

# CURRICULUM VITAE

**DATE PREPARED:** April 1, 2023  
**NAME:** Kevin J. Anstrom, PhD, MS

## DIRECTOR, COLLABORATIVE STUDIES COORDINATING CENTER

**PRIMARY ACADEMIC DEPARTMENT:** Biostatistics, SPH, UNC-Chapel Hill

**PRESENT ACADEMIC RANK AND TITLE:** Professor

## EDUCATION:

<u>Institution</u>	<u>Year</u>	<u>Degree</u>
North Carolina State University, Raleigh, NC	2002	PhD, Statistics
University of North Carolina, Chapel Hill, NC	1994	MS, Biostatistics
Cornell University, Ithaca, NY	1992	BS, Biometry and Statistics

## PROFESSIONAL TRAINING AND ACADEMIC CAREER:

<u>Institution</u>	<u>Position/Title</u>	<u>Years</u>
University of North Carolina, Chapel Hill	Professor	2022-present
University of North Carolina, Chapel Hill	Director, CSCC	2022-present
Duke University	Adjunct Professor	2022-present
Duke University	Professor	2018-2022
Duke University	Director, DCRI Biostatistics	2018-2022
Duke University	Associate Professor	2011-2018
Duke University	Assistant Professor	2002-2011
Duke University Medical Center	Statistician	1997-2002
University of Washington	Research Consultant	1995-1997

## PUBLICATIONS

1. Naggie S, Milstone A, Castro M, Collins SP, Lakshmi S, Anderson DJ, Cahuayme-Zuniga L, Turner KB, Cohen LW, Currier J, Fraulo E, Friedland A, Garg J, George A, Mulder H, Olson RE, O'Brien EC, Rothman RL, Shenkman E, Shostak J, Woods CW, **Anstrom KJ**, Hernandez AF; HERO Research Program. Hydroxychloroquine for pre-exposure prophylaxis of COVID-19 in health care workers: a randomized, multicenter, placebo-controlled trial Healthcare Worker Exposure Response and Outcomes of Hydroxychloroquine (HERO-HCQ). *Int J Infect Dis.* 2023 Apr;129:40-48. doi: 10.1016/j.ijid.2023.01.019. Epub 2023 Jan 20. PMID: 36682681
2. Wang TY, Wahed AS, Morris A, Kreuziger LB, Quigley JG, Lamas GA, Weissman AJ, Lopez-Sendon J, Knudson MM, Siegal DM, Kasthuri RS, Alexander AJ, Wahid L, Atassi B, Miller PJ, Lawson JW, Patel B, Krishnan JA, Shapiro NL, Martin DE, Kindzelski AL, Leifer ES, Joo J, Lyu L, Pennella A, Everett BM, Geraci MW, **Anstrom KJ**, Ortel TL; ACTIV-4C Study Group. Effect of Thromboprophylaxis on Clinical Outcomes After COVID-19 Hospitalization. *Ann Intern Med.* 2023 Mar 21. doi: 10.7326/M22-3350. Online ahead of print. PMID: 36940444

3. Felker GM, North R, Mulder H, Jones WS, **Anstrom KJ**, Patel MJ, Butler J, Ezekowitz JA, Lam C, O'Connor CM, Roessig L, Hernandez AF, Armstrong PW; VICTORIA Study Group. Clinical Implications of Negatively Adjudicated Heart Failure Events: Data From the VICTORIA Study. *Circulation*. 2023 Feb 21;147(8):694-696. doi: 10.1161/CIRCULATIONAHA.122.062055. Epub 2023 Feb 20. PMID: 36802884
4. Zeitler EP, Li Y, Silverstein AP, Russo AM, Poole JE, Daniels MR, Al-Khalidi HR, Lee KL, Bahnson TD, **Anstrom KJ**, Packer DL, Mark DB; CABANA Investigators. Effects of Ablation Versus Drug Therapy on Quality of Life by Sex in Atrial Fibrillation: Results From the CABANA Trial. *J Am Heart Assoc*. 2023 Feb 7;12(3):e027871. doi: 10.1161/JAHA.122.027871. Epub 2023 Jan 23. PMID: 36688367
5. Mentz RJ, **Anstrom KJ**, Eisenstein EL, Sapp S, Greene SJ, Morgan S, Testani JM, Harrington AH, Sachdev V, Ketema F, Kim DY, Desvigne-Nickens P, Pitt B, Velazquez EJ; TRANSFORM-HF Investigators. Effect of Torsemide vs Furosemide After Discharge on All-Cause Mortality in Patients Hospitalized With Heart Failure: The TRANSFORM-HF Randomized Clinical Trial. *JAMA*. 2023 Jan 17;329(3):214-223. doi: 10.1001/jama.2022.23924. PMID: 36648467
6. Mauck MC, Lotz J, Psioda MA, Carey TS, Clauw DJ, Majumdar S, Marras WS, Vo N, Aylward A, Hoffmeyer A, Zheng P, Ivanova A, McCumber M, Carson C, **Anstrom KJ**, Bowden AE, Dalton D, Derr L, Dufour J, Fields AJ, Fritz J, Hassett AL, Harte SE, Hue TF, Krug R, Loggia ML, Mageswaran P, McLean SA, Mitchell UH, O'Neill C, Pedroia V, Quirk DA, Rhon DI, Rieke V, Shah L, Sowa G, Spiegel B, Wasan AD, Wey HM, LaVange L. The Back Pain Consortium (BACPAC) Research Program: Structure, Research Priorities, and Methods. *Pain Med*. 2023 Jan 9:pnac202. doi: 10.1093/pm/pnac202. Online ahead of print. PMID: 36622041
7. Kaul P, Rathwell S, Lam CSP, Westerhout CM, Spertus JA, **Anstrom KJ**, Blaustein RO, Ezekowitz JA, Pieske B, Roessig L, Butler J, Armstrong PW; VITALITY-HFpEF Study Group. Patient-Reported Frailty and Functional Status in Heart Failure With Preserved Ejection Fraction: Insights From VITALITY-HFpEF. *JACC Heart Fail*. 2023 Jan 3:S2213-1779(22)00707-7. doi: 10.1016/j.jchf.2022.11.015. Online ahead of print. PMID: 36881394
8. Butler J, Usman MS, **Anstrom KJ**, Blaustein RO, Bonaca MP, Ezekowitz JA, Freitas C, Lam CSP, Lewis EF, Lindenfeld J, McMullan CJ, Mentz RJ, O'Connor C, Rosano GMC, Saldarriaga CI, Senni M, Udelson J, Voors AA, Zannad F. Soluble guanylate cyclase stimulators in patients with heart failure with reduced ejection fraction across the risk spectrum. *Eur J Heart Fail*. 2022 Nov;24(11):2029-2036. doi: 10.1002/ejhf.2720. Epub 2022 Nov 16. PMID: 36250238
9. Lamas GA, **Anstrom KJ**, Navas-Acien A, Boineau R, Kim H, Rosenberg Y, Stylianou M, Jones TLZ, Joubert BR, Santella RM, Escolar E, Aude YW, Fonseca V, Elliott T, Lewis EF, Farkouh ME, Nathan DM, Mon AC, Gosnell L, Newman JD, Mark DB; TACT2 Investigators. The trial to assess chelation therapy 2 (TACT2): Rationale and design. *Am Heart J*. 2022 Oct;252:1-11. doi: 10.1016/j.ahj.2022.05.013. Epub 2022 May 19. PMID: 35598636
10. Eisenstein EL, Sapp S, Harding T, Harrington A, Velazquez EJ, Mentz RJ, Greene SJ, Sachdev V, Kim DY, **Anstrom KJ**. Ascertaining Death Events in a Pragmatic Clinical Trial: Insights From the TRANSFORM-HF Trial. *J Card Fail*. 2022 Oct;28(10):1563-1567. doi: 10.1016/j.cardfail.2022.01.020. Epub 2022 Feb 16. PMID: 35181553
11. Ko ER, **Anstrom KJ**, Panettieri RA, Lachiewicz AM, Maillo M, O'Halloran JA, Boucher C, Smith PB, McCarthy MW, Segura Nunez P, Mendivil Tuchia de Tai S, Khan A, Mena Lora AJ, Salathe M, Kedar E, Capo G, Rodríguez Gonzalez D, Patterson TF, Palma C, Ariza H, Patelli Lima M, Blamoun J, Nannini EC, Sprinz E, Mykietiuik A, Wang JP, Parra-Rodriguez L, Der T, Willsey K, Benjamin DK, Wen J, Zakrotsky P, Halabi S, Silverstein A, McNulty SE, O'Brien SM, Al-Khalidi HR, Butler S, Atkinson J, Adam SJ, Chang S, Maldonado MA, Proscham M, LaVange L, Bozzette SA, Powderly WG; ACTIV-1 IM study group members. Abatacept for Treatment of Adults Hospitalized with Moderate or Severe Covid-19. *medRxiv*. 2022 Sep 26:2022.09.22.22280247. doi: 10.1101/2022.09.22.22280247. Preprint. PMID: 36203544

