** for the SPS3 Study Group.
October 2006: Annual Meeting of the International Society of Hypertension (Fukuoka, Japan)

26. *Predictors of Achievement of Assigned Blood Pressure Target at Six Months and One Year in the SPS3 Study.*
 Graves JW, Pergola PE, Benavente OR, Hart RG, **Coffey CS**, & White CL for the SPS3 Study Group.
October 2006: Annual Meeting of the International Society of Hypertension (Fukuoka, Japan)

25. *Secondary Prevention of Small Subcortical Strokes with BP Lowering and Antiplatelet Therapies: A 2x2 Factorial Trial (SPS3).*
 Grimm R, Pergola P, Hart R, Anderson D, Benavente O, White C, Graves J, **Coffey C**, and Brauer D.
October 2006: Annual Meeting of the International Society of Hypertension (Fukuoka, Japan)

24. *GLUMIP 2.0: Free SAS/IML Software for Planning Internal Pilots.*
 Kairalla JA, **Coffey CS**, Muller KE.
August 2006: Annual Joint Statistical Meeting (Seattle, WA)

23. *Monitoring Futility in 2x2 Factorial Studies.*
 McClure LA, **Coffey CS**, and Howard GH.
August 2006: Annual Joint Statistical Meeting (Seattle, WA)

22. *Predictive Value of Adipokines for Development of Cardiovascular Events in a Population-Based Cohort.*
 Wolffenduttel BHR, van Beek AP, Hebert PR, **Coffey CS**, and de Jong PE.
June 2006: Annual Meeting of the American Diabetes Association (Washington, DC)

21. *Treatment of Hypertension with Epithelial Sodium Channel Inhibitors Combined with Hydrochlorothiazide Reduces Sudden Coronary Death and Total Coronary Mortality.*
 Hebert PR, Murry KT, Rottman JN, **Coffey CS**, Byrne DW, McCormack VA, Fagard RH, Meade TW, and Oates JA.
November 2005: Annual Meeting of the American Heart Association (Dallas, TX)

20. *African-Americans with Kidney Disease Have Better Survival Than Whites After Acute Myocardial Infarction.*
 Newsome BB, McClellan WM, Allison JJ, Kiefe CI, **Coffey CS**, and Warnock DG.
November 2005: Annual Meeting of American Society of Nephrology (Philadelphia, PA)

19. *African-Americans Have a Greater Risk of End-Stage Renal Disease Following Hospitalization for Acute Myocardial Infarction.*
 Newsome BB, Warnock DG, Allison JJ, Eggers P, Kiefe CI, Collins A, Chen S, **Coffey CS**, and McClellan WM.
November 2005: Annual Meeting of American Society of Nephrology (Philadelphia, PA)

18. *Quality of Blood Pressure Measurement in the SPS3 (Secondary Prevention of Small Subcortical Strokes) Study.*
 Graves JW and **Coffey CS** for the SPS3 Study Group.
May 2005: Annual Meeting of American Society of Hypertension (San Francisco, CA)

17. *GLUMIP 2.0: Free SAS/IML Software for Planning Internal Pilots.*
 Kairalla JA, **Coffey CS**, Muller KE.
March 2005: Annual Meeting of the Eastern North America Region (ENAR) of the Biometrics Society (Austin, TX)

16. *Repeated Measures for Gaussian Multivariate Linear Models: A Tutorial.*
 Simpson SL, **Coffey CS**, Muller KE.
March 2005: Annual Meeting of the Eastern North America Region (ENAR) of the Biometrics Society (Austin, TX)

15. *Avoiding Test Size Bias Due to Internal Pilots with Gaussian Repeated Measures.*
 Clement ME, **Coffey CS**, Muller KE.
March 2005: Annual Meeting of the Eastern North America Region (ENAR) of the Biometrics Society (Austin, TX)

