

# A DEEPER DIVE INTO STROKE

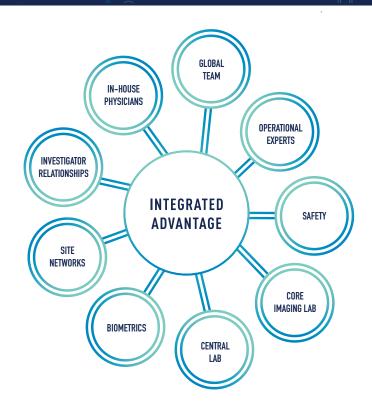
### AN INTEGRATED ADVANTAGE

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

- Highly relevant operational know-how and subject-matter expertise in neuroscience, advanced therapies, and associated antithrombotic and lipid lowering therapies
- A well-profiled network of experienced stroke sites enables timely enrollment and highquality conduct of trials
- End-to-end suite of global imaging services seamlessly integrated into the overall structure of clinical trials
- A wide range of relevant biomarker assays through our wholly-owned central lab network

## 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 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 perspective 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 next stroke study with Medpace's noted medical and regulatory experts, highly-experienced clinical trial management teams, central labs, and core imaging labs.

## **EXPERTS**

### **EXPERT INSIGHT**

Serving as therapeutic team leaders, our in-house medical doctors 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. Our MDs are embedded throughout every study, providing greater depth of expertise and the ability to tackle complex and challenging diseases.

#### In-House Physicians



Daniel O'Leary, MD Senior Vice President Medical Department



Richard D. Scheyer, MD Vice President, Medical Department



Marco Tangelder, MD, PhD Senior Medical Director



James Vornov, MD, PhD Vice President, Medical Department

#### Daniel O'Leary, MD

Senior Vice President, Medical Department, Neuroimaging, Neurology

Dr. Daniel O'Leary is a board-certified neurologist, radiologist, and neuroradiologist with 30 years of clincial 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 Department, 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 productderived 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

#### Marco Tangelder, MD, PhD

Senior Medical Director

Dr. Marco Tangelder is a board-certified Clinical Epidemiologist. He brings 30+ years of experience in Clinical Research and Drug Development.

#### **Experience Summary**

- Held multiple academic and Sr. Director roles at Drug Development Companies
- Research areas include vascular surgery, vascular medicine, thrombosis and hemostasis, peripheral arterial disease, coronary artery disease, atrial fibrillation
- Active member in multiple professional affiliations revolving around Cardiology
- Board Member of the International Surgical Thrombosis Forum (ISTF)
- Key opinion leader with over 50 scientific publications

#### **Education Summary**

- Doctor of Medicine, University of Utrecht Utrecht, Netherlands
- Doctor of Philosophy, University of Utrecht Utrecht, Netherlands
- Residency in Surgery, Twenteborg Hospital Almelo – Almelo, Netherlands
- Fellowship, Vascular Surgery, University Medical Center Utrecht – Utrecht Netherlands
- Master of Science in Epidemiology, University of Utrecht - Utrecht, Netherlands
- Master in Pharmaceutical Medicine, Medical University Karolinska Institutet – Stockholm, Sweden

#### James Vornov, MD, PhD

Vice President, Medical Department, Neurology, Analgesia, Psychiatry

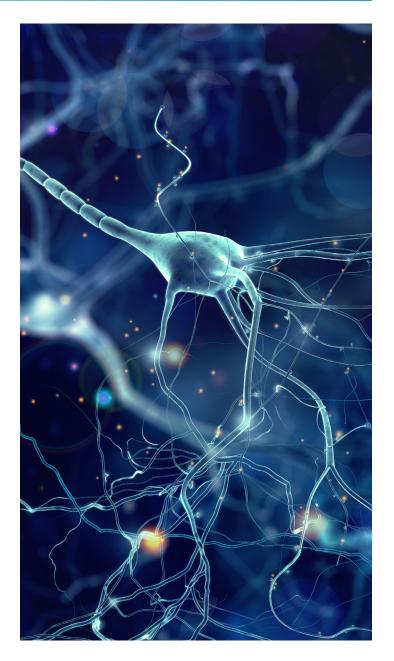
Dr. James Vornov is a board-certified neurologist with over 18 years of director level clinical development experience.