12. O'Halloran J, Kedar E, **Anstrom KJ**, McCarthy MW, Ko ER, Segura Nunez P, Boucher C, Smith PB, Panettieri RA, Mendivil Tuchia de Tai S, Maillo M, Khan A, Mena Lora AJ, Salathe M, Capo G, Rodriguez Gonzalez D, Patterson TF, Palma C, Ariza H, Patelli Lima M, Lachiewicz AM, Blamoun J, Nannini E, Sprinz E, Mykietiuk A, Alicic R, Rauseo AM, Wolfe CR, Wittig B, Benjamin DK, McNulty SE, Zakrofsky P, Halabi S, Butler S, Atkinson J, Adam SJ, Melsheimer R, Chang S, LaVange L, Proschan M, Bozzette SA, Powderly WG. Infliximab for Treatment of Adults Hospitalized with Moderate or Severe Covid-19. *medRxiv*. 2022 Sep 26;2022.09.22.22280245. doi: 10.1101/2022.09.22.22280245. Preprint. PMID: 36172138
13. Vader JM, Givertz MM, Starling RC, McNulty SE, **Anstrom KJ**, Desvigne-Nickens P, Hernandez AF, Braunwald E, Mann DL; LIFE Investigators. Tolerability of Sacubitril/Valsartan in Patients With Advanced Heart Failure: Analysis of the LIFE Trial Run-In. *JACC Heart Fail*. 2022 Jul;10(7):449-456. doi: 10.1016/j.jchf.2022.04.013. PMID: 35772853
14. Chew DS, Li Y, Cowper PA, **Anstrom KJ**, Piccini JP, Poole JE, Daniels MR, Monahan KH, Davidson-Ray L, Bahnson TD, Al-Khalidi HR, Lee KL, Packer DL, Mark DB; CABANA Investigators. Cost-Effectiveness of Catheter Ablation Versus Antiarrhythmic Drug Therapy in Atrial Fibrillation: The CABANA Randomized Clinical Trial. *Circulation*. 2022 Jul 21:101161CIRCULATIONAHA.122058575. doi: 10.1161/CIRCULATIONAHA.122.058575.
15. Butler J, Stebbins A, Melenovský V, Sweitzer NK, Cowie MR, Stehlik J, Khan MS, Blaustein RO, Ezekowitz JA, Hernandez AF, Lam CSP, Nkulikiyinka R, O'Connor CM, Pieske BM, Ponikowski P, Spertus JA, Voors AA, **Anstrom KJ**, Armstrong PW; VICTORIA Study Group. Vericiguat and Health-Related Quality of Life in Patients With Heart Failure With Reduced Ejection Fraction: Insights From the VICTORIA Trial. *Circ Heart Fail*. 2022 Jun;15(6):e009337. Doi: 10.1161/CIRCHEARTFAILURE.121.009337. Epub 2022 Jun 3. PMID: 35656822
16. Lamas GA, **Anstrom KJ**, Navas-Acien A, Boineau R, Kim H, Rosenberg Y, Stylianou M, Jones TLZ, Joubert BR, Santella RM, Escolar E, Aude YW, Fonseca V, Elliott T, Lewis EF, Farkouh ME, Nathan DM, Mon AC, Gosnell L, Newman JD, Mark DB; TACT2 Investigators. The Trial to Assess Chelation Therapy 2 (TACT2): Rationale and Design. *Am Heart J*. 2022 May 19:S0002-8703(22)00105-3. doi: 10.1016/j.ahj.2022.05.013.
17. Greene SJ, Ezekowitz JA, **Anstrom KJ**, Demyanenko V, Givertz MM, Piña IL, O'Connor CM, Koglin J, Roessig L, Hernandez AF, Armstrong PW, Mentz RJ. Medical Therapy During Hospitalization for Heart Failure With Reduced Ejection Fraction: The VICTORIA Registry. *J Card Fail*. 2022 Mar 14:S1071-9164(22)00103-8. doi: 10.1016/j.cardfail.2022.02.011. PMID: 35301107
18. Butler J, Spertus JA, Bamber L, Khan MS, Roessig L, Vlajnic V, Norquist JM, **Anstrom KJ**, Blaustein RO, Lam CSP, Armstrong PW; VITALITY-HFpEF Study Group. Defining changes in physical limitation from the patient perspective: insights from the VITALITY-HFpEF randomized trial. *Eur J Heart Fail*. 2022 May;24(5):843-850. doi: 10.1002/ejhf.2481. Epub 2022 Apr 3. PMID: 35274420
19. Mark DB, Spertus JA, Bigelow R, Anderson S, Daniels MR, **Anstrom KJ**, Baloch KN, Cohen DJ, Held C, Goodman SG, Bangalore S, Cyr D, Reynolds HR, Alexander KP, Rosenberg Y, Stone GW, Maron DJ, Hochman JS; ISCHEMIA Research Group. Comprehensive Quality-of-Life Outcomes With Invasive Versus Conservative Management of Chronic Coronary Disease in ISCHEMIA. *Circulation*. 2022 Apr 26;145(17):1294-1307. doi: 10.1161/CIRCULATIONAHA.121.057363. Epub 2022 Mar 9. PMID: 35259918
20. Saldarriaga C, Atar D, Stebbins A, Lewis BS, Abidin IZ, Blaustein RO, Butler J, Ezekowitz JA, Hernandez AF, Lam CSP, O'Connor CM, Pieske B, Ponikowski P, Roessig L, Voors AA, **Anstrom KJ**, Armstrong PW; VICTORIA Study Group. Vericiguat in patients with coronary artery disease and heart failure with reduced ejection fraction. *Eur J Heart Fail*. 2022 May;24(5):782-790. doi: 10.1002/ejhf.2468. Epub 2022 Mar 20. PMID: 35239245
21. Ravalli F, Vela Parada X, Ujueta F, Pinotti R, **Anstrom KJ**, Lamas GA, Navas-Acien A. Chelation Therapy in Patients With Cardiovascular Disease: A Systematic Review. *J Am Heart Assoc*. 2022 Mar 15;11(6):e024648. doi: 10.1161/JAHA.121.024648. Epub 2022 Mar 1. PMID: 35229619