14. *Toward Unbiased Estimation of the Effects of Risk Factors in the Presence of Latent Confounders Estimated with Error by Simulation-Extrapolation in Cox Proportional Hazard Model: The Example of Intentional Weight Loss and Mortality Rate.*
Wang C, Coffey CS, Allison DB.
November 2004: North American Association for the Study of Obesity Annual Scientific Meeting (Las Vegas, NV).
13. *Restructuring of Biostatistics at UAB.*
Howard G, Beasley TM, Coffey CS, George V
August 2004: Annual Joint Statistical Meetings (Toronto, ON).
12. *Genetic Programming Neural Network Has Improved Power in Comparison to Logistic Regression for Detecting Gene-Gene Interactions in Studies of Human Disease.*
Ritchie MD, Coffey CS, Moore JH.
June 2004: Annual Genetic and Evolutionary Computation Conference (Seattle, WA);
 Nominated for the Best Paper Award.
11. *Pharmacogenomics in Pulmonary Arterial Hypertension (PAH): The Relationship between an ET-1 Gene Polymorphism (PM) and Efficacy of Bosentan.*
Benza RL, Mohanty GS, Grenett HE, Coffey CS, Rayburn BK, Tallaj JA, Law MA, Pinderski LJ, Pambokian SV, Bourge RC.
May 2004: International Conference of the American Thoracic Society (Orlando, FL)
10. *Genotypes and Acute Chronic Rejection in Cardiac Transplant Recipients.*
Benza RL, Barchue JP, Grenett HE, Coffey CS, Tallaj JA, Rayburn BK, Pinderski LJ, Pambokian SV, McGiffin DC, Kirklin JK, Bourge RC.
April 2004: Annual Meeting and Scientific Sessions of the International Society for Heart and Lung Transplantation (San Francisco, CA)
9. *PAI-1 and Allograft Vasculopathy: Insights from a Murine Model of Transplantation.*
Benza RL, Mohanty GS, Coffey CS, Anderson PG, Lyle K, George JF.
April 2004: Annual Meeting and Scientific Sessions of the International Society for Heart and Lung Transplantation (San Francisco, CA)
8. *Caloric Restriction and Body Weight Independently Affect Longevity in Wistar Rats.*
Wang C, Weindruch R, Fernandez JR, Coffey CS, Patel P, Allison DB.
November 2003: North American Association for the Study of Obesity Annual Scientific Meeting (Ft. Lauderdale, FL).
7. *Fibrinolytic Proteins and Genotypes: Implications for Allograft Coronary Disease.*
Benza RL, Coffey CS, Barchue JP, Cavender MA, Rayburn BK, Bourge RC, Tallaj JA, Kirklin JK, Pinderski LJ.
November 2003: American Heart Association Annual Meeting (Orlando, FL).
6. *A Comparison of Data Mining and Logistic Regression Approaches for Detecting Gene-Gene Interactions.*
Ritchie MD, Coffey CS, Moore JH.
November 2003: Intl Genetic Epidemiology Society Meeting (Redondo Beach, CA)
5. *Adverse Effects of Beta Blocker Therapy for Heart Failure Patients: A Quantitative Overview.*
Ko DT, Hebert PR, Coffey CS, Foody JM, Curtis JP, Sedrakyan A, Krumholz HM
November 2002: American Heart Association Annual Meeting (Chicago, IL).
4. *Population Based Study of Methotrexate Use and Risk of Lymphoma in Patients with Rheumatoid Arthritis.*
Watterson MK, Arrowsmith ER, Coffey CS, Cookson MS, Mitchel E, Stein CM
October 2002: American College of Rheumatology/Association of Rheumatology Health Professionals Annual Meeting (New Orleans, LA).
3. *Is There an Interaction between the ACE I/D and the PAI-1 4G/5G Gene Polymorphisms on Risk of Myocardial Infarction.*
Hebert PR, Coffey CS, Ajani UA, Morgan TM, Brown NJ, Vaughan DE, Ridker PM.
November 2001: American Heart Association Annual Meeting (Anaheim, CA).

2. *Amiodarone Delays Cellular Rejection in Bradycardic Transplant Patients.*

Goldstein DR, Benza RL, Rayburn BK, Foley BA, **Coffey CS**, Thomas KL, Bourge. RC.

November 2001: American Heart Association Annual Meeting (Anaheim, CA).

1. *Pathological Parameters in Radical Prostatectomies of Clinical Stage T1c versus T2 Prostate Carcinoma.*

Jack GS, Vader V, **Coffey CS**, Cookson MS, Smith JA, Shappell SB

June 2001: American Urological Association National Meeting (Anaheim, CA).

GRANT ACTIVITY

ACTIVE

Network of Excellence in Neuroscience Clinical Trials (NEXT) – DCC [NIH U01 NS077352]

09/30/2011-08/31/2028 [Role: PI]

A central goal of the Network for Excellence in Neuroscience Clinical Trials (NeuroNEXT) is to facilitate, from initial conception through final analysis, high-quality early phase clinical trials and biomarker studies with clear go/no-go decisions in adult and pediatric neurological disorders. The Data Coordinating Center (DCC) at the University of Iowa will continue to support study design, data collection, data management, data sharing, project management, clinical site monitoring, quality management, safety monitoring, and all statistical aspects of trials conducted within the network. The DCC will continue to build on our robust, standardized, and accessible infrastructure in a manner that is explicitly designed to accommodate dynamically changing requirements that naturally occur in clinical trials, and will continue to help NeuroNEXT succeed in providing more rapid evaluation of promising treatments in the neurosciences.

Clinical Coordinating Center for the Acute to Chronic Pain Signature Program [NIH U24 NS112873]

08/15/2019-07/31/2024 [Role: Co-PI (w/ K. Sluka & L Frey Law)

The Acute to Chronic Pain Signatures (A2CPS) Program aims to develop a large consortium to identify biomarkers and their collective biosignatures (a combination of several individual biomarkers) that predict susceptibility or resilience to the development of chronic pain after an acute pain event. Two pain populations will be followed for 6 months, with baseline and 3-month collection of multiple psychosocial, imaging, "omics", quantitative sensory testing (QST), physical function, and pain variables. The success of the A2CPS program is dependent on effective management and coordination of activities across the consortium. The Clinical Coordinating Center will apply thorough and well-organized principles to facilitate, support, and enhance the scientific rigor and effectiveness of key stakeholders for the identification of critical biomarkers for the acute to chronic pain transition.

The Parkinson's Progression Markers Initiative Statistical Core

The Michael J. Fox Foundation for Parkinson's Research

06/24/2010-06/30/2024 [Role: PI]

The Parkinson's Progression Markers Initiative is a longitudinal, observational, multi-center natural history study to assess progression of clinical features, digital outcomes, and imaging, biologic, and genetic markers of Parkinson's disease (PD) progression in study participants with manifest PD, prodromal PD, and healthy controls. The overall goal of PPMI is to identify markers of disease progression for use in clinical trials of therapies to reduce progression of PD disability.

Iowa Summer Institute for Research Education in Biostatistics [NIH R25 HL147231]

03/01/2022-02/28/2027 [Role: Co-Investigator; PI: G. Zamba(U. Iowa)]

The ultimate vision of the Summer Institute for Research Education in Biostatistics is to increase the number of undergraduates who enter graduate programs in biostatistics, and to maintain a solid underrepresented minority pipeline into biostatistics graduate programs. This project supports the University of Iowa, Department of Biostatistics in recruiting a diverse group of trainees each year with focus on minority, underrepresented, and disadvantaged students who may not have otherwise been exposed to the field of biostatistics.

