Virtual Clinical Trials: Challenges and Opportunities: A Workshop

Committee

Linda S. Brady

Co-Chair

Dr. Brady serves as the Director of the Division of Neuroscience and Basic Behavioral Science at the National Institute of Mental Health (NIMH). In this role, she provides scientific, programmatic, and administrative leadership for an extramural research program portfolio in basic neuroscience to support NIMH's mission of transforming the understanding and treatment of mental illnesses. Dr. Brady has directed programs in neuropharmacology, drug discovery, and clinical therapeutics and organized Consortia focused on ways to accelerate the development and clinical application of radiotracers in clinical research. She has provided leadership for many programs, including: Development and Application of PET and SPECT Imaging Ligands as Biomarkers for Drug Discovery and for Pathophysiological Studies of CNS Disorders, the National Cooperative Drug/Device Discovery/Development Groups for the Treatment of Mental Disorders, and First in Human and Early Stage Clinical Trials of Novel Investigational Drugs or Devices for Psychiatric Disorders. Dr. Brady serves as co-chair of the Neuroscience Steering Committee for the Biomarkers Consortium, a public-private research partnership of the Foundation for the National Institutes of Health (FNIH) that focuses on discovery, development, and qualification of biological markers to support drug development, preventive medicine, and medical diagnostics. From 2004-2013, she co-led the Molecular Libraries and Imaging Program, a trans-NIH Common Fund initiative to provide biomedical researchers access to small organic molecules that can be used as chemical probes to study the functions of genes, cells, and biochemical pathways in health and disease. Dr. Brady was trained in pharmacology and neuroscience. She completed her Ph.D. at Emory University School of Medicine, followed by post-doctoral work and research positions at the Uniformed Services University of the Health Sciences and the NIMH Intramural Research Program. She is the author of more than 70 peer reviewed scientific publications and is a member of the Society for Neuroscience and a Fellow in the American College of Neuropsychopharmacology. Dr. Brady has received NIH Director's Awards and NIH Merit Awards in recognition of her activities in biomarker development and drug development for mental disorders.

S. Claiborne Johnston

Co-Chair

Dr. Johnston has served as the inaugural Dean of the Dell Medical School at the University of Texas, Austin since March 2014. In this position, he plans to build a world-class academic medical center focused on providing new models of education and healthcare delivery. He is also Professor of Neurology, specializing in stroke care and research. Clay arrived in Austin from the University of California, San Francisco, where he directed the Clinical and Translational Science Institute, overseeing the planning, development, and implementation of a $112-million, five-year, National Institutes of Health (NIH) grant award, the second largest among the 60-member national CTSA consortium. Working with a team of 300+ faculty and staff serving all four schools at UCSF, Clay positioned the Institute as a catalyst in efforts to accelerate research to improve health on campus and throughout the University of California system. He founded the Center for Healthcare Value at UCSF in order to engage faculty and trainees in lowering the costs of healthcare while improving quality. He was also instrumental in cultivating and securing partnerships with leading biotech companies, foundations, and private funders. In his role as Associate Vice Chancellor of Research, Clay was integrally involved in efforts to realize the University's vision of being the world's preeminent health sciences innovator. After receiving his undergraduate education at Amherst College, he completed medical school at Harvard University. He later received a PhD in epidemiology from the University of California, Berkeley, and was a resident in Neurology at UCSF, where he later trained in Vascular Neurology. During his 20 years at UCSF, he rose the academic ranks to Professor of Neurology and Epidemiology, and directed the Stroke Service. Clay has authored more than 300 publications in scientific journals and has won several national awards for his research and teaching. In particular, he has published extensively in the prevention and treatment of stroke and transient ischemic attack. He is perhaps best known for his studies describing the short-term risk of stroke in patients with transient ischemic attack and identifying patients at greatest risk, and also for his work related to measuring the impact of research. He has led several large cohort studies of cerebrovascular disease and three international multicenter randomized trials, two of which are ongoing.

