

Curriculum Vitae

Benjamin R. Saville, Ph.D.
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Contact Information

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Goals

Current Advance innovative Bayesian adaptive clinical trial design in both methods and application

Long term Provide leadership and impact to clinical trial design and improve public health

Education

2008 Doctor of Philosophy in Biostatistics
 University of North Carolina at Chapel Hill (UNC-CH), North Carolina
 - Adviser: Dr. Amy H. Herring

2004 Master of Science in Biostatistics
 University of North Carolina at Chapel Hill, North Carolina
 - Adviser: Dr. Gary G. Koch

2002 Bachelor of Science in Statistics
 Brigham Young University (BYU), Provo, Utah
 - Magna Cum Laude
 - 3.91 GPA, Dean's List 4 years

Work Experience

2024–present President & Lead Statistical Scientist, Adaptix Trials LLC, Austin, TX
 - Bayesian and adaptive clinical trial design

2023–present Adjoint Associate Professor of Biostatistics, Department of Biostatistics, Vanderbilt University School of Medicine

2019–2024 Director, Trial Design & Analysis, Berry Consultants, Austin, TX
 - Responsible for a team of 14 statistical scientists
 - Bayesian and adaptive clinical trial design
 - Therapeutic areas: Medical devices, cardiovascular disease (e.g. heart failure), infectious disease, stroke and traumatic brain injury, respiratory and digestive disorders, neurological diseases, rare and progressive diseases, many others

- All Phases of development including regulatory (FDA/EMA) interactions and approvals
- Collaborations: Medical device, pharmaceutical, academic trials
- 2018–2024 Senior Statistical Scientist, Berry Consultants, Austin, TX
- 2014–2017 Statistical Scientist, Berry Consultants, Austin, TX
- 2014–2023 Adjunct Assistant Professor, Department of Biostatistics, Vanderbilt University School of Medicine
- 2011–2014 Assistant Professor, Division of Cancer Biostatistics, Department of Biostatistics, Vanderbilt University School of Medicine
 - Senior Biostatistician for Department of Pediatrics, duties included collaborating with over 100 principal investigators and supervising staff biostatisticians
 - Co-leader of adaptive trials design workforce to promote innovative Bayesian methodology for clinical trials in the Vanderbilt-Ingram Cancer Center
- 2011–2014 Member, Vanderbilt Center for Quantitative Sciences
- 2009–2014 Assistant Professor (Secondary Appointment), Department of Biomedical Engineering, Vanderbilt University
- 2008–2014 Assistant Professor, Department of Biostatistics, Vanderbilt University School of Medicine
- 2003–2008 Graduate Research Assistant: Biometric Consulting Lab, UNC-CH Dept. of Biostatistics
 - Supervised by Dr. Gary Koch
- 2005–2006 Intern: GlaxoSmithKline, Research Triangle Park, NC
 - Duties: Statistical support in clinical trials & publications, Psychiatry
- 2002 Intern: Cleveland Clinic, OH, Dept. of Biostatistics
 - Duties: Statistical consulting
- 2001–2002 Research Assistant: BYU Dept. of Statistics
- 2001 Intern: Tillinghast-Towers Perrin, Atlanta, GA
 - Duties: Actuarial consulting & financial services
- 2000 Intern: Payless ShoeSource Corporate World Headquarters, Topeka, KS
 - Duties: Statistical analysis of merchandise distribution

FDA Regulatory Experience

- 2024–present Member: FDA Ear, Nose, and Throat Devices Panel
- 2024 Temporary Non-Voting Member: FDA Anesthesiology and Respiratory Therapy Devices Advisory Panel
- 2016–present Consultant: FDA Circulatory System Devices Advisory Panel
- 2014–present Involved in dozens of regulatory submissions/meetings as a client representative
- 2017 Responder as client representative at FDA Circulatory System Devices Advisory Panel

Data Monitoring and Review Committees

- 2024 Member, Data and Safety Monitoring Committee: AVD-104-C01: A Single and Multiple Dose Study to Evaluate the Safety, Pharmacokinetics, and Treatment Effect of Intravitreal AVD-104 in Participants with Geographic Atrophy Secondary to Age-related Macular Degeneration
- 2023 Instructor, DSMB Academy Training Pilot Workshop, FDA, Washington D.C.; sponsored by Heart Failure Collaboratory
- 2021-2023 Member, Data Monitoring Committee: A Double Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy and Safety of PRA023 in Subjects With Systemic Sclerosis Associated With Interstitial Lung Disease (SSc-ILD); sponsored by Prometheus Biosciences, Inc.
- 2021-2023 Member, Data Monitoring Committee: A Phase 2a, Multi-Center, Open-Label Study to Evaluate the Safety, Efficacy, and Pharmacokinetics of PRA023 in Subjects With Moderately to Severely Active Crohn's Disease; sponsored by Prometheus Biosciences, Inc.
- 2021-2023 Member, Data Monitoring Committee: A Phase 2, Multi-Center, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Efficacy, and Pharmacokinetics of Induction Therapy With PRA023 in Subjects With Moderately to Severely Active Ulcerative Colitis; sponsored by Prometheus Biosciences, Inc.
- 2016-2017 Member, Independent Data Monitoring Committee: Study to Evaluate the Efficacy and Safety of Danirixin Co-administered With Oseltamivir in the Treatment of Adults Hospitalized With Influenza; sponsored by GlaxoSmithKline.
- 2013-2018 Member, Data Safety Monitoring Board: Preterm Epo Neuroprotection Trial (PENUT): A Multi-Center, Randomized Placebo-Controlled Phase III 940-subject Trial of Erythropoietin for the Neuroprotection of Extremely Low Gestational Age Neonates. University of Washington. Supported by National Institute of Neurological Disorders and Stroke (NINDS).

