

Curriculum Vitae
Thomas D. Cook

Address:

Department of Biostatistics and Medical Informatics
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Education:

1993 University of Wisconsin, Madison, Wisconsin: Ph.D. in Statistics.
1985 University of Wisconsin, Madison, Wisconsin: M.S. in Statistics.
1982 University of Wisconsin, Madison, Wisconsin: M.A. in Mathematics.
1979 University of Michigan, Ann Arbor, Michigan: B.S. Applied Mathematics.

Professional Employment:

1993–present: Clinical Trials Program, Department of Biostatistics and Medical Informatics, School of Medicine and Public Health, University of Wisconsin-Madison

2020–present: Professor (CHS)
2004–2020: Senior Scientist
1996–2004: Associate Scientist
1993–1996: Assistant Scientist

1992–1993: Thesis research funded by NIH Training Grant.

1990–1992: Assistant Researcher, Departments of Biostatistics and Surgery, University of Wisconsin, Madison.

1986–1990: Data Analyst, Wisconsin Peer Review Organization, Madison, Wisconsin.

1979–1986: University of Wisconsin, Madison.

1975–1986: Project Assistant, Biostatistics Center, Department of Human Oncology
1979–1985: Teaching Assistant, Department of Mathematics

Awards:

1992–1993 National Institutes of Health, National Cancer Institute, Biostatistics Training Grant

2015 UW-Madison Chancellor's Award for Excellence in Research

Memberships: Society for Clinical Trials

Professional Experience:

- Professor (CHS)** Clinical Trials Program, Department of Biostatistics and Medical Informatics, School of Medicine and Public Health, University of Wisconsin-Madison
- 2021-Present: Principal Investigator, Statistical Analysis Center, A Phase 3 Study of the Efficacy and Safety of Lixivaptan in Participants with Autosomal Dominant Polycystic Kidney Disease
- 2020: Principal Investigator, Statistical Analysis Center, An Adaptive Phase 2/3, Randomized, Double-Blind, Placebo-Controlled Study of Sarilumab for Hospitalized Patients with COVID-19
- 2020-2021: Principal Investigator GFB-887-201 Diabetic Nephropathy, Focal Segmental Glomerulosclerosis, and Treatment-Resistant Minimal Change Disease
- 2020-present: Principal Investigator C2541013 Nonalcoholic Steatohepatitis and Fibrosis Stage 2 or 3
- 2020-present: Principal Investigator RGN1788 Cutaneous Squamous Cell Carcinoma Trial
- 2019–present: Principal Investigator, Statistical Analysis Center, A randomized double-blind, placebo-controlled, multicenter trial of TQJ230 on major cardiovascular events in patients with established cardiovascular disease
- 2019–2020: Principal Investigator, Statistical Analysis Center, A Global, Randomized, Phase 3, Open-Label Study Of Regn2810 (Anti-Pd-1 Antibody) Versus Platinum-Based Chemotherapy In First-Line Treatment Of Patients With Advanced Or Metastatic Pd-L1+ Non-Small Cell Lung Cancer
- 2019–2021: Principal Investigator, Statistical Analysis Center, A Randomized, Phase 3 Study Of Combinations Of Cemiplimab (Anti-Pd-1 Antibody) And Platinum-Based Doublet Chemotherapy In First-Line Treatment Of Patients With Advanced Or Metastatic Non-Small Cell Lung Cancer
- 2019–present: Principal Investigator, Statistical Analysis Study to Evaluate the Efficacy and Safety of Vutrisiran in Patients with Transthyretin Amyloidosis with Cardiomyopathy
- 2019–present: Principal Investigator, Statistical Analysis Center, Study to Evaluate the Efficacy and Safety of Patisiran in Patients with Transthyretin Amyloidosis with Cardiomyopathy
- 2019–2020: Principal Investigator, Statistical Analysis Center for interim analyses, non-small cell lung cancer
- 2019–present: Principal Investigator, Statistical Analysis Center, platform trial of novel therapies in non-small cell lung cancer
- 2018–present: Principal Investigator, Statistical Analysis Center, trial of PF-06651600 in adult and adolescent alopecia areata.
- 2018–2021: Principal Investigator, Statistical Analysis Center, trial of TD-1473 in moderately-to-severely active ulcerative colitis.
- 2018–2021: Principal Investigator, Statistical Analysis Center, trial of lumasiran in children and adults with primary hyperoxaluria Type 1

