Clinical Trials Methodology Course

2022

Core Faculty Bios

Adam Hartman, MD

Dr. Hartman is a Program Director in the Division of Clinical Research with a background in child neurology and epilepsy. Before joining NINDS, he was an Associate Professor of Neurology and Pediatrics at Johns Hopkins School of Medicine, with a joint appointment in the Johns Hopkins Bloomberg School of Public Health Department of Molecular Microbiology and Immunology. He also was Co- Director of the Neurosciences Intensive Care Nursery and Associate Program Director for the Child Neurology residency at Johns Hopkins. Dr. Hartman earned a bachelor's degree in Chemistry from Northwestern University and an MD from Northwestern University Medical School. After completing a residency in Pediatrics in the National Capital Uniformed Services Pediatric Residency Program, he served as a general pediatrician in the US Navy for five years (the last as Division Head of General Pediatrics at Naval Medical Center San Diego). He completed his residency in child neurology and a fellowship in clinical neurophysiology/pediatric epilepsy, both at Johns Hopkins. His current interest is in Pediatric Neurology clinical trials. adam.hartman@nih.gov

Charity Patterson, PhD, MSPH

Charity G. (Moore) Patterson is a professor in the Department of Physical Therapy. She is the founding Director of the Physical Therapy Data Center. Her primary area of research expertise is biostatistics, clinical trials and data coordination for exercise, rehabilitation, and physical therapy studies. Patterson has collaborated on studies funded by the National Institutes of Health, Patient Centered Outcomes Research Institute (PCORI), and the Department of Defense. She has more than 150 peer-reviewed publications in journals of high impact. She also serves as a reviewer for peer-reviewed scientific journals and national funding agencies. cgp22@pitt.edu

Chris Coffey, PhD

Dr. Coffey is a Professor of Biostatistics and Director of the Clinical Trials Statistical and Data Management Center (CTSDMC) in the University of Iowa College of Public Health. He received his Ph.D. in biostatistics from the University of North Carolina at Chapel Hill in 1999 and has over 15 years of experience providing data management and statistical support to large randomized clinical trials. He is the principal investigator of the Data Coordinating Centers for the NIH funded Network of Excellence in Neuroscience Clinical Trials (NeuroNEXT) and Childhood and Adolescent Migraine Prevention study (CHAMP); and the Statistics Core for the Michael J. Fox Foundation funded Parkinson's Progression Markers Initiative (PPMI). Dr. Coffey is a Fellow of the Society for Clinical Trials, currently sits on the Board of Directors for the SCT, and serves on a number of data and safety monitoring boards. His research interests lie in the area of novel trial designs, particularly the use of adaptive designs.
christopher-coffey@uiowa.edu

Dawn Kleindorfer, MD

Dr. Kleindorfer is the Chair of the Department of Neurology at the University of Michigan. She received her B.S. in biology from Indiana University, and completed her undergraduate medical education at Washington University, St. Louis, followed by a neurology residency at the University of Michigan, where she also served as Chief Resident, before completing a fellowship in Cerebrovascular Disease at the University of Cincinnati. Upon completion of her training, she was recruited to the faculty of UC, where she rose to become Director of Vascular Neurology, and also Associate Dean of Faculty Development and Women's Initiatives. She then was named as the Robert W. Brear Professor and Chair of the Department of Neurology at the University of Michigan.

She is an accomplished and respected researcher and leader in vascular neurology, with a research focus on stroke epidemiology and racial disparities. She has been continuously funded at the R01 level since 2006 and has produced more than 200 peer-reviewed publications. She has a leadership role within the National Institutes of Health StrokeNet, and is a fellow of the American Heart Association and a member of the Stroke Council of the American Stroke Association. She has received many awards for her work, including the American Neurological Association's Derek Denney-Brown Outstanding Neurological Clinical Research Scholar Award, and the American Stroke Association International Stroke Research Mentor Award, and completed the prestigious Executive Leadership in Academic Medicine (ELAM) program. Most recently she chaired the AHA's Secondary Prevention of Stroke Treatment Guidelines.

Dietrich Haubenberger, MHSc, MD

Dr. Haubenberger is the Medical Director of Early Clinical Development for Neurocrine Biosciences Inc. He's the former Director of the Clinical Trials Unit and Assistant Clinical Director for Clinical Research at the NINDS Intramural Research Program, National Institutes of Health. Dr. Haubenberger received his medical degree and training as a neurologist at the Medical University of Vienna, Austria, followed by a tenure trach position to become an Associate Professor of Neurology in 2014. Dr. Haubenberger's research focus- es on the area of movement disorders, where he conducted clinical trials and outcome measure development projects in tremor disorders. He, furthermore, published in the field of clinical genetics, neurophysiology, as well as outcome measures development. At Neurocrine, Dr. Haubenberger is leading clinical development programs as well as a translational biomarkers team. dhaubenberger@neurocrine.com