ACTIVE NEURONEXT SUBCONTRACTS (NO FUNDED EFFORT – CTSDMC SUPPORT ONLY)

NN108 Sub Award – Topiramate as a Disease Altering Therapy for CSPN

[U01 NS095388]

07/01/2017 – 12/31/2023 [Role: Subcontract PI; PI: G. Smith (VCU)]

NN109 Sub Award – A Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Evaluate the Efficacy of ManNAc in Subjects with GNE Myopathy

[U01 AR070498]

09/01/2017 – 04/30/2024 [Role: Subcontract PI; PI: A. Amato (Massachusetts General Hospital)]

NN110 Sub Award – A Dose Selection Trial of Light Therapy for Impaired Sleep in Parkinson’s Disease

[U01 NS114001]

09/15/2019-06/30/2024 [Role: Subcontract PI; PI: A. Videnovic (Massachusetts General Hospital)]

NN111 Sub Award – A Phase 2b, Double-Blind, Randomized Controlled Trial to Evaluate the Activity and Safety of Inebilizumab in Anti-N-Methyl-D-Aspartate Receptor (NMDAR) Encephalitis and Assess Markers of Disease

[U01 NS120901]

09/15/2021-08/31/2026 [Role: Subcontract PI; PI: S. Clardy (Utah)]

PREVIOUS

University of Iowa

A Randomized, Double-Blind, Placebo Controlled, Phase IIa, Parallel Group, Two-Cohort Study to Determine the Safety, Tolerability, Clinical, and Exploratory Biological Activity of the Chronic Administration of Nilotinib in Patients with Parkinson’s Disease – Biostatistics Coordinating Center

The Michael J. Fox Foundation for Parkinson’s Research

03/01/2017 – 05/31/2020 [Role: PI, Biostatistics Coordinating Center; PI: T. Simuni (Northwestern)]

MEDication Focused Outpatient Care for Underutilization of Secondary Prevention

NIH R18 HL116259

04/01/2014 – 03/31/2020 [Role: PI, Data Coordinating Center; PI: BL Carter (U. Iowa)]

Enhancing Scientific Inquiry in Clinical Neurosciences Through Methodology Training

NIH U34 DK099845

04/01/2014 – 03/31/2020 [Role: Subcontract PI, Course Co-Director; PI: W. Meurer (U. Michigan)]

Systemic Synuclein Sampling Study (S4) – Clinical, Data Management & Statistical Core

The Michael J. Fox Foundation for Parkinson’s Research

03/01/2015 – 12/31/2019 [Role: PI, Statistics Core]

Amyloid Imaging – PPMI Substudy

The Michael J. Fox Foundation for Parkinson’s Research

03/01/2014-02/28/2019 [Role: PI, Statistics Core]

Three Site Assessment of the Potential for Home Dexterity Monitoring in a PD Biomarker Study (TAP-PD) – PPMI Sub Study

The Michael J. Fox Foundation for Parkinson’s Research

03/01/2014-02/28/2019 [Role: PI, Statistics Core]

Amitriptyline and Topiramate in the Prevention of Childhood Migraine: DCC

NIH U01 NS077108

09/30/2011-08/31/2017 [Role: PI, Data Coordinating Center]

LRRK2 Cohort Consortium – Statistics

The Michael J. Fox Foundation for Parkinson’s Research

06/02/2011-11/30/2017 [Role: PI, Statistics Core]

A Collaborative Model to Improve BP Control and Minimize Racial Disparities – DCC

NIH R01 HL0918434

08/01/09 – 02/28/15 [Role: PI, Data Coordinating Center]

Secondary Prevention of Small Subcortical Strokes SPS3)

NIH U01 NS038529

12/01/09 – 12/31/03 [Role: Subcontract PI; PI: OR Benavente (U. British Columbia)]

Adaptive Comparative Effectiveness Trials for Comparing Two Treatments

UF11128

05/23/11 – 03/31/12 [Role: Subcontract PI; PI: DR Nelson (U. Florida)]

Clinical Islet Transplantation: Data Coordinating Center (CIT: DCC)

NIH U01 DK070431

08/01/09 – 10/01/11 [Role: Co-Investigator; PI: WR Clarke (U. Iowa)]

Role: Co-Investigator

Carotid Occlusion Surgery Study (COSS): Data Management Center

NIH U01 NS041985

08/01/09 – 12/01/10 [Role: Co-Investigator; PI: WR Clarke (U. Iowa)]

NEURONEXT SUBCONTRACTS (NO FUNDED EFFORT – CTSDMC SUPPORT ONLY)

NN101 Sub award – SMA Biomarkers in the Immediate Post-Natal Period of Development
[U01 NS079163]

08/15/2012 – 07/31/2016 [Role: Subcontract PI; PI: S. Kolb (The Ohio State University)]

NN102 Sub award – Ibudilast in Phase II Trial in Progressive MS
[U01 NS082329]

07/15/2013 – 06/30/2020 [Role: Subcontract PI; PI: R Fox (Cleveland Clinic)]

NN103 Sub award – A Phase II Trial of Rituximab in Myasthenia Gravis
[U01 NS084495]

09/15/2013 – 07/31/2019 [Role: Subcontract PI; PI: R Nowak (Yale)]

NN104 Sub award – ZZ3K3A-201: Safety Evaluation of 3K3A-APC in Ischemic Stroke
[U01 NS088312]

07/01/2014 – 06/30/2018 (Role: Subcontract PI; PI: P Lyden (Cedars Sinai)]

NN105 Sub award – Tolerability of SRX246 in Huntington's Disease Patients
[U44 NS090616]