Steven Anderson

Member

Dr. Anderson is currently the Director of the Office of Biostatistics and Epidemiology (OBE) at the FDA Center for Biologics Evaluation and Research (CBER). He provides leadership for all CBER statistical, epidemiological and benefit-risk assessment programs. Previously, Dr. Anderson had been the Deputy Director for OBE since 2005. In 2001, he was hired by CBER as the Associate Director for Risk Assessment to establish a program in quantitative risk assessment for biologic products including vaccines, blood products and others. Since his arrival at FDA he has led numerous important risk assessment projects and epidemiological studies. He led the first studies at FDA using Centers for Medicare & Medicaid Services (CMS) data to estimate blood utilization and address important blood product safety questions of regulatory concern. He has conducted collaborative studies using the FDA Sentinel system and CMS data to evaluate the safety of blood products and vaccines and worked to integrate use of these data systems into CBER's regulatory processes to improve biologic product safety evaluations and surveillance. Dr. Anderson earned a Master's Degree in Public Policy (MPP) at Georgetown University and while there developed the first quantitative risk assessment for antimicrobial resistant pathogens. Dr. Anderson received his PhD in Biology from the University of Cincinnati where he worked on biochemistry, drug resistance and ion pumps, pathogenicity and genomics of unique tropical disease pathogens. He has published a number of articles in biologic product safety, risk assessment, epidemiology, pharmacoepidemiology, infectious diseases, biologics safety, and genomics and protein structure/targeting.

Robert M. Califf

Member

Dr. Califf is the Donald F. Fortin, M.D., Professor of Cardiology. He is also Professor of Medicine in the Division of Cardiology and remains a practicing cardiologist. Dr. Califf was the Commissioner of Food and Drugs in 2016-2017 and Deputy Commissioner for Medical Products and Tobacco from February 2015 until his appointment as Commissioner in February 2016. Prior to joining the FDA, Dr. Califf was a professor of medicine and vice chancellor for clinical and translational research at Duke University. He also served as director of the Duke Translational Medicine Institute and founding director of the Duke Clinical Research Institute. A nationally and internationally recognized expert in cardiovascular medicine, health outcomes research, healthcare quality, and clinical research, Dr. Califf has led many landmark clinical trials and is one of the most frequently cited authors in biomedical science, with more than 1,200 publications in the peer-reviewed literature. Dr. Califf is a Member of the National Academy of Medicine, one of the highest honors in the fields of health and medicine. Dr. Califf has served on numerous committees, and he has served as a member of the FDA Cardiorenal Advisory Panel and FDA Science Board's Subcommittee on Science and Technology. Dr. Califf has also served on the Board of Scientific Counselors for the National Library of Medicine, as well as on advisory committees for the National Cancer Institute, the National Heart, Lung, and Blood Institute, the National Institute of Environmental Health Sciences and the Council of the National Institute on Aging. He has led major initiatives aimed at improving methods and infrastructure for clinical research, including the Clinical Trials Transformation Initiative (CTTI), a public-private partnership co-founded by the FDA and Duke. He also served as the principal investigator for Duke's Clinical and Translational Science Award and the NIH Health Care Systems Research Collaboratory coordinating center and Co-PI of the Patient Centered Outcomes Research Institute Network.

Joshua C. Denny

Member

Dr. Denny is a Professor of Biomedical Informatics and Medicine. He completed an internal medicine residency as a Tinsley Harrison Scholar at Vanderbilt. His interest in medical informatics began while in medical school with the development of a concept-based curriculum database to improve medical education. Other interests include natural language processing, accurate phenotype identification from electronic medical record data, and using the electronic medical record to discover genome-phenome associations to better understand disease and drug response, including the development of the EMR-based phenome-wide association (PheWAS He has been involved with the NIH Precision Medicine Initiative and currently leads the All of Us(sm) Research Program Data and Research Center. He is also PI for Vanderbilt sites in the Electronic Medical Records and Genomics (eMERGE) Network, Pharmacogenomics Research Network (PGRN), and the Implementing Genomics Into Practice (IGNITE) Network. At Vanderbilt, he is also part of the PREDICT (Pharmacogenomic Resource for Enhanced Decisions in Care and Treatment)program, which prospectively genotypes patients to tailor drug response.Dr. Denny serves on several local committees and remains active in teaching medical students and clinical roles. He received the Homer Warner award from the American Medical Informatics Association (AMIA) in 2008 and 2009. He received the AMIA New Investigator Award in 2012 and was elected into the American College of Medical Informatics in 2013.

Robert Gentleman

Member

Dr. Gentleman’s career has spanned more than 30 years. Prior to joining Genentech, Dr. Gentleman was a member of the Fred Hutchinson Cancer Research Center, where he was the Head of the Computational Biology Department. Dr. Gentleman served as a professor at Harvard University, the University of Auckland, and the University of Waterloo. During his tenure at Harvard, Dr. Gentleman founded the Bioconductor Project, an open source, open development software project to provide tools for the analysis and comprehension of high-throughput genomic data.In addition to his industry and academic experience, Dr. Gentleman recently served as member of the Board of Directors of Revolution Analytics where he helped guide the company through a successful acquisition by Microsoft. He has been awarded the Benjamin Franklin Award, an award for Open Access in the Life Sciences presented by the Bioinformatics Orgainization and is Fellow of the International Society for Computational Biology (ISCB). Dr. Gentleman, along with Ross Ihaka at the University of Auckland, is also recognized as one of the originators of the R programing language, a widely-used programming language software environment for statistical computing and graphics. Dr. Gentleman earned a Bachelor of Science in Mathematics from The University of British Columbia and holds a Doctor of Philosophy, Ph.D., in Statistics from the University of Washington.

