



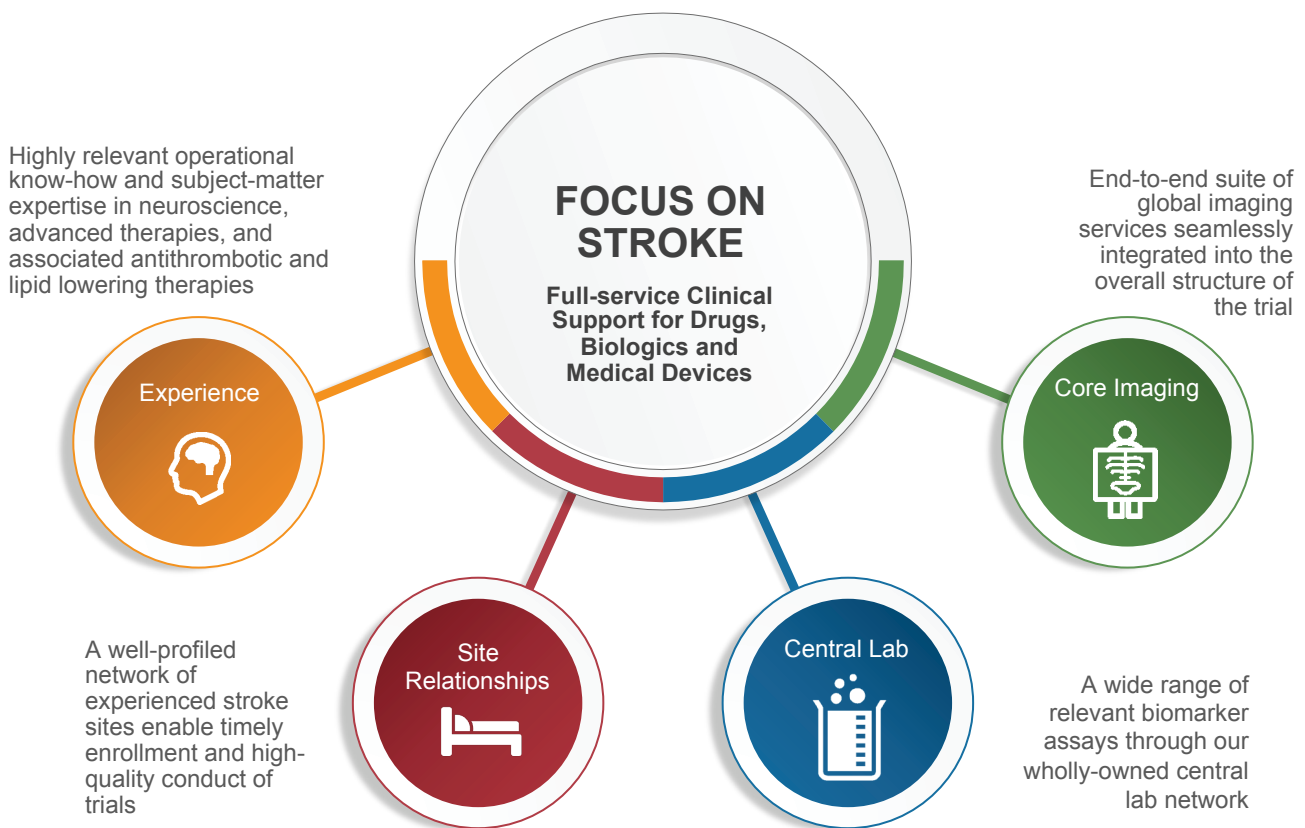
# STROKE CLINICAL RESEARCH

Experts. Experience. Execution.

## Deep Dive: Stroke Clinical Research

*Accelerate your next stroke study with Medpace's noted medical and regulatory experts, highly experienced clinical trial management teams, central labs, and core imaging labs.*

As a therapeutically-focused CRO, Medpace specializes in the design and conduct of global trials in neuroscience clinical research, including stroke. We bring a global footprint, strategic medical, regulatory and operational leadership as well as fully integrated Central Labs and Core Imaging Services to accelerate stroke studies.