Teaching

- 2012-2013 Instructor, Vanderbilt University, Department of Biostatistics, *Advanced Regression Analysis (Linear and Generalized Linear Models)*
- 2009-2012 Instructor, Vanderbilt University, Department of Biomedical Engineering, *Analysis of Biomedical Data*
- 2007 Graduate Teaching Assistant: UNC-CH Dept. of Biostatistics, *Categorical Data Analysis*
- 2004 Graduate Teaching Assistant: UNC-CH Dept. of Biostatistics, *Principles of Statistical Inference*
- 2001-2002 Undergraduate Teaching Assistant: BYU Dept. of Statistics, *Principles of Statistics*

Awards & Honors

2016	Joint Statistical Meetings (JSM): Medical Devices and Diagnostics Section Best Contributed Paper Award
2002–2008	National Institute of Environmental Health Sciences (NIEHS) pre-doctoral traineeship
2002	Phi Kappa Phi Honor Society
2001	Mu Sigma Rho National Statistical Honor Society
1997	Speaker at Washburn Rural High School graduation ceremony
1994	Eagle Scout, Boy Scouts of America

Professional Service

2022–present	Member, ENAR Regional Advisory Board
2019–present	Member, Heart Failure Collaboratory Working Group
2020–2021	Member, Bayesian Methods in Rare Disease Working Group
2020–2021	Member, Mild COVID-19 Disease Therapeutic Working Group
2020–2021	Member, NHLBI-CONNECTS Master Protocol Development Group
2020	Member, International Mucopolysaccharidoses (MPS) Consensus Panel, Orlando, FL
2008–2014	Member, Graduate Program Committee, Vanderbilt University School of Medicine, Department of Biostatistics
2012	Session Chair, International Biometric Society, Eastern North America Region (ENAR), Washington, D.C.
2009–2012	Organizer, Biostatistics Seminar Series, Vanderbilt University School of Medicine, Department of Biostatistics
2007	Session Chair, International Biometric Society, Eastern North America Region (ENAR), Atlanta, GA

Professional Memberships

2012–present	Society for Clinical Trials
2010–present	International Society for Bayesian Analysis
2007–present	International Biometric Society, Eastern North American Region
2006–present	American Statistical Association

Journal Referee

2009–	Nature, Clinical Trials, American Journal of Epidemiology, Journal of the Royal Statistical Society (Series C), Statistics in Medicine, Journal of Biopharmaceutical Statistics, Pharmaceutical Statistics, Diagnostics, Biometrika, Journal of the
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American Statistical Association, Biometrical Journal, Pediatrics, Biometrics, British Journal of Cancer, Statistical Methods in Medical Research, Journal of Cystic Fibrosis, Canadian Journal of Cardiology, JACC Journals of American College of Cardiology

Publications

1. Blumer V., Januzzi J.L., Lindenfeld J., Solomon S.D., Psotka M.A., Carson P.E., Bristow M.R., Abraham W.T., Gandotra C., **Saville B.R.**, O'Connor C., Fiuzat M. (2024). Heart Failure Drug Development Over the Eras. *JACC: Heart Failure* (in press).
2. Ospel J.M., Brown S., Holodinsky J., Rinkel L, Ganesh A., Coutts S.B., Menon B., **Saville B.R.**, Hill M.D., Goyal M. (2024). An Introduction to Bayesian approaches to trial design and statistics for stroke researchers. *Stroke* (in press).
3. Pradilla G., Ratcliff J.J., Hall A.J., **Saville B.R.**, Allen J.W. , Paulon G., McGlothlin A., Lewis R.J., Fitzgerald M., Caveney A.F., Li X.T., Bain M., Gomes J., Jankowitz B., Zenonos G., Molyneaux B.J., Davies J., Siddiqui A., Chicoine M.R., Keyrouz S.G., Grossberg J.A., Shah M.V., Singh R., Bohnstedt B.N., Frankel M., Wright D.W., Barrow D.L. (2024). Trial of Early Minimally Invasive Removal of Intracerebral Hemorrhage. *The New England Journal of Medicine*: 390(14):1277-1289.
4. **Saville B.R.**, Burkhoff D., Abraham W.T. (2024). Streamlining Randomized Clinical Trials for Device Therapies in Heart Failure: Bayesian Borrowing of External Data. *Journal of the American Heart Association*: 13(3), e033255.
5. Quintana Q., **Saville B.R.**, Vestrucci M., Detry M.A., Chibnik L., Shefner J., Berry J.D., Chase M., Andrews J., Sherman A., Yu H., Drake K., Cudkowicz M., Paganoni S., Macklin E.A., for the HEALEY ALS Platform Trial Study Group. Design and Statistical Innovations in a Platform Trial for ALS. *Annals of Neurology*: 94(3) 547-560.
6. Ratcliff J.J., Hall A.J., Porto E., **Saville B.R.**, Lewis R.J., Allen J.W., Frankel M., Wright D.W., Barrow D.L., Pradilla G. (2023). Early Minimally Invasive Removal of Intracerebral Hemorrhage (ENRICH): Study Protocol for a Multi-centered Two-arm Randomized Adaptive Trial. *Frontiers in Neurology*: 14, 1126958.
7. Schultz A., McLeod C., Berry S.M., Marsh J., McKenzie A., Messer M., Wood J., **Saville B.R.**, Jaffe A, Ranganathan S., Stick S., Wark P., Webb S., Snelling T. (2023). BEAT CF pulmonary exacerbations core protocol for evaluating management of pulmonary exacerbations in people with cystic fibrosis. *Trials*: 24(1), 1-15.
8. **Saville B.R.**, Viele K., Detry M.A. (2023). Conditional Power: How Likely is Trial Success? *JAMA*: 329(6), 508-509.
9. Butler C.C., Hobbs F.D., Gbinigie O.A., Rahman N.M., Hayward, Richards D.B., Dorward J., Lowe D.M., Standing J.F., Breuer J., MD8; Khoo S., Petrou S., Hood K., Nguyen-Van-Tam J.S., Patel M.G, **Saville B.R.**, Marion J., Ogburn E., Allen J., Rutter H., Francis N., et al. (2022). Molnupiravir plus usual care versus usual care alone as early treatment for adults with COVID-19 at increased risk of adverse outcomes (PANORAMIC): findings from the United Kingdom randomised, controlled open-label, platform adaptive trial. *The Lancet*: 401(10373), 281-293.

