



NEUROSCIENCE

Experts. Experience. Execution.

A Deeper Dive into Neurology

Medpace supports our sponsors who are advancing new neurological products by providing specialized expertise in the design and management of their programs. We have assembled a team of therapeutically-focused physicians and professional staff who have extensive experience designing and conducting neurological clinical trials and understand the issues from the perspective of the sponsor, the clinical investigator, the scientific leader, and the reviewer at the regulatory agencies. From beginning to end, Medpace can define and execute a clear development plan for your drug, device or combination product.

Scientifically-Driven Clinical Development

Meet our team of Neuroscience Physicians

Medpace, a global drug and medical device Clinical Research Organization (CRO), is unique in its scientifically-driven approach to clinical research. The Medpace model gives Sponsors 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.



Sarah DeRossett, MD, PhD
Senior Medical Director



Sankalp Gokhale, MD
Medical Director



Michael Oldham, MD, MPH
Medical Director



Dan O'Leary, MD
Senior Vice President,
Medical Affairs



Richard D. Scheyer, MD
Vice President,
Medical Affairs



Thomas R. Thompson, MD
Vice President,
Medical Affairs



James Vornov, MD, PhD
Vice President,
Medical Affairs

EXPERTS

Sarah DeRossett, MD, PhD

Senior Medical Director, Neurology

Dr. Sarah DeRossett is a board certified neurologist with more than 15 years of experience in clinical and academic neurology plus ten years of experience in pharmaceutical development.

Experience Summary

- Drug development experience across Phases I-IV
- Leadership of clinical development programs in early and late Parkinson's disease, Alzheimer's disease, migraine, Restless Leg Syndrome (RLS) and RLS-associated sleep disturbance, neuropathic pain including post-herpetic neuralgia and painful diabetic neuropathy, and epilepsy
- Leadership or support of drug development programs resulting in two European Medicines Agency and four Food and Drug Administration approvals (Parkinson's disease, RLS, PHN, epilepsy)
- Extensive prior experience in pharmaceutical R&D and Medical Affairs, including single point accountability for deriving clinical development plans, providing medical governance and operational oversight, and supporting regulatory submissions
- Well-published in the peer-reviewed medical and scientific literature

Education Summary

- Doctor of Medicine, cum laude, Emory University School of Medicine
- Doctor of Philosophy, Neural and Behavioral Studies, University of Kentucky
- Postdoctoral Fellowship, Pharmacology, Emory University School of Medicine
- Residency in Neurology, The Johns Hopkins Hospital

Sankalp Gokhale, MD

Medical Director, Neuroscience, Internal Medicine & Critical Care

Dr. Gokhale is a board-certified Neurologist and a Neuro-intensivist. He brings 15 years' experience in Internal Medicine/Neurology/Critical Care, Academia, and Translational Research.

Experience Summary

- Served on faculty as an assistant professor in the department of Neurology at the University of Texas Southwestern Medical Center, Dallas and at the University of Arizona, Tucson
- Served as Medical Director of the Neurocritical Care Unit at the Banner University Medical Center, Tucson, Arizona
- Board Certified by the American Board of Psychiatry and Neurology & United Council for Neurologic subspecialties (neurocritical care)
- 45+ peer reviewed publications and numerous international conference presentations
- Successfully funded as a Principal Investigator by multiple agencies for translational research (basic science and clinical) in the area of stroke and acute brain injury
- Served as an honorary member on the National Research Committee at the Neurocritical Care Society from 2015-2017
- Active member in multiple professional affiliations in the fields of Neurology and Critical Care Medicine

Education Summary

- Doctor of Medicine, Seth G.S Medical College – Mumbai, India
- Residency in Internal Medicine, All India Institute of Medical Sciences, New Delhi, India
- Residency in Neurology, Harvard University, Boston, MA
- Fellowship, Neurocritical Care, Duke University Hospital, Durham, NC
- Master of Business Administration, University of Arizona, Tucson, AZ

Michael Oldham, MD, MPH

Medical Director, Neuroscience

Dr. Oldham is a board-certified neurologist. He brings many years of clinical and research experience in Neurology, with positions in Academia and Industry.

