

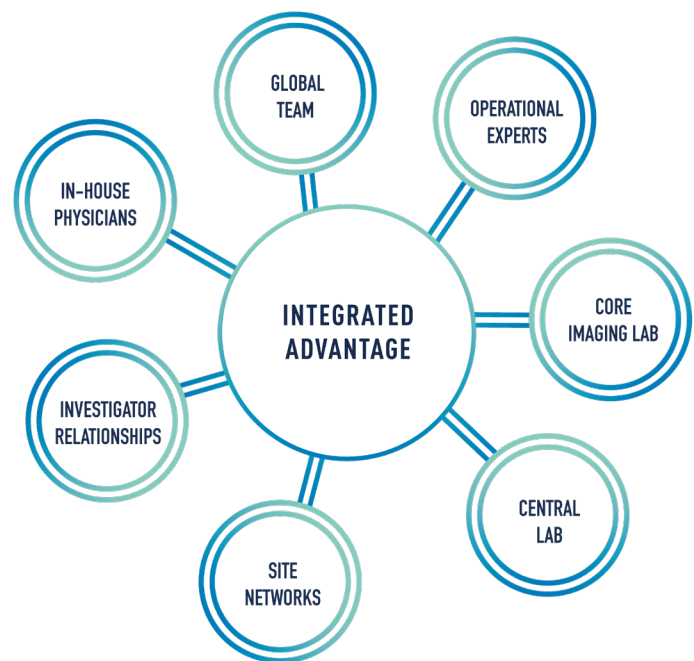
# A DEEPER DIVE INTO PSYCHIATRY



## AN INTEGRATED ADVANTAGE

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

- Highly relevant operational know-how and subject matter expertise in psychiatry and neurology drug development
- A well-profiled network of investigative sites enables timely enrollment and high-quality conduct of trials
- A team of Clinical Research Associates and Clinical Trial Managers experienced in psychiatric research
- Integrated imaging and central laboratory services, ensuring seamless logistics, review, and testing



## THERAPEUTICALLY-FOCUSED TEAM

Medpace is unique in its scientifically-driven approach to clinical research. Our model gives Sponsors the advantage of early and ongoing insight and guidance from a team of therapeutic experts throughout the trial design and execution. Our highly experienced team of medical, regulatory, and operational experts work collaboratively to conduct clinical trials. We understand issues from the perspectives of Sponsors, clinical investigators, scientific leaders, and reviewers at regulatory agencies. With this insight, we successfully define and execute clear development plans from beginning to end.

***Accelerate your psychiatric studies with Medpace's full-service team of medical and regulatory experts, highly-experienced clinical trial management teams, central labs, and core imaging labs.***



## EXPERT INSIGHT

Serving as therapeutic team leaders, our in-house medical doctors apply years of psychiatric drug development experience to each study. Our medical leaders provide strategic direction for study design and planning, train operational staff, work with Investigators, provide medical monitoring, and meet with regulatory agencies as well as our global regulatory affairs experts to provide strategic guidance into the best pathways to accelerate approvals. Medpace MDs are embedded throughout every study, providing greater depth of expertise and the ability to tackle complex and challenging diseases.



**Rich D. Scheyer, MD**  
Sr. Vice President,  
Medical Department



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



**Toshihiro Hokonohara, MD**  
Medical Director



**Boban Joksimovic, MD, PhD**  
Medical Director



**Filipe Brogueira Rodrigues, MD, PhD**  
Medical Director

## ADVANCED CLINICAL PRACTITIONERS ADD A PATIENT'S PERSPECTIVE

Our medical directors are supported by experienced ACPs whose unique perspective brings added value to the clinical development team. These highly-trained nurse practitioners with advanced degrees and hands-on clinical experience provide an additional layer of knowledge and insights that can streamline your studies and address potential challenges early in the study planning. ACPs are embedded in the teams to ensure your study is feasible and operationalized for efficient execution by looking at the protocol through the lens of the patient and site staff. ACPs also help with the review of safety events, ongoing team education, recruitment strategies, and study document review. Their understanding of what works in a clinical setting makes them a valuable part of our embedded medical expertise model.



**Morgan Ball, MSN, FNP-BC**  
Advanced Clinical  
Practitioner



**Danielle Caudell-Stamper, MSN, AGACNP-BC**  
Advanced Clinical  
Practitioner



**Danielle Mattingly, FNP-BC, MPH**  
Advanced Clinical  
Practitioner



**Daniela Rae, MSc, RGN, IP**  
Advanced Clinical  
Practitioner



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## IN-HOUSE PHYSICIAN BIOGRAPHIES

### Richard D. Scheyer, MD

*Sr. Vice President, Medical Department,  
Neurology, Pharmacology*

Dr. Richard Scheyer is a board-certified neurologist with over 30 years of professional medical experience which includes over 20 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

### James Vornov, MD, PhD

*Vice President, Medical Department,  
Neurology, Analgesia, Psychiatry*

Dr. James Vornov is a board-certified neurologist with over 20 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 using 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



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## **Toshihiro Hokonohara, MD**

*Medical Director*

Dr. Toshihiro Hokonohara is a board-certified neurologist with over 15 years of clinical practice and academic neurology including experience in leadership roles at pharmaceutical and global contract research organizations.