10. Yeatts S.D., Foster L.D., Barsan W.G., Berry N.S., Callaway C.W., Lewis R.J., **Saville B.R.**, Silbergleit R., Kline J.A (2022). An Adaptive Clinical Trial Design to Identify the Optimal Dose of Tenecteplase for Treatment of Acute Pulmonary Embolism. *Clinical Trials*: 19(6), 636-646.
11. Marion J., Ruiz J., **Saville B.R.**, (2022). Bayesian model of disease progression in mucopolysaccharidosis IIIA. *Statistics in Medicine*: 41(18), 3579-3595.
12. **Saville B.R.**, Berry D.A., Berry N.S., Viele K., Berry S.M. (2022). The Bayesian Time Machine: Accounting for Temporal Drift in Multi-arm Platform Trials. *Clinical Trials*: 19(5), 490-501.
13. Dorward J., Yu L.M., Hayward G, **Saville B.R.**, Gbinigie O., Hecke O.V., Ogburn E. et al. (2022). Colchicine for COVID-19 in adults in the community (PRINCIPLE): a randomised, controlled, adaptive platform trial. *British Journal of General Practice*, 72(720), e446-e455.
14. Paganoni S., Berry J.D., Quintana M., Macklin E., **Saville B.R.**, Detry M.A., Chase M., Sherman A., Yu H., Drake K., Andrews J., Shefner J., Chibnik L., Vestrucci M., Cudkowicz M.E. (2022). Adaptive Platform Trials to Transform ALS Therapy Development. *Annals of neurology* 91.2 (2022): 165-175.
15. Yu L.M., Bafadhel M., Dorward J., Hayward G., **Saville B.R.**, Gbinigie O., Van Hecke O., Ogburn E., Evans P.H., Thomas N.PB, Patel M.G., Richards D., Berry N., Detry M., Saunders C., Fitzgerald M., Harris V., Shanyinde M., de Lusignan S., Andersson M.I., Barnes P.J., Russell R.EK, Nicolau D.V., Ramakrishnan S., Hobbs R, Butler C.C. (2021). Inhaled budesonide for COVID-19 in people at higher risk of complications in the community: a randomised, controlled, adaptive platform trial (PRINCIPLE). *The Lancet* 398(10303), 843-855.
16. Butler C.C., Yu L.M., Dorward J., Gbinigie O., Hayward G., **Saville B.R.**, Van Hecke O., Berry N., Detry M., Saunders C., Fitzgerald M., Harris V., Djukanovic R., Gadola S., Kirkpatrick J., de Lusignan S., Ogburn E., Evans P.H., Thomas N.PB, Patel M.G., Hobbs R (2021). Doxycycline for suspected COVID-19 in people at high risk in the community: results from PRINCIPLE, the UK randomised, controlled, open-label adaptive platform trial. *The Lancet Respiratory Medicine* 9(9), 1010-1020.
17. Butler C.C., Hayward G., Yu L.M., **Saville B.R.**, Berry N., Dorward J., Gbinigie O., Van Hecke O., Ogburn E., Swayze H., Bongard E., Allen J., Tonner S., Tonkin-Crine S., Borek A., Judge D., Grabey J., de Lusignan S., Thomas N.P.B., Evans P.H., Andersson M.I., Llewelyn M.J., Patel M.G., Hopkins S., Hobbs R. (2021). Platform Randomised trial of INterventions against COVID-19 In older peoPLE (PRINCIPLE): Protocol for a randomised, controlled, open-label, adaptive platform, trial of community treatment of COVID-19 syndromic illness in people at higher risk. *BMJ open* 11.6: e046799.
18. Butler C.C., Dorward J., Yu L.M., Gbinigie O., Hayward G., **Saville B.R.**, Van Hecke O., Berry N., Detry M., Saunders C., Fitzgerald M., Harris V., Patel M.G., de Lusignan S., Ogburn E, Evans P.H., Thomas N.P.B., Hobbs R et al. (2021). Azithromycin for community treatment of suspected COVID-19 in people at increased risk of an adverse clinical course in the UK (PRINCIPLE): a randomised, controlled, open-label, adaptive platform trial. *The Lancet* 397(10279): 1063-1074.

