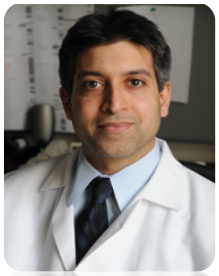
CRN Learnings from Vascular to Neurovascular

Monday, December 7, 2020
VIRTUAL Meeting
Biographies

DAISI CRN LEADS



Sameer A. Ansari, MD, PhD is an academic interventional neuroradiologist at Northwestern Memorial Hospital, Professor in the Departments of Radiology, Neurology and Neurological Surgery, Northwestern University Feinberg School of Medicine. He received his medical and doctoral degrees from Jefferson Medical College, Philadelphia, completed a Diagnostic Radiology residency at the University of Illinois, Chicago, and both Diagnostic and Interventional Neuroradiology fellowships at the University of Michigan, Ann Arbor. Dr. Ansari is a nationally recognized expert in minimally invasive percutaneous and endovascular procedures of the brain, head/neck and spine. As an NIH funded principal investigator, Dr. Ansari's basic science research interests are centered on MR imaging based patient selection and risk stratification of various neurovascular pathologies, particularly inflammation imaging of intracranial atherosclerotic disease and intracranial aneurysms. Furthermore, his clinical research interests have centered on improved diagnostic performance of 3D rotational digital subtraction angiography and cone beam CT angiography.

David S. Liebeskind, MD, FAAN, FAHA, FANA, FSVIN, FWSO is Professor of Neurology at the University of California, Los Angeles (UCLA) where he is Director of Outpatient Stroke and Neurovascular Programs. He is Director of the Neurovascular Imaging Research Core, leading global efforts to advance data science and precision medicine of stroke imaging for prevention, acute therapies and recovery after stroke. He is Director of the UCLA Cerebral Blood Flow Laboratory, Director of the UCLA Stroke Center and Director of the UCLA Vascular Neurology Residency Program, training the next generation of vascular neurologists and stroke experts. He trained in chemical engineering at Columbia University and completed his MD at New York University School of Medicine. Postgraduate medical training included internship at Beth Israel Hospital, Boston and neurology residency at UCLA. After his residency, he completed a fellowship in stroke and cerebrovascular disease at UCLA and subsequently joined the faculty in the Departments of Neurology and Radiology at the University of Pennsylvania. He has advanced education, research and clinical care of stroke at UCLA since 2004. He has maintained extensive clinical activity across a broad range of cerebrovascular disorders ranging from carotid disease to unusual causes of stroke. Clinical expertise includes cerebral venous thrombosis, arterial dissection, moyamoya syndrome and other causes of stroke in the young. His principal research interests include novel neuroimaging approaches to elucidate fundamental pathophysiology of cerebrovascular disease in humans with a particular focus on the collateral circulation. His work on collateral perfusion in acute ischemic stroke draws on advances in noninvasive, multimodal CT and MRI and detailed analyses of digital subtraction angiography. As Director of the

Neurovascular Imaging Research Core, he runs an angiography and imaging core laboratory that has participated in central readings of MERCI, Multi MERCI, IMS-III, TREVO EU, TREVO 2, SWIFT, STAR, SWIFT-PRIME, DAWN, TREVO Registry, STRATIS, HERMES and many other stroke studies. His research on collaterals in intracranial atherosclerosis complements his work on acute stroke, utilizing computational fluid dynamic modeling and estimates of fractional flow to predict risk of ischemia and reperfusion hemorrhage. He has intertwined his scientific research and clinical interests in the longitudinal evaluation of blood flow in cerebrovascular disorders to help improve outcomes of all stroke patients.