- 2017–2020: Principal Investigator, Statistical Analysis Center, trial of givosiran in patients with acute hepatic porphyrias
- 2017–present: Principal Investigator, Statistical Analysis Center, trial of CardiAmp therapy for patients with Heart Failure
- 2016–2020: Principal Investigator, GALACTIC-HF Trial Statistical Analysis Center
- 2015–2017: Principal Investigator, NAVIGATE-ESUS Trial Statistical Analysis Center
- 2015–2020: Principal Investigator, REGN475 Phase 2/3 Program Statistical Analysis Center
- 2014–2017: Principal Investigator, REPRISE Trial Statistical Analysis Center
- 2011–2017: Principal Investigator, AMG423 Phase 2 Trial Statistical Analysis Center
- 2011–2017: Principal Investigator, Statistical Analysis Center, Trial of DVS SR in the Treatment of Children and Adolescents with Major Depressive Disorder Statistical Analysis Center
- 2009–2013: Principal Investigator, RED-HF Trial Statistical Analysis Center
- 2008–2015: Principal Investigator, Lurasidone Program Statistical Analysis Center
- 2007–2017: Principal Investigator, TEMPO Trial Statistical Analysis Center
- 2006–2007: Principal Investigator, EPY 3001/3002 Trials Statistical Analysis Center
- 2004–2005: Principal Investigator, PAA20001 Trial Statistical Analysis Center
- 2004–2007: Principal Investigator, EVEREST Trial Statistical Analysis Center
- 2003–2005: Statistical Consultant with Department of Neurology

Independent Data Monitoring Committees

- 2021-Present: A Phase 2/3, Randomized, Placebo-Controlled, Double-Blind Clinical Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of MK-4482 in Hospitalized Adults with COVID-19
- 2021-Present: A Randomized, Double-Blind, Phase 3 Study Evaluating the Safety and Efficacy of Venetoclax in Combination with Azacitidine in Patients Newly Diagnosed with Higher Risk Myelodysplastic Syndrome (Higher-Risk MDS)
- 2021-Present: Randomized, Double-blind, 2-Arm, Multicenter, Phase 3 Study of Venetoclax and Oral Azacitidine Versus Oral Azacitidine as Maintenance Therapy for Patients with Acute Myeloid Leukemia in First Remission After Conventional Chemotherapy
- 2021-Present: A Phase 1 First in Human, Multicenter, Open-Label Dose-Escalation Study to Determine the Safety, Tolerability, Pharmacokinetics, and RP2D of ABBV-184 in Subjects with Previously Treated Cancers
- 2020-Present: Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of SNF472 When Added to Background Care for the Treatment of Calciphylaxis
- 2020-Present: A Randomized, Double-Blind, Placebo- Controlled, Phase 3 Study of Navitoclax in Combination with Ruxolitinib versus Ruxolitinib in Subjects with Myelofibrosis

- 2020-Present: A Randomized, Open-Label, Phase 3 Study Evaluating Efficacy and Safety of Navitoclax in Combination with Ruxolitinib Versus Best Available Therapy in Subjects with Relapsed/Refractory Myelofibrosis
- 2021-Present: Sequential randomized, pragmatic, 2-step comparative effectiveness trial to identify the optimal approach to chronic lower back pain treatment employing commonly recommended non-surgical, non-pharmacological options.
- 2020-Present: Phase 2, multi-center, randomized, double-blind, placebo-controlled, parallel-group study comparing ATH-1017 with placebo in subjects with a clinical diagnosis of mild to moderate Alzheimer's disease (AD).
- 2020-Present: Systemic Lupus Erythematosus (SLE) Treatment with N-acetylcysteine (chair)
- 2019-Present: A Clinical Glide Path to Close the Guidelines-to-Practice Gap in HTN Management
- 2019-Present: Randomized, Phase 3 study of the efficacy and safety of macitentan and tadalafil monotherapies with the corresponding fixed dose combination in subjects with pulmonary arterial hypertension (PAH)
- 2019-Present: Randomized Phase 3 study of macitentan in inoperable or persistent/recurrent chronic thromboembolic pulmonary hypertension.
- 2019-Present: A Phase 3, of efficacy, safety, and tolerability of macitentan in Patients with Pulmonary Arterial Hypertension
- 2019-Present: Randomized clinical trial of andexanet alfa in acute intracranial hemorrhage in patients receiving an oral factor xa inhibitor.
- 2019-Present: A Phase III, Randomized, Double-Blind, Study to Evaluate the Efficacy and Safety of Letemovir Versus Valganciclovir for the Prevention of Human Cytomegalovirus (CMV) Disease in Adult Kidney Transplant Recipients
- 2019-Present: Multicenter, randomized, double-blind, double-dummy, parallel group, dose-finding Phase 2 study of the safety of oral FXIa inhibitor patients with atrial fibrillation
- 2019-Present: A Phase 2/3 Randomized, Study to Evaluate the Safety, Tolerability, Efficacy and Pharmacokinetics of Imipenem/Cilastatin/Relebactam in Pediatric Participants With Confirmed or Suspected Gram-negative Bacterial Infection
- 2019-Present: Safety, efficacy and tolerability of letermovir prophylaxis post-transplant in recipients of allogeneic hematopoietic stem cell transplant.
- 2019-2020: Phase 2, randomized, double-blind, placebo-controlled, multi-center study in Chronic Kidney Disease and uncontrolled hypertension.
- 2018–2019: Multi-center, randomized, open-label, parallel-group study with LJPC-401 for myocardial iron overload in patients with transfusion-dependent beta thalassemia.
- 2018–present: A randomized parallel-group, placebo-controlled, double-blind, multi-center 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