Robert Goodwin

Member

Robert Goodwin is Vice President and WW Head, Safety, Evaluation and Reporting in the World Wide Safety and Regulatory Operations at Pfizer Pharmaceuticals. Mr. Goodwin brings over 19 years of experience in all facets of clinical operations including statistics, data acquisition, reporting and pharmacovigilance. He has established a track record of achieving cost reductions while increasing productivity through restructuring, process transformation and system reengineering, utilizing methods such as Lean and Six Sigma. Mr. Goodwin has held numerous positions within Pfizer Pharmaceuticals, Bayer Corporation, and the VA Medical Center in diverse roles, beginning as a biostatistician to current management roles in Pharmacovigilance.

Kathy Hudson

Member

Dr. Hudson is the former Deputy Director for Science, Outreach, and Policy at the National Institutes of Health (NIH). Dr. Hudson led the science policy, legislation, communications, and outreach efforts of the NIH and served as senior advisor to the NIH director. She directed the agency's efforts to advance biomedical science through policy development and innovative projects and partnerships. Dr. Hudson created major new strategic and scientific initiatives including the National Center for Advancing Translational Sciences, the BRAIN Initiative, the NIH Precision Medicine Initiative, and the Cancer Moonshot. She led the development of major policies that enable science to advance more rapidly including enhancing clinical trials, data sharing, and participation of patients as partners in research. She was the key NIH architect responsible for modernizing the regulations governing research with human subjects professional experience includes serving as the Acting Deputy Director of the National Center for Advancing Translational Sciences, NIH; the NIH Chief of Staff; the Assistant Director of the National Human Genome Research Institute, NIH; and the founder and Director of the Genetics and Public Policy Center at John Hopkins University. Also at Hopkins, Dr. Hudson was an Associate Professor in the Berman Institute of Bioethics, Institute of Genetic Medicine, and Department of Pediatrics.Dr. Hudson holds a Ph.D. in Molecular Biology from the University of California at Berkeley, an M.S. in Microbiology from the University of Chicago, and a B.A. in Biology from Carleton College.

David H. Ledbetter

Member

Dr. Ledbetter is Executive Vice President and Chief Scientific Officer at Geisinger Health System. He came to Geisinger from Atlanta's Emory University School of Medicine where he was the Robert W. Woodruff Professor and Director of the Division of Medical Genetics in the Department of Human Genetics.Dr. Ledbetter previously held academic and leadership positions at the University of Chicago, the National Center for Human Genome Research (now NHGRI) at NIH and Baylor College of Medicine. He is a graduate of Tulane University and earned his doctorate at the University of Texas-Austin. After his early discovery of the genetic cause of Prader-Willi syndrome and Miller-Dieker syndrome, Dr. Ledbetter has focused his research efforts on discovering the underlying etiology of childhood developmental disabilities such as autism, and the translation of new genomics technologies into clinically useful genetic tests for early diagnosis and intervention.His current research interest includes leveraging the massive amount of genomics data generated during routine patient care for knowledge generation and integration of this information into electronic health records in a clinically useful manner.

David McCallie, Jr.

Member

Dr. McCallie is Senior Vice President for Medical Informatics at Cerner Corporation, a Cerner Engineering Fellow, and member of the American College of Medical Informatics. He is responsible for a research team focused on innovations in clinical informatics. His current research includes applications of semantic content extracted from the EHR using natural language parsing and machine learning techniques. In addition to his duties at Cerner, he frequently engages with industry collaborators to create vendor-neutral standards that foster interoperability. He was a co-founder of CommonWell Health Alliance, a multi-vendor trade association devoted to national-scale interoperability. Prior to that, he helped create Direct, a national standard for secure clinical messaging. Dr. McCallie served for 6 years on the ONC HIT Standards Committee, and was recently active with the TEFCA task force. He is a member of the HL7 Advisory Council, and is one of the founders of the Argonaut Project, a multi-vendor collaborative promoting the development of API-based interoperability standards that leverage HL7's FHIR standard. Dr. McCallie earned a BSEE from Duke, and his MD from Harvard.