09/01/2015 – 08/31/2018 [Role: Subcontract PI; PI: M Brownstein (Azevan)]

NN106 Sub award – Cytochrome C Oxidase: Biomarker in Newly Diagnosed Glioblastoma Multiforme
[U01 NS093663]

09/30/2016 – 06/30/2022 [Role: Subcontract PI; PI: C Griguer (U Iowa)]

NN107 Sub Award – Effects of AFQ056 on Language Learning in Young Children with Fragile X Syndrome (FXS)
[U01 NS096767]

09/30/2016 – 06/30/2023 [Role: Subcontract PI; PI: E. Berry-Kravis (Rush)]

University of Alabama at Birmingham

Merck Quantitative Science Fellowship Program

Merck

08/22/07 – 07/31/09 [Role: PI]

Pharmacogenomics in Pulmonary Arterial Hypertension

NIH RO1 HL078946

09/01/05 – 07/31/09 [Role: Statistician; PI: RL Benza (UAB)]

Levels of Inflammatory Markers in the Treatment of Stroke

NIH RO1 NS050724

05/25/05 – 04/30/09 [Role: Subcontract PI; PI: MSV Elkind (Columbia)]

Effects of Intentional Weight Loss on Mortality Rate

NIH RO1 DK067487

01/01/05 – 12/31/08 [Role: Co-Investigator; PI: DB Allison (UAB)]

Secondary Prevention of Small Subcortical Strokes

NIH UO1 NS038529

03/01/03 – 01/31/08 [Role: Subcontract PI; PI: OR Benavente (UT Health Sciences Center at San Antonio)]

Design and Analysis of Microarray Gene Expression Studies in Plants: Towards Sound Statistical Principles

NSF-01-158

01/01/03 – 12/31/07 [Role: Co-Investigator; PI: G Page (UAB)]

Internal Pilots for Repeated Measures ANOVA

NIH RO1 CA095749

01/15/03 – 12/31/07 [Role: Subcontract PI; PI: KE Muller (U. North Carolina)]

Genetic Variants and Thrombosis: Renin Angiotensin.

NIH RO1 HL99015

04/01/01 – 07/31/07 [Role: Subcontract PI; PI: PR Hebert (Yale)]

Modulation of Innate Immunity in Lung Transplantation

NIH RO1 HL72871

09/30/02 – 07/31/06 [Role: Statistician; PI: S Matalon (UAB)]

UT-15 Open Grant in Pulmonary Hypertension

United Therapeutics

10/01/01 – 04/01/05 [Role: Statistician]

STUDENTS MENTORED

UNIVERSITY OF IOWA

Chair (Doctoral Level):

2024 (Expected): Megan McCabe (Co-Chair w/ E. Bayman).

2022: Daniel Kang (Co-Chair w/ V. Yin), “Efficient Bayesian Adaptive Designs for Oncology Clinical Trials with Multiple Biomarker Subgroups”.

2019: Anne Wellhaven. “Pacing Modification by Incorporation of Lag in Early Phase Designs”

2015: Mitchell Thomann. “The Flexible Bivariate Continual Reassessment Method”

Committee Member (Doctoral Level):

2021: Alex Curtis. “Subgroup-Specific Dose Finding Using Bayesian Clustering in Phase I-II Clinical Trials”

2017: Janel Barnes. “Regression and Boosting Methods to Inform Precisionized Treatment Rules Using Data from Crossover Studies”

Advisor (Preceptorship – Master’s Level):

2019: Elliot Burghardt. “Reproducibility of Living Data: Validation of Published Research Using the Parkinson’s Progression Marker Initiative Living Database”

2013: J. Tucker Krone. “Simulation Study Addressing Common Phase II Endpoint Selection Issues”

2012: Elizabeth Zahn. “A Survey on the Perception and Use of Adaptive Designs in Clinical Trials”

2011: Emily Lundt. “Prediction of the Implementation of the Physician-Pharmacist Collaborative Model Using the Theory of Planned Behavior”

2011: Chelsea Caspell. “Analysis of Parkinson’s Biomarker Candidates”

UNIVERSITY OF ALABAMA AT BIRMINGHAM

Chair (Doctoral Level):

2008: William Prucka. “Wavelet-Based Regression and Classification for Longitudinal Diffusion Tensor Imaging Data”

2008: Nitin Nair. “Adaptive Procedures to Detect Treatment Effect Under Suspected Treatment-Covariate Interactions”

2007: David Sawrie. “Preemptive Power for the Consulting Statistician: Novel Applications of Internal Pilot Design and Information Based Monitoring Systems”

Advisor (Master’s Level):

2010: Jiatao Ye (Co-Chair with Inmaculada Aban). “Power and Sample Size Estimation for a Three-Level Hierarchical Cluster Randomized Trial”

2009: Kerri Howard. “Ambulatory Blood Pressure as Related to White Matter Hyperintensity: A Preemptive Power Approach”

2008: John Bentley. "Cardiovascular Risk Associated with Polymorphisms in Genes from the Renin-Angiotensin, Bradykinin, and Fibrinolytic Systems"

2005: Qing Li. "The Association of the Metabolic Syndrome with PAI-1 and t-PA Antigen Levels"

2002: Lili Wang. "An Evaluation of a Two-Stage Procedure to Address Interactions in Two-Stage Designs"

Committee Member (Doctoral Level):

2008: Samprit Banerjee. "Bayesian Genome-Wide QTL Mapping for Multiple Traits"

2008: Qing Li. "Interim Monitoring Efficacy, Safety, and Futility in Phase III Clinical Trials"

2007: Tamekia Jones. "A Statistical Approach Identifying and Limiting the Effect of Influential Observations in Linear Regression"