#### **Experience Summary**

- Brought multiple compounds into firstin-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



## **EXPERIENCE**

Medpace has in-house neurologists, imaging specialists, and operational teams with relevant and recent stroke experience as well as backgrounds (and publications) in stroke-specific scientific research. We have designed and conducted numerous stroke detection and stroke prevention studies and our experience includes direct administration of drug to brain, either intraventricularly or intrathecally.

#### Biopharmaceutical and medical device experience:

- Advanced therapies including stem cell
- Restorative therapies
- Thrombolytic therapies
- Preventative therapies
- Medical device therapies

## RECRUITMENT AND SITE RELATIONSHIPS

Recruiting patients for stroke studies requires a partner who has strong relationships with a well-profiled global network of experienced stroke sites, and who can manage complex logistics, negotiations, education, and site maintenance to ensure success. Medpace has earned a reputation for managing highly complex studies and has the relationships to work with the complex and evolving referral networks (hub and spoke), community hospitals, comprehensive stroke centers, and other acute care settings to drive successful patient enrollment around the world.

Medpace provides site training and certification processes to obtain reliable assessments on clinical scales including mRS, NIHSS & Barthel, PROs and QoLs.

## SPECIALIZED MEDICAL DEVICE EXPERTISE

Medpace Medical Device (MMD) provides specialized operational and regulatory expertise for stroke detection and prevention medical device studies. MMD designs and conducts device and diagnostic trials in all stages — from single-center, first-in-human and feasibility trials to multi-center, full-service pivotal trials and large-scale, post-market outcomes studies. Stroke experience includes embolic protection devices used in TAVR, LAA closure devices, and carotid stents.



## **EXECUTION**

### MEDPACE CENTRAL LABS

Medpace Central Labs provide consistency in methods and instrumentation across wholly-owned and purpose-built laboratories located in the US, Europe, China, and Singapore. We offer a wide range of relevant biomarker assays for stroke and have the ability to 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.

## **CORE IMAGING**

Imaging (CT and MRI) plays a crucial role to optimize the detection of patients who are more likely to benefit from a new treatment (eligibility), to monitor safety aspects such as hemorrhagic transformation during the acute and sub-acute phases, and to evaluate imaging-based secondary efficacy endpoints such as intermediary and final infarct size and post-stroke neurodegeneration (atrophy).

Medpace Imaging Core Lab provides an end-toend suite of global imaging services to enhance and expedite biopharmaceutical and medical device development in stroke studies. A combination of imaging expertise and clinical trial experience ensure that imaging components are seamlessly integrated into the complex structure of the overall stroke trial.

#### Capabilities include:

- Expedited imaging-based (CT/MRI) central eligibility evaluation using fully web-based image evaluation solutions coupled with Medpace's IWR/EDC systems
- Imaging-based safety and efficacy evaluations based on the following parameters:
  - Hemorrhages
  - Infarct size: differentiation between acute and chronic vascular lesions using FLAIR/T2 and Diffusion Weighted Imaging (DWI)
  - Perfusion-weighted imaging (PWI) parametric maps such as Time to Peak (TTP), Mean Transit Time (MTT), Cerebral Blood Volume (CBV) and Cerebral Blood Flow (CBF)

Medpace can identify and qualify CT and MRI scanners to maximize the consistency and quality of image acquisition across the sites. If external hospitals are allowed to refer patients to the study sites, the screening scans performed at those external sites may be acceptable if they meet the minimum quality requirements to detect recent ischemic infarcts and hemorrhages as well as the localization and grading of the corresponding vascular occlusion.

## **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.

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