- 2018–present: A prospective, multicenter, open-label, single-arm, Phase 2 study to investigate the safety, tolerability and pharmacokinetics of selexipag in children with pulmonary arterial hypertension
- 2018–present: A Phase 1 Study of the Safety and Pharmacokinetics of Venetoclax in Pediatric and Young Adult Patients with Relapsed or Refractory Malignancies
- 2018–present: Phase 3 study of Venetoclax in Subjects with Refractory Chronic Lymphocytic Leukemia
- 2018–present: Safety and Tolerability of Subcutaneous Elafin in Healthy Normal Subjects
- 2018–present: Blood Pressure self monitoring for hypertension control.
- 2018–present: Phase 3 study assessing the efficacy and safety of macitentan in Fontan-palliated adult and adolescent subjects
- 2018–present: 2018 Phase 2 study of selexipag in children with pulmonary arterial hypertension
- 2018–present: Phase 2b Macitentan in Heart failure with preserved ejection fraction and pulmonary vascular disease
- 2017–2018: Phase 3 study of cadazolid in pediatric subjects with clostridium difficile-associated diarrhea
- 2017–present: A Phase 3 Study of Rovalpituzumab Tesirine for Advanced or Metastatic DLL3 high Small Cell Lung Cancer
- 2017–present: A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study of Rovalpituzumab Tesirine as Maintenance Therapy Following First-Line Platinum-Based Chemotherapy in Subjects with Extensive Stage Small Cell Lung Cancer
- 2017–present: Phase 3 Study of Venetoclax in Acute Myeloid Leukemia
- 2017–present: A Randomized, Double-Blind, Placebo Controlled Study of Venetoclax Acute Myeloid Leukemia
- 2017–present: A Phase 3 study of Venetoclax in Subjects with Relapsed or Refractory Multiple Myeloma
- 2016–2019: Pilot study to evaluate in treatment resistant nephrotic syndrome
- 2016–2019: A Phase III Trial Imipenem/Cilastatin/Relebactam in subjects with Hospital-Acquired or Ventilator-Associated Bacterial Pneumonia
- 2016–present: A multicenter, open-label, randomized, study of macitentan in children with pulmonary arterial hypertension
- 2016-2019: Multicenter trial of vericiguat in patients with heart failure
- 2014–2018: Multi-center trial in Active Class III or IV Lupus Nephritis
- 2014-2016: Letemovir for the Prevention of Clinically Significant Human Cytomegalovirus Infection in Adult, CMV-Seropositive Allogeneic Hematopoietic Stem Cell Transplant Recipients
- 2014–2019: Vitamin D for falls prevention in the elderly (NIH).
- 2014–2015: Phase 3 Randomized, Double-blind, Placebo-controlled, Multicenter Clinical Trial of Purified Poloxamer in Acute Limb Ischemia

- 2013–2016: DPP-4 inhibitor program for the treatment of Type 2 Diabetes
- 2013–2016: Phase 3 Randomized, Double-blind, Placebo-controlled, Multicenter Clinical Trial of Purified Poloxamer in Vaso-occlusive Crisis of Sickle Cell Disease
- 2012–2016: Meditation and Exercise for Prevention of Acute Respiratory Infection II: Single center trial conducted at UW-Madison
- 2012–2018: A Multi-center, Randomized Parallel Group, Placebo-Controlled Double-Blind Trial to Evaluate the Safety, Efficacy, and Pharmacokinetics of Belimumab, a Human Monoclonal Anti- BLYS Antibody, Plus Standard Therapy in Pediatric Patients with Systemic Lupus Erythematosus (SLE)
- 2012–2018: Combined Behavioral & Analgesic Trial For Fibromyalgia (COMBAT-FM) (NIH)
- 2011–2012: A Phase 2 Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of NP001 in Subjects with Amyotrophic Lateral Sclerosis (ALS)
- 2011–2014: A Phase 3, Multicenter, Double-blind, Placebo-controlled Randomized Discontinuation Study to Evaluate the Efficacy and Safety of Amifampridine Phosphate in Patients with Lambert-Eaton Myasthenic Syndrome (LEMS)
- 2011–2013: Randomized, placebo controlled study of eltrombopag in pediatric patients with chronic idiopathic thrombocytopenic purpura.
- 2010–2012: A Randomized, Parallel, Placebo-Controlled, Double-Blind Phase IIA Study of Efficacy and Safety of Recombinant Human Neuregulin-1 (Neucardin) in Subjects with Stable Chronic Heart Failure
- 2010–2016: Fluid Therapy and Cerebral Injury in Pediatric Diabetic Ketoacidosis (NIH)
- 2009–2013: Stem Cell Revascularization In Patients with Critical Limb Ischemia trial: Single center trial conducted at UW-Madison
- 2009–2010: Meditation and Exercise for Prevention of Acute Respiratory Infection: Single center trial conducted at UW-Madison
- 2008–2011: Degarelix: Industry sponsored trial in prostate cancer
- 2005–2009 NINDS study of Tenecteplase in Acute Ischemic Stroke
- 2006–2007: Alvimopan, Industry sponsored trial in bowel disease
- 2006–2007: MOMENTUM, Industry sponsored device trial in severe heart failure
- 2006: ECLIPSE, Industry sponsored trial in severe heart failure
- 2004: C0328T03, Industry sponsored phase II trial of monoclonal antibody for several indications
- 2003–2004: C0328T01, Industry sponsored phase II trial of monoclonal antibody for renal cancer
- 2003–2008: Depression and Health Outcomes in Refractory Epilepsy, NINDS sponsored (Chair)
- 2001–2003: A-PLUS, Industry sponsored phase II trial of avasimibe for angina.