22. Chew DS, Cowper PA, Al-Khalidi H, **Anstrom KJ**, Daniels MR, Davidson-Ray L, Li Y, Michler RE, Panza JA, Piña IL, Rouleau JL, Velazquez EJ, Mark DB; STICH Investigators. Cost Effectiveness of Coronary-Artery Bypass Surgery versus Medicine in Ischemic Cardiomyopathy: The STICH Randomized Clinical Trial. *Circulation*. 2022 Jan 19. doi: 10.1161/CIRCULATIONAHA.121.056276. PMID: 35044802
23. Eisenstein EL, Sapp S, Harding T, Harrington A, Velazquez EJ, Mentz RJ, Greene SJ, Sachdev V, Kim DY, **Anstrom KJ**. Ascertaining Death Events in a Pragmatic Clinical Trial: Insights From the TRANSFORM-HF Trial. *J Card Fail*. 2022 Feb 16:S1071-9164(22)00054-9. doi: 10.1016/j.cardfail.2022.01.020. Online ahead of print. PMID: 35181553
24. Tobin RS, Samsky MD, Kuchibhatla M, O'Connor CM, Fiuzat M, Warraich HJ, **Anstrom KJ**, Granger BB, Mark DB, Tulsy JA, Rogers JG, Mentz RJ, Johnson KS. Race Differences in Quality of Life following a Palliative Care Intervention in Patients with Advanced Heart Failure: Insights from the Palliative Care in Heart Failure Trial. *J Palliat Med*. 2022 Feb;25(2):296-300. doi: 10.1089/jpm.2021.0220. Epub 2021 Dec 1. PMID: 34851740
25. Lam CSP, Mulder H, Lopatin Y, Vazquez-Tanus JB, Siu D, Ezekowitz J, Pieske B, O'Connor CM, Roessig L, Patel MJ, **Anstrom KJ**, Hernandez AF, Armstrong PW; VICTORIA Study Group. Blood Pressure and Safety Events With Vericiguat in the VICTORIA Trial. *J Am Heart Assoc*. 2021 Nov 16;10(22):e021094. doi: 10.1161/JAHA.121.021094. Epub 2021 Nov 6. PMID: 34743540
26. Luo N, O'Connor CM, Chiswell K, **Anstrom KJ**, Newby LK, Mentz RJ. Survival in Patients With Nonischemic Cardiomyopathy With Preserved vs Reduced Ejection Fraction. *CJC Open*. 2021 Jun 17;3(11):1333-1340. doi: 10.1016/j.cjco.2021.06.007. eCollection 2021 Nov. PMID: 34901801
27. Gershon AS, Lindenauer PK, Wilson KC, Rose L, Walkey AJ, Sadatsafavi M, **Anstrom KJ**, Au DH, Bender BG, Brookhart MA, Dweik RA, Han MK, Joo MJ, Lavergne V, Mehta AB, Miravittles M, Mularski RA, Roche N, Oren E, Riekert KA, Schoenberg NC, Stukel TA, Weiss CH, Wunsch H, Africk JJ, Krishnan JA. Informing Healthcare Decisions with Observational Research Assessing Causal Effect. An Official American Thoracic Society Research Statement. *Am J Respir Crit Care Med*. 2021 Jan 1;203(1):14-23. doi: 10.1164/rccm.202010-3943ST. PMID: 33385220.
28. Granger BB, Tulsy JA, Kaufman BG, Clare RM, **Anstrom K**, Mark DB, Johnson KA, Patel CB, Fiuzat M, Steinhauer K, O'connor C, Rogers JG, Mentz RJ. Polypharmacy in Palliative Care for Advanced Heart Failure: The PAL-HF Experience. *J Card Fail*. 2021 Oct 7:S1071-9164(21)00390-0. doi: 10.1016/j.cardfail.2021.08.021. PMID: 34628013
29. Wan L, Samsky MD, O'Connor CM, Stebbins A, Alhanti B, Warraich HJ, Johnson KS, **Anstrom KJ**, Fiuzat M, Granger BB, Mark DB, Tulsy JA, Rogers JG, Mentz RJ. Patterns of Change in Individual Domains of the Kansas City Cardiomyopathy Questionnaire with a Palliative Care Intervention for Patients with Advanced Heart Failure: Insights from PAL-HF. *J Card Fail*. 2021 Feb 26:S1071-9164(21)00079-8. doi: 10.1016/j.cardfail.2021.02.007. PMID: 33647475
30. Greene SJ, Velazquez EJ, **Anstrom KJ**, Eisenstein EL, Sapp S, Morgan S, Harding T, Sachdev V, Ketema F, Kim DY, Desvigne-Nickens P, Pitt B, Mentz RJ; TRANSFORM-HF Investigators. Pragmatic Design of Randomized Clinical Trials for Heart Failure: Rationale and Design of the TRANSFORM-HF Trial. *JACC Heart Fail*. 2021 Mar 10:S2213-1779(21)00061-5. doi: 10.1016/j.jchf.2021.01.013. PMID: 33714745
31. Martinez FJ, Yow E, Flaherty KR, Snyder LD, Durheim MT, Wisniewski SR, Sciruba FC, Ganesh Raghu G, Brooks MM, Kim D-Y, Dilling DF, Criner GJ, Kim H, Belloli EA, Nambiar AM, Scholand MB, **Anstrom KJ**, Noth I. Effect of Antimicrobial Therapy on Respiratory Hospitalization or Death in Adults With Idiopathic Pulmonary Fibrosis: The CleanUP-IPF Randomized Clinical Trial. *JAMA*. 2021 May 11;325(18):1841-1851. doi: 10.1001/jama.2021.4956. PMID: 33974018
32. Voors AA, Mulder H, Reyes E, Cowie MR, Lassus J, Hernandez AF, Ezekowitz JA, Butler J, O'Connor CM, Koglin J, Lam CSP, Pieske B, Roessig L, Ponikowski P, **Anstrom KJ**, Armstrong PW; VICTORIA Study Group. Renal function and the effects of vericiguat in patients with worsening heart failure with reduced ejection fraction: insights from the VICTORIA (Vericiguat Global Study in Subjects with HFrEF) trial. *Eur J Heart Fail*. 2021 May 17. doi: 10.1002/ejhf.2221. PMID: 33999486.