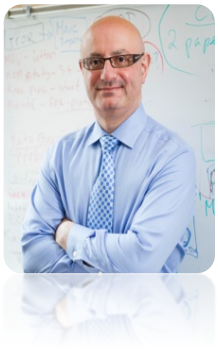
Carlos Pena, MS, PHD is Division Director for the Division of Neurological and Physical Medicine Devices, in the Office of Device Evaluation, Center for Devices and Radiological Health (CDRH), at the U.S. Food and Drug Administration (FDA). Dr. Peña is involved in all aspects of the safety and effectiveness review of neurostimulation, neurodiagnostic, neurosurgical, neurotherapeutic, and physical medicine devices. Prior to joining CDRH, Dr. Peña served on detail as Assistant Director for Emerging Technologies in the Office of Science and Technology Policy (OSTP), in the Executive Office of the President of the United States. His areas of expertise included science, technology, policy, analysis, and regulatory matters related to biology, neuroscience, biotechnology, emerging technologies, and agriculture. Before joining OSTP/FDA, Dr. Peña served at the National Institute of Neurological Disorders and Stroke, National Institutes of Health. He completed his neurosciences doctoral training at Case Western Reserve University in Cleveland, Ohio. He also attended the University of Connecticut for the Masters in Comparative Physiology, and the City College of New York, City University of New York, where he received a Bachelors specializing in Developmental Biology.

Adnan Siddiqui, MD, PhD, FAANS, FACS, FAHA is Vice-Chairman and Professor of Neurosurgery at the State University of New York at Buffalo. Dr. Siddiqui has special interest and expertise in the performance of complementary microsurgical, radiosurgical and endovascular techniques for the comprehensive management of cerebrovascular conditions. Dr. Siddiqui serves as Director of Neuroendovascular Research, Kaleida Health Stroke Service as well as the University at Buffalo Canon Stroke and Vascular Research Center. He also serves as the Chief Medical Officer for the Jacobs Institute. Dr. Siddiqui is married and has three children. He is a proud Buffalonian who is challenged and invigorated by taking care of neurosurgical patients and their families. He is grateful for the opportunity to work at the Gates Vascular Institute, a facility with some of the world's best technologies, where he and other experts can interact with leading researchers in order to make scientific advancements.

MDEpiNet LEADS

Danica Marinac-Dabic, MD, PhD, MMSc, FISPE serves as the Associate Director of the Office of Clinical Evidence and Analysis, at the Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH). Prior to this position she was the Director of the CDRH Division of Epidemiology. Dr. Marinac-Dabic has over twenty-five years of experience in obstetrics, gynecology, perinatal epidemiology, and regulatory science and surveillance settings. Under Dr. Marinac-Dabic's leadership, in 2010 FDA/CDRH launched its Medical Device Epidemiology Network (MDEpiNet) Initiative to develop national/international infrastructure and innovative methodological approaches for conducting robust studies and surveillance to improve medical device safety and effectiveness understanding throughout the device life cycle through Public Private Partnership with

academia and other stakeholders. Dr. Marinac-Dabic also leads the development of the International Consortium of Orthopedic Registries (ICOR) Initiative (launched in 2011) focusing on development and utilization of distributed model of over 30 national and international orthopedic registries as well as International Consortium of Cardiac Registries (ICCR) in 2013 and International Consortium of Vascular Registries (ICVR) in 2014, designed to expand collaborative work between international cardiovascular registries and integrate it into medical device regulatory science, active surveillance and comparative effectiveness and safety research. Dr. Marinac-Dabic serves as a Fellow of the International Society of Pharmaco-epidemiology and Therapeutic Risk Management (ISPE), FDA Principal and the member of the Executive Operations Committee of the MDEpiNet Public Private Partnership, member of the Steering Committee of the STS/ACC Transcatheter Valve Therapies (TVT) Registry, National Breast Implants Registry (NBIR) and Oxford-based IDEAL Collaborative, EXCITE International Collaborative and International Consortium of Breast Registry Activities (ICOBRA). From 2015-2018 Dr. Marinac-Dabic has led the Registry Working Group at the International Medical Device Regulators Forum (IMDRF) to develop essential principles for international convergence of registrygenerated data for regulatory decision making. Since 2017, she leads the PCORTF- funded effort to establish Women's Health Coordinated Registry Network. She authored several book chapters, several dozens of manuscripts and has given hundreds of invited presentations on various topics in the fields of medical device epidemiology and surveillance, registry development and utilization for medical device research, innovative methods for evidence synthesis and comparative effectiveness and safety research. Prior to coming to FDA, Dr. Marinac-Dabic garnered experience in obstetrics, gynecology, and epidemiology in the academic and hospital settings as well as teaching experience in academic environment.



