

PAIN

Experts. Experience. Execution.

A Deeper Dive into Pain

Medpace is managed by leading therapeutic and regulatory experts with extensive experience in the development of products for use in neuroscience indications. Over the past 15 years, Medpace has been involved in many studies focused in neuroscience including pain indications (chronic non-cancer pain, acute pain, neuropathic pain, migraine, ankle sprain, etc.), and neurological indications (ischemic stroke, subarachnoid hemorrhage, multiple sclerosis, Alzheimer's Disease, Huntington's Disease, TTR amyloid neuropathy, Duchene muscular dystrophy, etc.). Medpace has experience working with leading specialists around the country on trials aimed at limiting the abuse liability of pain medications and mitigating the adverse effects of opioids.

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 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 experts provide strategic direction for study design and planning, train study teams, interact with investigators, provide medical monitoring services, and meet with regulatory agencies.



Sarah DeRossett, MD, PhD,
Senior Medical Director



Sankalp Gokhale, MD, MBA
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
Vice President, Medical Affairs

EXPERTS

Sarah DeRossett, MD, PhD

Senior Medical Director, Neurology, Analgesia

Dr. DeRossett is board certified in neurology and has over 15 years of experience in clinical and academic medicine and 10 years of experience in pharmaceutical development

Experience Summary

- Clinical development experience across a variety of neuroscience therapy areas including Parkinson's disease, Alzheimer's disease, Epilepsy, Restless Legs Syndrome, Migraine, Neuropathic Pain, and Opioid Dependence.
- Directed the Chronic Pain & Headache Clinic in the Department of Neurology at The Emory Clinic for more than a decade
- Previous experience directing the development of medicines for post herpetic neuralgia and painful diabetic neuropathy
- Previous experience leading the medical affairs activities for a marketed buprenorphine-containing product
- Authored a number of book chapters on the topics of pain and headache and has published more broadly in numerous peer-reviewed journals
- Consecutively listed for 6 years as one of the Best Doctors in America when in clinical practice

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 John Hopkins Hospital

Sankalp Gokhale, MD, MBA

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 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

- 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
- Pioneer in translational medicine and Phase I/IIa drug development with special interest in early demonstration of clinical efficacy
- 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 psychiatry with 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
- Proficiency working with psychiatric, geriatric psychiatric, and adolescent psychiatric patient populations
- Industry leadership roles with responsibility for clinical development plans, medical affairs, regulatory submissions, medical governance, and medical monitoring
- Co-authored book chapters on psychiatry and has been published in numerous peer reviewed journals

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

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

- Extensive experience in development of pain therapies including neuropathic pain, headache, extended release opioid therapies, biologicals for chronic pain, trigeminal neuralgia and niche chronic pain indications such as chronic pancreatitis
- 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

Medpace is best-in-class strategic partner for clinical development of analgesia products. Our expert team knowledge of complex study design based on therapeutic depth, project management, regulatory issues, as well as noted relationships with key investigative sites, assure your projects are completed on time and on budget.

Analgesia and related indication experience includes:

- Acute pain
 - Post-operative pain
 - Procedure related pain
 - Breakthrough pain: burn pain, cancer pain, etc.
- Chronic Pain
 - Non-cancer pain: osteoarthritis, back pain, adhesive capsulitis, etc.
 - Cancer pain
- Neuropathic pain:
 - Post herpetic neuralgia
 - Diabetic neuropathy pain
 - Other rare neuralgias
- Migraine
 - Prevention
 - Attacks
- Opioid Induced Constipation
- Opioid addiction

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 or product to market.

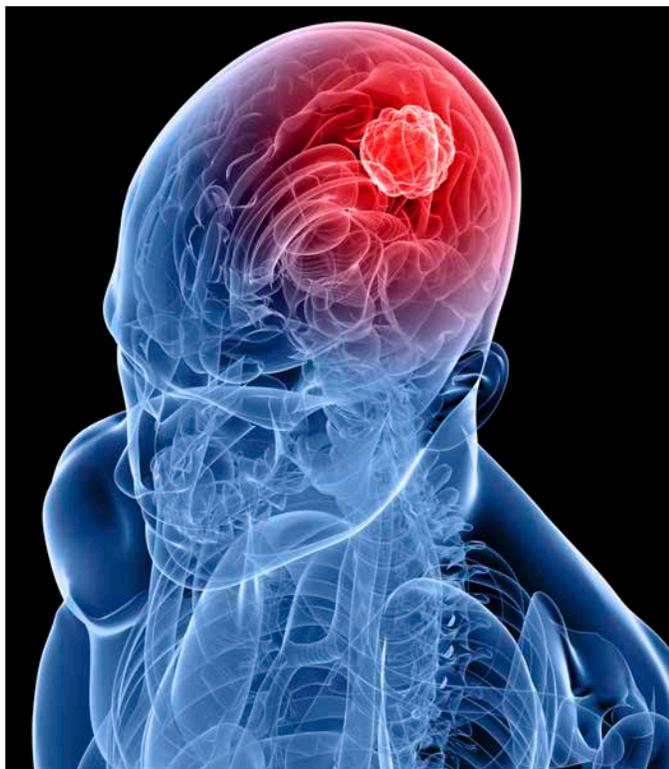


EXECUTION

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 analgesia experience and relationships with Investigators and opinion leaders worldwide, we can select the best sites for your specific program. We have relationships with pain specialists in a wide variety of pain indications and pain models. 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, led by Dr. O'Leary.

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)