33. Mentz RJ, Mulder H, Mosterd A, Sweitzer NK, Senni M, Butler J, Ezekowitz JA, Lam CSP, Pieske B, Ponikowski P, Voors AA, **Anstrom KJ**, Armstrong PW, O'Connor CM; VICTORIA Study Group. Clinical Outcome Predictions for the VeriCiguaT Global Study in Subjects With Heart Failure With Reduced Ejection Fraction (VICTORIA) Trial: VICTORIA Outcomes Model. *J Card Fail.* 2021 May 26;S1071-9164(21)00206-2. doi: 10.1016/j.cardfail.2021.05.016. Online ahead of print. PMID: 34216757.
34. Eisenstein EL, Zozus MN, Terry SF, Davidson-Ray L, **Anstrom KJ**. Ascertaining Nonfatal Endpoints in Clinical Trials: Central Adjudication Versus Patient Insurance Claims. *Ther Innov Regul Sci.* 2021 Jul 6. doi: 10.1007/s43441-021-00321-9. Online ahead of print. PMID: 34228318
35. Martinez FJ, **Anstrom KJ**, Noth I. Antimicrobial Therapy and Respiratory Hospitalization or Death in Adults With Idiopathic Pulmonary Fibrosis-Reply. *JAMA.* 2021 Sep 21;326(11):1071-1072. doi: 10.1001/jama.2021.11813. PMID: 34546303
36. Friedland A, Hernandez AF, **Anstrom KJ**, Chen-Lim ML, Cohen LW, Currier JS, Forrest CB, Fraser R, Fraulo E, George A, Handberg E, Jackman J, Koellhoffer J, Lawrence D, Leverty R, McAdams P, McCourt B, Mickley B, Naqvi SH, O'Brien EC, Olson R, Prater C, Rothman RL, Shenkman E, Shostak J, Turner KB, Webb L, Woods C, Naggie S; HERO Research Program. Design of the healthcare worker exposure response and outcomes (HERO) research platform. *Contemp Clin Trials.* 2021 Aug 8;109:106525. doi: 10.1016/j.cct.2021.106525. Online ahead of print. PMID: 34371163
37. Greene SJ, Velazquez EJ, **Anstrom KJ**, Eisenstein EL, Mentz RJ. Reply: Pragmatic Clinical Trials: The Big Picture. *JACC Heart Fail.* 2021 Aug;9(8):606-608. doi: 10.1016/j.jchf.2021.05.018. PMID: 34325892
38. Chew DS, Li Y, Cowper PA, **Anstrom KJ**, Piccini JP, Poole JE, Daniels MR, Monahan KH, Davidson-Ray L, Bahnson TD, Al-Khalidi HR, Lee KL, Packer DL, Mark BD, for the CABANA Investigators Cost-Effectiveness of Catheter Ablation versus Antiarrhythmic Drug Therapy in Atrial Fibrillation: The CABANA Randomized Clinical Trial (under review)
39. Saldarriaga C, Atar D, Stebbins A, Lewis BS, Zainal Abidin I, Blaustein RO, Butler J, Ezekowitz JA, Hernandez AF, Lam CSP, O'Connor CM, Pieske B, Ponikowski P, Roessig L, Voors AA, **Anstrom KJ**, Armstrong PW for the VICTORIA Study Group. Vericiguat in Patients with Coronary Artery Disease and Heart Failure with Reduced Ejection Fraction (under review)
40. Greene SJ, Ezekowitz JA, **Anstrom KJ**, Demyanenko V, Givertz MM, Piña IL, O'Connor CM, Koglin J, Roessig L, Hernandez AF, Armstrong PW, Mentz RJ. Medical Therapy During Hospitalization for Heart Failure with Reduced Ejection Fraction: The VICTORIA Registry (under review)
41. Mann DL, Givertz MM, Vader JM, Starling RC, Palak Shah P, McNulty SE, **Anstrom KJ**, Margulies KB, Kiernan MS, Mahr C, Gupta D, Redfield MM, Lala A, Lewis GD, DeVore AD, Desvigne-Nickens P, Hernandez AF, Eugene Braunwald E for the LIFE Investigators. Sacubitril/Valsartan in Advanced Heart Failure With Reduced Ejection Fraction - A Randomized Clinical Trial. *JAMA Cardiol.* 2022 Jan 1;7(1):17-25. doi: 10.1001/jamacardio.2021.4567. PMID: 34730769
42. Naggie S, Milstone A, Castro M, Collins SP, Seetha L, Deverick J, Anderson DJ, Cahuayme-Zuniga L, Batey Turner K, Cohen LW, Currier JS, Fraulo E, Friedland A, Garg J, George A, Mulder H, Olson RE, O'Brien EC, Rothman RL, Shenkman E, Woods CW, **Anstrom KJ**, Hernandez AF, on behalf of the HERO Research Program. Hydroxychloroquine for pre-exposure prophylaxis of COVID-19 in health care workers: a randomized, multicenter, placebo-controlled trial (HERO-HCQ) (accepted)
43. Cunningham JW, Sun JL, Mc Causland FR, Ly S, **Anstrom KJ**, Lindenfeld J, Givertz MM, Stevenson LW, Lakdawala NK. Lower urine sodium predicts longer length of stay in acute heart failure patients: Insights from the ROSE AHF trial. *Clin Cardiol.* 2020 Jan;43(1):43-49. doi: 10.1002/clc.23286. Epub 2019 Nov 12. PMID: 31721249.
44. Fudim M, Kelly JP, Jones AD, AbouEzzeddine OF, Ambrosy AP, Greene SJ, Reddy YNV, **Anstrom KJ**, Alhanti B, Lewis GD, Hernandez AF, Felker GM. Are existing and emerging biomarkers associated with cardiorespiratory fitness in patients with chronic heart failure? *Am Heart J.* 2020 Feb;220:97-107. doi: 10.1016/j.ahj.2019.11.006. Epub 2019 Nov 16. PMID: 31805424.