Emine Bayman, MS, PhD

Dr. Bayman is an Associate Professor of Anesthesia, with a secondary appointment in Biostatistics. She has over nine years of experience providing statistical design expertise to multi-center clinical trials, and has been a member of the NN statistical design team for 5 years. Dr. Bayman has a deep understanding of translating clinical questions to study designs. Dr. Bayman's methodological areas of interest include design of clinical trials and applications of Bayesian methods along with frequentist methods. Her recent work focuses on design of multi-center clinical trials, detection of outliers with Bayesian approach and statistical methods for the prediction of chronic post-surgical pain. emine-bayman@uiowa.edu

Erika Fullwood Augustine, MD, MS

Erika Augustine is Associate Chief Science Officer at the Kennedy Krieger Institute. Her clinical research program focuses on advancing therapeutic development for rare pediatric neurological disorders, with emphasis on comprehensive clinical phenotyping and trial design. Her current NIH-funded work examines trial readiness of clinical outcome measures in the neuronal ceroid lipofuscinoses (Batten diseases). Dr. Augustine also has a strong commitment to education and mentoring. As Diversity Officer for the K12 Child Neurologist Career Development Program, she launched the Minority Research Scholars Program, a collaborative initiative with the Child Neurology Society dedicated to fostering diversity in the next generation of clinician-scientists. augustinee@kennedykrieger.org

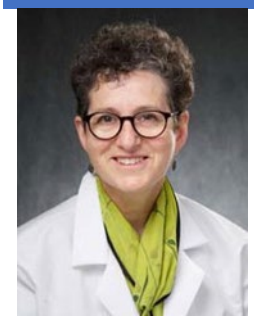
Katherine Mathews, MD, FAAN

Dr. Mathews completed training in pediatrics, child neurology and medical genetics, all at the University of Iowa. She remains at the University of Iowa where she is a Professor of Pediatrics and Neurology, and Vice Chair for Clinical Investigation in the Department of Pediatrics. She directs the pediatric neuromuscular program and co-directs the U of Iowa Muscular Dystrophy Association clinic. She began her research career in basic science and contributed to the genetic mapping of facioscapulohumeral dystrophy (FSHD). She subsequently transitioned to clinical research and is funded by the NIH and CDC, in addition to serving as site PI for many industry-sponsored clinical trials and foundation-supported studies. She sees both pediatric and adult patients with a wide range of neuromuscular diseases in clinic. Her goal throughout these activities has been to improve care of children and adults with neuromuscular diseases and to support development of the next generation of physicians and researchers. katherine-mathews@uiowa.edu

Kert Viele, PhD

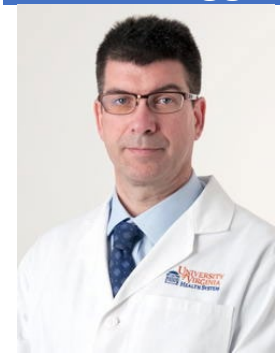
Dr. Viele is a Director and Senior Statistical Scientist with Berry Consultants, LLC. His research interests involve Bayesian computational methods applied to adaptive clinical trials, functional data analysis, mixture modeling, and model selection. Dr. Viele received his Ph.D. from Carnegie Mellon University and prior to joining Berry Consultants in 2010, he was an Assistant and Associate Professor at the University of Kentucky. He has been a principal investigator (or co-PI) on NIH and NSF funded grants and has led statistical collaborations in proteomics, biology, medicine, psychology, and engineering. He has received University teaching awards, served as chair for data safety monitoring boards, and chaired numerous university committees. Dr. Viele has contributed more than 30 papers to the literature and is a former editor of the journal Bayesian Analysis. Dr. Viele was a software architect for FACTS (Fixed and Adaptive Clinical Trial Simulator), a Bayesian adaptive design software product currently licensed to several of the top 20 Pharmaceutical companies in the United States. kert@berryconsultants.net

Laurie Gutmann, MD



Dr. Gutmann has had long-standing clinical trials experience beginning at WVU, enhanced by her four years of experience in the extramural clinical trials program at NINDS/NIH. She served there as program officer for several U01 trials, was a consultant for Coriell Repository, and was actively involved in the Office of Clinical Research activities. She is currently a member of the University of Iowa neuromuscular research divisionand director of the Myotonic Dystrophy Clinic. She is co-PI of the CTMC and Associate Director of Workforce Development for the University of Iowa Institute of Clinical and Translational Studies. She is vice chair of the AAN Education committee, chair of the AC- GME Residency Review Committee and serves as a director for the American Board of Psychiatry and Neurology. laurie-gutmann@uiowa.edu

Mark Quigg, MD



Mark Quigg MD MSc is the TR Johns Professor of Neurology at the University of Virginia. His clinical responsibilities include Medical Directorship of the Clinical EEG, Intensive Monitoring, and Evoked Potential Laboratories as well as founder of the Neurological Sleep Laboratory (now part of the multidisciplinary Sleep Center). His early research work was in the use of experimental epilepsy models in investigation of the interactions among sleep, epilepsy, and circadian regulation. His current research includes clinical investigations in chronobiology, aspects of epilepsy surgery, and serving as the site PI for the NIH-funded NeuroNEXT consortium. His educational activities have included training of fellows in neurophysiology and epilepsy, the chair of the Research and Education Council of the American Epilepsy Society, and a current co-chair of the Clinical Neurophysiology Section of the American Board of Psychiatry and Neurology's Examination Committee.. quiggmarky@gmail.com