Other Committees

- 2020-Present: Cardiovascular and Renal Drugs FDA Advisory Committee

Teaching (year[s] taught)

Statistics 641, *Statistical Methods for Clinical Trials* (1996, 2008, 2009, 2011–2021)

Statistics 642, *Statistical Methods for Epidemiology* (1996, 1997, 1998, 2005)

BMI 546, *Practicum in Biostatistics* (2014, 2015)

Statistics 543, *Practicum in Clinical Trial Data Analysis and Interpretation* (2003, 2004, 2014, 2015)

Population Health 800 *Quantitative Methods in Population Health I* (2000)

Student Mentoring

Graduate Students (year graduated):

Chaoqun Mei (PhD 2020)

Rebecca Post (MS 2017)

Geng Li (MS 2016)

Ryan Zea (MS 2014)

Brittany Schwefel (PhD 2014)

Charlie Casper (PhD 2008)

Shanhong Guan (PhD 2007)

Rui Song (PhD 2006)

Shuangge Ma (PhD 2004)

Yuanjun Shi (PhD 2001)

Yonghua Chen (PhD 2000)

Muhammad Jalaluddin (PhD 1999)

Integrated Biological Sciences Summer Research Program (year)

Raúl Torres (2014)

Jordan Cammorotta (2013)

Senior Honors Thesis (academic year)

Hanqing Ma (2014-15)

Meizi Liu (2015-16)

Summer Research Program in Biostatistics (year)

Travell Lockhart (2004)

Lakeesha Carmichael (2002)

Jennifer James (2001)

Institutional Committees

2016–Present: Co-Chair Institute for Clinical and Translational Research Data Monitoring Committee

2008–2015: Health Sciences Scientific Review Committee

2002–2008: Health Sciences Institutional Review Board

1999–2010: Research Computing Committee (Department of Biostatistics and Medical Informatics)

Publications:

- Kim K, Hennekens CH, Martinez L, Gaziano JM, Pfeffer MA, Biglione B, Gitin A, McCabe JB, Cook TD, DeMets DL, Wood SK (2021) Primary care providers should prescribe aspirin to prevent cardiovascular disease based on benefit-risk ratio, not age. *Fam Med Community Health*. **9**(4)
- Amish N Raval, Peter V Johnston, Henricus J Duckers, Thomas D Cook, Jay H Traverse, Peter A Altman, Ravi Dhingra, Peiman Hematti, Ivan Borrello, R David Anderson, Carl J Pepine (2021) Point of care, bone marrow mononuclear cell therapy in ischemic heart failure patients personalized for cell potency: 12-month feasibility results from CardiAMP heart failure roll-in cohort *Int J Cardiol* **326**:131-138
- Carol C. Mitchell, Stephanie M. Wilbrand, Thomas D. Cook, Nirvedh H. Meshram, Catherine N. Steffel, Rebecca Nye, Tomy Varghese, Bruce P. Hermann, Robert J. Dempsey (2020) Carotid Plaque Strain Indices Were Correlated With Cognitive Performance in a Cohort With Advanced Atherosclerosis, and Traditional Doppler Measures Showed no Association *J Ultrasound Med* **39**(10):2033-2042
- Catherine N Steffel, Shahria Salamat, Thomas D Cook, Stephanie M Wilbrand, Robert J Dempsey, Carol C Mitchell, Tomy Varghese (2020) Attenuation Coefficient Parameter Computations for Tissue Composition Assessment of Carotid Atherosclerotic Plaque in Vivo *Ultrasound in Medicine and Biology*, **46**(6):1513–1532
- Nirav J Patel, Kirk J Hogan, Elias Rizk, Krista Stewart, Andy Madrid, Sivan Vadakkadath Meethal, Reid Alisch, Laura Borth, Ligia A Papale., Solomon Ondoma, Logan R Gorges, Kara Weber, Wendell Lake,rew Bauer, Nithya Hariharan, Thomas Kuehn, Thomas Cook, Sunduz Keles, Michael A Newton, Bermans J Iskandar (2020) Ancestral Folate Promotes Neuronal Regeneration in Serial Generations of Progeny *Molecular Neurobiology*, **57**: 2048–2071
- Thomas D. Cook, Ryan Zea (2020) Missing Data and Sensitivity Analysis for Binary Data with Implications for Sample Size and Power of Randomized Clinical Trials. *Statistics in Medicine* **39**(2):192–204
- David L. DeMets, Thomas D. Cook (2019) Challenges of Non-Intention-to-Treat Analyses *JAMA* **321**(2):145–146
- TaeHee Kim, Suresh L. Mehta, Kahlilia C. Morris-Blanco, Anil K. Chokkalla, Bharath Chelluboina, Mary Lopez, Ruth Sullivan, Hung Tae Kim, Thomas D. Cook, Joo Yong Kim, HwuiWon Kim, Chanul Kim, and Raghu Vemuganti (2018) The microRNA miR-7a-5p ameliorates ischemic brain damage by repressing α -synuclein. *Science Signaling* **560**(11)
- Amish Raval, Thomas D. Cook, Henricus J. Duckers, Peter V. Johnston, Jay H. Traverse, William T. Abraham, Peter A. Altman, Carl J. Pepine (2018) The CardiAMP Heart Failure trial: A randomized controlled pivotal trial of high-dose autologous bone marrow mononuclear cells using the CardiAMP cell therapy system in patients with post-myocardial infarction heart failure: Trial rationale and study design. *American Heart Journal*, **201**:141–148

- David L. DeMets, Thomas D. Cook, Kevin A. Buhr (2017) Guidelines for Statistical Analysis Plans (Editorial) *JAMA* **318**(2)
- John Fleming, Gianna Hernandez, Leslie Hartman, Jane Maksimovic, Sara Nace, Benjamin Lawler, Todd Risa, Thomas Cook, Rashmi Agni, Mark Reichelderfer, Christopher Luzzio, Loren Rolak, Aaron Field, Zsuzsanna Fabry (2017) Safety and Efficacy of Helminth Treatment in Relapsing-remitting Multiple Sclerosis: Results of the HINT 2 Clinical Trial. *Multiple Sclerosis Journal*
- Carol C. Mitchell, James H. Stein, Thomas D. Cook, Shahriar Salamat, Xiao Wang, Tomy Varghese, Daren C. Jackson, Carolina Sandoval Garcia, Stephanie M. Wilbrand and Robert J. Dempsey (2017) Histopathologic Validation of Grayscale Carotid Plaque Characteristics Related to Plaque Vulnerability. *Ultrasound in Medicine & Biology*, **43**(1):129–137
- Cook TD, Greene SJ, Kalogeropoulos AP, Fonarow GC, Zea R, Swedberg K, Zannad F, Maggioni AP, Konstam MA, Gheorghiade M, Butler J (2016) Temporal Changes in Postdischarge Mortality Risk After Hospitalization for Heart Failure (from the EVEREST Trial), *The American Journal of Cardiology* **117**:611–616
- Ambrosy AP, Pang PS, Khan S, Konstam MA, Fonarow GC, Traver B, Maggioni AP, Cook T, Swedberg K, Burnett JC, Grinfeld L, Udelson JE, Zannad F, and Gheorghiade M. (2013) Clinical course and predictive value of congestion during hospitalization in patients admitted for worsening signs and symptoms of heart failure with reduced ejection fraction: findings from the EVEREST trial, *European Heart Journal* **34**(11):835–43
- Casper, T Charles and Cook, Thomas D (2012) Estimation of the Mean Frequency Function for Recurrent Events when Ascertainment of Events Is Delayed *The International Journal of Biostatistics*, **8**(1):1–20
- Gheorghiade M, Pang PS, Ambrosy AP, Lan G, Schmidt P, Filippatos G, Konstam M, Swedberg K, Cook T, Traver B, Maggioni A, Burnett J, Grinfeld L, Udelson J, Zannad F. (2012) A comprehensive, longitudinal description of the in-hospital and post-discharge clinical, laboratory, and neurohormonal course of patients with heart failure who die or are re-hospitalized within 90 days: analysis from the EVEREST trial. *Heart Fail Rev.* **17**(3):485–509.
- Blair JE, Pang PS, Schrier RW, Metra M, Traver B, Cook T, Campia U, Ambrosy A, Burnett JC Jr, Grinfeld L, Maggioni AP, Swedberg K, Udelson JE, Zannad F, Konstam MA, Gheorghiade M; EVEREST Investigators. (2011) Changes in renal function during hospitalization and soon after discharge in patients admitted for worsening heart failure in the placebo group of the EVEREST trial. *Eur Heart J.* **32**(20):2563–72
- Fleming JO, Isaak A, Lee JE, Luzzio CC, Carrithers MD, Cook TD, Field AS, Boland J, Fabry Z., Probiotic helminth administration in relapsing-remitting multiple sclerosis: a phase 1 study., *Mult Scler.* 2011 **17**(6):743–54.
- Cook, Thomas and DeMets, David (2010) Review of Draft Adaptive Design FDA Guidance *Journal of Biopharmaceutical Statistics*, **20**(6):1132–1142