### **Experience Summary**

- Drug development expertise in neuropsychiatric disorders, dementia, autoimmune disease, oncology and other CNS and Internal Medicine disease
- Clinical and drug development experience in neuro-immunological disease
- Extensive research experience in some neurological hereditary disease
- Pharmacovigilance Leader of clinical development programs in Epilepsy
- Broad experience in pharmacovigilance medical governance and support of regulatory submissions

### **Education Summary**

- Doctor of Medicine, Kyushu University – Fukuoka, Japan
- Residency in Neurology, Kyushu University Hospital – Fukuoka, Japan

## **Boban Joksimovic, MD, PhD**

*Medical Director*

Dr. Boban Joksimovic is a board-certified neurologist with a PhD in neuroscience and over 20 years of clinical experience in neurology.

### **Experience Summary**

- 17 years of CRO experience as a Medical Director, Clinical Operations Lead, and Clinical Research Associate in Phase I-IV studies
- Expert in intraoperative neurophysiology and EMNG with neuromuscular disorders in focus
- Previously practiced as a neurophysiologist and introduced intraoperative neurophysiology to Serbia in 2008
- Extensive experience as Sub-investigator and rater in CNS studies
- Rankin Scale, NIHSS, Neurostatus EDSS, MDS-UPDRS, Modified Hoehn and Yahr, MoCA training certificates

### **Education Summary**

- Doctor of Philosophy in Intraoperative Neurophysiology, University of Kragujevac – Kragujevac, Serbia
- Board Certified Neurologist, University of Novi Sad – Novi Sad, Serbia
- Medical Doctor, University of Belgrade – Belgrade, Serbia



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## Filipe Brogueira Rodrigues, MD, PhD

*Medical Director*

Dr. Filipe Rodrigues is an academic neurologist with over 6 years of drug development experience in neurology and psychiatry.

### Experience Summary

- Served as academic neurologist at University College London Queen Square Institute of Neurology and as clinician at the National Hospital for Neurology & Neurosurgery in London
- Hands-on clinical trial experience in neurodegeneration, movement disorders and neurogenetics, including antisense technology and intrathecal delivery
- Member of working groups for Movement Disorders Society, Research Ethic Committee, Critical Path Institute, and Cochrane Collaboration
- Academic research in biofluid biomarkers and clinical pharmacology
- 50+ peer-reviewed medical and scientific publications

### Education Summary

- Master's Degree in Medicine, Faculty of Medicine, University of Lisbon – Lisbon, Portugal
- Bachelor of Science Degree in Medicine, Faculty of Medicine, University of Lisbon – Lisbon, Portugal

## Morgan Ball, MSN, FNP-BC

*Advanced Clinical Practitioner*

Morgan Ball is a board-certified family nurse practitioner with over 7 years of clinical experience, bringing expertise in interventional pain management and neurology with a focus on movement disorders.

### Experience Summary

- Experience providing care both inpatient and outpatient, including pediatric cardiac ICU, general pediatrics, neurology, and interventional pain management
- Assessed, diagnosed, and managed a variety of neurological and chronic pain conditions
- Provided patient and family education about diagnosis and treatment plans
- Served as the lead nurse practitioner and manager
- Active member of the American Academy of Neurology and multiple advanced practice nursing associations

### Education Summary

- Post-Master's Family Nurse Practitioner Certificate Diploma, Xavier University – Cincinnati, OH
- Master of Science in Nursing, Xavier University – Cincinnati, OH
- Bachelor of Science in Biology, University of Kentucky – Lexington, KY



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## **Danielle Caudell-Stamper, MSN, AGACNP-BC**

*Advanced Clinical Practitioner*

Mrs. Danielle Caudell Stamper is a board-certified advanced practice registered nurse bringing over 8 years of clinical and preclinical research experience, over 3 years of nursing experience and over 7 years of experience as a nurse practitioner providing direct patient care.

### **Experience Summary**

- Clinical experience in neuro critical care, pulmonary critical care, and transplant medicine.
- Served as a sub-investigator on multiple clinical trials, including investigation of genomic classifiers for idiopathic pulmonary fibrosis, proteomic risk evaluation for lung cancer, the treatment of persistent air leak after pneumothorax, a novel device for the treatment of emphysema, and devices in improving the diagnostic yield of biopsies
- Over eight years of clinical and preclinical neurological research experience as a senior clinical research assistant specializing in hemorrhagic stroke, traumatic brain injury, aneurysm, and ischemic stroke
- Involved in the conduct of over 40 clinical trials as a clinical trial nurse coordinator and regulatory specialist
- Member of the American Academy of Neurology (AAN), American Association of Bronchology and Interventional Pulmonology (AABIP) and American College of Chest Physicians (CHEST)

### **Education Summary**

- Master of Science in Nursing in Adult Gerontology Acute Care Nurse Practitioner, University of Cincinnati – Cincinnati, OH
- Bachelor of Science in Nursing, University of Cincinnati – Cincinnati, OH
- Bachelor of Arts in Biology, Thomas More University – Crestview Hills, KY
- Associate of Arts in Spanish, Thomas More University – Crestview Hills, KY

## **Danielle Mattingly, FNP-BC, MPH**

*Advanced Clinical Practitioner*

Ms. Mattingly is a certified Family Nurse Practitioner and Neuroscience Registered Nurse. She brings experience in clinical research, public health, and health policy.