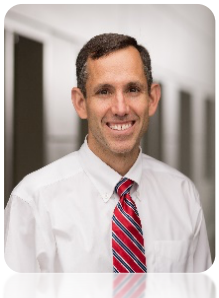
Art Sedrakyan, MD, PhD, is a Professor at Weill Cornell Medical College and is also leading the FDA Medical Device Epidemiology (MDEpiNet) Coordinating, Science and Infrastructure Center. At Cornell, he directs the Institute for Health Technologies and Interventions. He is a trained CT surgeon and a graduate of Johns Hopkins University with a Ph.D. in Health Policy and Management. He worked in the Government for five years before joining Cornell University. Prior to appointments at the government he worked in the United Kingdom and has registry research, evidence synthesis and teaching experience from Royal College of Surgeons (RCS) of England and London School of Hygiene (LSHTM). He is currently serving as the Vice-Chair of Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) and is serving on MEDCAC from June 1, 2010. Dr. Sedrakyan is also the Vice-Chair of the IDEAL initiative with special interest/leadership area in devices and co-editor-in-chief of BMJ Surgery, Interventions, & Health Technologies. He initiated (with Dr. Danica Marinac-Dabic) and is principal investigator of the FDA's International Consortium of Orthopedic Registries and International Consortium of Cardiovascular Registries (ICCR).

Speakers

Adam Beck, MD, FACS, is an Associate Professor and the Division Director of Vascular Surgery and Endovascular Therapy at the University of Alabama at Birmingham (UAB). He is an internationally known expert in the treatment of aortic diseases, especially those involving the branched segments of the aorta. He also has an interest in health services research and surgical quality improvement and serves as the U.S. Director of the International Consortium of Vascular Registries (ICVR) and the Chairman of the Arterial Quality Council for the Society for Vascular Surgery Vascular Quality Initiative (SVS VQI), among a number of other roles in the SVS VQI. He maintains a busy clinical practice at UAB, with a focus on the treatment of complex aortic diseases.

Mairsíl Claffey, Director Clinical Science and Strategy, Ischemic Stroke, Cerenovus, has enjoyed 25 year long career in the Medical Device business. Mairsíl joined Cerenovus through the Neuravi acquisition. There she was responsible for the company's clinical, regulatory, and quality, activities and designed and led the ARISE studies of the EmboTrap device. Mairsíl initially qualified, and worked, as a polymer engineer before moving into quality and regulatory management. Her leadership career in medical devices research started when she joined Irish start up, MedNova Ltd. as QARA manager in1997. Promoted to RA Director, Mairsíl defined and led their QARA function, and implemented successful strategies for the approval of MedNova's product range. Subsequent to the acquisition of MedNova Ltd. by Abbott Vascular, Mairsíl held the position of Director of Regulatory Affairs Europe, with Abbott Vascular, working with the european business unit, before being promoted to Director of Regulatory Affairs, Carotid Global. After seven years with Abbott Vascular, Mairsíl joined Teleflex Inc. where she worked for five years culminating in the position of VP International Quality and Regulatory, a role leading an international team of over three hundred. In 2012, Mairsíl joined the Neuravi team to lead quality, regulatory, and clinical with a view to securing European and US approval of a novel stentretriever, EmboTrap. While completing a PG dip Clinical Research, through the National University of Ireland, Galway, Mairsil led the study design and execution of the successful ARISEII study, was subsequently a member of the team honoured with the Johnson medal for innovation in recognition of their roles in the success of the EmboTrap.