Michael Benatar, MD

Dr. Benatar is a Professor of Neurology and the Chief of the Neuromuscular Division in the Department of Neurology at the University of Miami. He is also the first incumbent of the Walter Bradley Chair in ALS Research. Dr. Benatar earned his medical degree from the University of Cape Town in South Africa and his PhD in Neuroscience at Oxford University in the United Kingdom. He also has a Masters in Science in Clinical Research, which he ac- quired at Emory University in Atlanta, Georgia. He completed his Neurology Residency and a Neurophysiology Fellowship at Beth Israel Deaconess Medical Center in Boston, Massachusetts. He is board certified in Neurology, Clinical Neurophysiology and ElectrodiagnosticMedicine. He leads an active program of clinical and translational ALS research that encompasses clinical trials, genetics, and the development of physiological and imaging biomarkers. His research program is devoted to understanding the reasons why therapy development efforts have not been successful in the past and to development of effective treatments for patients with ALS. MBenatar@med.miami.edu

Robin Conwit, MD

Dr. Conwit is a neurologist and program director in the Office of Clinical Research with extensive experience in clinical trials, neuromuscular disease and clinical neurophysiology. She is also a NINDS project scientist for NeuroNEXT. Prior to working at NIH she was a neurology department faculty member at Johns Hopkins subspecializing in electromyography and neuromuscular disease, with clinical trials experience in ALS and diabetic neuropathy. Her prior experience also includes running an ALS Clinic at the Universityof Pittsburgh where she was the principal investigator for ALS clinical trials. Dr. Conwit earned a bachelor's degree from Colgate University, where she was a Phi Beta Kappa graduate, magna cum laude; attended medical school at the University of Buffalo; and completed a residency in Neurology at George Washington University, followed by a fellowship in electromyography at NIH. Her

current interests include Neurological Emergencies Treatment Trials (NETT), neurologic intervention studies, adult neuromuscular diseases including ALS and neuropathies. conwitr@ninds.nih.gov

Roger Lewis, MD, PhD

Dr. Lewis is a Professor at the David Geffen School of Medicine at UCLA and Chair of the Department of Emergency Medicine at Harbor-UCLA Medical Center. Dr. Lewis's expertisecenters on adaptive and Bayesian clinical trials, including platform trials; translational, clinical, health services and outcomes research; interim data analysis; data monitoring committees; and informed consent in emergency research studies. Dr. Lewis is a member of the National Academy of Medicine. He is a Past President of the Society for Academic Emergency Medicine, currently a member of the Board of Directors for the Society for Clinical Trials, and the Senior Medical Scientist at Berry Consultants, LLC, a group that specializes in adaptive clinical trials. He has served as a grant reviewer for the Agency for Healthcare Research and Quality, the Canadian Institutes of Health Research, the Centers for Disease Control and Prevention, the National Cancer Institute of France, the National Institutes of Health, the Patient Centered Outcomes Research Institute and foundations. He is also a member of the Medicare Evidence Development & Coverage Advisory Committee of the Centers for Medicare & Medicaid Services. He serves as the chair of data andsafety monitoring boards for both federally-funded and industry-sponsored clinical trials, including international trials. He is a research methodology reviewer for JAMA and an editor of the JAMA series "JAMA Guides ' to Statistics and Methods." roger@emedharbor.edu

Valerie Durkalski-Mauldin, PhD, MPH

Dr. Durkalski is a Professor of Biostatistics in the Department of Public Health Sciences at the Medical University of South Carolina (MUSC) and the Director of the Data Coordination Unit, an NIH-funded statistical and data coordinating center at MUSC that specializes in the design and coordination of multicenter clinical trials. The DCU serves as the Statistical and Data Coordinating Center (SDCC) for several NIH-funded large multicenter clinical trials and three clinical trial networks. As Director of the DCU, she serves as PI for the SDCC and collaborates on several large multicenter clinical trials in various therapeutic areas and has published and presented on various topics related to the design and con- duct of clinical trials. In addition to these roles, Dr. Durkalski serves on several Data and Safety Monitoring Boards as well as serving as a member of an FDA Advisory Panel. Her research interests are in non-inferiority trials and the implementation and analysis of adaptive confirmatory trial designs. durkalsv@musc.edu

Will Meurer, MD, MS

Dr. Meurer is an Assistant Professor of Emergency Medicine and Neurology with fellowship training in Stroke and Cerebrovascular Disease, along with a Master's degree in Clinical Research Design and Statistical Analysis. His specific clinical and research focus is on adaptive trial design the treatment of acute neurological illness. He has extensive experience in the design and conduct of clinical trials and provides expertise from the entire spectrum of trial development from idea, design, enrollment, analysis and interpretation. wmeurer@med.umich.edu