## Experience



Medpace has in-house neurologists, imaging specialists, and operational teams with relevant and recent stroke experience as well as backgrounds (and publications) in stroke-specific scientific research. We have designed and conducted numerous stroke detection and stroke prevention studies and our experience includes direct administration of drug to brain, either intraventricularly or intrathecally. Our biopharmaceutical and medical device experience spans:

- Advanced therapies including stem cell
- Restorative therapies
- Thrombolytic therapies
- Preventative therapies (Medpace is known for its deep expertise and experience in vascular research and development, including
- Medical device therapies

## Recruitment and Global Site Relationships



Recruiting patients for stroke studies requires a partner who has strong relationships with a well-profiled network of experienced stroke sites, and who can manage complex logistics, negotiations, education, and site maintenance to ensure success. Medpace has earned a reputation for managing highly complex studies and has the relationships to work with the complex and evolving referral networks (hub and spoke), community hospitals, comprehensive stroke centers, and other acute care settings to drive successful patient enrollment.

Medpace provides site training and certification processes to obtain reliable assessments on clinical scales including mRS, NIHSS & Barthel, PROs and QoLs.

## Scientifically-Driven Clinical Research

Medpace is unique in its approach to clinical research. The Medpace model gives you the advantage of early and ongoing insight and guidance from therapeutic experts throughout trial design and execution. Our highly experienced medical doctors provide strategic direction for study design and planning, train operational staff, work with Investigators, provide medical monitoring, and meet with regulatory agencies. In addition, our medical monitors work collaboratively with our global regulatory affairs experts to provide strategic guidance into the best pathways to accelerate approvals. *See sidebar to learn more about the stroke experience and background of our Medical Affairs and Imaging doctors.*

## Meet our Stroke Experts

### **Sankalp Gokhale, MD MBA**

*Medical Director, Neuroscience, Internal Medicine & Critical Care*

Dr. Sankalp Gokhale is a board-certified neurologist and neuro-intensivist with over 15 years of experience in Internal Medicine/Neurology/Critical Care, Academia and Translational Research. Prior to joining Medpace, he held a variety of leadership positions in various academic institutions. He served as an Assistant Professor at the UT Southwestern Medical Center where he was the Principal Investigator (PI) in translational stroke and acute brain injury recovery studies. His research has been successfully funded by the National Institutes of Health (NIH), the American Heart Association (AHA) as well as private foundations. He then transitioned to the University of Arizona where he was the Assistant Professor of Neurology and Anesthesiology and the Director of the Neurocritical Care Unit at Banner – University Medical Center in Tucson, Arizona. He spearheaded the expansion of the Neurocritical Care Unit and established a strong Neurocritical Care referral service line. He was actively involved in the Quality and Performance Metrics improvement program for the Inpatient Neurology (Stroke, General Neurology and Neurocritical Care) service line. He has published more than 40 articles in international journals, presented at numerous international meetings and serves as an expert reviewer for the top journals in the field of stroke and neurocritical care. He served on National Research Committee at the Neurocritical Care Society from 2015-2017. He holds an MBA from the University of Arizona.

### **Richard Scheyer, MD**

*Vice President, Medical Affairs, Neuroscience and Psychiatry*

Dr. Scheyer, in his academic career, worked as attending neurologist in a stroke acute care unit and participated in successful landmark studies of antiplatelet agents in stroke prophylaxis. In his industry career, he has led efforts in management and reversal of anticoagulant and antiplatelet agents for stroke prophylaxis. In the acute care setting, Dr. Scheyer has worked on neuroprotective agents and has led programs for both enhanced thrombolysis and acute prophylaxis in patients with TIA or minor stroke. While at Medpace he has led efforts in prevention of acute complications following severe stroke. Throughout, he has worked on enhanced biochemical and imaging technologies for patient selection, treatment optimization, and outcome assessment.