45. Fanaroff AC, Peterson ED, Kaltenbach LA, Cannon CP, Choudhry NK, Henry TD, **Anstrom KJ**, Cohen DJ, Fonseca E, Khan ND, Fonarow GC, Wang TY. Association of a P2Y12 Inhibitor Copayment Reduction Intervention With Persistence and Adherence With Other Secondary Prevention Medications: A Post Hoc Analysis of the ARTEMIS Cluster-Randomized Clinical Trial. *JAMA Cardiol.* 2020 Jan 1;5(1):38-46. doi: 10.1001/jamacardio.2019.4408. PMID: 31721978.
46. **Anstrom KJ**, Noth I, Flaherty KR, Edwards RH, Albright J, Baucom A, Brooks M, Clark AB, Clausen ES, Durham MT, Kim DY, Kirchner J, Oldham JM, Snyder LD, Wilson AM, Wisniewski SR, Yow E, Martinez FJ; CleanUP-IPF Study Team. Design and rationale of a multi-center, pragmatic, open-label randomized trial of antimicrobial therapy - the study of clinical efficacy of antimicrobial therapy strategy using pragmatic design in Idiopathic Pulmonary Fibrosis (CleanUP-IPF) clinical trial. *Respir Res.* 2020 Mar 12;21(1):68. doi: 10.1186/s12931-020-1326-1. PMID: 32164673.
47. Butler J, **Anstrom KJ**, Armstrong PW. Comparing the Benefit of Novel Therapies Across Clinical Trials: Insights From the VICTORIA Trial. *Circulation.* 2020 Aug 25;142(8):717-719. doi: 10.1161/CIRCULATIONAHA.120.047086. Epub 2020 Mar 28. PMID: 32223438.
48. Armstrong PW, Pieske B, **Anstrom KJ**, Ezekowitz J, Hernandez AF, Butler J, Lam CSP, Ponikowski P, Voors AA, Jia G, McNulty SE, Patel MJ, Roessig L, Koglin J, O'Connor CM; VICTORIA Study Group. Vericiguat in Patients with Heart Failure and Reduced Ejection Fraction. *N Engl J Med.* 2020 May 14;382(20):1883-1893. doi: 10.1056/NEJMoa1915928. Epub 2020 Mar 28. PMID: 32222134.
49. Butler J, **Anstrom KJ**, Armstrong PW. Comparing the Benefit of Novel Therapies Across Clinical Trials: Insights From the VICTORIA Trial. *Circulation.* 2020 Aug 25;142(8):717-719. doi: 10.1161/CIRCULATIONAHA.120.047086. Epub 2020 Mar 28. PMID: 32223438.
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## EDITORIALS, LETTERS and NON-REFEREED PUBLICATIONS

Mark DB, Patel MR, **Anstrom KJ**. Trade-Offs and Toss-Ups: Making Revascularization Decisions in Carotid Artery Disease. *J Am Coll Cardiol.* 2011 Oct 4;58(15):1566-8. PubMed PMID: 21958883.

**Anstrom KJ**, Eisenstein EL. From Batting Average to Wins Above Replacement to Composite End Points-Refining Clinical Research Using Baseball Statistical Methods. *Am Heart J.* 2011 May;161(5):805-6. PubMed PMID: 21570507.

Eisenstein EL, Kong DF, **Anstrom KJ**, Califf RM. Clopidogrel and Long-Term Outcomes After Drug-Eluting Stent Implantation-Reply. *JAMA.* 2007;297(16):1770-1.

**Anstrom KJ**, Quade D. Testing Whether a Count Variable Belongs to the Katz Family. *Proceedings of the Statistical Computing Section* 1994: 194-199.

## BOOK CHAPTERS

Eisenstein EL, Ortiz M, **Anstrom KJ**, Lobach DF. Health Information Technology Economic Evaluation. In: Klinger K, Roth K, Neidig J, Snavelly J, Coulson C, Smalley K, eds. *Human, Social, and Organizational Aspects of Health Information Systems*. IGI Global, USA (2008).

**Anstrom KJ**, Weinfurt KP, Allen AS. Estimating Causal Effects in Randomized Studies with Imperfect Adherence: Conceptual and Statistical Foundations. In: Bosworth H, Weinberger M, Oddone EZ, eds. *Patient Treatment Adherence: Concepts, Interventions, and Measurement*. Routledge, USA (2005).

## **PCORI REPORTS**

The HERO Research Program -- A PCORnet® Project to Support Studies on COVID-19. Anstrom KJ, Cohen LW, Currier JS, Garg J, Hong H, Mulder H, Naggie S, Olson R, Rothman R, Shostak J, Woods C, Hernandez AF. PCORI ID: COVID-19-2020-001 ClinicalTrials.gov ID: NCT04334148

## **TEACHING RESPONSIBILITIES**

At University of North Carolina at Chapel Hill

Semester courses (3 credit hours) taught ...

Biostatistics 841 – Principles of Statistical Consulting; co-Instructor, 2023

At Duke University

Canadian Vigour Center - Discussion of Secondary Analyses in Clinical Trials – June 2021

ACCs Diversity and Inclusion Initiative April 2021 – Adaptive Trial Designs

SIBS (Summer Institute in Biostatistics) – 2006-Present – one lecture per year

DCRI Fellows Seminar – one lecture per year on topics including

Pragmatic Clinical Trials

Adaptive Clinical Trials

ATS 2018 – Short course in the ILD session on Clinical Trial Endpoints

ACCs Clinical Trial Research Program 2019 – Assessing and Using Publicly Available Data Sources

ACCs Clinical Trial Research Program 2019 – The Critical Role of Quantitative Science

Heart Failure Collaboratory 2019 – Adaptive Design and Other Novel Approaches

Biostatistics 209 and Biostatistics 709 – 4 semesters total – basic epidemiology, methods for causal inference, propensity score analysis, methods for non-compliance in randomized clinical trials, and overview of observational studies

## **BIostatistics MENTEES (since 2014)**

At UNC – Chapel Hill

Anna Batorsky (Dr.PH Candidate – Co-Chair)

Ann Marie Weideman (PhD Candidate - Co-Chair)

Lang Li (PhD Candidate – Committee Member)

At Duke University

Xueqi Wang (PhD 2022)

Ying Sun (MS 2021)

Zachary Frere (MS 2021)

Yinxi Yu (MS 2017)

Siyun Yang (MS 2015)

Siyi Zhang (MS 2015)

Run Zhou (MS 2015)

Chenxiang Li (MS 2014)



Di Lu (MS 2014)

### **CLINICAL MENTEES (since 2015)**

Nathan Waldron, MD (2017)  
Michael Durham, MD (2017)  
Lauren Cooper, MD (2016)  
Jacob Kelly, MD (2016)  
Ben Steinberg, MD (2016)  
Adam DeVore, MD (2015)  
Njira Lugogo, MD (2015)

### **POSTDOCTORAL FELLOWS MENTORED (since 2017)**

Haider Warraich, MD – K-Club, K grant application (2019)  
Nathan Waldron, MD – K grant application (2017)  
Tariq Ahmad, MD – Yale, K grant application (2017)

### **COMMITTEE SERVICE**

Conflict of Interest Committee - Gillings School of Global Public Health (2022-present)

### **ONGOING RESEARCH SUPPORT**

#### **ACTIVE**

**1 U24 AT076730-01** (Anstrom (contact PI), Ivanova, LaVange) 9/26/2019 - 5/31/2024

National Institute of Arthritis & Musculoskeletal and Skin Disease

Back Pain Consortium Research Program (BACPAC) Data Integration, Algorithm Development and Operations Management Center

Role: PI

The goal of the Back Pain Consortium (BACPAC) Data Integration, Algorithm Development and Operations Management Center (DAC) is to ensure that the research collaborative objectives are met. The objectives of BACPAC include (i) discovery of lower back pain mechanisms through expert application of clinical and translational medicine methodologies; (ii) identification of new interventions targeted to individual patients; and (iii) evaluation of promising interventions.