19. van der Lee, J.H., Morton, J., Adams, H.R., Clarke, L., Eisengart, J.B., Escolar, M.L., Giugliani, R., Harmatz, P., Hogan, M., Kearney, S., Muenzer, J., Muschol N., Rust S., **Saville B.R.**, Semrud-Clikeman M., Wang R., Shapiro E (2020). Therapy development for the mucopolysaccharidoses: Updated consensus recommendations for neuropsychological endpoints. *Molecular Genetics and Metabolism*.
20. Viele K., **Saville B.R.**, McGlothlin A., Broglio K. (2019). Comparison of response adaptive randomization features in multiarm clinical trials with control. *Pharmaceutical Statistics*, 2020 Mar 21.
21. Butler C.C., Van der Velden A.W., Bongard E., **Saville B.R.**, Holmes J., Coenen S., Cook J., Francis N.A., Lewis R.J. et al. (2019). Oseltamivir plus usual care versus usual care for influenza-like illness in primary care: An open-label, pragmatic, randomised controlled trial. *The Lancet*: 395(10217), 42-52.
22. Coenen S., Cianci D., W Van Der Velden A., Goossens H., Bongard E., **Saville B.R.**, Gobat N., De Paor M., Ieven M., Verheij T.J., Butler C.C. (2020). Oseltamivir for coronavirus illness: Post-hoc exploratory analysis of an open-label pragmatic RCT. *British Journal of General Practice*: 70(696), e444-e449.
23. Schultz A., **Saville B.R.**, March J.A., Snelling T.L. (2019). An introduction to clinical trial design. *Paediatric Respiratory Reviews* 32: 30-35.
24. Carlson A.P., Hanggi D., Wong G.K., Etminan N., Mayer S.A., Aldrich E.F., Diring M.N., Schmutzhard E., Faleck H.J., Ng D., **Saville B.R.**, Macdonald R.L. (2019). Single-Dose Intraventricular Nimodipine Microparticles versus Oral Nimodipine for Aneurysmal Subarachnoid Hemorrhage. *Stroke*: 51(4), 1142-1149
25. Wiegand P., Chan R., Jost C., **Saville B.R.**, Parise H., Prutchi D., Carson P.E., Stagg A., Goldsmith R.L., Burkhoff D. (2019). Safety, Performance and Efficacy of Cardiac Contractility Modulation Delivered by the 2-Lead Optimizer Smart System: The FIX-HF-5C2 Study. *Circulation: Heart Failure* 13(4).
26. McLeod C, Norman R., Litton E., **Saville B.R.**, Webb S., Snelling T. (2019). Choosing primary endpoints for clinical trials of health care interventions. *Contemporary Clinical Trials Communications*, 16:00486.
27. **Saville B.R.**, Meurer W. (2019). Commentary on Ji et al: Sub-optimal illustration of response adaptive randomization. *Clinical Trials*: 16(6), 610-612.
28. Konstam M.A., Udelson J.E., Butler J., Klein H.U., Parker J.D., Teerlink J.R., Wedge P.M., **Saville B.R.**, Ardell J.L., Libbus I., DiCarlo L.A. (2019). Impact of Autonomic Regulation Therapy in Patients with Heart Failure: The ANTHEM-HFrEF Pivotal Study Design. *Circulation: Heart Failure*: 12(11), e005879.
29. Viele K., Broglio K., McGlothlin A., **Saville B.R.** (2019). Comparison of Methods for Control Allocation in Multiple Arm Studies Using Response Adaptive Randomization. *Clinical Trials*: 17(1), 52-60.
30. Rao K., Drikvandi R., **Saville B.R.** (2019). Permutation and Bayesian tests for testing random effects in linear mixed-effects models. *Statistics in Medicine* 38(25): 5034-5047.