### **Marco Tangelder, MD, PhD**

*Senior Medical Director, Cardiovascular*

Dr. Tangelder was an associate professor of clinical epidemiology, and has over 20 years of academic, pharmaceutical and biotech industry experience, mainly in the development of antithrombotic therapies for a broad range of indications. Dr. Tangelder is an expert in trial design and methodology, and has been involved in various stroke prevention trials, including regulatory submissions, totaling over 10,000 patients.

### **Thomas R. Thompson, MD**

*Vice President, Medical Affairs, Neuroscience and Psychiatry*

Dr. Thompson is board-certified in Psychiatry and Geriatric Psychiatry and has clinical development experience in numerous CNS indications including; stroke and post-stroke rehabilitation, Parkinson's disease, depression, schizophrenia, bipolar disorder, anxiety disorders, epilepsy, and pain. Dr. Thompson has clinical experience treating post-stroke depression and industry experience in stroke and post-stroke rehabilitation. His drug development experience in CNS includes leading a project in stroke and motor recovery, the completion of an MAA, leading a sNDA and designing head to head studies in CNS.

### **James Vornov, MD, PhD**

*Vice President, Medical Affairs, Neuroscience and Psychiatry*

Dr. Vornov's research during his academic career focused on mechanisms of acute ischemic injury both in animal models and in clinical trials, serving as an investigator in stroke trials. He directed development of compounds aimed at treatment of brain ischemia and other forms of acute CNS injury.

## Imaging

### **Daniel O'Leary, MD**

*Senior Vice President, Medical Affairs, Neuroimaging, Neurology*

Dr. Daniel O'Leary is the former Director of Neuroradiology at the Brigham and Women's Hospital and former Professor and Chairman of Radiology at Tufts University Medical School. He is a board certified neurologist, radiologist, and neuroradiologist. He is internationally known for his pioneering work in developing techniques for imaging atherosclerotic vascular disease. He has participated in numerous studies focused on identifying and quantifying risk factors leading to stroke and myocardial infarction. He is a Fellow of the Stroke Council of the American Heart Association.

## Medpace Central Labs Provide Safety and Biomarker Analysis



Medpace Labs provide consistency in methods and instrumentation across wholly-owned and purpose-built laboratories located in the US, Europe, China and Singapore. We offer a wide range of relevant biomarker assays for stroke and have the ability to rapidly establish and validate novel assays as needed. Over the past three years, Medpace has validated over 190 new biomarker assays based on guidelines from the Clinical and Laboratory Standards Institute (CLSI) and in accordance with CAP and CLIA regulations.

Below are key biomarkers used in stroke clinical trials.

Type	Biomarker	Medpace Validated Assays	Medpace Lab Partner Network
Coagulation	• aPTT	✓	
	• D-dimer	✓	
	• Factor Xa	✓	
	• Fibrinogen	✓	
	• TAFI Ag	✓	
	• PAI-1	✓	
	• Platelet Count		
	• Protein C		✓
	• Protein S		✓
	• PT/INR	✓	
	• Thrombin Generation Assay	✓	
	• vWF	✓	
	CHF / Atrial Fibrillation	• BNP	✓
• ProBNP		✓	
Vascular	• CRP	✓	
	• Lp-PLA2	✓	
	• MMP9	✓	
	• VCAM	✓	
Neuronal/Glial Injury	• S100beta		✓
	• NSE		✓
Routine Safety Chemistry	• Glucose	✓	
Gene Expression	• Various markers of gene expression being evaluated on exploratory basis		✓

