Clinical Trials Methodology Course
2021

Faculty Bios

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

Michael Benetar, MD, PhD

Dr. Michael Benatar is a Professor of Neurology and Walter Bradley Chair in ALS Research at the University of Miami. He is Executive Director of the University of Miami ALS Center and also serves as Chief of the Neuromuscular Division, and Vice Chair of Clinical & Translational Research in the Department of Neurology. He obtained his medical degree at the University of Cape Town in South Africa and is also trained in both basic neuroscience (DPhil, Oxford) and clinical research methods (Masters in the Science of Clinical Research Emory). He leads an active clinical and translational research program focused on biomarker and therapy development for ALS. He is the principal investigator of the ongoing Pre-Symptomatic Familial ALS (*Pre-fALS*) study as well as the CReATe Consortium, a rare diseases clinical research consortium focused on ALS and related neurodegenerative diseases.
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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

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 dia-betic 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 includingALS and neuropathies. conwitr@ninds.nih.gov

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 conduct 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

Laurie Gutmann, MD

Dr. Gutmann is Professor and Chair of Neurology and Co-Director of the Neuroscience Institute at Indiana University. She is a part of the Clinical Coordinating Center for the NeuroNEXT (NIH Network of Excellence for Neurologic Clinical Trials) in charge of site support, recruitment/retention, and diversity in clinical trials, as well as a similar role for the Healey ALS platform trials. Her research focus has been in neuromuscular disorders and also acute stroke trials. Previously, she was Professor of Neurology at West Virginia University and served as Stroke Director of their comprehensive stroke center and Professor and Vice Chair of Clinical Research at the University of Iowa. She worked for four years as a Program Officer in the NINDS/NIH Office of Clinical Research. She has served as a Director for the American Board of Psychiatry and Neurology, a member of the ACGME RRC, and on the ABMS committee addressing maintenance of certification for physician scientists. She received her BA from Oberlin College and her MD from West Virginia University. Her neurology residency and fellowship in EMG and neuromuscular diseases were at the University of Virginia. lgutmann@iu.edu

Adam Hartman, MD

Dr. Hartman is currently a Physician at NINDS/NIH, serving as a Program Director in the Division of Clinical Research. He oversees the Child Neurology clinical research portfolio at NINDS, providing guidance for the development and implementation of clinical research, developing initiatives aimed and reducing neurological disease burden, and promoting and coordinating research in Neurology.

Dr. Hartman also has an interest in rare diseases, serving as the NINDS representative to the International Rare Disease Research Consortium (IRDiRC) Consortium Assembly and Chair of the Funders Constituent Committee. He is a Consultant Neurologist for the Pediatric Undiagnosed Diseases Program at NIH. adam.hartman@nih.gov

Dietrich Haubenberger, MHSc,MD

Dr. Dietrich Haubenberger is Medical Director for Early Clinical Development at Neurocrine Biosciences in San Diego, CA. Before transitioning to industry in January 2019, Dr. Haubenberger served as Director of the Clinical Trials Unit at the Intramural Research Program and Assistant Clinical Director for Clinical Research at the National Institute of Neurological Disorders and Stroke of the National Institutes of Health in Bethesda, MD, USA. Dr. Haubenberger received his medical degree and training as neurologist at the Medical University of Vienna, Austria, followed by a tenure track position and appointment as Associate Professor of Neurology in 2014. Dr. Haubenberger's research focuses on the area of movement disorders, where he is an expert in tremor disorders. He published in the field of clinical genetics, neurophysiology as well as outcome measures research.

At Neurocrine, Dr. Haubenberger serves as clinical lead for programs in Epilepsy, Huntington Disease, and is leading a Translational Biomarkers Team. haubenberger@me.com

Fred Korley, MD, PhD

Frederick Korley, M.D., Ph.D. is an Associate Professor of Emergency Medicine at the University of Michigan. His research work is focused on the development of novel diagnostics and therapeutics for traumatic brain injury (TBI). With regards to the development of novel diagnostics, Dr. Korley has been awarded two patents for biofluid-based biomarkers for brain injury detection and outcome prognostication. He is also national principal investigator of two federally funded multi-center research studies that are investigating the use of biofluid-based biomarkers for: 1) subject selection in clinical trials; 2) monitoring individual patient response to promising neuroprotective agents. With regards to the development of therapeutics for TBI, Dr. Korley is a principal investigator of an NINDS funded phase II adaptive design clinical trial that is investigating the optimal treatment parameters of hyperbaric oxygen that is most likely to demonstrate improvement in the rate of good neurological outcome versus control in a subsequent confirmatory trial. During the on-going COVID-19 pandemic, Dr. Korley is leveraging his expertise in the testing of novel therapeutics to lead an NHLBI funded multi-center clinical trial of COVID-19 convalescent plasma in outpatients (C3PO) as one of the national co-PIs. He is a member of the National Academies of Sciences, Engineering and Medicine's Committee on Accelerating Progress in Traumatic Brain Injury Research and Care. korley@umich.edu

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 expertise centers 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 edi- tor of the JAMA series "JAMA Guides to Statistics and Methods." roger@emedharbor.edu

Patrick Lyden, MD

Dr. Lyden is Professor of Physiology & Neuroscience and Neurology at the Zilkha Neurogenetic Institute in the Keck School of Medicine at USC. Dr. Lyden helped lead the pivotal NINDS t-PA for Acute Stroke Trial, the first proven therapy for stroke. He is recognized globally for leadership in stroke therapy, having led large, multi-national trials for NIH and industry. Dr. Lyden is the Principal investigator of the NINDS-sponsored Stroke Preclinical Assessment Network, or SPAN, the first multi-site trial intended to identify candidate treatments likely to succeed in human clinical trials. He is the Chair-Elect of the Stroke Council of the American Heart Association/American Stroke Association. Dr. Lyden has been elected a Fellow of the American Academy of Neurology, American Neurology Association, American Heart Association, and the European Stroke Organization. In 2019 he was awarded the prestigious William M. Feinberg Award for Excellence in Clinical Stroke by the American Heart Association. plyden@usc.edu

Will Meurer, MD, MS

Dr. Meurer is an Associate 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. He is contact PI of the 50-site ICECAP trial for therapeutic hypothermia after cardiac arrest. He also serves as a multi-PI of the REACH-OUT randomized trial of text messaging to reduce hypertension in patients sent home from the ED and as a multi-PI of the DIZTINCT-2 project focused on improving the care of ED patients with acute vertigo. 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

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

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

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 prin-cipal investigator (or co-PI) on NIH and NSF funded grants and has led statistical collabora-tions in proteomics, biology, medicine, psychology, and engineering. He has received Uni- versity 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