31. Marsh J.A., Schultz A., **Saville B.R.**, Berry S.M., Snelling T (2019). Research Note: Adaptive trials: *Journal of Physiotherapy* 65(2): 113-116.
32. Schultz A., Marsh J.A, **Saville B.R.**, Norman R., Middleton P.G., Greville H.W., Bellgard M.I., Berry S.M., Snelling T (2019). Trial Refresh: A Case for an Adaptive Platform Trial for Pulmonary Exacerbations of Cystic Fibrosis. *Frontiers in Pharmacology* 10:301.
33. **Saville B.R.**, Berry S.M. (2018). Platform Trials. In Antonijevic Z., Beckman R.A. (Eds.), *Platform Trial Designs in Drug Development: Umbrella Trials and Basket Trials* (pp 181-196). Chapman and Hall/CRC Press.
34. Hanggi D., Etminan N., Mayer S.A., Aldrich E.F., Diringer M.N., Schmutzhard E., Faleck H.J., Ng D., **Saville B.R.**, Macdonald R.L. (2018). Clinical Trial Protocol: Phase 3, Multi-center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Efficacy, and Safety Study Comparing EG-1962 to Standard of Care Oral Nimodipine in Adults with Aneurysmal Subarachnoid Hemorrhage [NEWTON-2 (Nimodipine Microparticles to Enhance Recovery While Reducing TOxicity After SubarachNoid Hemorrhage)]. *Neurocritical Care* 30(1): 88-97.
35. Butler C.C, Connor J.T., Lewis R.J., Broglio K., **Saville B.R.**, Cook J., W Van Der Velden A., Verheij T (2018). Answering patient-centred questions efficiently: response-adaptive platform trials in primary care. *British Journal of General Practice* 68 (671): 294-295.
36. Bongard E., Van der Vleden A., Cook J., **Saville B.R.**, Beutels P., Aabenhus R.M., Brugman C., Chlabicz S., Coenen S., Colliers A., Davies M., De Paor M., De Sutter A., Francis N., Glinz D., Godycki-cwirko M., Goossens H., Holmes J., Ieven M., de Jong M., Lindbæk M., Little P., Martínón-Torres F, Moragas A., Pauer J., Pfeiferová M., Radzeviciene-Jurgute R., Sundvall P.D., Torres A., Touboul P., Varthalis D., Verheij T., Butler C.C. (2018). Antivirals for influenza-Like Illness? A randomized Controlled trial of Clinical and Cost effectiveness in primary CarE (ALIC⁴E): The ALIC⁴E Protocol. *BMJ Open* 8:e021032.
37. Butler C., Coenen S., **Saville B.R.**, Cook J., Van der Velden A., Holmes J., De Jong M., Little P., Goossens H., Beutels P., Leven M., Francis N., Moons P., Bongard E., Verheij T (2018). A trial like ALIC⁴E: Why design platform, response-adaptive, open, randomised controlled trial of antivirals for influenza like illness? *ERJ Open Research* 4: 00046-2018.
38. Abraham W.T., Kuck K.H., Goldsmith R.L., Lindenfeld J., Reddy V.Y., Carson P.E., Mann D.L., **Saville B.R.**, Parise H., Chan R., Wiegand P., Hastings J.L., Kaplan A.J., Edelmann F.T., Luthje L., Kahwash R., Tomassoni G.F., Gutterman D.D., Stagg A., Burkhoff D., Hasenfuß G. (2018). A Randomized Controlled Trial to Evaluate the Safety and Efficacy of Cardiac Contractility Modulation. *Journal of the American College of Cardiology: Heart Failure* 6(10):874-883.
39. Lavin L.R., Penrod C.H., Estrada C.M., Arnold D.H., **Saville B.R.**, Xu M., Lowen D.E. (2018). Fractures in the Pediatric Emergency Department: Are We Considering Abuse? *Clinical Pediatrics* 57(10):1161-1167.
40. Simpson S.A., Field S.L., Xu M., **Saville B.R.**, Parra D.A., Soslow J.H. (2017). Effect of Weight Extremes on Ventricular Volumes and Myocardial Strain in Repaired Tetralogy of Fallot as Measured by CMR. *Pediatric Cardiology* 39(3): 575-584.