- Iskandar BJ, Rizk E, Meier B, Hariharan N, Bottiglieri T, Finnell RH, Jarrard DF, Banerjee RV, Skene JH, Nelson A, Patel N, Gherasim C, Simon K, Cook TD, Hogan KJ (2010) Folate regulation of axonal regeneration in the rodent central nervous system through DNA methylation. *J Clin Invest* **120**(5):1603–16
- Sperling MR, Greenspan A, Cramer JA, Kwan P, Kälviäinen R, Halford JJ, Schmitt J, Yuen E, Cook T, Haas M, Novak G. (2010) Carisbamate as adjunctive treatment of partial onset seizures in adults in two randomized, placebo-controlled trials. *Epilepsia* 2010 **51**(3):333–43
- O'Connor, Christopher M., Alan B. Miller, John E.A. Blair, Marvin A. Konstam, Patricia Wedge, Maria C. Bahit, Peter Carson, Markus Haass, Paul J. Hauptman, Marco Metra, Ron M. Oren, Richard Patten, Ileanam Piña, Sherryn Roth, Jonathan D. Sackner-Bernstein, Brian Traver, Thomas Cook, and Mihai Gheorghide, for the EVEREST investigators (2010) Causes of death and rehospitalization in patients hospitalized with worsening heart failure and reduced left ventricular ejection fraction: Results from efficacy of vasopressin antagonism in heart failure outcome study with tolvaptan (EVEREST) program *American Heart Journal*, **159**(5):841–849
- Wang NC, Piccini JP, Konstam MA, Maggioni AP, Traver B, Swedberg K, Udelson JE, Zannad F, Cook T, O'Connor CM, Miller AB, Grinfeld L, Gheorghide M; EVEREST Investigators, Implantable cardioverter-defibrillators in patients hospitalized for heart failure with chronically reduced left ventricular ejection fraction. (2010) *Am J Ther.* **17**(4):e78–87.
- Wang, N., A. Maggioni, M. Konstam, F Zannad, H. Krasa, J. Burnett Jr, L Grinfeld, K Swedberg, J. Udelson, T Cook, B Traver, C Zimmer, C Orlandi, M Gheorghide, for the Efficacy of Vasopressin Antagonism in Heart Failure Outcome Study With Tolvaptan (EVEREST) Investigators (2008) Clinical Implications of QRS Duration in Patients Hospitalized With Worsening Heart Failure and Reduced Left Ventricular Ejection Fraction *JAMA*. **299**(22):2656–2666
- Blair J, Zannad F, Konstam M, Cook T, Traver B, Burnett Jr J, Grinfeld L, Krasa H, Maggioni A, Orlandi C, Swedberg K, Udelson J, Zimmer C, Gheorghide M for the EVEREST Investigators (2008) Continental Differences in Clinical Characteristics, Management, and Outcomes in Patients Hospitalized With Worsening Heart Failure: Results From the EVEREST (Efficacy of Vasopressin Antagonism in Heart Failure: Outcome Study with Tolvaptan) Program *J Am Coll Cardiol* **52**:1640–1648.
- Song, Rui; Cook, Thomas; and Kosorok, Michael (2008) What We Want versus What We Can Get: A Closer Look at Failure Time Endpoints for Cardiovascular Studies *Journal of Biopharmaceutical Statistics*, **18**(2):370–381
- Brooks NP, Turk AS, Niemann DB, Aagaard-Kienitz B, Pulfer K, Cook T (2008) Frequency of thromboembolic events associated with endovascular aneurysm treatment: retrospective case series. *J Neurosurg* **108**(6):1095–100.
- Konstam MA, Gheorghide M, Burnett JC, Jr, Grinfeld L, Maggioni AP, Swedberg K, Udelson JE, Zannad F, Cook TD, Ouyang J, Zimmer C, Orlandi C (2007) Effects of Oral Tolvaptan in Patients Hospitalized for Worsening Heart Failure: The EVEREST Outcome Trial *JAMA*, **297**(12):1319–1331