2007: Ayanbola Ayanlowo. "Examination of Novel Statistical Designs for Phase II and Phase III Clinical Trials"

Committee Member (Master's Level):

2009: Leigh Morton. "Comparison of Simon's Two-Stage Design, Sequential Probability Ratio Test, and Triangular Test in Phase II Clinical Trials"

2006: Scott Marshall. "A Comparison of Procedures to Control Type I Error in Multiple Testing Situations: False Positive Report Probability (FPRP) vs. False Discovery Rate (FDR)"

2004: Lang Chen. "Model Selection in Microarrays"

2002: Dongyan Yang. "The Confounding of Race and Geography: How Much of the Excess Mortality among African Americans is Explained by Geography"

Committee Member (Other):

2009: Christopher Snyder, MSPH. (Epidemiology) "The Relationship of Blood Product Ratio to Mortality: Survival Benefit or Survival Bias?"

2009: Robert B. Hines, PhD. (Epidemiology) "Comorbidity and Body Mass Index (BMI) as Predictors of Survival for African-Americans and Caucasians Following Surgery for Adenocarcinoma of the Colon"

2007: Madhav Bhatta, PhD. (Epidemiology) "Impact of Immunosuppression on the Incidence and Clearance of Human Papillomavirus (HPV) in HIV-Infected Women in Alabama"

2005: Hanzhu Qian, PhD. (Epidemiology) "Association of Plasma Donation with Human Immunodeficiency Virus and Hepatitis C Virus Infections in Rural Shanxi Province, China"

2005: Christopher Krawczyk, PhD. (Epidemiology) "Factors Associated with Delayed Initiation of HIV Medical Care Among Infected Persons Attending an Urban HIV/AIDS Clinic"

2004: Jonathon Bender, PhD. (Epidemiology) "Cancer Incidence Among Employees at Semiconductor and Storage Device Manufacturing Facilities"

2004: Dominik Alexander, PhD. (Epidemiology) "Post-Surgical Disparity in Survival Between African-Americans and Caucasians with Colorectal Adenocarcinomas"

2003: Akanid Wapeewutikorn, MS. (Epidemiology) "Use of Complementary and Alternative Medicine Among Cancer Patients and Menopausal Women in the U.S. General Population"

UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL

Chair (Doctoral Level):

2007: John Kairalla (Co-Chair with Keith Muller). "An Internal Pilot Study with Interim Analysis for Gaussian Linear Models"

Committee Member (Doctoral Level):

2007: Sola Park. "Accounting for Bias and Uncertainty in Power for Multivariate Gaussian Linear Models"

2002: Michael Jiroutek (Dr. Ph). "Choosing a Sample Size for Estimating a Confidence Interval to Insure Good Properties"

HONORS AND AWARDS

2022: University of Rochester Michael P. McDermott Endowed Lectureship in Experimental Therapeutics

2020: Named a Fellow of the American Academy of Neurology

2018: University of Iowa College of Public Health Distinguished Faculty Lecture

2016: University of Iowa College of Public Health Faculty Service Award
2016: Named a Fellow of the American Statistical Association
2015: Named a Fellow of the Society for Clinical Trials
2013: University of Iowa College of Public Health Faculty Research Award
2008: Science Unbound Foundation Award, Best Paper by a UAB Based Investigator in General Statistics
2005: Grizzle Distinguished Alumni Award, UNC Department of Biostatistics
2004: Science Unbound Foundation Award, Best Paper by a UAB Based Investigator in General Statistics
2004: UAB President's Award for Excellence in Teaching - School of Public Health
2003: Nomination for the Charles C. Shepard Science Award for most outstanding peer-reviewed paper published by CDC/ATSDR scientists during the preceding year (Prevention and Control Category)
1999: Barry H. Margolin Dissertation Award, UNC Department of Biostatistics
1995-1999: National Institute for Environmental Health Sciences Training Grant
1997: Special Commendation, Theory Doctoral Exam, UNC Department of Biostatistics
1997: Special Commendation, Applied Doctoral Exam, UNC Department of Biostatistics
1997: Delta Omega Book Award, UNC School of Public Health
1997: UNC School of Public Health Student Award
1996: Inducted into Delta Omega Public Health Honor Society
1993: Chancellor's Citation for Academic Excellence, University of Tennessee-Knoxville
1992: Named "Top Graduate" in University of Tennessee College of Business Administration
1992: Epsilon Eta Chapter of Sigma Nu Fraternity Scholar of the Year

OTHER PROFESSIONAL POSITIONS HELD

UNIVERSITY OF NORTH CAROLINA DEPARTMENT OF BIOSTATISTICS (Chapel Hill, NC)

1995-1999 Graduate Research Assistant

RHO, Inc. (Chapel Hill, NC)

1998 Statistician II

COLLABORATIVE STUDIES COORDINATING CENTER (Chapel Hill, NC)

1995 SAS Programmer

SCHLEGEL TENNESSEE, INC. (Maryville, TN)

1993-1994 Advanced Quality Planning Engineer

SCHLEGEL, IOWA DIVISION (Keokuk, IA)

1993 SPC Statistician

PROFESSIONAL SERVICE

PROFESSIONAL ORGANIZATIONS

Society of Clinical Trials

2023-Present: Treasurer

2023-Present: Chair, Fellows Committee

2022-2023: Co-Chair, Fellows Committee

2020-Present: Member, Fellows Committee

2016-2020: Member, Communications Committee (Social Media Chair)