41. **Saville B.R.**, Berry S.M. (2017). Balanced Covariates with Response Adaptive Randomization. *Pharmaceutical Statistics* 16(3):210-217.
42. Lam D., Koch G.G., Preisser J.P., **Saville B.R.** (2017). Randomization-Based Adjustment of Treatment Hazard Ratio for Covariates With Missing Data. *Statistics in Biopharmaceutical Statistics* 9(2): 195-203.
43. Lam D., Koch G.G., Preisser J.P., **Saville B.R.**, Hussey M.A. (2017). Randomization-based adjustment of multiple treatment hazard ratios for covariates with missing data. *J Biopharm Stat.* 27(3): 373-386.
44. McKane M., Soslow J.H., Xu M., **Saville B.R.**, Slaughter J.C., Burnette B., Markham L. (2016). Does Body Mass Index Predict Premature Cardiomyopathy Onset For Duchenne Muscular Dystrophy? *Journal of Child Neurology* 32(5):499-504.
45. **Saville B.R.**, Berry S.M. (2016). Efficiencies of Platform Clinical Trials: A Vision of the Future. *Clinical Trials*, 13(3):358-66.
46. Jimenez-Truque N., Saye E.J., Soper N., **Saville B.R.**, Thomsen I., Edwards K.M., Creech C.B. (2016). Association Between Contact Sports and Colonization with *Staphylococcus aureus* in a Prospective Cohort of Collegiate Athletes. *Sports Medicine* (2016): 1-9.
47. Colonna S., Higgins A., Alvarez J., **Saville B.R.**, Lawrence J.A., Abramson V. (2016). Analysis of Risk of Recurrence by Subtype in ≤ 1 cm breast tumors. *Clinical Breast Cancer* 16(3):223-31.
48. Welch R., Ayaz S., Uden J., Chen J., Mika V., **Saville B.R.**, Tyndall J., Nash M, Buki A., Barzo P., Hack D., Tortella F., Schmid K., Hayes R., Vossough A., Sweriduk S., Bazarian J. (2016). Ability of Serum Glial Fibrillary Acidic Protein, Ubiquitin C-Terminal Hydrolase-L1, and S100B to Differentiate Normal and Abnormal Head Computed Tomography Findings in Patients with Suspected Mild or Moderate Traumatic Brain Injury. *Journal of Neurotrauma*, 33(2):203-14.
49. Zhao Y., **Saville B.R.**, Zhou H., Koch G.G. (2016). Sensitivity Analysis for Missing Outcomes in Time-to-event Data with Covariate Adjustment. *Journal of Biopharmaceutical Statistics*, 26(2):269-79.
50. Hussey M.A., Koch G.G., Preisser J.S., **Saville B.R.** (2016). Nonparametric Randomization-Based Covariate Adjustment for Stratified Analysis of Time-to-Event or Dichotomous Outcomes. *Journal of Biopharmaceutical Statistics* 26(3):579-589.
51. Miller E.K., Linder J., Kraft D., Johnson M., Lu P., **Saville B.R.**, Williams J.V., Griffin M.R., Talbot H.K. (2016). Hospitalizations and outpatient visits for rhinovirus-associated acute respiratory illness in adults. *Journal of Allergy and Clinical Immunology* 137(3) 734-743.
52. Lee R.J., Lakkireddy D., Mittal S., Ellis C., Connor J.T., **Saville B.R.**, Wilber D. (2015). Percutaneous alternative to the Maze procedure for the treatment of persistent or long-standing persistent atrial fibrillation (aMAZE trial): Rationale and design. *Am Heart J.* 170(6):1184-94.

53. Castel L.D., Wallston K.A., **Saville B.R.**, Alvarez J.R., Shields B.D., Feurer I.D., Cella D.F. (2015). Validity and reliability of the Patient-Reported Arthralgia inventory: validation of a newly-developed survey instrument to measure arthralgia. *Patient Related Outcome Measures* 2015(6):205-214.
54. Fitzgerald M., **Saville B.R.**, Lewis R.J. (2015). Decision Curve Analysis. *JAMA*, 313(3): 409-410.
55. Shuplock J.M., Smith A.H., Owen J., Van Driest S.L., Marshall M., **Saville B.R.**, Xu M., Radbill A.E., Fish F.A., Kannankeril P.J. (2015). The Association between Peri-Operative Dexmedetomidine and Arrhythmias after Surgery for Congenital Heart Disease. *Circulation: Arrhythmia and Electrophysiology* 8:643-650
56. Van Driest S.L., McGregor T.L., Velez Edwards D.R., **Saville B.R.**, Kitchner T.E., Hebring S.J., Brilliant M., Jouni H., Kullo I.J., Creech C.B., Kannankeril P.J., Vear S.I., Brothers K.B., Bowton E.A., Shaffer C.M., Patel N., Delaney J.T., Bradford Y., Wilson S., Olson L.M., Crawford D.C., Potts A.L., Ho R.H., Roden D.M., Denny J.C. (2015). Genome-Wide Association Study of Serum Creatinine Levels during Vancomycin Therapy. *PLOS One*, 10(6):e0127791.
57. Loria C.L., Domm J.A., Halasa N.B., Heitman E., Miller E.K., Xu M., **Saville B.R.**, Frangoul H., Williams J.V. (2015). Human Rhinovirus C Infections in Pediatric Hematology and Oncology Patients. *Pediatric Transplantation* 19(1): 94-100.
58. Agarwal H.S., Barrett S.S., Barry K., Xu M., **Saville B.R.**, Donahue B.S., Harris Z.L., Bichell D.P. (2015). Association of blood products administration during cardiopulmonary bypass and excessive post-operative bleeding in pediatric cardiac surgery. *Pediatric Cardiology*, 36(3):459-67.
59. **Saville B.R.**, Connor J.T., Ayers G.D., Alvarez J. (2014). The utility of Bayesian predictive probabilities for interim monitoring of clinical trials. *Clinical Trials* 11: 485-493.
60. Horst S., Shelby G., Anderson J., Acra S., Polk D.B., **Saville B.R.**, Garber J., Walker L.S. (2014). Predicting Persistence of Functional Abdominal Pain From Childhood Into Young Adulthood. *Clinical Gastroenterology and Hepatology* 12(12):2026-2032.
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Short Courses and Tutorials

