MEDPACE

# PAIN-RELATED CLINICAL DEVELOPMENT

Medpace has conducted studies focused in neuroscience indications, specifically pain and pain-related products, in collaboration with reputable specialists around the world. Our knowledge of complex study designs based on therapeutic depth, patient recruitment, project management, regulatory issues, as well as noteworthy relationships with key investigative sites, helps to ensure that projects are completed on time and on budget.

## PAIN-RELATED INDICATION EXPERIENCE

- **Acute pain**
  - Post-operative
  - Procedure-related pain
- **Chronic and breakthrough pain**
  - Non-cancer pain: osteoarthritis, back pain, adhesive capsulitis, etc.
  - Cancer pain
  - Breakthrough pain: burn pain, cancer pain, etc.
- **Neuropathic pain**
  - Postherpetic neuralgia
  - Diabetic neuropathy pain
- **Migraine**
  - Prevention
  - Acute attacks
- **Opioid-induced constipation**
- **Opioid substance use disorder**

MAKING THE COMPLEX

# SEAMLESS™

## EXPERTS

- Specialized in-house physicians with expertise in pain-related clinical development
- Access to pain specialists and key opinion leaders around the world
- Integrated neuro-imaging and central labs expertise
- Strategic regulatory affairs
- Regulatory submissions expertise for efficient start-up
- Seasoned, collaborative neuroscience/pain project team with a wide variety of experience

## EXPERIENCE

- Broad clinical trial experience in neuroscience and pain
- Experienced in complex, large-scale, global studies
- Knowledgeable in global regulatory requirements which accelerates start-up
- Medical device and IVD experience
- Deep expertise in Patient Reported Outcomes

## EXECUTION

- Well-established relationships with investigators and key sites
- Work with academic and clinical experts in protocol development for new approaches to treatment and approval
- Global imaging services through Medpace Imaging Core Lab
- Biomarker and safety testing through Medpace Central Labs
- Fully-integrated, study management technology, including eDiary/ePRO, via ClinTrak, Medpace's Clinical Trial Management System
- Skilled at the implementation of measures aimed at minimizing placebo response in pain studies

## CENTRAL LAB ADVANTAGE

Medpace Central Labs offer comprehensive global lab services during all stages of the development process. Focused on both the scientific and service aspects with wholly-owned laboratories in the US, Europe, China and Singapore, our central lab has the reach to support global studies, assist with regulatory requirements, and deliver custom solutions for any need.

**Services provided include:**

- Scientific consulting
- Project Management
- Logistics Management
- Comprehensive testing for routine safety, biomarkers, and specialized assays
- Short and long term sample storage
- Data management
- Preparation, packaging, and delivery of supplies
- ClinTrak® Lab web portal for study documents, study progress, and result viewing

## SPECIALIZED NEURO-IMAGING

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.

- Standard diagnostic imaging
- Magnetic Resonance imaging (MRI)
- Functional Magnetic Resonance Imaging (FMRI)
- Computer tomography (CT)
- Bone densitometry or dual-energy x-ray absorptiometry (DXA)

## CUSTOM PATIENT REPORTING

Medpace's customizable ePRO/eDiary component allows for the safe and secure collection of patient-reported outcomes (PRO) data directly from patients through multiple platforms. This easy-to-use, yet sophisticated tool can increase active subject participation in research which in turn leads to a higher level of data integrity for studies.

**System highlights include:**

- Built-in prompts improving patient compliance
- Investigator sites can have access to this system, reducing variability issues
- Fully customizable with multiple pain scale abilities
  - Sliding scales
  - Image scales
  - Customized medication lists
  - Flexible time schedule

## SCIENTIFICALLY-DRIVEN

Medpace is unique in its scientifically-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 neuroscience physicians provide strategic direction for study design and planning, train operational staff, work with Investigators, provide medical monitoring, and are available to meet with regulatory agencies if the Sponsor desires. They are embedded throughout every study, providing greater depth and the ability to tackle complex and challenging diseases.

## 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.**

CNS-0003-0719

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