2012-2017: Board Member

2012-2015: Member, Program Committee

2013-2014: Program Chair

2009-2012 Chair, Education Committee

2007-2012: Member, Education Committee

2009-2011: Member, Education Outreach Committee

2008-2009: Co-Chair, Education Committee

American Statistical Association

2011-2013: Member, Biopharmaceutical Section Executive Committee

2002-2009: Chapter Representative for Alabama Chapter

1999-2000: Secretary for Middle Tennessee Chapter

Eastern North American Region (ENAR) of the International Biometric Society

2007-2009: Regional Advisory Board

2007: ENAR Program Chair for the Joint Statistical Meetings
Drug Information Association
American Academy of Neurology

JOURNAL EDITOR

2020-Present: Statistical Editor – *Stroke*
2019-Present: Associate Editor – *Trials*
2016-Present: Associate Editor – *Clinical Trials*
2011-2020: Consulting Biostatistician – *Stroke*
2011-2017: Associate Editor – *Movement Disorders*

STUDY SECTIONS / GRANT REVIEWS

National Institute of Neurological Disorders and Stroke (NINDS)

August 2019-Present: Reviewer, ZNS1 SRBA (EPPIC-NET Clinical Trials Review – 15 Total: 2019 – 2; 2020 – 6; 2021 – 7))
December 2023: Reviewer, ZNS1 SRBA (Clinical Trial Readiness for Rare Neurological & Neuromuscular Diseases)
June 2023: Reviewer (NIH StrokeNet Clinical Trials and Biomarker Studies for Stroke Treatment, Recovery, and Prevention)
August 2022: Reviewer [Network For Emergency Clinical Trials: Strategies to Innovate EmeRgENcy Care Clinical Trials Network (SIREN) – Data Coordinating Center (DCC)]
August 2021: Reviewer, ZNS1 SRBG (Clinical Trials and Comparative Effectiveness Studies)
March 2021: HEAL Initiative ZNS1 SRB G (37) (Non-Addictive Analgesic Therapeutics Development to Treat Pain)
December 2018: Reviewer, ZNS1 SRBA (Clinical Trial Readiness for Rare Neurological & Neuromuscular Diseases)
June 2018: Ad-Hoc Reviewer, NSD-K Study Section
December 2017: Reviewer, ZNS-SRBA (Clinical Trial Readiness for Rare Neurological and Neuromuscular Diseases) Special Emphasis Panel
July 2017: Acting Chair, Reviewer, ZNS-1SRBA (Clinical Trial Readiness for Rare Neurological and Neuromuscular Diseases) Special Emphasis Panel
December 2016: Reviewer, ZNS1-SRBC (SIREN CCC) Special Emphasis Panel
December 2016: Reviewer, ZNS1-SRBC (SIREN DCC) Special Emphasis Panel
March 2015: Ad-Hoc Reviewer, ZNS1-SRBB Special Emphasis Panel
August 2012: Ad-Hoc Reviewer, ZNS1-SRBB Special Emphasis Panel
March 2012: Ad-Hoc Reviewer, NSD-K Study Section
October 2011: Ad-Hoc Reviewer, ZNS1-SRBS Special Emphasis Panel
August 2011: Ad-Hoc Reviewer, ZNS1-SRBS Special Emphasis Panel
November 2010: Ad-Hoc Reviewer, ZNS1-SRBB Special Emphasis Panel
October 2010: Ad-Hoc Reviewer, NSD-K Study Section
June 2006-June 2010: Member, NSD-K Study Section
January 2010: Ad-Hoc Reviewer, ZNS1-SRBG Special Emphasis Panel
December 2009: Ad-Hoc Reviewer, ZNS1-SRBB Special Emphasis Panel
December 2008: Ad-Hoc Reviewer, ZNS1-SRBG Special Emphasis Panel
October 2005: Ad-Hoc Reviewer, NSD-K Study Section
June 2005: Ad-Hoc Reviewer, NSD-A Study Section
November 2004: Ad-Hoc Reviewer, NSD-A Study Section
February 2004: Ad-Hoc Reviewer, NSD-A Study Section
June 2003: Ad-Hoc Reviewer, NSD-K Study Section

National Institute for Allergy and Infectious Diseases (NIAID)

February 2023: Ad-Hoc Reviewer – Allergy and Asthma Statistical and Clinical Coordinating Center (AA-SCCC)

National Center for Advancing Translational Sciences (NCATS)

October 2022: Reviewer, CTSA Resource Center U24 Review

February 2013: Ad-Hoc Reviewer, Limited Competition – Clinical and Translational Science Awards (CTSA) Consortium Wide Centers: Resources for Rapid Demonstration and Dissemination

National Institute of Diabetes & Digestive & Kidney Diseases (NIDDK)

July 2022: Reviewer, ZDK1 GRB-6 (Understanding and Targeting the Pathophysiology of Youth-Onset Type 2 Diabetes – Biostatistics Research Center)

December 2021: Reviewer, ZDK1 GRB-9 (NIDDK Clinical Trials)

February 2021: Reviewer, ZDK1 GRB-9 (NIDDK Clinical Trials)

July 2020: Reviewer, ZDK1 GRB-6 (A Trial of Transplanting Hepatitis C-Viremic Kidneys into Hepatitis C-Negative Kidney Recipients)

May 2020: Reviewer, ZDK1 GRB-N (Multi-Center Clinical Study Implementation Planning Cooperative Agreements)

July 2019: Reviewer, ZDK1 GRB-9 (Clinical Centers)

May 2019: Reviewer, ZDK1 GRB-9 (Biostatistics Research Centers)

March 2019: Reviewer (Data Coordinating Center for Diabetic Foot Consortium)

NIH Post-Acute Sequelae of SARS-CoV-2 Infection (PASC) Initiative

April 2021: Reviewer

Center for Scientific Review

June 2019: Reviewer, Acute Neural Injury & Epilepsy (ANIE) Study Section

Cure Parkinson's Trust

May 2019: Grant Reviewer

The Michael J. Fox Foundation for Parkinson's Research

March 2019: Reviewer for Biomarkers Across Neurodegenerative Diseases (BAND) Program