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| 2023 | Short Course: The ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop, Washington D.C. <i>Design and Implementation of Master Protocols for Complex Diseases. What have we learned?</i> |
| 2021 | Short Course: International Biometric Society, Eastern North American Region (ENAR) <i>Master Protocols: Tackling Complex Diseases (and COVID-19!) with Bayesian Adaptive Platform Trials</i> (virtual) |
| 2021 | Short Course: International Biometric Society, Western North American Region (WNAR) <i>Master Protocols: Tackling Complex Diseases (and COVID-19!) with Bayesian Adaptive Platform Trials</i> (virtual) |
| 2019 | Short Course: Telethon Kids Institute, Perth, Australia <i>Designing Complex Adaptive Trials</i> |
| 2018 | Short Course: Society of Clinical Trials (SCT), Portland, OR: <i>Adaptive Multi-arm Platform Trials</i> |
| 2017 | Short Course: ICSA Applied Statistics Symposium, Chicago, IL: <i>Bayesian Adaptive Clinical Trials in the 21st Century</i> |
| 2016 | Short Course: Vanderbilt University Department of Biostatistics, Nashville, TN: <i>Bayesian Methods for Clinical Trials in the 21st Century: An Interactive Tutorial</i> |
| 2016 | Short Course: Society of Clinical Trials (SCT), Montreal, Canada: <i>Efficiencies of Platform Clinical Trials: A Vision of the Future</i> |
| 2015 | Short Course: The Biopharmaceutical Applied Statistics Symposium (BASS), Rockville, MD: <i>Bayesian Methods for Clinical Trials in the 21st Century: An Interactive Tutorial</i> |

Invited Presentations

- 2023 Panelist, The Global CardioVascular Clinical Trialists Workshop, Washington, D.C.
- 2023 International Symposium on ALS/MND, Basel Switzerland: *Evaluating the Performance of the Bayesian Primary Efficacy Analysis Model in the HEALEY ALS Platform Trial*
- 2023 ENRICH Trial Investigator Close-out meeting, Aventura, FL: *ENRICH: A Novel Approach to Clinical Trials in ICH Statistical Design & Results*
- 2023 Professional Medical Education Webinar Series (virtual): *ENRICH: A Novel Approach to Clinical Trials in ICH*
- 2023 Bayesian Scientific Working Group Lecture Series (virtual): *The Bayesian Time Machine: Accounting for temporal drift in multi-arm platform trials*
- 2023 Australian Trials Methodology (AusTriM) Research Network Webinar (virtual): *Master Protocols: Tackling Complex Diseases (and COVID-19!) with Bayesian Adaptive Platform Trials*
- 2022 WONCA Europe Conference (virtual). *Adaptive Platform Trials: Innovation in Clinical Trial Design*
- 2022 Research Advances for Urologic Chronic Pelvic Pain Syndrome: Informing the Next Generation of Clinical Studies (virtual) *Adaptive Platform Trials: Innovation in Clinical Trial Design*
- 2022 FDA/AdvaMed Medical Device Statistical Issues Conference (virtual). *Goldilocks Sample Size: The ANTHEM Trial for Heart Failure.*
- 2022 The ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop, Washington D.C. Roundtable: *The Use of Non-concurrent Randomized Controls in Multi-arm Adaptive Platforms Trials*
- 2022 The Joint Statistical Meetings, Washington D.C. Roundtable: *The Use of Non-concurrent Randomized Controls in Multi-arm Adaptive Platforms Trials*
- 2021 NIH Collaboratory Grand Rounds (virtual): *The PRINCIPLE adaptive platform trial for community treatment of COVID-19: Innovation in trial design and delivery*
- 2021 Midwest Math & Stats Student Conference (virtual): *Master Protocols: Innovations in Clinical Trial Design*
- 2021 Duke Industry Statistics Symposium (virtual): *A Platform Trial for Amyotrophic Lateral Sclerosis (ALS) with a Shared Control Arm*
- 2020 Webinar to American Statistical Association community (virtual): *PRINCIPLE Platform Trial Design Treatment for COVID-19 in Primary Care*
- 2019 International Symposium on ALS/MND, Perth, Australia: The ALS Platform Trial: Design Considerations and Statistical Efficiencies
- 2019 Heart Failure Collaboratory Statistical Workshop at FDA, Silver Spring, MD: *Bayesian Methodology*

- 2019 Heart Failure Collaboratory Statistical Workshop at FDA, Silver Spring, MD: *Recent Approvals using Bayesian Borrowing*
- 2019 Heart Failure Collaboratory Think Tank Meeting, Falls Church, VA: *Bayesian Borrowing*
- 2018 Vanderbilt University Dept. of Biostatistics, Nashville, TN *Introduction to Bayesian methods and implementation via R/JAGS*
- 2018 National Heart, Lung, and Blood Institute (NHLBI) Innovative Clinical Trials Resource: *Subgroup Analyses in Clinical Trials*
- 2018 American Thoracic Society International Conference, San Diego, CA: *The Adaptive Platform Trial: An Alternative Trial Design for Complex Infections*
- 2017 Western Australia Health Translation Network Clinical Trials Forum, Perth, Australia: *Adaptive Clinical Trials in the 21st Century*
- 2017 Cardiac Society of Australia and New Zealand, Perth, Australia: *Adaptive Clinical Trials for Cardiovascular Disease*
- 2017 Victorian Centre for Biostatistics, Melbourne, Australia: *Bayesian Adaptive Clinical Trials in the 21st Century*
- 2017 Australasian Cystic Fibrosis Conference, Melbourne, Australia: *Adaptive Platform Clinical Trials in Respiratory Medicine*
- 2017 Joint Conference on Biometrics & Biopharmaceutical Statistics, Vienna, Austria: *Innovations in Multi-arm Platform Adaptive Clinical Trials*
- 2017 International Biometric Society, Eastern North American Region (ENAR), Washington, DC: *Bayesian Analyses in Confirmatory Trials: What has been done and what can be done?*
- 2016 Society of Clinical Trials, Quantitative Sciences in the Pharmaceutical Industry (SCT-QSPI) Regulatory Fall Innovation Workshop, Washington, D.C.: *The Adaptive Platform Trial: Efficiencies, Examples, and Potential*
- 2016 Key Opinion Leaders (KOL) Lecture Series on Adaptive Trials: *ALIC⁴E Introduction and overview: Antivirals for influenza Like Illness? A rCt of Clinical and Cost effectiveness in primary Care (ALIC⁴E)*
- 2016 PREPARE Annual Investigator Meeting: *ALIC⁴E PREPARE Trial Design*
- 2015 Key Opinion Leaders (KOL) Lecture Series on Adaptive Trials: *The utility of Bayesian predictive probabilities for interim monitoring of clinical trials*
- 2015 Midwest Biopharmaceutical Statistics Workshop, Muncie, IN; *Tailoring Therapies in Adaptive Platform Clinical Trials*
- 2013 Novartis Biostatistics Workshop, East Hanover, NJ; *Estimating covariate-adjusted incidence density ratios for multiple intervals using nonparametric randomization-based ANCOVA*
- 2012 Vanderbilt University Dept. of Biostatistics, Nashville, TN: *Estimating covariate-adjusted log hazard ratios in randomized clinical trials using Cox proportional hazards models and nonparametric randomization based analysis of covariance*