### **Experience Summary**

- Extensive experience as a Neurology Nurse Practitioner at multiple university medical centers
- Experience providing both inpatient and outpatient care of patients, including patients with epilepsy and sleep disorders
- Served as sub-investigator on active clinical trials for novel treatments of localization related epilepsy, narcolepsy, and idiopathic hypersomnia
- Actively worked to create an education lecture series for neurology advanced practice providers
- Active member of multiple neurology and advanced practice nursing associations

### **Education Summary**

- Master of Science in Nursing, Family Nurse Practitioner, Columbia University – New York, NY
- Master of Public Health in Health Policy and Management, Columbia University – New York, NY
- Bachelor in Nursing Science, Columbia University – New York, NY
- Bachelor of Arts in Public Health, Vanderbilt University – Nashville, TN





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## Daniela Rae, MSc, RGN, IP

*Advanced Clinical Practitioner*

Daniela Rae is a registered Consultant nurse and Independent Prescriber (UK). She brings nearly decades of senior clinical leadership and research experience in neuroscience, with a focus in neurodegeneration, neuropsychiatry and neurogenetics.

### Experience Summary

- Extensive experience in Huntington's disease, rare dementia and cognitive disorders – genetic counselling, clinical assessment and management, policy and standards of care development as well as clinical and academic research.
- Former clinical lead providing operational and clinical leadership for a large, multidisciplinary team, including medical consultants, nurses, trainees, and external key stakeholders.
- Managed an autonomous clinical caseload in a world leading tertiary outpatient clinic for patients and families with neurological, neuropsychiatric, neurogenetic, and neurodegenerative disease.
- Former Scottish government research fellow functioning as Chief investigator and Lead researcher for a multi-center organizational case study investigating care delivery systems in Huntington's disease
- Served as lead and key contributor for international working groups developing standards of care guidelines in rare, neurodegenerative disease
- Extensive experience as senior research nurse, trials manager, sub- and principal investigator in clinical trials with neurodegenerative and critical care focus
- Served as lead and key contributor for international working groups/ taskforce developing standards of care guidelines in rare, neurodegenerative disease

### Education Summary

- Diploma in Psychological Therapies, Association of Psychological Therapies – London, United Kingdom
- Master of Science in Public Health and Health Services Research, University of Aberdeen – Aberdeen, United Kingdom
- Diploma in Adult Nursing, Berufsfachschule fuer Krankenpflege – Munich, Germany



## EXPERIENCE

Developing effective treatments for psychiatric disorders such as depression, bipolar disorder, anxiety disorders, and schizophrenia requires unique expertise. Medpace medical, regulatory, and operational experts bring a broad range of experience in designing and conducting psychiatric studies for psychiatric clinical development across adult, geriatric, and pediatric populations.

### Indication Expertise:

- Addictive Disorders - Substance Use Disorders
- Anxiety Disorders
- Attention-Deficit/Hyperactivity Disorder
- Bipolar Disorder
- Cognition Disorders
- Developmental Disorders
- Eating Disorders
- Major Depressive Disorder
- Schizophrenia
- Sleep Disorders
- Neuropsychiatric Disorders

## RECRUITMENT AND SITE 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.



## SPECIALIZED MEDICAL DEVICE EXPERTISE

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 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

### CENTRAL LABS

Medpace Central Labs provide consistency in methods and instrumentation across four wholly-owned and purpose-built laboratories located in the US, Europe, China, and Singapore. We provide safety and efficacy testing to support psychiatric trials. Central labs offer a wide range of relevant biomarker assays and can rapidly establish and validate novel assays as needed. Over the past several years, Medpace has validated hundreds of new biomarker assays based on guidelines from the Clinical and Laboratory Standards Institute (CLSI) and in accordance with CAP and CLIA regulations. With hundreds of thousands of patients screened, Medpace central labs has supported some of the world's largest and most complex clinical trials



### CENTRAL LABS

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 while providing real-time global tracking and tracing of specimens.

### 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.

### FULL-SERVICE CLINICAL DEVELOPMENT

Medpace is a scientifically-driven, global, full-service clinical contract research organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical and medical device industries. Medpace's mission is to accelerate the global development of safe and effective medical therapeutics through its high-science and disciplined operating approach that leverages local regulatory and deep therapeutic expertise across all major areas including oncology, cardiology, metabolic disease, endocrinology, central nervous system and anti-viral and anti-infective.

**WE CAN'T SIMPLIFY  
CLINICAL DEVELOPMENT –  
BUT WE CAN EXECUTE  
IT SEAMLESSLY.**

MAKING THE COMPLEX  
**SEAMLESS**