October 2016: Chair, PPMI Data Challenge Review

October 2016: Reviewer for Improved Biomarkers & Clinical Outcome Measures Program – Data Science Review

August 2015: Reviewer for Biomarkers across Neurodegenerative Diseases (BAND) Program

August 2014: Reviewer for Biomarkers across Neurodegenerative Diseases (BAND) Program

January 2014: Reviewer for Biomarker/Data Use Applications

October 2011: Reviewer for LRRK2 RFA Applications

National Institute on Deafness and Other Communication Disorders (NIDCD)

January 2019: Reviewer, ZDC1 SRB-Y 54 (Clinical Trial Review)

May 2018: Reviewer, ZDC1 SRB-X 63 (NIDCD Aphasia Treatment Clinical Trial Review)

National Institute of Dental & Craniofacial Research (NIDCR)

November 2018: Chair, ZDE1 GZ08 (DPBRN Coordinating Center)

ALS Association

March 2018: Reviewer for Phase II Applications

March 2016: Reviewer for Phase II Applications

December 2015: Reviewer for Phase II Applications

May 2015: Reviewer for Phase II Applications

February 2014: Reviewer for Phase II Applications

October 2013: Reviewer for Phase II Applications

The Pacific Symposium on Biocomputing

2004: Reviewer

The Austrian Science Foundation Schroedinger Fellowship

2002: Reviewer

2001: Reviewer

DATA AND SAFETY MONITORING BOARDS

2022-Present: Member, NIA Sponsored – “SHARE Pilot: Sharing Health Care Wishes in Primary Care”

2021-Present: Member, NIDDK Sponsored – “Hyperbaric Oxygen Therapy for Ulcerative Colitis Patients Hospitalized for Moderate to Severe Flares: A Multi-Center, Randomized, Double-Blind, Sham-Controlled Trial (HBOT-UC)

2020-Present: Member, NIDDK Sponsored – “Glycemic Observation and Metabolic Outcomes in Mothers and Offspring (GO MOMS)

2018-2023: Member, VA-Sponsored – “Microbiota or Placebo After Antimicrobial Therapy for Recurrent C. Difficile at Home (MATCH)” (CSP #2004)

2017-2020: Chair, NIH-Sponsored – Traumatic Injury Clinical Trial Evaluating Tranexamic Acid in Children (TIC-TOC): A Pilot and Feasibility Study

2012-2019: Member, NINDS-Sponsored – “Rapid Administration of Carnitine in Sepsis (RACE)” Trial

2012-2019: Member, NIA Sponsored – “Non-Invasive Treatment of Abdominal Aortic Aneurysm Clinical Trial (N-TA³CT)”

2015-2018: Member, DOD Sponsored – Chronic Effects of Neurotrauma Consortium (CENC)

2005-2012: Member, NINDS Sponsored - “Interventional Management of Stroke Study (IMS III) Trial”

2005-2012: Member, NINDS Sponsored - “Albumin in Acute Stroke (ALIAS)” Trial

2009-2011: Member, Medivation, Inc. Sponsored - “A Phase III, Randomized, Double-Blind, Placebo-Controlled Safety and Efficacy Study of Dimebon in Patients with Mild to Moderate Huntington’s Disease (HORIZON)”

2008-2010: Chair, NINDS Sponsored – “Chronic Migraine Treatment Trial”

2008-2009: Member, NINDS Sponsored - “Lithium in ALS (LALS) Trial”

2008: Member, NCCAM Sponsored - “Creatine Safety Tolerability & Efficacy in Huntington’s Disease (CREST-E) Trial”

2004-2008: Member, NINDS Sponsored – “Clinical Trial of High Dose coQ10 in ALS (QALS) Trial”

2003-2004: Member, NINDS Sponsored - “Ankle Strengthening to Improve Gait and Function in CP Trial”

FDA ADVISORY PANELS

2018-Present: Member, FDA Gastrointestinal Drugs Advisory Committee

June 2023: Ad-Hoc Member, FDA Endocrinologic and Metabolic Drugs Advisory Committee

April 2022: Ad-Hoc Member, FDA Oncologic Drugs Advisory Committee

REFEREE MANUSCRIPTS

Statistical Reviewer for:

Stroke (42 Total: 2003 - 4; 2004 - 2; 2005 - 5; 2006 – 2; 2007 – 3; 2008 – 1; 2009 – 1; 2010 – 3; 2011 – 5; 2012 – 6; 2013 – 1; 2014 – 3; 2017 – 1; 2018 – 1; 2019 – 1; 2020 – 1; 2021 – 1; 2022 – 1)

Movement Disorders (35 Total: 2010 – 4; 2011 – 11; 2012 – 4; 2013 – 6; 2014 – 3; 2015 – 4; 2016 – 3)

Circulation (6 Total: 2005 – 1; 2006 – 2; 2008 – 1; 2009 – 1; 2010 – 1)

Ad-Hoc Reviewer for Many Journals:

Statistics in Medicine (11 Total: 2000 - 1; 2003 - 1; 2004 - 1; 2005 – 1; 2006 – 3; 2011 – 1; 2012 - 1; 2013 – 1; 2014 – 1)

Clinical Trials (9 Total: 2008 -2; 2012 – 1; 2014 – 1; 2016 – 1; 2018 – 4)

Neurology (7 Total: 2008 – 2; 2017 – 2; 2018 – 1; 2020 – 1; 2022 – 1)

The Journal of the American Medical Association (6 Total: 2004 - 1; 2005 – 1; 2007 - 1; 2013 - 3)