**5UH3-AT009150-05** (Anstrom/Mark) 09/30/2015 - 7/31/2024

NIH

Trial to Assess Chelation Therapy 2 (TACT2) DCC

Role: Co-Principal Investigator

The purpose of the Trial to Assess Chelation Therapy 2 (TACT2) is to perform a pragmatic and efficient replication of TACT1 in patients with diabetes and a prior heart attack. The results of TACT2 will determine whether disodium ethylene diamine tetraacetic acid (Na<sub>2</sub>EDTA) chelation therapy receives approval from the US Food and Drug Administration (FDA) and is subsequently accepted to reduce the risk of major adverse events from coronary artery disease (CAD) in patients with diabetes.

**5R01AT009273-04** (Anstrom/Mark) 09/30/2016 – 7/31/2024

Mount Sinai School of Medicine (R01 AT009273)

Metals in the Trial to Assess Chelation Therapy 2 (TACT2M)

Role: Co-Investigator

The main objectives of the Metals in the Trial to Assess Chelation Therapy 2 (TACT2M) are to evaluate whether long-term edetate disodium (EDTA)-based chelation infusions can significantly reduce body lead and cadmium levels and to determine whether this effect explains the reduction in major cardiovascular events caused by EDTA chelation therapy.

**5U01-HL125478-03** (Anstrom) 08/15/2017 - 07/31/2022

NIH  
TRANSFORM-HF DCC  
Role: Principal Investigator  
TRANSFORM-HF is a robustly-powered, prospective, randomized, comparative-effectiveness study which will change guidelines and have immediate clinical implications for the management of millions of patients with HF.

**5R01-HL134694-01** (Anstrom) 09/15/2017-07/31/2022

NIH  
SPIRRIT-HFPEF – DCC  
Role: Principal Investigator  
This is a pragmatic, registry-based randomized clinical trial that proposes to evaluate the clinical effectiveness of spironolactone versus usual care. The primary hypothesis of SPIRRIT-HFpEF is that treatment with spironolactone will reduce cardiovascular mortality compared with usual care.

**5U01-HG010225-02** (Ginsburg/Chakraborty) 09/22/2018 – 06/30/2023

NIH  
Role: Co-Investigator  
The IGNITE II CC: Engagement, Coordination, Demonstration, and Dissemination  
The CC will play a major research role in the development of the clinical protocols, analyses of data, protocol finalization and execution, development and statistical modeling, analyses of clinical and cost-effectiveness outcomes, and subgroup effect analyses.

**Ph3 ATTR Cardiomyopathy Study** (Anstrom KJ) 03/26/2019 – 06/15/2023

Eidos Therapeutics  
Role: Statistical PI  
ATTRibute-CM is a global Phase 3 trial of AG10 in patients with transthyretin (TTR) amyloid cardiomyopathy (ATTR-CM). The design of the ATTRibute-CM study, which incorporates feedback from FDA, includes two potentially registrational endpoints. In Part A, benefit in change from baseline in 6-minute walk distance (6MWD) will be evaluated at 12 months, potentially accelerating the time to registration. In Part B, reduction in all-cause mortality and frequency of cardiovascular-related hospitalizations will be evaluated at 30 months.

**COVID-19-2020-001** (Hernandez) 04/01/2020 – 03/31/2023

PCORI  
Role: Co-Investigator  
The HERO Registry and Trial: Healthcare Worker Exposure Response and Outcomes of Hydroxychloroquine to study the efficacy of HCQ to prevent COVID-19 clinical infection in healthcare workers.

**HERO-HCQ Trial** (Naggie) 04/01/2020 – 03/31/2023

Role: Co-Investigator  
The HERO Registry provides a resource for collecting information on Healthcare Workers (HCWs) currently working in the United States. The overall goal of the Registry is to develop the infrastructure necessary to create and engage a community of HCWs who may be eligible for participation in future clinical studies, including those of COVID-19 prophylaxis and treatment. The HERO-HCQ Trial will evaluate the efficacy of HCQ to prevent COVID-19 clinical infection in HCWs.

**HERO-HCQ Program Administration** (Hernandez) 04/01/2020 – 03/31/2023

Role: Co-Investigator

Dr. Anstrom serves as the Data Coordinating Center Investigator. The primary objective of the study is to evaluate the efficacy of HCQ to prevent COVID-19 clinical infection in healthcare workers. The secondary objectives are to evaluate the efficacy of HCQ to prevent viral shedding of SARS-CoV-2 among at risk HCWs and to evaluate safety and tolerability of HCQ.

27-312-0217571-66255L/1OT2HL156812-01 (Ortel) 12/1/2020 – 11/30/2021

Research Triangle Institute International/NIH

**ACTIV IV COVID-19 Post-hospital Thrombosis Prevention Study (ACTIV4c)**

Role: Co-Investigator

Primary Objective: To determine the most effective and safe antithrombotic strategy to prevent the composite outcome of symptomatic deep vein thrombosis, pulmonary embolism, other venous thromboembolism, ischemic stroke, myocardial infarction, other arterial thromboembolism, and all-cause mortality by 30 days following discharge from the hospital.

SA-D401-02/HHSO100201400002I (Benjamin) 08/17/2020 – 08/16/2022

Technical Resources International/BARDA

**ACTIV-1**

Role: Co-Investigator

The ACTIV-1 master protocol will test promising immune modulator compounds, a class of drugs that help minimize the deleterious effects of an overactive immune response to SARS-CoV-2 infection. This Phase 3 trial will enroll hospitalized adults with moderate to severe COVID-19 disease. It will evaluate the safety and efficacy of at least three immune modulators when given as an add-on therapy to remdesivir, an antiviral approved for treatment of COVID-19, and the standard of care in use at local clinics. The different treatments will be assessed with respect to illness severity, recovery speed, mortality and hospital resource utilization.

## COMPLETED RESEARCH PROJECTS

**5U10 HL084904** (Anstrom) 09/30/2006-10/31/2021

NHLBI

Role: Co-PI / Co-Investigator

Heart Failure Clinical Research Network Coordinating Center

The goal of this project is to accelerate research in the diagnosis, management, and treatment of heart failure, and to improve patient outcomes through evaluation of existing and novel therapies.

**5U01AG034661-06** (Cohen) 09/30/09 – 03/31/2021

NIH

PACTTE-Partnership for Anemia: Clinical and Translational Trials in the Elderly

Role: Co-Investigator

Our research will have far-reaching implications ranging from: 1) developing a standard panel of geriatric instruments applicable to any anemia interventional trial in older adults, 2) determining whether erythropoiesis stimulating agent (UAE) for unexplained anemia in elderly is safe and adequately improves functional status to justify larger scale clinical trials, and 3) elucidating major mechanisms leading to UAE that will guide future trials and research.