## Core Imaging Expertise for Stroke Studies

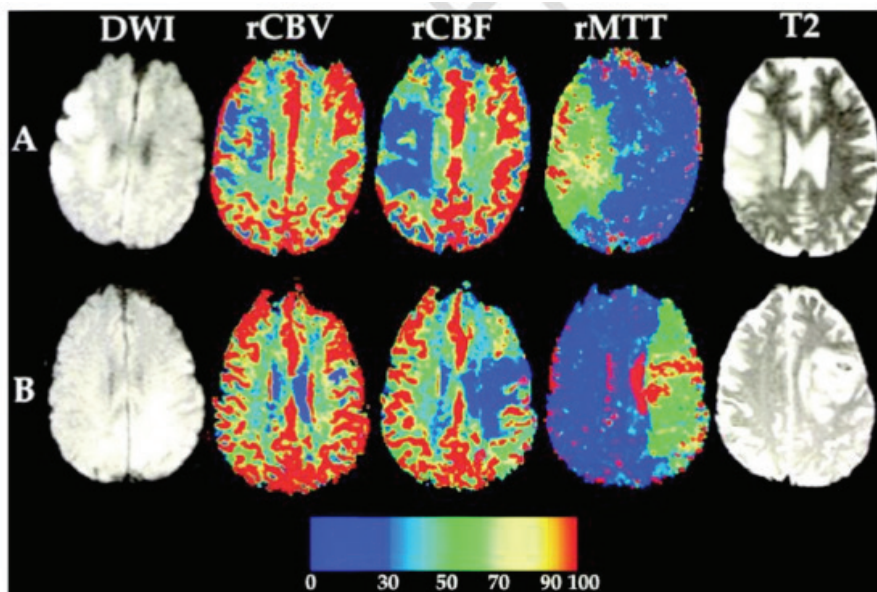


Imaging (CT and MRI) plays a crucial role to optimize the detection of patients who are more likely to benefit from a new treatment (eligibility), to monitor safety aspects such as hemorrhagic transformation during the acute and sub-acute phases, and to evaluate imaging-based secondary efficacy endpoints such as intermediary and final infarct size and post-stroke neurodegeneration (atrophy).

Medpace Imaging Core Lab provides an end-to-end suite of global imaging services to enhance and expedite biopharmaceutical and medical device development in stroke studies. A combination of imaging expertise and clinical trial experience ensure that imaging components are seamlessly integrated into the complex structure of the overall stroke trial. Capabilities include:

- Expedited imaging-based (CT/MRI) central eligibility evaluation using fully web-based image evaluation solutions coupled with Medpace's IWR/EDC systems
- Imaging-based safety and efficacy evaluations based on the following parameters:
  - Hemorrhages
  - Infarct size: differentiation between acute and chronic vascular lesions using FLAIR/T2 and Diffusion Weighted Imaging (DWI)
  - Perfusion-weighted imaging (PWI) parametric maps such as Time to Peak (TTP), Mean Transit Time (MTT), Cerebral Blood Volume (CBV) and Cerebral Blood Flow (CBF) – an illustration is provided below. These maps are various ways to evaluate the severity of hypo-perfusion using an MRI examination including the injection of a gadolinium-based contrast agent. Similar maps can be generated using Perfusion CT.

Medpace can identify and qualify CT and MRI scanners to maximize the consistency and quality of image acquisition across the sites. If external hospitals are allowed to refer patients to the study sites, the screening scans performed at those external sites may be acceptable if they meet the minimum quality requirements to detect recent ischemic infarcts and hemorrhages as well as the localization and grading of the corresponding vascular occlusion.



ClinTrak® Imaging—a component of Medpace's proprietary study management system—can manage and analyze Digital Imaging and Communications in Medicine (DICOM) images.

### Specialized Medical Device Expertise



Medpace Medical Device (MMD) provides specialized operational and regulatory expertise for stroke detection and prevention medical device studies. MMD designs and conducts device and diagnostic trials in all stages— from single-center, first-in-human and feasibility trials to multi-center, full-service pivotal trials and large-scale, post-market outcomes studies.

Stroke experience includes embolic protection devices used in TAVR, LAA closure devices, and carotid stents.

### A Full-Service Approach to Clinical Research



Driven by a full-service CRO model that coordinates and integrates all services for our clients, Medpace provides an accountable, seamless, integrated and efficient platform for executing clinical research – increasing quality and speed while significantly reducing the need for duplicate management oversight. Our disciplined processes, site relationships, and technologies enable us to execute even the most complex global studies, from first-in-human through post-approval.



Medical Affairs



Regulatory Affairs and Medical Writing



Clinical Monitoring



Clinical Trial Management



Biometrics and Data Sciences



Safety and Pharmacovigilance



Quality Assurance



Core Labs