Journal of Neurotrauma (5 Total: 2004 – 3; 2005 – 2)

Obesity (3 Total: 2010 – 1; 2011 – 1; 2017 – 1)

Journal of Biopharmaceutical Statistics (2 Total: 2019 – 1; 2021 – 1)

Trials (2 Total: 2014 – 1; 2015 – 1)

Journal of Statistical Computation and Simulation (2 Total: 2008 – 1; 2010 – 1)

Epidemiology (2 Total: 2007 – 1; 2008 - 1)

The American Statistician (2 Total: 2000 – 1; 2008 - 1)

Hypertension (2 Total: 2004 - 1; 2005 - 1)

Biometrical Journal (2 Total: 2009 – 1; 2012 - 1)

Brain (1: 2022)

Journal of the Royal Statistical Society – Series A (1: 2017)

The American Journal of Clinical Nutrition (1: 2017)
Biometrics (1: 2014)
International Journal of Biostatistics (1: 2013)
Parkinsonism & Related Disorders (1: 2012)
Pharmaceutical Statistics (1: 2012)
Computer Methods and Programs in Biomedicine (1: 2007)
Computational Statistics and Data Analysis (1: 2005)
Behavior Research Methods, Instruments, & Computers (1: 2004)
Applied Bioinformatics (1: 2004)
Genetic Epidemiology (1: 2004)
Neuroepidemiology (1: 2004)
The American Journal of Human Genetics (1: 2003)
Diabetes (1: 2003)
Diabetologia (1: 2003)
Obesity Reviews (1: 2003)
Bioinformatics (1: 2002)
Human Heredity (1: 2002)
The Journal of the American Statistical Association (1: 2002)

GENERAL

2023: External Reviewer, University of Rochester Experimental Therapeutics Fellows Program
2007-2022: Member, Drug Information Association (DIA - previously sponsored by PhRMA) Adaptive Designs Working Group
2020: Participant, “Enabling Efficient Paths to Early Intervention in Parkinson’s Disease”, Joint Meeting of Critical Path for Parkinson’s Disease, Michael J. Fox Foundation for Parkinson’s Research, and FDA (Virtual Due to COVID-19)
2011-2017: Member, DIA Adaptive Designs Working Group Case Studies Subteam
2017: External Reviewer, University of Rochester Experimental Therapeutics Fellows Program
2017: Participant, The Michael J. Fox Foundation for Parkinson’s Research Exenatide Trial Assessment Meeting
2017: Participant, The Michael J. Fox Foundation for Parkinson’s Research Regulatory Workshop Planning Meeting – “Patient Selection & Stratification Biomarkers in Disease-Modifying Trials for Early-Stage PD”
2016: Member, ALS FDA Clinical Trials Guidelines Committee
2007-2009: Member, PhrMA Adaptive Designs Working Group Communications Workstream

UNIVERSITY SERVICE

UNIVERSITY OF IOWA

2016-Present: University Conflict of Interest Review Committee
2018: Member, Search Committee for Stroke Division Director

UNIVERSITY OF ALABAMA AT BIRMINGHAM

2006-2009: UAB Graduate Council
2004-2008: UAB Alternate Faculty Senator for School of Public Health
2004-2008: UAB Faculty Senate Curriculum and Research Committee
2007: Member, Committee to Select Recipient of the Ellen Gregg Ingalls/UAB National Alumni Society Award for Lifetime Achievement in Teaching

SCHOOL / COLLEGE OF PUBLIC HEALTH SERVICE

UNIVERSITY OF IOWA

2023: Member, Department of Epidemiology Faculty Search Committee
2020: Member, Associate Dean for Academic Affairs Search Committee
2011-2014: College of Public Health Research Council
2011: College of Public Health Associate Dean Search Committee
2009-2010: Member, CEPH Accreditation Workshop 2.0 Committee

UNIVERSITY OF ALABAMA AT BIRMINGHAM

2008-2009: Chair of the Faculty, UAB School of Public Health
2008-2009: School of Public Health Finance Committee
2002-2009: Contributor and Grader for Department of Epidemiology Written Examination
2006-2007: Member, Committee to Select Recipient of SoPH President's Excellence in Teaching Award
2006-2007: Member, School of Public Health Associate Dean Search Committee
2005: Biostatistics representative to Department of Epidemiology PhD Review Committee
2003-2005: Chair, SoPH Admissions and Graduation Committee
2002-2005: SoPH Editorial Review Board
2001-2005: Dept. representative to SoPH Admissions and Graduation Committee

DEPARTMENT SERVICE

UNIVERSITY OF IOWA

2021: Co-Chair, Faculty Search Committee
2020-Present: Chair, MS & PhD Curriculum Review Committee
2014-Present: Chair, Woolson Award Selection Committee
2016-2020: Member, PhD Curriculum Review Committee
2018: Co-Chair, Tenure Track Faculty Search Committee
2017: Member, Tenure Track Faculty Search Committee
2015-2016: Chair, Curriculum Committee
2015: Member, Department of Biostatistics DEO Search Committee
2013: Member, Doctoral Exam Restructuring Committee
2012: Chair, Clinical Track Faculty Search Committee
2011: Chair, Tenure Track Faculty Search Committee
2009-2011: MS Examinaton Committee
2009-2011: Admissions Committee

UNIVERSITY OF ALABAMA AT BIRMINGHAM

2006-2009: Director of Graduate Studies
2002-2009: Graduate Program Committee
2003-2006: Dept. alternate representative to SPH Educational Policy Committee
2005: Interim Chair, Graduate Program Committee
2001-2002: Teaching Evaluation Committee

Member of several faculty search committees