Del Kjos serves as the Director of Clinical Research and Market Access Strategy and the Director of Marketing/Franchise Leader at Stryker Neurovascular, the Director International Cardiology Marketing at Boston Scientific, and the Director Business Development at Salu, Inc. Internet-based healthcare services. He also holds positions in Marketing & Sales at Hudson RCI, a Teleflex Medical Company and Sales at ICI Pharma/ICI Americas, Inc.



Philip P. Goodney, MD, MS, is a vascular surgeon, health services researcher who maintains an active clinical practice in vascular surgery, at both Dartmouth Hitchcock and the VA Medical Center in White River Junction, and he enjoys performing a wide spectrum of open and endovascular procedures for patients with vascular disease. After joining the faculty at Dartmouth in 2008, he received an NIH K08 Career Development Award in 2010, and the Lifeline Research Award from the Society for Vascular Surgery (SVS) in 2011. Over the last eight years, with funding from NIH, AHRQ, VA, FDA, PCORI, and others, Dr. Goodney has enjoyed studying ways to help patients obtain the best results when they face surgical treatments using observational approaches and clinical trials. Within the Vascular Quality Initiative, the SVS's quality improvement program, Dr. Goodney is Chair of the Research Advisory Committee. Wsithin the VA Outcomes Group, he co-leads mentorship activities for 15 clinician-investigators, recruits and trains fellows, and organizes a data analytic core. With Drs. Art Sedrakyan and Jack Cronenwett, he leads efforts funded by FDA to develop the Vascular Implant Surveillance and Interventional Outcomes Network (VISION), a claims/registry-based surveillance distributed research network for vascular care. He is a member of the American Surgical Association, and serves on a variety of editorial boards for journals in surgery, cardiovascular care, and health services research.

Scott Janis, MD has been with the National Institute of Neurological Disorders and Stroke (NINDS) since 2001 and is currently a Program Director in the Division for Clinical Research. His main areas of scientific interest include clinical trials in stroke. He oversees the NINDS Stroke Trials Network StrokeNet which includes 11 ongoing studies in stroke treatment, prevention and recovery. Prior to joining NINDS, Dr. Janis received his training in Neuroscience from the School of Medicine at the Georgetown University Medical Center and the Center of Molecular and Behavioral Neuroscience at Rutgers University.

Jialin Mao, MD, PhD, is an Assistant Professor in Healthcare Policy and Research Research in the Division of Comparative Effectiveness and Outcomes Research, working with Dr. Art Sedrakyan. She works on surgical and device outcomes research, with a primary focus on population level studies. Dr. Mao earned her MD degree from Shanghai Jiao Tong University School of Medicine in 2011 and completed an internship and part of her residency in General Surgery at Ruijin Hospital in Shanghai, China. She earned her Master of Science in Epidemiology from Harvard School of Public Health in 2013. Her research experience includes working at Shanghai Jiao Tong University School of Medicine on a cell biology research project focusing on diabetic retinopathy, at Harvard School of Public Health on a cancer epidemiology project and a meta-analysis project on the use of probiotics to enhance the protectiveness of the influenza vaccination, and at Beth Israel Deaconess Medical Center on studies assessing quality of life among nephrectomy patients.

Nagesh Uppuluri, PhD, MBA Nagesh Uppuluri leads the Medical and Clinical Affairs function for Medtronic Neurovascular and has been in the Med Tech space for >15 yrs. He oversees clinical and medical functions globally that include clinical research, regulatory interactions, medical education and strategic alliances. He was responsible for global execution of key studies that led to the approval of Solitaire for use in treating AIS and expanded indications of the Pipeline embolization device. He continues to lead research activities that bring new devices and indications to the global market.Nagesh holds a PhD in Biochemistry, and an MBA from University of Texas at Austin and lives in Orange County, CA.