Experience Summary

- Held multiple roles as Assistant Professor at the University of Louisville
- Served as Medical Director for a CNS-focused pharmaceutical company
- Active member in multiple professional affiliations revolving around Neurology
- Board Certified by the American Board of Psychiatry and Neurology with certifications in Child Neurology & Epilepsy
- Numerous peer-reviewed publications and presentations in the field of Neurology

Education Summary

- Doctor of Medicine, The George Washington University
- Residency in Pediatrics and Child Neurology, Cincinnati Children's Hospital Medical Center
- Fellowship, Clinical Neurophysiology, University of California-San Francisco
- Master of Public Health, Johns Hopkins University
- Bachelor of Arts in Psychology, Georgetown University

Daniel O'Leary, MD*Senior Vice President, Medical Affairs, Neuroimaging, Neurology*

Dr. Daniel O'Leary is a board certified neurologist, radiologist, and neuroradiologist with 30 years of clinical trial experience

Experience Summary

- Currently holds appointments as Professor of Radiology at Tufts University School of Medicine and Lecturer on Neurology at Boston University
- Extensive experience in all phases of studies and trials including feasibility assessments, design processes, educational efforts, management of medical information, and reviewing and editing medical documents
- Co-founder of Medpace Imaging Core Laboratory in 2006
- Principal Investigator on multiple NIH awards
- Invited speaker at numerous national and international scientific meetings and has written or co-authored over 200 peer-reviewed publications

Education Summary

- Doctor of Medicine, Tufts University, School of Medicine
- Postdoctoral Training, Neurology, Radiology & Neuroradiology, Massachusetts General Hospital

Richard D. Scheyer, MD*Vice President, Medical Affairs, Neurology, Pharmacology*

Dr. Richard Scheyer is a board certified neurologist with over 30 years of professional medical experience which includes 18 years dedicated to clinical drug development.

Experience Summary

- Pioneer in translational medicine and Phase I/IIa drug development with special interest in early demonstration of clinical efficacy
- Led a team that designed and executed an early development program for next-generation alpha-2 delta ligand, including capsaicin challenge, and crafting Proof of Concept strategy for novel ion channel blockers
- Highly-regarded author with over 60 manuscripts and abstracts, with a focus on clinical pharmacology and therapeutic activity in areas ranging from diabetes to oncology
- Launched first controlled trial natural product-derived protein kinase C activator in Alzheimer's at previous company

Education Summary

- Bachelor of Science, Physics, Stanford University
- Doctor of Medicine, The State University of New York, Upstate Medical University
- Residency in Neurology, Yale University
- Fellowship Training in Epilepsy, Yale University

Thomas R. Thompson, MD*Vice President, Medical Affairs, Neurology, Psychiatry*

Dr. Thomas Thompson is board certified in both neurology and psychiatry and has over 12 years of director level Phase II-IV clinical development experience.

Experience Summary

- Experience in numerous indications including Parkinson's disease, bipolar disorder, stroke, epilepsy, depression, schizophrenia, anxiety disorders, and pain
- Industry leadership roles with responsibility for clinical development plans, medical affairs, regulatory submissions, medical governance, and medical monitoring
- Previously the Director of Neurosciences and Clinical Development for 12 years at a large pharmaceutical company

Education Summary

- Bachelor of Science, Biology, University of Central Florida
- Doctor of Medicine, Temple University, School of Medicine
- Diplomate, American Board of Neurology and Psychiatry

James Vornov, MD, PhD*Vice President, Medical Affairs, Neurology, Analgesia, Psychiatry*

Dr. James Vornov is a board certified neurologist with over 18 years of director level clinical development experience

Experience Summary

- Brought multiple compounds into first-in-man to proof-of-concept and successful NDA submission. Provided broad clinical trial design expertise, clinical pharmacology experience, operational excellence and global regulatory strategy development across a broad range of CNS diagnostics and therapeutics
- Expertise in the rapid transition of compounds from the laboratory to clinical proof of concept through the use of Critical Path technologies such as biomarkers, PK/PD modeling and clinical trial simulation
- Worked in multiple CNS therapeutic areas having directed programs in Depression, Suicidal Ideation, Parkinson's disease treatment and diagnosis, stroke, neuropathic pain, diabetic and chemotherapy-induced peripheral neuropathies, anesthesia and brain tumors