**DCRI #4778** (Mark) 02/01/2009-12/31/2020

Mayo Clinic

CABANA EQOL Trial

Role: Co-Investigator

The goals of this project are to test the hypothesis that the treatment strategy of percutaneous left atrial catheter ablation for the purpose of eliminating atrial fibrillation (AF) is superior to state-of-the-art drug therapy for reducing total mortality (primary endpoint) and decreasing the composite secondary endpoint of death, disabling stroke, serious bleeding or cardiac arrest in patients with untreated or incompletely treated AF warranting therapy.

**183693-01/5U01-HL128964-04** (Anstrom KJ) 08/01/2019 – 07/31/2020

Cornell/NIH subaward

Lung Microbiome Study in IPF

Role: Co-Investigator

The goal is to design and conduct a large, simple randomized trial to determine whether 12-months of treatment with Bactrim improves clinical outcomes in participants with idiopathic pulmonary fibrosis.

**DCRI #6769 (Hernandez)** 04/01/2016 - 12/15/2020

Merck Sharp & Dohme

Vericiguat Victoria

Role: Steering Committee Member

A randomized, placebo-controlled, parallel-group, multi-center, double-blind, event driven trial of vericiguat in subjects with heart failure with reduced ejection fraction. The goal of this study is to determine whether vericiguat improves clinical outcomes in these patients.

**DCRI #7441 BAYER-03** (Jones) 07/10/2018 – 09/30/2020

Bayer HealthCare AG

Vitality Clinical Trial

Role: Steering Committee Member

A clinical trial to evaluate the efficacy and safety of the oral sGC stimulator vericiguat to improve physical functioning in activities of daily living in patients with heart failure and preserved ejection fraction.

**5U01-HL105565-07** (Mark) 07/22/2011 – 10/31/2020

NIH

The ISCHEMIA Trial-EQOL

Role: Co-Investigator

The objective of ISCHEMIA is to determine the optimal management strategy for patients with stable ischemic heart disease (SIHD) and moderate-severe ischemia.

**DCRI 4772** (Lee, K) 07/09/2009-06/30/2018

Mayo Clinic

CABANA AF Trial

Role: Co-Investigator

This trial has the overall goal of establishing the appropriate roles for medical and ablative intervention for atrial fibrillation (AF) in a sufficiently broad spectrum of patients, to allow far-reaching applicability to the dramatically increasing numbers of patients with this arrhythmia.

**7737sc/5UM1-HL119089-03** (Anstrom) 08/01/2013 - 05/31/2018

University of California – San Francisco

IPF Wrap

Role: Co-Investigator

The DCRI will serve as the Coordination Center (CC) for this project. The CC will be responsible for the following:

- Project management: The CC will provide operational project oversight, with direct responsibility for the core study components identified below. The CC will also coordinate with UCSF to provide information necessary for study components handled by that institution.
- Data management: The CC will utilize the study protocol and clinical input to develop the electronic case report form (eCRF) for this trial. The CC will program and maintain the eCRF and randomization system and will provide regular reporting to sites and stakeholders on data quality and completeness.
- Site management: The CC will handle site management efforts, including collection and verification of site regulatory and consent documents, initiation and monitoring visits, and site closeout activities. The CC site management team will handle site training and protocol-related support throughout the trial.
- Statistical analysis and reporting: The CC will conduct all statistical analyses related to ongoing data and safety monitoring board (DSMB) reporting and to study manuscript development. The CC PI and statistical team will serve as the contact with the DSMB throughout the study.

**1511-33599** (Ortel, T)

02/15/2017 - 07/01/2019

Role: Statistical Investigator

Patient-Centered Outcomes Research Institute

Warfarin versus Direct Oral Anticoagulants for Secondary Prevention of Recurrent Venous Thromboembolism

This is a pragmatic, randomized control trial (RCT) comparing rivaroxaban and apixaban to the standard treatment (warfarin) in patients who have completed 3-6 months of anticoagulation for acute, unprovoked VTE.

**180007** (Anstrom, K)

08/01/2015 - 07/31/2019

Cornell University/NIH 5U01-HL128964 sub

Lung Microbiome Study in IPF

Role: Co-PI

The goal is to design and conduct a large, simple randomized trial to determine whether 12-months of treatment with Bactrim and/or doxycycline compared with usual care improves clinical outcomes in participants with idiopathic pulmonary fibrosis.

*Oxygen Biotherapeutics (LEVO-CTS)*

Role: Statistical Investigator

A double-blind, randomized, placebo-controlled study of Levosimendan in patients with left ventricular systolic dysfunction undergoing cardiac surgery requiring cardiopulmonary bypass.

DCRI 5462 (Alexander, J)

04/01/2014 - 07/02/2017

*Wrap-IPF (University of California – San Francisco/NIH)*

Role: Co-Investigator

The DCRI will serve as the Coordination Center for this project. The purpose of the WRAP-IPF trial is to determine whether a surgical intervention to treat acid reflux improves clinical outcomes in patients with idiopathic pulmonary fibrosis.

UM1HL119089/7737sc (Anstrom, KJ)

08/01/2013 - 11/30/2017

*Palliative Care in Heart Failure (PAL-HF)*

Role: Co-Investigator

To examine the burden of illness imposed by advanced Heart Failure and the complex palliative care needs due to the multi factorial etiology and varying trajectories of disease in this population; study the medical, physical and psychosocial relationships between disease status, symptoms, psychological and functional conditions, spiritual concerns and QOL; and develop and test appropriate palliative and end-of-life care interventions for those with advanced HF and their caregivers.

1R01-NR013428 (Rogers, J)

09/27/2011 - 07/31/2016

*ICD Therapy in Patients with Congestive Heart Failure*

Role: Co-Investigator

The goal of this project is to examine the current use of primary prevention implantable cardioverter defibrillator (ICD) in clinical practice.

1 R01 HL093071 (Al-Khatib, S)

07/15/2009 - 06/30/2013

NIH/NHLBI

*Idiopathic Pulmonary Fibrosis Clinical Research Network (Data Coordinating Center)*

Role: Principal Investigator

The goal of this project is to establish a Clinical Research Network to design and perform multiple therapeutic trials for treatment of patients with idiopathic pulmonary fibrosis.

1U10HL080413-01 (Anstrom, KJ)

05/01/2005 – 04/30/2013

NIH/NHLBI

*Positive Impact of EndoVascular Options for Treating Aneurysm Early (PIVOTAL)*

Role: Co-Investigator

The goals of this project are to compare endovascular repair versus surveillance, with respect to patient survival, AAA rupture, and AAA related death.

(Eisenstein, EL)

01/01/2005 – 12/31/2012

Medtronic Vascular

*Engaging the Next Generation of Biostatisticians (with North Carolina State University)*

Role: Instructor

The program provided mentoring to a new generation of biostatisticians through class room learning and field trips to DCRI and other companies in the RTP. The participants are students from a wide variety of backgrounds spending a summer at NCSU learning about biostatistics.