Rebecca D. Pentz

Member

Dr. Rebecca D. Pentz is Professor of Research Ethics, Winship Cancer Institute, Emory University School of Medicine, Atlanta, Georgia. She specializes in empirical ethics research with a focus on informed consent for targeted molecular therapies, immunotherapy and early drug development. She also works extensively at Grady Memorial Hospital on informed consent for underserved populations. She advises the leadership and crafts policy for organizational ethics issues, such as drug shortages and provision of charity care. She provides research ethics consultation for all Emory Investigators across the University. Dr. Pentz is the Director of the Davidson College Winship Impact Fellowship and mentors post-baccalaureate Ethics Fellows who intend to attend medical school after the fellowship. The ethics research team designs ethics companion studies for the multi-project grants submitted by Winship Cancer Institute, and therefore studies wide ranging issues from the use of botanicals to health disparities. We work closely with the Winship Tissue Bank on proper informed consent and return of results. Dr. Pentz represents Emory on various national data safety monitoring boards and scientific advisory committees, including the Bone Marrow Transplant Clinical Trials Network, GTEx, National Academies of Medicine, St. Jude and the National Disease Research Interchange. Before coming to Emory, Dr. Pentz reconstituted and directed the Clinical Ethics service at The University of Texas M.D. Anderson Cancer Center for a decade. She is a Seattle native and returns as frequently as possible to a family home on Puget Sound. Dr. Pentz' other interests include research in the emergency setting and promoting an ethical research culture.

Leonard Sacks

Member

Dr. Sacks is the acting Deputy Director of the Office of Medical Policy within the FDA’s Center for Drug Evaluation and Research, initially joined the FDA in 1998 as a medical reviewer in the Office of New Drugs and has subsequently held several positions within the agency. Besides his involvement in the design and analysis of clinical trials, he maintains a special interest in tuberculosis and other tropical diseases and has published and presented extensively on these topics. Board certified in internal medicine and infectious diseases, Sacks is also an associate clinical professor of medicine at George Washington University. He received his medical education in South Africa and completed fellowships in the U.S. in immunopathology and infectious diseases.

Todd Sherer

Member

Dr. Sherer has been the Chief Executive Officer of Michael J. Fox Foundation for Parkinson’s Research since May 2011. Dr. Sherer joined Michael J. Fox Foundation as Associate Director of Research Programs in April 2004, and served as Vice President of Research Programs since June 2006 and Chief Program Officer since November 2010. In this role, he leads a team that proactively manages the world’s largest privately funded Parkinson’s disease research portfolio. Every year, this team reviews up to 800 grant proposals to fund approximately $45 million in Parkinson’s research, with a strong focus on pre-clinical therapeutic development and clinical research. At any given time, Dr. Sherer’s team manages up to 300 active grants, working closely with academic and industry scientists to help speed promising new discoveries from research labs to pharmacy shelves. In addition to research funding, Dr. Sherer’s team leads an effort to engage the pharmaceutical industry in Parkinson’s disease drug development and encourage and expand subject participation in clinical research Prior to joining the Foundation, Dr. Sherer was a respected Parkinson’s disease bench researcher with over 30 peer-reviewed scientific publications.

Kelly Simcox

Member

Kelly Simcox, Head of the Americas, Clinical Study Units and Clinical Operations joined Sanofi (formerly Rhone-Poulenc Rorer, and Aventis and Sanofi-Aventis) in 1993. She has been a role model regarding staff development and team building, fostering a business mindset, as well as a culture of excellence and continuous improvement. Starting her career in toxicology, Kelly's heart is in the full time cycle of drug development. Post her preclinical experience, Kelly moved to clinical development as a monitor and now manages a group of over 650 clinical operations in the Americas. A season global pharmaceutical executive, Kelly has a proven track record in clinical development, project management, and global operations. Kelly has significant leadership experience, having served as one of only 70 leaders in R&D to be selected to participate in the exclusive Evolve Center for Leadership training. Kelly's contributions have been recognized among the industry as she was honored as a Healthcare Businesswomen's Association Rising Star in 2012. Kelly received her undergraduate degree from Muhlenberg College, Allentown, PA and received a Master's Degree from Temple University, Philadelphia, PA. She represents her member company among industry initiatives such as TransCelerate BioPharma Inc.

John Wilbanks

Member

John Wilbanks is the Chief Commons Officer at Sage Bionetworks. Previously, Wilbanks worked as a legislative aide to Congressman Fortney "Pete" Stark, served as the first assistant director at Harvard's Berkman Center for Internet & Society, founded and led to acquisition the bioinformatics company Incellico, Inc., and was executive director of the Science Commons project at Creative Commons. In February 2013, in response to a We the People petition that was spearheaded by Wilbanks and signed by 65,000 people, the U.S. government announced a plan to open up taxpayer-funded research data and make it available for free. Wilbanks holds a B.A. in philosophy from Tulane University and also studied modern letters at the Sorbonne.