- Gheorghide M, Konstam MA, Burnett JC, Jr, Grinfeld L, Maggioni AP, Swedberg K, Udelson JE, Zannad F, Cook TD, Ouyang J, Zimmer C, Orlandi C (2007) Short-term Clinical Effects of Tolvaptan, an Oral Vasopressin Antagonist, in Patients Hospitalized for Heart Failure: The EVEREST Clinical Status Trials *JAMA*, **297**(12):1332–1343
- Fleming, John and Cook, Thomas (2006) Multiple sclerosis and the hygiene hypothesis, *Neurology*, **67**:2085–2086
- Cook, Thomas (2006) Discussion of *P*-Value Calculation for Multistage Phase II Cancer Clinical Trials, *Journal of Biopharmaceutical Statistics*, **16**(6):777–780
- Cook, Thomas, Benner, Rebecca and Fisher, Marian, (2006) The WIZARD Trial as a Case Study of Flexible Clinical Trial Design, *Drug Information Journal*, **40**:345–353
- Aguilar, David, Fisher, Marian, O'Connor, Christopher, Dunne, Michael, Muhlestein, Joseph, Yao, Louis, Gupta, Sandeep, Benner, Rebecca, Cook, Thomas, Edwards, Dearborn, Pfeffer, Marc (2006) Metabolic Syndrome, C-Reactive Protein, and Prognosis in Patients with Established Coronary Artery Disease, (2006) *American Heart Journal* **152**(2):298–304
- Newman GC, Hospod FE, Fain SB, Cook TD. (2006) Optimizing dynamic T2* MR imaging for measurement of cerebral blood flow using infusions for cerebral blood volume. *Am J Neuroradiol*, **27**(6):1239–40.
- Newman, George, Hospod, Frank, Patlak, Clifford, Fain, Sean, Pulfer, Kari, Cook, Thomas and O'Sullivan, Finbarr (2006) Experimental estimates of the constants relating signal change to contrast concentration for cerebral blood volume by T2*MRI, *Journal of Cerebral Blood Flow & Metabolism* **26**(6):760–70.
- Moftakhar, Roham, Turk, Aquilla, Niemann, David, Hussain, Sayed, Rajpal, Sharad, Cook, Thomas, Geraghty, Madeleine, Aagaard-Kienitz, Beverly, Turski, Patrick and Newman, George (2005) Effects of Carotid or Vertebrobasilar Stent Placement on Cerebral Perfusion and Cognition. *Am J Neuroradiol*, **26**:1772–1780
- Getz Kelly, Kiesa, Cook, Thomas, and Backonja, Misha-Miroslav, (2005) Pain Ratings at the Thresholds are Necessary for Interpretation of Quantitative Sensory Testing. *Muscle and Nerve*, **32**(2):179–184
- Cook, Thomas D., Kosorok, Michael R. (2004) Analysis of Time-to-event Data with Incomplete Event Adjudication *JASA*, **99**(468):1140–1152
- Iskandar, Bermans. J., Nelson, Aaron, Resnick, Daniel, Skene, J. H. Pate, Gao, Peng, Johnson, Chenara, Cook, Thomas and Hariharan, Nithya (2004) Folic Acid Supplementation Enhances Repair of the Adult Central Nervous System. *Annals of Neurology*, **56**(2):221–227
- Cook, Thomas. D., (2003) Methods for Mid-course Corrections for Clinical Trials with Survival Outcomes, *Statistics in Medicine*, **22**(22):3431–3447
- O'Connor, Christopher M., Dunne, Michael W., Pfeffer, Marc A., Muhlestein, Joseph B., Yao, Louis, Gupta, Sandeep, Benner, Rebecca J., Fisher, Marian R., and Cook, Thomas D., (2003) A double-blind, randomized, placebo controlled trial of azithromycin for the secondary prevention of coronary heart disease: the WIZARD Trial, *JAMA*, **290**(11):1459–1466

- Cook, Thomas D., (2002) *P*-value Adjustment in Sequential Clinical Trials, *Biometrics*, **58**(4):1005–1011
- Cook, Thomas D., (2002) Up with odds ratios! A case for the use of odds ratios when outcomes are common. *Academic Emergency Medicine*, **9**(1430–1434)
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Presentations/Meetings