2003-1428-01 (Anstrom, KJ)

06/01/2009 - 05/31/2012

NIH/NHLBI

*DEcIDE DES TO4 WA2*

Role: Statistical Investigator

To determine the comparative effectiveness of drug eluting stents (DES) versus bare metal stents (BMS) in men and women in routine community practice with early and long term patient outcomes.

HHSA-290-2005-0032ITO4-WA2 (Douglas, P)

07/01/2009 - 08/15/2011

AHRQ

*CERTs Research Center*

Role: Co-Investigator

The main objective of this project is to investigate clinical therapeutics in cardiovascular medicine by providing vision, leadership, and direction to translate clinical findings into improved medical practice.

5 U18 HS010548 (Kramer, J.)

04/01/2004 – 09/29/2007

AHRQ

*Improving Care Quality and Coordination through Patient Inclusion in a Community-Based Telehealth Network*

Role: Co-Investigator

The objectives of this study are to assess the costs and benefits of HIT in an established community-wide network of academic, private and public healthcare facilities created to share clinical information for the purpose of population-based care management of Medicaid beneficiaries.

1R01 HS15057-01 (Lobach D.)

09/01/2004 – 08/31/2007

Agency for Healthcare Research & Quality

*Health Information Technology*

Role in Project – Co-Investigator

The goal of the project is showing health information value in a community network.

1R01 HS/E113106 (Lobach, D.)

09/01/2004 – 08/31/2007

AHRQ

*Phase II Multidose Study of Intravenous PEG-Uricase in Patients with Refractory Gout*

Role in Project – Co-Investigator

The primary objectives of this study are to evaluate the safety, tolerability, efficacy, and antibody response to multiple intravenous infusions of PEG-uricase.

FD-R-0025301 (Sundy J.)

06/01/2004 – 05/31/2007

Food and Drug Administration

*CERTs Research Center Supplement – Developing Effectiveness Research Methodologies*

Role: Co-Investigator

In a collaboration with Medical Review of NC, a QIO, we propose to apply these estimators to address questions of comparative effectiveness in elderly HF patients who are eligible for both Medicare and Medicaid.

3 U18 HS010548 (Kramer, J.)

07/01/2005 – 06/30/2006

AHRQ

*APEX-MI EQOL*

Role: Co-Investigator

The specific objectives of this study are to compare medical resource use patterns and associated medical costs for the Pexelizumab arm versus the control arm by intention-to-treat in patients randomized into APEX-MI; and to perform a cost-effectiveness analysis of Pexelizumab versus control using the empirical outcomes.

*GUIDing Evidence Based Therapy Using Biomarker Intensified Treatment (DCC)*

Role: PI of the Data Coordinating Center

GUIDE-IT is a randomized clinical trial of biomarker guided therapy in HF. The primary aim is to compare a strategy of medical therapy titrated to a natriuretic peptide target to usual care in 1100 high risk HF patients.

5R01-HL105451-05 (Anstrom, K)

06/08/2012 - 04/30/2017

NIH/NHLBI

**NATIONAL COMMITTEES – Journal and Grant Review Committees**

2015 - present      American Thoracic Society  
                                 American Journal of Critical Care and Respiratory Medicine

2014 - present      Statistical Editor  
                         Shriners International

#### Select NIH Review Committees (since 2016)

2019 - present      Member, Commission of the American Heart Association  
                         Institute for Precision Cardiovascular Medicine  
                         Data Study Section

2017 - Prevention Renal Loss Clinical Trial

2017 - TOPmed Data Coordinating Center

2016 - SIREN Data Coordinating Center

2016 - Food Allergy Research Consortium

#### UNIVERSITY LEADERSHIP ROLES

2020 – present      Statistics and Data Science Therapeutic Area Lead, DCRI

2019 – present      Co-Chief, Division of Biostatistics, Duke University

2018 – present      Director of Biostatistics, Duke Clinical Research Institute

2017 - 2018          Director, Data Solutions for Clinical Trials

2015 - 2018          Executive Operations Committee, Duke Clinical Research Institute

2015 - 2018          Faculty Council, Duke Clinical Research Institute

2012 - 2018          Associate Director of Biostatistics, Duke Clinical Research Institute

#### RECENT AWARDS

2018                  Elected to serve on the Faculty Committee at DCRI

2015                  Robert M. Califf Mentoring Award

#### SERVICE - Committee Work (Intra and Extramural):

1. American Thoracic Society – Guidelines Committee on Observational Studies
2. Steering Committees and / or Executive Committee for several large, industry-funded, clinical research projects including: TRANSLATE-ACS, ARTEMIS (NCT02406677), VICTORIA (NCT02861534) and the Quantum-AF quality improvement project
3. Steering Committees for NIH-funded projects: Heart Failure Network, Guide-IT, TACT2, Wrap-IPF, CleanUP-IPF, TRANSFORM-HF, and SPIRRIT-HFpEF
4. Steering Committee for PCORI-funded – COVET clinical trial
5. Organized sessions for the 2018 and 2021 DISS meetings
6. Served on the Biostatistics and Bioinformatics PhD Exam Committee

#### EXTRAMURAL SEMINARS (Since 2017)

1. Invited Speaker - ACC's Clinical Research Trial Program: Upping Your Game (June 2022)
2. University of North Carolina – Chapel Hill – Department of Biostatistics Seminar – 2021 - The Evolving Role of the Coordinating Center for Heart Failure Research Studies
3. Heart Failure Collaboratory 2019 – What's More Important? Gather Data or Estimate Parameters?
4. Heart Failure Collaboratory 2019 - Adaptive Design and Other Novel Approaches
5. DIA / FDA Statistics Workshop 2018 - Risk-Based Monitoring – A Local Experience
6. DCRI / AZ Meeting 2018 – DCRI's Approach to Risk-Based Monitoring and Central Monitoring
7. ATS 2018 – Post-Graduate Short Course - Clinical Trial Endpoints for Assessing Treatment Response for Patients with IPF: What Is Meaningful and To Whom?



8. ATS 2018 – Novel IPF Trial Design in the Era of Anti-Fibrotic Therapy
9. May 2018 - Victoria Steering Committee Meeting – What’s New in Heart Failure?
10. The International Colloquium on Lung Fibrosis (ICLAF) 2018 - Pragmatic Trials – When, Why, and How
11. Duke Industry Statistics Symposium 2017 – Handheld or Wearable Devices for Clinical Trials - Lessons Learned from the Use of Mobile Monitoring Devices in Patients with Chronic Disease

**DIVERSITY, EQUITY, and INCLUSION**

**Chair of the YMCA Annual Campaign Community Gifts (2011-2014)** - The purpose of the Y campaign was to raise funds to support educational enrichment for children who experience academic and economic challenges

**Community Advisory Board Member for the Triangle YMCA (2015-2020)** - The purpose of the board was to develop relationships within local communities to support children and public health programs.