- 2010 Vanderbilt University Dept. of Biostatistics, Nashville, TN: *Introduction to Bayesian methods and implementation via OpenBUGS*
- 2009 Vanderbilt University Dept. of Biostatistics, Nashville, TN: *Testing random coefficients in multilevel models using approximate Bayes factors*
- 2008 Vanderbilt University Dept. of Biostatistics, Nashville, TN: *Testing random coefficients in multilevel models using approximate Bayes factors*
- 2008 University of Alabama-Birmingham, Dept. of Biostatistics, *Testing random coefficients in multilevel models using approximate Bayes factors*
- 2008 East Carolina University, Dept. of Biostatistics, *Testing random coefficients in multilevel models using approximate Bayes factors*
- 2008 Moffitt Cancer Center, Dept. of Biostatistics, *Testing random coefficients in multilevel models using approximate Bayes factors*
- 2008 Oregon Health & Science University, Dept. of Biostatistics, *Testing random coefficients in multilevel models using approximate Bayes factors*
- 2008 Brigham Young University, Dept. of Statistics, *Testing random coefficients in multilevel models using approximate Bayes factors*
- 2006 Presentation, GlaxoSmithKline: Psychiatry statistics group
- 2002 Presentation, BYU Graduate Research Conference
- 2000 Presentation, Payless ShoeSource Corporate World Headquarters

Contributed Presentations

- 2021 Society of Clinical Trials Conference (virtual): *PRINCIPLE: A randomized adaptive platform clinical trial for treatment of COVID-19 in primary care*
- 2019 Joint Statistical Meetings (JSM), Denver, Colorado: *A Platform Trial for Amyotrophic Lateral Sclerosis (ALS) with a Shared Control Arm*
- 2017 International Biometric Society, Eastern North American Region (ENAR), Washington, DC: *Efficiencies of Platform Trials*
- 2016 Joint Statistical Meetings (JSM), Chicago, IL: *Olfactory Diagnostic: A Phase 2b Clinical Trial for Detecting Traumatic Brain Injury*
- 2015 Joint Statistical Meetings (JSM), Seattle, WA: *Antiviral treatments for pandemic influenza: A Bayesian adaptive and open platform randomized trial*
- 2015 The International Chinese Statistical Association Applied Statistics Symposium, Fort Collins, CO: *Simulations: The future of clinical trial design*
- 2015 Eastern North American Region (ENAR) International Biometric Society, Miami, FL, *Efficiencies of Bayesian Adaptive Platform Clinical Trials* (poster)
- 2013 International Biometric Society, Eastern North American Region (ENAR), *Assessing variance components in multilevel linear models using approximate Bayes factors*

- 2012 Joint Statistical Meetings (JSM), *The case for Bayesian predictive probabilities for interim monitoring of clinical trials*
- 2012 International Biometric Society, Eastern North American Region (ENAR), *Estimating covariate-adjusted log hazard ratios in randomized clinical trials using Cox proportional hazards models and nonparametric randomization based analysis of covariance*
- 2011 International Biometric Society, Eastern North American Region (ENAR), *Estimating covariate-adjusted incidence density ratios for multiple intervals using nonparametric randomization-based ANCOVA* (poster)
- 2011 Bayesian Biostatistics Conference, *Assessing variance components in multilevel linear models using approximate Bayes factors: A case study of ethnic disparities in birthweight.* (poster)
- 2010 International Society for Bayesian Analysis World Meeting, *Testing random coefficients in multilevel models using approximate Bayes factors* (poster)
- 2007 Joint Statistical Meetings (JSM): Salt Lake City, UT, *Testing random coefficients in multilevel models using approximate Bayes factors*
- 2007 International Biometric Society: Atlanta, GA, *Testing random coefficients in multilevel models using approximate Bayes factors* (poster)