



# 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.

## Physician-Driven Clinical Development

### Meet our team of Neuroscience Physicians

Medpace, a global drug and medical device Clinical Research Organization (CRO), is unique in its physician-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 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



**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

### **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.

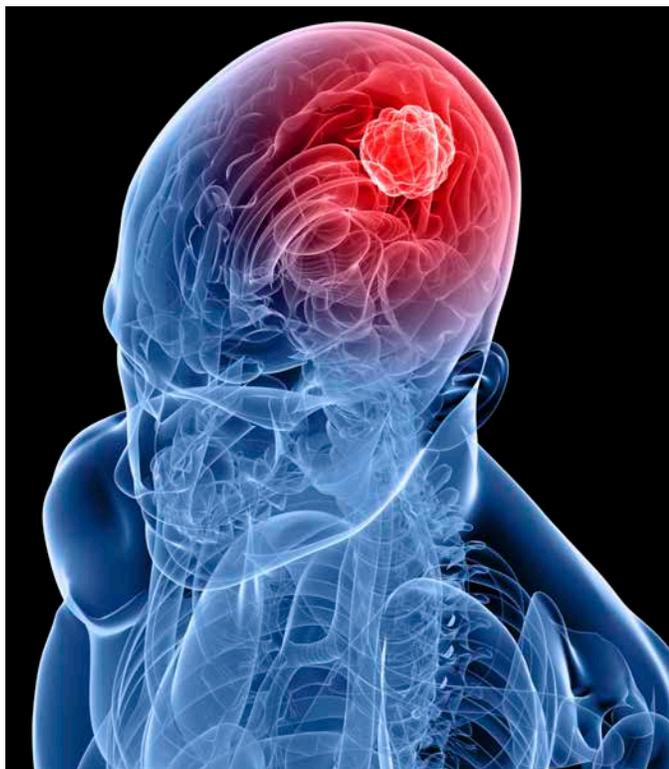


## EXECUTION

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)