



# PSYCHIATRY

Experts. Experience. Execution.

## A Deeper Dive into Psychiatry

Incidences of mental disorders such as depression, bipolar, anxiety disorders, and schizophrenia continue to grow around the world, with significant impacts on health as well as major social, human rights and economic consequences. According to the World Health Organization (WHO):

- ~20% of the world's children and adolescents have mental disorders or problems
- Mental and substance use disorders are the leading cause of disability worldwide
- About 800,000 people commit suicide every year
- Mental disorders are important risk factors for other diseases, as well as unintentional and intentional injury

As a therapeutically focused Clinical Research Organization (CRO), Medpace has been working with Sponsors who are developing therapies in Neuroscience for over 15 years to accelerate the global development of safe and effective medical therapeutics. In addition to its full service CRO model that embeds strategic medical and regulatory leadership in every study and program, Medpace offers a suite of integrated services that provide further efficiencies including global labs, core imaging, and early phase clinical pharmacology.

## Scientifically-Driven Clinical Development

### Meet our Psychiatry team

Medpace 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,  
Medical Affairs



**Sankalp Gokhale, MD, MBA**  
Medical Director



**Michael Oldham, MD, MPH**  
Medical Director



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



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



**James Vornov, MD, PhD**  
Vice President, Medical Affairs

## EXPERTS

### **Sarah DeRossett, MD, PhD**

*Senior Medical Director, Medical Affairs, Neurology, Psychopharmacology, Analgesia*

Dr. Sarah DeRossett is a board certified neurologist with 15 years of experience in clinical and academic neurology, plus more than 10 years of drug development experience.

#### **Experience Summary**

- Drug development expertise in neuropsychiatric disorders, dementia, opioid use disorder, sleep, and other CNS disorders
- Clinical and drug development experience in pain and analgesia
- Extensive research experience in psychopharmacology with special focus on opioids
- Leadership of clinical development programs in Parkinson's disease, Alzheimer's disease, Migraine, Restless Leg Syndrome (RLS), Neuropathic pain, Epilepsy, and Opioid Use Disorder
- Broad experience in pharmaceutical R&D, including single point of accountability for clinical development plans, medical governance, and support of regulatory submissions
- Well-published in the peer-reviewed medical and scientific literature

#### **Education Summary**

- Doctor of Medicine, cum laude, Emory University School of Medicine
- Postdoctoral Fellowship, Pharmacology, Emory University School of Medicine
- Residency in Neurology, The Johns 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

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

Dr. Thomas Thompson is board certified in both psychiatry and geriatric psychiatry with over 17 years of clinical and drug development experience.

**Experience Summary**

- Clinical and development experience in psychiatry and neurology indications including bipolar disorder, depression, anxiety disorders, schizophrenia, epilepsy, and other CNS disorders
- Proficiency working with psychiatric, geriatric psychiatric, and adolescent psychiatric patient populations
- Industry leadership roles with responsibility for clinical development plans, study designs, medical affairs, regulatory submissions, medical governance, and medical monitoring
- Co-authored book chapters on psychiatry and has been published in numerous peer reviewed journals, as well as clinical lecturer

**Education Summary**

- Doctor of Medicine, Temple University, School of Medicine
- Bachelor of Science, Biology, University of Central Florida
- Residency in Psychiatry, Emory University, School of Medicine
- Fellowship Training, Geriatric Psychiatry, Emory University, School of Medicine

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

Dr. Richard Scheyer is board certified in both neurology and pharmacology with over 18 years of experience in clinical drug development.

**Experience Summary**

- Psychiatric experience in program strategy and study design across numerous indications including dementia, sleep disorders, schizophrenia, ADHD, depression, and bipolar disorder
- Pioneer in translational medicine and Phase I/IIa drug development, with special interest in early demonstration of clinical efficacy
- Highly regarded author, speaker, and industry participant and has published over 60 manuscripts and abstracts, with a focus on clinical pharmacology and therapeutic activity in areas ranging from diabetes to oncology

**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, Epilepsy, Yale University

**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**

- Broad experience in psychiatric drug development. Directed programs in depression, suicidal ideation, and drug abuse
- 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
- Brought multiple compounds into man to proof of concept and successful NDA submission, providing broad clinical trial design expertise, clinical pharmacology experience, operational excellence and global regulatory strategy development across a broad range of CNS diagnostics and therapeutics

**Education Summary**

- Doctor of Medicine, Emory University, School of Medicine
- Doctor of Philosophy, Anatomy, Emory University, School of Medicine
- Bachelor of Arts, Biology & Psychology, Columbia University
- Residency Training, Neurology, Johns Hopkins, School of Medicine

## EXPERIENCE

Medpace medical, regulatory, and operational experts bring a broad range of experience in designing and conducting psychiatric studies. Areas of focus include:

- Addictive Disorders
- Anxiety Disorders
- Attention-Deficit/Hyperactivity Disorder
- Bipolar Disorder
- Cognition Disorders
- Depression
- Developmental Disorders
- Eating Disorders
- Schizophrenia
- Sleep Disorders
- Neuropsychiatric Disorders

**Therapeutic** – Medpace has earned a reputation for managing some of the industry’s most complex and challenging trials. Our scientifically-driven, therapeutically focused model enables our medical doctors to apply years of psychiatric drug development experience, helping to streamline studies.

**Operational** - Our global clinical operations team provides years of experience and leadership. Nearly 100 Clinical Research Associates and Clinical Trial Managers are experienced in psychiatric research. Skilled, proactive operational staff provide Sponsors with the knowledge and insights to tackle the unique challenges of psychiatric studies.

**Regulatory** – Our medical leadership and regulatory affairs experts provide global regulatory strategy development. In addition, Medpace has a separate regulatory submissions group that oversees all aspects of your investigator document collection and submissions.

**Device and Diagnostics** – There is a growing number of neurologic and psychiatric devices and diagnostics in various stages of research and development. 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 an experienced team from the onset and, with turnover rates that are lower than the industry standard, and that team is expected to be with you from project initiation to completion. As a result, we typically develop strong 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:** With broad neuroscience experience and relationships with Investigators and Key Opinion Leaders (KOLs) worldwide, we can select the best sites for your specific program. We provide in-depth knowledge of screening tools and rating scales and will provide oversight for rater services including subjective assessments, inter-rater reliability, and scale validation.

### Integrated Services

The complexities of mental health research requires a heightened level of integration and efficiency. Medpace offers full-service clinical research support as well as complimentary services that are wholly integrated into our processes.

**Early Phase Clinical Pharmacology:** Integrated study design at early stages can set the stage for study efficiency and success at later phases. Medpace provides expertise in translational medicine and Phase I/IIa drug development, as well as early demonstration of clinical efficacy. In addition, the Medpace Clinical Pharmacology Unit is dedicated to the conduct of early-phase clinical pharmacology studies in normal healthy volunteers, special populations, and patient populations.

**Central Lab:** Our global labs, located in Cincinnati, Ohio; Leuven, Belgium; Beijing, China; and Singapore, provide safety and efficacy testing to support your psychiatric trials. With nearly 150,000 patients screened, Medpace Labs has supported some of the world’s largest and most complex clinical trials, and provides real-time global tracking and tracing of specimens.

**E-Clinical:** ClinTrak®, Medpace’s proprietary study management platform, facilitates team coordination and decision support for Sponsors and sites, and ensures global teams can collaborate and maximize efficiency. It supports eDiary/ePROs, an increasingly important requirement for psychiatric studies.

**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 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.