Education Summary

- Bachelor of Arts, Biology & Psychology, Columbia University
- Doctor of Medicine, Emory University, School of Medicine
- Doctor of Philosophy, Anatomy, Emory University, School of Medicine

EXPERIENCE

Clinical research involving the Central Nervous System (CNS) and neurological disorders is a key therapeutic focus for Medpace. Well-established Sponsor relationships, exceptional clinical operations, and committed study teams drive your success. Medpace has built a team of medical, clinical, and regulatory experts who have been involved with the management and execution of neuroscience trials from the Sponsor/CRO project management role and the site study coordination/patient care perspective. All team members are involved from project initiation to completion, producing truly seamless drug development.

Medpace has conducted Phase I-IV neuroscience trials around the world.

Our physicians and staff are experienced in the following areas:

- Alzheimer's disease
- Migraine
- Multiple sclerosis
- Epilepsy
- Muscular dystrophy
- Huntington disease
- Subarachnoid hemorrhage
- Sleep-wake disorder
- Ischemic stroke
- TTR amyloidosis
- Fragile X syndrome
- Pain (including chronic, acute, and neuropathic)
- Parkinson's Disease

Specialty Areas: Rare Disease and Orphan Indications, Advanced Therapies and Pediatrics

Medpace is known for taking on some of the most complex and challenging clinical research programs, including rare disease and orphan indications, advanced therapies and pediatrics. Medpace offers sponsors comprehensive solutions to the unique and rapidly evolving clinical, operational and regulatory challenges of these areas. Our work with innovators, regulators, key opinion leaders, investigators, and advocacy groups gives us unique insight into the challenges and hurdles to be overcome as we advance your product through the development process. We have the global footprint and the relationships to recruit patients for these studies and a highly-disciplined operational model to execute efficiently and deliver quality results.

Drug, Medical Device and Combination Products

With a dedicated Medical Device division, Medpace brings together its medical and regulatory experts into a collaborative team that understands the nuances from both the drug and device perspectives. Medpace is experienced in helping clients meet regulatory compliance and ensuring patient safety while accelerating their medical device and combination products to market.

EXECUTION

Achieve quality results, meet deadlines, and maximize efficiencies by partnering with a CRO that excels in execution. Medpace demonstrates a commitment to quality and a united dedication to conducting full-service studies in an exacting manner to produce the highest quality results.

Keys to successful execution include:

Committed Teams: Your studies are assigned the best team from the onset and, with turnover rates that are lower than the industry standard, that team is with you from project initiation to completion. As a result, we typically develop better team dynamics that are based on trust and respect.

Resourcefulness: Medpace promotes a culture of problem-solving. Our global operational staff proactively identify potential issues and communicate solutions, ensuring your sites and studies are managed effectively and efficiently

Site and KOL relationships: Due to Medpace's experience and relationships with Investigators and opinion leaders worldwide, we can select the best sites for your specific program. This provides an advantage in meeting your recruitment timelines with high quality data.

Regulatory Support: Medpace offers a dedicated global regulatory submissions team as well as global regulatory affairs for comprehensive support.

Specialized Neuro-Imaging

High quality image acquisition and interpretation is crucial for the success of trials relying on neuroimaging for patient selection or as a primary or secondary endpoint. Medpace provides centralized neuroimaging expertise.

Medpace Imaging Core Lab provides an end-to-end suite of imaging services to enhance and expedite biopharmaceutical and imaging contrast agent development, including consultation on imaging biomarker strategies, image acquisition protocols, image collection/archiving services, and image analysis across imaging modalities and therapeutic areas.

Capabilities Include:

- Standard diagnostic imaging
- Magnetic resonance imaging (MRI)
- Computed tomography (CT)
- Bone densitometry or dual-energy x-ray absorptiometry (DXA)