- 2021 Society for Clinical Trials Annual Meeting, invited session (organizer/speaker).
“Missing Data in Clinical Trials: principles, planning, prevention”
- 2019 Society for Clinical Trials Annual Meeting. “Missing Data and Sensitivity Analysis with Implications for Sample Size of Randomized Clinical Trials.” (poster)
- 2019 Society for Clinical Trials Annual Meeting. “Statistical Approaches for Summarizing the Clinical Event Reporting and Adjudication Process.” (poster)
- 2018 ICSA Applied Statistical Symposium, New Brunswick, NJ “Blinded sample size re-estimation in trials with survival outcomes and incomplete information.” (Invited talk)
- 2016 Society for Clinical Trials preconference workshop organizer/presenter: “Conducting Valid Trials: The Critical (and Misunderstood) Roles of Randomization and Complete Follow-Up”
- 2015 ASA Biopharmaceutical Section Statistics Workshop, Washington, DC, “DMCs and Adaptive Clinical Trials: Keep it Simple, Statistically”
- 2015 Joint ICSA/Graybill Conference, Fort Collins, CO, “Blinded sample size re-estimation in trials with survival outcomes and incomplete information.” (Invited talk)
- 2015 Society for Clinical Trials preconference workshop organizer/presenter: “Conducting Valid Trials: The Critical (and Misunderstood) Roles of Randomization and Complete Follow-Up”
- 2014 Society for Clinical Trials Annual Meeting. “Evolution of a Data Monitoring Report in Response to Concerns About Potential Hepatotoxicity” (poster)
- 2014 Society for Clinical Trials preconference workshop presenter: “Independent Data Monitoring Committees—Recommendations for Trials with an Adaptive Design: What, How, and To Whom?”
- 2014 “Survival Estimation When Event Reporting and Adjudication are Subject to Delay,” University at Buffalo, Department Seminar (Invited talk).
- 2010 “Are we out of the woods yet? Assessing changes in risk over time for both mortality and non-fatal clinical events,” University of Wisconsin, Madison, Department of Biostatistics and Medical Informatics. Department Seminar.
- 2007 “Analysis of Time-to-event Data with Incomplete Adjudication”, University of Minnesota, Division of Biostatistics. (Invited talk)
- 2007 “When to Stop a Clinical Trial for efficacy? Summary of Available Methods Including Stopping Boundaries”, Joint Statistical Meetings. (Invited talk)
- 2006 “Analysis of Time-to-event Data with Incomplete Adjudication”, University of North Carolina, Chapel Hill, Department of Biostatistics. (Invited talk)
- 2006 “Use of open-source software by an academic center in a regulatory environment”, Joint Statistical Meetings. (Invited talk)

- 2006 “Approaches to the Mid-course Assessment of Design Assumptions for Long Term Survival Trials”, Eastern North American Region, Biometrics Society Annual Meeting. (Invited talk)
- 2004 “Issues in Management of Event Reporting and Adjudication Data from the Perspective of Interim Analysis” (poster). Society for Clinical Trials Annual Meeting.
- 2004 “Time-to-event Data with Incomplete Event Adjudication”, Eastern North American Region, Biometrics Society Annual Meeting. (Contributed talk)
- 2002 “The Intention to Treat Principle and Implications for Analysis of Clinical Trial Data.” Cystic Fibrosis Foundation Annual DSMB meeting. (Invited talk)
- 2000 Bayesian Methods in Randomized Clinical Trials. Society for Clinical Trials Annual Meeting. (Organizer/Chair)
- 2000 A Graphical Approach for Displaying Ordered Patient Status Categories over Time. Society for Clinical Trials Annual Meeting. (Poster)
- 1999 Report production for a data and safety monitoring board: A Unix-based system for report generation. Upper Midwest Biostatistics Colloquium. (Invited talk.)
- 1999 Report production for a data and safety monitoring board: A Unix-based system for report generation. Society for Clinical Trials Annual Meeting. (Contributed talk)
- 1999 Tools for Sample Size Estimates for Randomized Trials with Survival Outcomes. Society for Clinical Trials Annual Meeting. (poster)
- 1997 Adjusting Survival Analysis for the Presence of Unadjudicated Study Events. Society for Clinical Trials Annual Meeting. (Contributed talk)
- 1996 Adherence-Response Relationships in Clinical Trials. Society for Clinical Trials Annual Meeting. (Invited Talk)
- 1996 Using S-PLUS for production of data and safety monitoring board reports. Joint Statistical Meeting. (Invited presentation at reception sponsored by MathSoft, Inc.)
- 1995 Sequential Bayesian Quadrature. Eastern North American Region, Biometrics Society Annual Meeting. (Contributed talk)

Books

- Cook, T. D. and DeMets, D. L. (2008) *Introduction to Statistical Methods for Clinical Trials*. Chapman & Hall/CRC

Manuscript Referee

- Annals of Applied Statistics*
Annals of Internal Medicine
Archives of Physical Medicine and Rehabilitation
BMJ
Biometrics
Cardiovascular Pharmacology and Therapeutics

Circulation

Communications in Statistics

Contemporary Clinical Trials (formerly *Controlled Clinical Trials*)

JAMA

Journal of Biopharmaceutical Statistics

Journal of Pharmaceutical Statistics

Journal of the American Statistical Association

Neurology

Stroke

Statistics in Medicine